No Stock, High Stakes Problems

Perspectives on the ethics of whether to source medical products of uncertain quality for humanitarian health projects during urgent stock-outs.

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Photograph of a razed medical warehouse in Afghanistan. (2015)

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A single death is a tragedy; a million deaths is a statistic.

Joseph Stalin

Dedication.

For John and George, my North Star and twinkle star, for all your light and love.

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I would like to sincerely thank the participants of this study. I cannot name you, but were it not for your trust and honesty this study and its findings would never have been possible. I am particularly grateful to the individual who helped set-up the Focus Group Discussions.

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Impact of the COVID-19 pandemic on this study.

The COVID-19 pandemic began soon after I commenced my doctoral studies. The project that was originally designed in late 2019, pre-pandemic, was case study research. I had planned to gather ethnographic data pertaining to perspectives on substandard and falsified medical products of patients and communities served by iNGO healthcare providers. This would have required on-site data collection in humanitarian contexts, in two separate countries, with substantial travel. Pandemic travel restrictions and social distancing requirements made this plan entirely unfeasible. These constraints also placed my sample population out of reach as, for that project, I felt that remote data collection was an inappropriate substitute for in-person interaction and observation. Consequently, I was no longer able to investigate my initial research questions. Upon returning from parental leave in the Summer of 2020 I designed a new project; one that considered a similar problem, but from a different perspective, and that exclusively conducted data collection remotely.

On a personal note, the virus had a significant impact on my own life and, by extension, my capability to conduct the study. I believe that I contracted COVID three times; one of these episodes is suspected to have caused long-COVID. This manifested as a strange archipelago of symptoms, of which extreme fatigue, 'brain fog', muscular pain, and joint problems were the most disruptive to the project. In addition, my DPhil coincided with a time in which I was starting a family and taking a hiatus from a salaried career; the pandemic intensified the challenging aspects of these life events and caused financial, social, and emotional difficulties that impeded my capacity and progress.

Contents

1 - **Introduction** 1

1.1 The ethical problem of choosing between medical product quality or availability. 1

1.2 Personal motivation to research this subject. 2

1.3 Presentation and organisation of the thesis. 4

2 - **Literature & Policy Review** 6

2.1 Introduction. 6

2.1.1 The initial literature and policy review. 6

2.1.2 The wider, iterative literature and policy review. 7

2.2 The risks and regulations of medical products circulating in low-and middle- income countries. 10

2.2.1 What is a medical product? 10

2.2.2 The regulation of medical products. 13

2.2.3 Poor-quality medical products. 18

2.3 The organisation and governance of the procurement of medical products for humanitarian health projects delivered by international non-governmental organisations. 20

2.3.1 Defining the scope of 'humanitarian health'. 20

2.3.2 Humanitarian Health Supply Chains. 23

2.3.3 Policies regarding the procurement of medical products for humanitarian health projects. 25

2.4 Studies of the ethics of making difficult decisions in humanitarian contexts. 32

2.4.1 Decision-making and the humanitarian context. 32

2.4.2 Ethics of the prioritisation of medical product quality or availability. 38

2.5 Conclusion. 42

3 - **Methods** 45

3.1 Introduction. 45

3.2 Aim of the study and its research questions. 45

3.3 Design of the study. 46

3.3.1 Considerations arising in the selection of the chosen method. 46

3.3.2 Alternative methodological approaches that were discounted. 51

3.3.3 Ethical considerations 53

3.4 Pilot study. 54

3.4.1 Overview. 54

3.4.2 Sampling. 55

3.4.3 Data collection and analysis. 55

3.4.4 Impact. 56

3.5 Participants. 57

3.5.1 Sampling for in-depth interviews. 57

3.5.2 Sampling for focus group discussions. 61

3.5.3 Eligibility criteria. 64

3.5.4 Written communication with participants. 65

3.6 Data collection. 65

3.6.1 An overview of research activities and their timing. 65

3.6.2 In-depth interviews. 66

3.6.3 Focus Group Discussions. 72

3.6.4 Informal Conversations and Document Analysis. 77

3.7 Data analysis. 79

3.7.1 Positionality statement. 79

3.7.2 Theoretical framework. 83

3.7.3 Reflexive thematic analysis. 84

3.7.4 Reflexive practices. 88

3.7.5 Presentation of analysis in the thesis. 89

3.8 Conclusion. 90

4 - **Introducing 'No Stock, High Stakes' Problems** 91

4.1 The 'no stock, high stakes' problem, and participant reports of its occurrence. 91

4.1.1 The phenomenon of 'no stock, high stakes' problems within the context of this study. 911

4.1.2 Participant insights into the prevalence of 'no stock, high stakes' problems. 92

4.2 An illustration of a 'no stock, high stakes' problem, and its context. 94

4.2.1 Rationale for presenting findings as an illustrative vignette. 94

4.2.2 An illustrative vignette of the 'no stock, high stakes' problem, and its context. 95

4.2.3 About the illustrative vignette and its construction. 102

4.3 Participant perspectives of 'no stock, high stakes' choices. 105

4.3.1 A summary of definitions and the participants that are referenced in this section. 105

4.3.2 Perspectives on the moral implications of risks and consequences of a 'no stock, high stakes' problem 107

4.3.3 Perspectives on moral values and moral obligations in response to a 'no stock, high stakes' problem 111

4.4 Conclusion 121

5 - "If it's our funding, then it's our policies": participant perspectives on the quality assurance of medical products for the humanitarian health projects of grant-reliant international Non-Governmental Organisations 123

5.1 Introduction. 123

5.2 Concern for the quality of medical products from countries that do not have recognised Stringent Regulatory Authorities. 125

5.2.1 The historical emergence of medical product quality as a matter of concern for sourcing medical products for humanitarian health projects by grant-reliant iNGOs. 125

5.2.2 Participant perspectives on the National Drug Regulatory Authorities of Host Governments. 128

5.3 Donor quality requirements as a method of controlling the sourcing of medical products for humanitarian health projects of grant-reliant iNGOs. 134

5.3.1 Perspectives on the purpose of donor medical product quality requirements. 134

5.3.2 Perspectives on the enforcement of donor medical product quality requirements during 'no stock, high stakes' problems. 136

5.4 Perspectives and observations on responsibility for the Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs. 140

5.4.1 The Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs: the Host Government National Drug Regulatory Authority (HG-NDRA) perspective. 14040

5.4.2 The Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs: the donor perspective. 143

5.4.3 The Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs: the iNGO perspective. 145

5.5 Conclusion 152

6 - "It's SRA or it's not SRA": participant perspectives on the risk of substandard and falsified medical products from unknown sources in 'no stock, high stakes' problems ..153

6.1 Introduction. ..153

6.2 Participant perspectives on their sourcing options in 'no stock, high stakes' problems. ..153

6.2.1 Participant perspectives on borrowing medical products in a 'no stock, high stakes' situation. ..153

6.2.2 Participant perspectives on buying medical products from the national market in a 'no stock, high stakes' situation. ..157

6.3 The lack of ethical guidance for iNGOs urgently sourcing medical products from unproven national vendors for humanitarian health projects. ..162

6.3.1 Perspectives on the unfeasibility of complying with donor medical product quality requirements in 'no stock, high stakes' problems. ..162

6.3.2 Participant concerns regarding a lack of practical guidance in response to 'no stock, high stakes' problems. ..165

6.4 Participants' perspectives on estimating the risk of poor-quality medical products from unfamiliar national vendors during 'no stock, high stakes' problems. ..167

6.4.1 Participant perspectives on information from international organisations when responding to 'no stock, high stakes' problems. ..167

6.4.2 Participant perspectives on estimating the capability of an HG-NDRA for the purposes of reliance on their QA data. ..175

6.5 Conclusion. ..179

7 - "The risk, you could argue, is the right thing": an examination of factors that influenced participants' willingness to take risks when responding to 'no stock, high stakes' problems ..180

7.1 Introduction. ..180

7.1.1 Characterisation of 'no stock, high stakes' problems as conglomeration of risks 180

7.1.2 Participant proximity and its influence on risk perception. 183

7.2 Product: how participant perceptions of the medical product influenced their risk sensitivities and proximity to the patient.....184

7.2.1 The perceived importance of medical products and its influence on participant risk sensitivities. 184

7.2.2 The perceived urgency of medical products and its influence on participant risk sensitivities. 191

7.2.3 The concept of 'lifesaving' medical products. 198

7.3 Profession: how a participant's profession could influence their prioritisation and preference of risks using the case example of logisticians. 200

7.4 Place: participant perceptions of distance on priorities and risk preferences, and the intra-organisational conflict that this engendered.....206

7.4.1 Participant perspectives on distance.....206

7.4.2 Perspectives of Head Office participants on where 'no stock, high stakes' decisions should be made.....207

7.4.3 Perspectives on whether national staff require protection from the challenges and consequences of 'no stock, high stakes' decisions. 210

7.4.4 Perspectives of Country Office participants on where 'no stock, high stakes' decisions should be made.....214

7.5 Conclusion. 216

8 - **Discussion** 218

8.1 The patient gets forgotten. 218

8.2 Caring and proximity: how risk sensitivities and tolerances differed according to the proximity or obscurity of the patient in 'no stock, high stakes' problems. 220

8.2.1 A balance of risks. 220

8.2.2 Proximity, obscurity, and concern for the patient. 222

8.2.3 How proximity to the patient influenced the choice behaviour of participants in 'no stock, high stakes' problems. 225

8.3 Vulnerability and proximity: how institutional-level power dynamics shape the 'no stock, high stakes' problem and entrench systemic inequality. 231

8.3.1 The multi-stakeholder matrix of interdependency for sourcing medical products for humanitarian health projects. 231

8.3.2 How iNGO-stakeholder power dynamics influence proximity and the handling of 'no stock, high stakes' problems. 235

8.4 The injustices and inequities of 'no stock, high stakes' problems and decision-making. 243

8.4.1 Inequitable power and the injustice of prejudice. 243

8.4.2 Epistemic injustice and the hegemony of Quality Assurance in humanitarian contexts 249

8.4.3 Inequitable standards and health injustice. 252

8.5 Limitations of this study and opportunities for further research. 256

8.5.1 The types of iNGOs from which participants were recruited. 257

8.5.2 The attributes of participants sampled for this study. 258

8.5.3 Potential changes to workplace relationships, responsibilities, and policies. 259

8.5.4 Data collection techniques. 260

8.6 Recommendations 261

9 - **Conclusion** 266

References 269

List of appendices

Appendix A: Literature and policy search.

Appendix B: Stakeholder analysis.

Appendix C: Topic guides.

Appendix D: Analytic themes and codes.

Appendix E: Summary of participants.

Appendix F: Participant Information Sheet.

Appendix G: Participant consent.

Appendix H: Participant demographics form.

List of figures

Figure 1: A survey of relevant research topics and their interconnectedness. 8

Figure 2: Global Fund budget data and search criteria..... 28

Figure 3: The approval status of medical products according to donor quality requirements. 29

Figure 4: Illustration of stratified purposeful sampling strategy. 60

Figure 5: Overview of study schedule and activities. 66

Figure 6: The FGD vignettes..... 74

Figure 7: A short example of transcription, capturing speech and non-verbal communication..... 85

Figure 8: Sticky notes used for refining themes and organising chapters. 87

Figure 9: Act or abstain; tragic or mundane? A matrix of the possible choices and their potential consequences in a 'no stock, high stakes' problem, brought to life by the words of "Elliot". 109

Figure 10: A 'traffic light' summary of the QA auditors able to approve a vendor according to the medical product sourcing requirements of donors. 163

Figure 11: Image of a weight balance. 220

Figure 12: Explainer and key for the iNGO interdependencies illustrated in figure 13. 232

Figure 13: An illustration of the interdependent institutional relationships that shape the 'no stock, high stakes' problem. 233

Figure 14: Theoretical map of stakeholders with the potential to influence the quality or availability of medical products administered to a patient in a humanitarian health project. B-2

Figure 15: Focus Group Discussion topic guide. C-7

List of Tables

Table 1: Selection of the term "medical product". 13

Table 2: List of Stringent Regulatory Authorities. 16

Table 3: Definitions of WHO Listed Authority Maturity Levels. 17

Table 4: Definitions of Substandard and Falsified Medical Products. 19

Table 5: Summary of criteria for donor-accepted QA auditors. 31

Table 6: Sampling frame for criteria of iNGO at which a potential participant worked. 59

Table 7: Participant inclusion and exclusion criteria. 64

Table 8: Summary of FGD participants. 72

Table 9: Summary and clarification of vignettes presented to participant according to research activity. 77

Table 10: Summary of confidential documents included for analysis. 79

Table 11: Literature & policy review search terms and their organisation. A-2

Table 12: Inclusion and exclusion criteria for literature and policy review. A-8

Table 13: List of codes for the theme "problem". D-1

Table 14: List of codes for the theme "power through policy" D-3

Table 15: List of codes for the theme "procurement & prejudice". D-7

Table 16: List of codes for the theme "proximity". D-9

Table 17: List of codes for the theme "latent". D-18

Table 18: Summary of participants. E-1

Table 19: Summary of humanitarian agencies at which participants had worked E-9

Table 20: Aggregated summary of participant demographics. E-13

List of abbreviations

AIDS	Acquired Immunodeficiency Syndrome
BHA-USAID	Bureau of Humanitarian Assistance - United States Agency for International Development
CD	Country Director
DA	Document Analysis
DG-ECHO	Directorate-General for European Civil Protection and Humanitarian Aid Operations
EMA	European Medicines Agency
EML	Essential Medicine List
FGD	Focus Group Discussion
GBT	Global Benchmarking Tool
HG-NDRA	Host Government National Drug Regulatory Authority
HIV	Human Immunodeficiency Virus
IC	Informal Conversation
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IDI	In-Depth Interview
iNGO	International Non-Governmental Organisation
KE	Kate Enright (Interviewer)
ML	Maturity Level
NCE	New Chemical Entity
NDRA	National Drug Regulatory Authority
NRA	National Regulatory Authority
PDF	Participant Demographics Form
PIS	Participant Information Sheet
PO	Participant Observation
QA	Quality Assurance
R	Respondent
RTA	Reflexive Thematic Analysis
SF	Substandard and Falsified
SRA	Stringent Regulatory Authority
TA	Thematic Analysis
UN	United Nations
US FDA	Food & Drug Administration of the United States
WHO	World Health Organization
WLA	World Health Organization Listed Authority

Glossary

Cluster.

The "Cluster Approach" is a United Nations Office for the Coordination of Humanitarian Affairs (OCHA) method for coordinating groups of humanitarian organisations who are responding to the same emergency and working on the same activity (such as health, logistics, shelter, or nutrition).[1]

Country Office.

The worksites of an international Non-Governmental Organisation (iNGO) that are focussed on supporting projects in that country. Usually based within the country, but sometimes in a neighbouring country where security risks are extreme.

Decision-makers.

The term is *not* intended to represent those with formal decision-making authority. Rather, I use it broadly to denote individuals who may encounter the 'no stock, high stakes' problem and whose actions and choices (formal or informal) may influence its outcome.

Decision of Interest.

The situation that I have termed a 'no stock, high stakes' problem.

Disallowance.

Funds that have not been spent in compliance with the donor's sourcing requirements and that will be reclaimed.

Essential medicine list.

A list of medical products that are considered essential for a basic package of healthcare services. This may refer to the World Health Organization (WHO) Essential Medicine List for national health systems, or a list compiled by an iNGO for a specific health project, for example.

Head Office.

The location of the iNGO's executive function, which is remote from the locations of its projects.

Host Government.

The body that governs the State in which the iNGO's health project is situated.

Local Market.

Vendors on the national pharmaceutical market.

Medical Product.

A substance or tool that is marketed for human use and intended for the treatment, prevention, diagnosis, or measurement of health conditions and is subject to controls by the National Drug Regulatory Authority (NDRA).

National Drug Regulatory Authority.

The governmental department responsible for assuring the quality, safety, and efficacy of all medical products that are distributed within the country.

'No Stock, High Stakes' Problems.

A situation in which essential medical products are absent, the only immediate replenishment options are of uncertain quality, and in which the lives and livelihoods of patients are perceived to be at risk.

Patient-focussed.

Participants who predominantly focussed their attention on the welfare of the patient and tended to voice their concerns around these perceived risks during 'no stock, high stakes' problems.

Phenomenon of Interest.

The situation that I have termed a 'no stock, high stakes' problem.

Policy-focussed.

Participants who spoke more emphatically and for longer about complying with Quality Assurance (QA) policy requirements during 'no stock, high stakes' problems.

Proximity.

A potentially multi-factorial connectedness that one person feels towards another being.

Quality Assurance.

A method for confirming the safety and efficacy of a medical product by verifying that its manufacture and subsequent handling has complied with minimum practice standards.

Registered medical product.

A medical product that has been authorised by the NDRA for sale within the country or region of their jurisdiction.

Risk.

The potential for negative sequalae (a participant derived meaning).

Roving.

Participants that are accountable to, or line managed by, both Head and Country Office. For example, those in Regional Offices, or those who are line managed by one but based in the other.

Sourcing.

Obtaining a medical product. For example, via procurement, borrowing, or donation.

Waiver.

Permissions to waive policy requirements. For example, a QA policy waiver could waive some or all medical product quality requirements to enable national procurement.

Transcription Key

Quote	Respondent speech.
Quote	The interjection of a focus group participant or interviewer.
Quote	Verbal emphasis.
Quo-	Word cut short by participant.
// quote //	Overlapping speech.
…	Change of subject mid-sentence.
(.)	Short pause in speech.
{action}	Description of concomitant non-verbal behaviours.
[…]	Some speech redacted for brevity.
[explanation]	Author's note to the reader for the purposes of clarification or anonymisation.

Abstract

Substandard and falsified medical products threaten patient lives and, although a global problem, disproportionately affect low- and middle-income countries. International Non-Governmental Organisations (iNGOs) delivering humanitarian health services in these regions often import medical products from trusted international sources. However, if extended health supply chains fail or demands suddenly change, iNGOs face a tragic choice: urgently source medical products of uncertain quality or suspend healthcare provision until resupplied. I term this situation a 'no stock, high stakes' problem. This ethical problem is previously undocumented; existing literature focuses on the quality or availability of medical products, failing to attend to the tension between them.

A range of qualitative research methods were employed to obtain a thick description of this difficult decision from the perspectives of those who have experienced it. I conducted a stakeholder analysis and used purposeful, stratified sampling methods to identify suitable participants. Vignettes constructed from interview-generated data were used as both an elicitation technique and to convey complex findings in the thesis. Reflexive thematic analysis was used to interpret the dataset, informed by discourse analysis techniques to uncover the implicit significance of participants' key phrases and behaviours.

Findings indicate that participants commonly experience 'no stock, high stakes' problems as moral problems, and that they are intensified by the conflicting expectations of the donor and Host Government. A dominant neoliberal paradigm incentivises iNGOs to preference the donor's expectations, leading them to undermine the authority of the State and prioritize fiscal responsibility (via compliance with Quality Assurance policies) over patient care. Participants responsible for implementing donor policies tended to prioritize quality (and economic stability) to a greater extent than those in proximity to patients, who often prioritised continued healthcare provision over personal or organisational risk. These inconsistencies highlight a health injustice in patient care necessitating urgent normative guidance and policy review.

1

Introduction.

1.1 The ethical problem of choosing between medical product quality or availability.

Substandard and falsified medical products have been likened to a public health emergency.[2-4] They arise through improper manufacturing or handling due to criminality, error, degradation, or the use of inferior materials and, as such, result in an item that is lacking in safety or efficacy.[5-7] As poor-quality medical products may be indistinguishable from those that are of sound quality, even with chemical analysis, they present a serious health risk to patients who may be harmed or untreated by their use or administration.[3 8 9] The burden that this neglects *and* creates undermines the capacity and resources of the wider health system, thus increasing the reach of those affected.[4 10 11] Predictably, the problem is not equitably distributed across the globe; countries that have fewer resources to invest in controlling the quality of medical products tend to be disproportionately affected.[11-15]

Due to these concerns, many international Non-Governmental Organisations (iNGOs) import their medical products from international wholesalers.[16-18] However, these extended health supply chains are vulnerable to rupture and may be poorly responsive to unpredictable demands.[19-21] As such, humanitarian health projects may experience stock-outs of urgent and essential medical products, for which the only immediately available solution are national sourcing options.[22-24] In this study, I uncovered that this presents the decision-maker with a tragic choice:[25-27] they can *either* maintain the quality standards to which they are contracted *or* the availability of medical products for the population to whom they are committed, but not both. This decision, which is previously undocumented in academic literature, is a situation in which ethical tension exists, because

compromising either medical product quality or availability risks causing the patient terrible harm.[22 28-30] I term it a 'no stock, high stakes' problem.

My literature review found that publications and guidelines either draw attention to the challenges and inequities of accessing medical products or focus on the importance of combatting substandard and falsified medical products. Whilst both lines of inquiry are important, research into tension between the two is currently neglected.[22 30] Failing to acknowledge these competing pressures, by presenting them as discrete and absolute concepts, places "*ethical labour*" on those in non-ideal settings who cannot achieve both.[26 31-33] Moreover, without a clear understanding of the context and its operational challenges, normative guidance that is grounded in the constraints of real-world settings cannot be developed.[34-36] This qualitative study contributes to addressing this gap. My thesis provides a rich description of 'no stock, high stakes' problems according to those who have experienced them and uncovers a complex sociopolitical web of norms and constraints that influence its resolution. Running throughout my data is the significance of proximity and vulnerability; it informs the decision-maker's identity and who they are willing to trust, as well as (de)sensitizing their connection to the patient and the moral reasoning that they employ.[14 37-40]

1.2 Personal motivation to research this subject.

Between 2013 and 2018, I worked as a pharmacist for various UK based iNGOs. In each organisation, my role was to support the preparation and delivery of healthcare projects by doing what I could to ensure the 'five rights': the right medical product, available at the right time, at the right location, at the right price, and of the right quality.[19] The scope was undefined and massive. It encompassed all types of humanitarian response, health project, location, and discipline of pharmacy (from dispensing medicines and inspecting warehouses, to redesigning supply chains and controlling quality).[41] No matter the task, I found that the challenges and constraints of the humanitarian context meant that my role was less about *ensuring* the five rights and more about determining which ones to compromise in each situation, for how long, and to what extent.[42-45] The difficult decisions that I

faced were shaped by the culture of the iNGOs that I worked for, the political nature of their relationships, and their need for continuous support from funders and the public.[46-49]

The problem that I encountered with the most frequency, and of which I was most uncertain about what I *should* do, was the sourcing of medical products for which there was an urgent need, but where the only immediately available options were of uncertain quality.[29] I came to realise the enormous nuance that could exist within this single problem. For example, I was once asked whether a project should source chlorhexidine gel for umbilical cord care to prevent infection in newborns from a national manufacturer, or not at all. The manufacturer held some credentials from other iNGOs, but I was privy to a report in which quality issues questioned the safety of the medical product. Another time, I was asked for permission to preposition intravenous fluids with a supplier in Yemen, to enable a rapid response to the next cholera outbreak. Rehydration is essential to survive cholera, and the terribly slow movement of goods into and around the country prevented a rapid response using international supply chains. However, nationally available medical products were suspected to be of poor-quality, unsterile, and potentially dangerous.[50 51] On another occasion I was urged to endorse procurement from indiscriminate national sources in a very poorly regulated country that was beset by conflict, because one of the warring parties had demanded that the clinic was well-stocked – and had apparently threatened to assassinate staff if these demands were unmet.[52 53]

Although I navigated each decision the best that I could, I was constrained by time, information, an inability to communicate with those closest to the problem, resources for follow-up, and peers who could debate the issue with me.[54] Moreover, I necessarily dealt with it within the system that I operated: it was an iNGO problem, resolved by iNGO workers, using iNGO resources. During the five years that I encountered these problems, I consulted widely, thought deeply, and found increasingly intricate ways to manage them. Yet, no matter the decision that I reached, I inevitably transgressed my own moral values, caused unquantified harm to a remote population, and received an unpredictable backlash from colleagues.[25 26] These decisions are not ones that leave you once you

leave an organisation.[33] I wonder about how I have impacted lives, about how the legacy of policies I developed may continue to help or harm patients, and about the decisions that someone else would have made in my stead.

Although I wonder about whether I made the right choices – or even *good* choices – this cannot be answered with a single, initial, empirical study by an isolated doctoral researcher. It requires normative research into the legal and ethical facets of the problem, and arguments for the morally just course of action, in numerous contexts, and by engaging with numerous stakeholders.[55 56] These investigations also require thought of their practical application, to determine how decisions should be made, by whom, and under what circumstances.[34 55 57 58] Consideration must be made of what role the patient should play in decision-making, and whether different patients, populations, or contexts require a different approach.[59-62] All this work is important and urgent, and I believe that it must begin by revealing the problem to the academic community and advocating for its attention. Therefore, my motivation is to present the problem, its complexity, and its context in the hope that this project will encourage further research that will, someday, result in ethically informed 'no stock, high stakes' decision-making.

1.3 Presentation and organisation of the thesis.

In this chapter I have briefly outlined the purpose and significance of the study, and my motivation for pursuing it.

In chapter two, I identify the research gap that this study will address and situate it within its literary landscape through a review of relevant literature and policies. My literature search revealed a paucity of academic publications that refer to the phenomenon of interest (which is the ethically difficult decision of how to respond to an urgent medical product stock-out in a humanitarian health project where available medical products are of uncertain quality). However, the topic touches upon numerous and vast veins of scholarship (in health supply chain management, bioethics, and global

health, for example), which I broadly survey and organise around a central theme of medical products.

In chapter three, I define my research questions and outline the methods that I will use to investigate them. As I will explain, I will use qualitative methods to obtain a thick description of the decision and participants' experience of it and reflexive thematic analysis to identify patterns in the data.[63-66] Due to my previous experience with the research context and chosen analytic methods, I will also offer a detailed account of my reflexive practices and positionality.[67-69]

In chapters four to seven, I present my empirical findings using a vignette and participant quotes, with a detailed analysis of their significance to the study.[70] The chapters are organised around four themes that emerged from the data. In order, these are: the problem, power through policy, procurement and prejudice, and proximity.[71 72]

In chapter eight, I will analyse my findings in relation to the broader Global Health context and connect them to research and thoughts in the wider academic literature. I will also propose a model to explicate systemic reasons for why medical product stock-outs may not be resolved in the interests of the patient. The chapter will focus on how a participant's relative proximity to the patient can influence their decision-making and the troubling consequences of some decision-making practices.

In chapter 9, I will reflect on the significance of this study and call for urgent attention in addressing the inequities and injustices of the 'no stock, high stakes' problem and its handling.

2

Literature & Policy Review.

2.1 Introduction.

2.1.1 The initial literature and policy review.

A systematic approach was used to search for publications that were relevant to the phenomenon of interest.[73-75] I aimed to answer two questions. First, how do international Non-Governmental Organisations (iNGO) delivering humanitarian health projects in countries with pharmaceutical markets that are not stringently regulated reach ethical sourcing decisions for medical products that are urgently needed? Second, what are the ethical considerations of a difficult decision in which medical product quality and availability are in tension in humanitarian health settings? The search terms that I used are detailed in appendix A. I found no (grey or academic) literature of direct relevance to either question. However, in my search to answer these questions I uncovered an extraordinary wealth of literature of wider relevance. In this chapter, I will describe how I set about surveying this broad literature base in a way that was manageable and logical. Then I will offer an overview and analysis of papers that were deemed significant to the ethics of urgent stock-out decisions in humanitarian health settings. Finally, I will identify the specific research gap that I will aim to address with my study.

2.1.2 The wider, iterative literature and policy review.

Having conducted a literature review and determined that there were no publications relating to the subject, I contemplated how best to approach and synthesize literature of wider relevance. My aim was to obtain a solid understanding of the theories, research, and practices that have been documented in academic and grey literature that relate to the situation and its context.[74 76-78] Specifically, my objectives were to: survey research gaps and select the project's focus; situate the study within its academic landscape; understand the background of the topic, such that I could effectively design and direct the study; inform my stakeholder analysis, sampling frame, topic guides, and research instruments.[76 77 79] It should be noted that this work was iterative; while it began well in advance of data collection activities, it continued throughout the entirety of the project.[78 80] This was beneficial for exploratory research that utilised an inductive approach because emerging findings informed my literature reviews, just as the publications that I found could impact my topic guides and data analysis. I found that this 'dialogue' between literary and field research strengthened the foundations of my work, by situating them within a broader scholarship that actively offered avenues to test and consider.

First, I considered the nature of the problem and conducted literature searches to explore which high-level research areas were of pertinence to this project. My results found numerous research fields, each with a vast repository of scholarship, of unmanageable scope and number. Therefore, second, I read widely around the subject to gain a greater understanding of which fields might offer the greatest potential value. Due to the broad and exploratory nature of my research, and the lack of focussed papers on the phenomenon of interest, I identified numerous research topics of benefit to my study. Figure 1 is a summary of this work: it articulates the research areas that I concluded were of greatest interest to my study (according to a rapid review of titles and abstracts). (The diagram is intended as a simple overview, rather than a comprehensive or definitive landscape.)



Figure 1: A survey of relevant research topics and their interconnectedness.

This review indicated that the number of publications with *potential* relevance would be unfeasible in a doctoral project. Thus, third, I sought to narrow down the topics into one or two areas upon which to focus a literature review.[77] This exercise yielded two important conclusions that informed the writing of this chapter. When considering what *not* to focus on, I found a strong interconnectedness between the subjects, such that removing one left an unsatisfactory gap in understanding the context of the decision. For example, as illustrated in figure 1, my literature searches and emerging themes from data analysis suggested that power was important to the problem; moreover, this overlapped with early findings related to inequities in Global Health as well as observations of contested decision-making. During this analysis I found a unifying theme: medical products. Therefore, rather than focussing on an in-depth interrogation of a small number of aspects, I chose to pursue a broad and high-level review of literature that touched upon many fields of research, organised around the theme of medical products, to establish my research agenda.[78]

I used an iterative approach to literature and policy searching.[80] [81] I incorporated natural language and keyword searches to identify articles of interest. Keywords, cultivated from the focal concept and its synonyms, were refined using preliminary searches and heavily cited articles of interest. Deep,

structured searches used suitable syntax, MeSH terms, Boolean logic, and specified parameters (such as limiting searches by language or keyword location) to tailor search results. Databases (Medline via PubMed, Google Scholar, Proquest, and Web of Science) were selected due to their suitability to Global Health and their ability to identify grey literature. Further papers were retrieved manually, using forward and backward citation tracing and searches for key authors or organisations. I used EndNote X9 and Clarivate analytics EndNote web to manage references, and Airtable for identifying and categorising their themes.[77] [82]

I have organised the findings of my literature review into three parts that complement and build upon one another, but that also narrow towards the focal point of this study. In the first part, I consider the definition of medical products, before surveying literature on how they are regulated and why this is necessary (which is, namely, the problem of substandard and falsified medical products).[10] The second part considers this scholarship (on the nature, control, and risk of medical products) in a humanitarian setting. I begin by establishing boundaries for what I mean by 'humanitarian health' and then review how medical products are procured and moved within humanitarian health supply chains. The latter connects to the regulatory background introduced in part one, by analysing the Quality Assurance (QA) rules and policies that are adopted by some humanitarian organisations.

In the third part, I review research pertaining to the ethics of decision-making in humanitarian settings. In the first half, I explore morally challenging situations in 'non-ideal' contexts and describe research into the phenomenon of moral (di)stress.[33] [54] This work highlights that policies, standards, and norms can cause or intensify these problems.[43] [45] Thus, I also explore research into choice behaviours in institutions and crises and consider research into the practical and normative significance of proximity.[83-85] In the second half, I focus on literature pertaining to the ethics of medical product quality or availability, as a paucity of literature attends to tension between the two.[29] [30] I conclude by synthesizing the literature review into a specific research need, which is the research gap that my study will address.

2.2 The risks and regulations of medical products circulating in low-and middle-income countries.

2.2.1 What is a medical product?

To thoughtfully select the language that I would use (or avoid) when interacting with interviewees, I researched and reflected on the histories of key terms and their usage.[86 87] (For example, the term "patient" was preferred to "beneficiary", as explained in Chapter 3). A primary consideration was how to encompass such diversity (categories[1] like medicines, medical gases, medical devices, assistive technologies, laboratory reagents, and diagnostic tools, for example) into a single term. I sought something neutral, that signalled the study's focus on health (rather than nutrition, for example), and enabled the interviewee to think and speak of any item that they felt was relevant, without constraint, as I was aware that the language that I used may create implicit boundaries.[56 66 88-90] Moreover, I was sensitive that words have origins and associations; I aimed to avoid using words that are laden with specific meaning and could unintentionally direct conversation.[86 87 91 92]

For example, if I was asked to "speak about a time when you have needed to urgently source a *medicinal* item", it would evoke imagery of highly regulated activities: of allopathic prescriptions handed out by pharmacists in laboratory coats in air-conditioned dispensaries. In Europe, the term "medicinal" is often found in legislative texts;[93 94] therefore, I might think of the time that I was asked to urgently find an antifungal for a baby with necrotizing fasciitis when working in a specialist hospital. The question directs my mind to *this* landscape, whereas the synonyms "pharmaceutical",[95] "drug",[96] or "chemotherapeutic agent" travel to entirely *different* contexts (for me, of research, illicit medicines, and oncology, respectively) and result in different answers. Words are imprinted with specific associations, sometimes from their definition and sometimes from personal experience and

[1] The categories and nomenclature that I use here have been informed by those of the World Health Organization. See their website for further insights: www.who.int/teams/health-product-policy-and-standards/ [accessed 27th Sep 2024].

belief.[66 86 87 91] Therefore, I approached the literature with the intent of uncovering different perspectives on medical products (which is the term that I finally selected) to broaden my own understanding, to identify potential options, and to choose the one that was most befitting of this study.

When you receive a medical product, it may come in a box with a leaflet.[97] If it is a medicine, it will contain excipients, whilst a device may include a power source or attachments. How do these 'parts' relate and contribute to the medical product as a whole? From a regulatory point of view, all facets of an item that reach the patient, caregiver, or healthcare professional should be controlled.[94 98] While the active pharmaceutical ingredient of a medicine, or the core component of a medical device, are essential for achieving the intended effect, the medical product's safety and efficacy may be impacted by any of its substituents and, therefore, it is necessary to regulate their quality.[5 13 99 100] For example, the integrity of a hypodermic needle's primary packaging is important for maintaining its sterility; the accuracy of a measuring spoon is essential for ensuring the correct dosing of a paediatric suspension; the information detailed in the instructions for a diagnostic test may be critical for its correct use and a reliable result.[97 101-104] Little empirical evidence was found to challenge this legal perspective but, despite this, one intuits that many people would view a bottle of antibiotic suspension to be a medical product, even if it was missing its spoon and instructions.

An anthropological view of medical products considers them according to their interactions with people and societies.[95 105-107] This perspective inherently defines medical products through the lens of those who seek them and use them.[107 108] For example, because such research relates to substances that are *perceived* to be medical products, their observations and findings could span from the tonics of traditional healers to the commodified health products of pharmaceutical giants.[105 107] However, many pharmaceutical scientists would raise concerns with so-called "alternative" or "traditional" therapies being categorised in the same manner as allopathic ones.[109-112] Their perspective, perhaps, requires a medical product to have sufficient (non-anecdotal) evidence for its use.[113 114] Yet, publications that report the results of clinical trials for an item in the latter stages of development

(i.e. used on patients) relate to *trial* medical products: if proven safe and effective within the confines of the experiment and for named therapeutic conditions, the innovator can consider applying for market authorisation.[115] (The apparent safety and efficacy of placebos presents an interesting philosophical quandary in this regard.)[116-118]

However, defining a medical product according to whether it holds a marketing authorisation creates ambiguities. For example, when a batch of marketed medical product expires, or has been handled in a manner that may degrade it, has it ceased to be a medical product?[119-121] Certainly, a member of the public may still treat such an item as a medical product when reaching for it from their medicine cabinet, yet the manufacturer may no longer take responsibility for it and a prescriber may be unwilling for it to be used.[6 122 123] Moreover, what of medical products that are registered in one country but not in another? Consider a quality assured medical product that is smuggled into Mali from Germany, and another that is legitimately imported from Pakistan, but is exposed to excessive heat whilst doing so. Research indicates that perspectives on which of these two items is a medical product may differ between patient, clinician, and regulator.[50 124-128]

Yet, for some, the focus on marketed products is a narrow view.[127] A more philosophical perspective identifies that medicines are chemicals, and that "new chemical entities" (NCEs) may also be marketed and traded (amongst drug developers).[129] These NCEs represent those formulae that are anticipated to have the greatest legal, economic, and social significance to the actors and institutions that surround and create them. By tracing a line between the chemicals that are commoditised by pharmaceutical industries and those that are expectantly waiting in chemical libraries, one might expand and blur the line of what constitutes a medical product: from what is prescribable to what is discovered.[109 129] Little was found that captures the patient perspective on what is, is not, and is somewhat, a medical product.

With these perspectives in mind, a range of options were noted from grey literature and academic publications gathered during the literature review. Terms that were applied to medicines, in addition

to medical devices or assistive products, were noted and are summarised in table 1. Most were composed of two words, with the second being relatively interchangeable. The words pharmaceutical and medicinal were excluded due to their strong associations with medicines.[93 115] It was noted that the term "commodity" was used heavily by the United Nations Population Fund (UNFPA) and in association with reproductive health, and was therefore excluded.[130] "Goods", "materials", and "supplies" were frequently found in supply chain literature.[20] "Product" had more widespread usage and, therefore, was potentially more neutral.

For the primary term I chose "medical" rather than "health" or "healthcare", to better distinguish from "health project" and because it is already widely used in Global Health publications.[3 131] For the purposes of this thesis, I will use the term "medical product", and I will define it as a substance or tool that is marketed for human use and intended for the treatment, prevention, diagnosis, or measurement of health conditions and is subject to controls by the National Drug Regulatory Authority. It is noted and accepted that participants may understand the term differently and, as such, the suitability of the term will be reviewed during data collection.

Terms considered for "medical product"	
First half of term	Second half of term
Health	Commodities
Healthcare	Goods
Medicinal	Materials
Medical	Products
Pharmaceutical	Supplies

Table 1: Selection of the term "medical product".

2.2.2 The regulation of medical products.

According to regulators, marketed medical products must be of sound quality; they should be safe and efficacious for their intended use.[6 99 132] This means that they should comply with their specifications, they should not cause unanticipated harm to the patient, and that they should achieve the desired result. Unfortunately, quality cannot be determined by appearance, nor reliably guaranteed *solely* via chemical analysis, (although this may complement some investigations).[5 133 134] Rather, quality is assessed according to knowledge of the medical product's lifecycle: of how it has

been manufactured and handled.[6 100 135] Once a certain manufacturing process has been proven to create a medical product of acceptable quality, safety, and efficacy then it is assumed that, logically, an identical process will have the same effect.[6] This is the founding concept of manufacturing. To establish that a medical product was of sound quality when it was made, a regulator confirms that its manufacturing process was accurately replicated (by checking records relating to the procedure, equipment maintenance, water purity, and staff hygiene, for example).[6 99] To establish that the medical product remains safe and efficacious, a regulator confirms that it has been stored and distributed in accordance with its environmental needs (for example, relating to temperature, humidity, and sunlight), and that it has not expired.[6 99 132]

This system, of confirming the safety, efficacy, and quality of a medical product via a knowledge of its history, is termed Quality Assurance (QA). There is broad consensus regarding the definition of QA amongst regulators; in this thesis I will adopt the World Health Organization (WHO) definition, as their global remit broadly aligns with this study's interests in Global Health: "*a wide-ranging concept covering all matters that individually or collectively influence the quality of a [medical][2] product. It is the totality of the arrangements made with the object of ensuring that medical products are of the quality required for their intended use*".[136] The WHO's definition of 'quality' from the same database is also salient to this study, which they define as: "*the total set of characteristics of an entity that affect its ability to satisfy stated and implied needs and to ensure the consistent and reliable performance of services or products in conformity with specified requirements.*" I will use this as a working definition but reflect on it throughout my research as I anticipate that participants will have their own concept of medical product 'quality' in humanitarian health settings.[86]

The responsibility for quality assuring medical products falls to each government, as they are responsible for ensuring the quality of health services that are accessed by their citizens (and, by extension, the quality of medical products that are used within that health system).[6 13 131 137 138] In

[2] The WHO definition uses the term "pharmaceutical", but I have amended this to "medical" to align with my own terms, in the interests of consistency and clarity.

simple terms, this involves registering which medical products are authorised to be marketed within the country, and then controlling and regulating the medical products that are manufactured in, or imported into, it.[139 140] Different governments have different names for the department that is tasked with these responsibilities. For example, in Kenya it is the 'Pharmacy and Poisons Board' whereas in the Philippines it is called the 'Food and Drug Administration'. For the purposes of this thesis, I will refer to them collectively as 'National Drug Regulatory Authorities' (NDRAs). This term, and very similar variations, are well recognised within the field of regulatory affairs.

Evaluating the quality of every medical product that is made or moved in a country is a behemoth task: each health system requires thousands of medical products to meet its requirements, and each will have its own technical specifications and testing requirements that are delivered in discrete batches from different manufacturers and vendors.[5 6 29 132 141] Therefore, many NDRAs adopt risk or reliance-based approaches to focus their efforts and to share the burden, respectively.[142-147] Despite this, a great deal of resource, skill, and technical capability is still needed to effectively regulate and control the quality of nationally available medical products.[15 147 148] Some NDRAs are deemed to have sufficient capacity to meet this challenge.[149 150] These NDRAs were labelled as "Stringent Regulatory Authorities" (SRAs), which the WHO defines as a regulatory authority that, as of 23rd October 2015, was a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), was an ICH observer, or was a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement.[151] The NDRAs that qualify as SRAs via this definition are listed in table 2.

A list of Stringent Regulatory Authorities (SRAs)[151]
Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lichtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Netherlands, United Kingdom, and the United States.

Table 2: List of Stringent Regulatory Authorities.

In theory, this approach (of singling out those NDRAs that were deemed to be capable of fulfilling their responsibilities) identified verdicts and markets that were reliable and those that required "strengthening".[138] However, it is a system that recognises membership of an international group, rather than being a transparent and evidence-based method of evaluation.[92 152 153] It also provides no insight into the capability or advancement of NDRAs that, categorised by exclusion, are "not SRA". These limitations conflict with the WHO's work to strengthen regulatory systems, to 'localise' medical product manufacturing, and to strive for 'health for all' – both in practice and in ethos.[154-157] Therefore, the WHO launched a global benchmarking initiative to depart from the SRA system and which, at the time of publication, is still in train.[149 158] It entails detailing indicators for various NDRA functions[3], and for various categories of medical products[4], and provides a method for grading performance (in relation to those functions and categories) using a "Global Benchmarking Tool" (GBT).[159] With this system, the 'maturity level' (ML) of an NDRA's function, or regulation of a medical product category, is evaluated by scoring ("benchmarking") their fulfilment of relevant indicators from one (the worst) to four (the best). Table 3 provides WHO descriptions of MLs.

[3] The regulatory functions are: national regulatory systems, registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, and national regulatory authorities (NRA) lot release. See reference: 159. World Health Organization. Operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed authorities: World Health Organization 2023.

[4] The medical product categories are: vaccines, medicines, medical devices (including in-vitro diagnostics), blood and blood products, and vector control products. See reference: 159. Ibid.

Maturity Levels (MLs) of NDRA functions for specified medical product categories.[159]
ML1: some elements of regulatory systems exist.
ML2: evolving national regulatory systems that partially perform essential regulatory functions.
ML3: stable, well-functioning and integrated regulatory systems.
ML4: regulatory systems operating at advanced level of performance and continuous improvement.

Table 3: Definitions of WHO Listed Authority Maturity Levels.

NDRAs that achieve ML3 or ML4 may apply to become a 'WHO listed authority' (WLA) (for each function or category).[158 159] The WHO defines a WLA as "*a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process*".[159] Thus, the concept of WLAs should replace that of SRAs and, in academic literature, has been welcomed as an overdue shift towards greater transparency, equality, and granularity.[149 152 160] However, the system is novel and still in transition; as of October 2024 there were thirty-six WLAs, the majority of which were added the same year.[161] At the time of publication, the WHO anticipated that the term "SRA" would be in use until 2027, at which point they expected transition to be complete.[150] Therefore, while there appears to be widespread support for establishing NDRA maturity levels and designating WLAs in academic literature, at present this seems to represent enthusiasm for the ambition, rather than the practice. The global functioning of the WLA system is theoretical, application on a national basis is yet to be thoroughly appraised, how it may impact humanitarian health supply chains is unknown, and documented opposition (or negative criticism) of the transition is notably absent.[15 162]

2.2.3 Poor-quality medical products.

A poor-quality medical product is one that fails to comply with its specifications, presenting safety or efficacy concerns.[6 11 132] Numerous high-profile incidents have been reported in the media, in which a poor-quality medical product has tragically killed swathes of unsuspecting patients.[163-166] Less well reported are the incidents that cause non-fatal harm or that erode trust between patient and healthcare provider.[50 51 167-169] These consequences not only have a detrimental impact on the wellbeing of the *individual* (and their family), but they also take a toll on the health of the *public*, due to changes in health-seeking behaviour, an increased burden on health budgets, and a rise in antimicrobial resistance.[4 10 12 170 171] Indeed, the problem has been described as a public health emergency: a global threat affecting both high- and low-income countries, both generic and innovator products, both adults and children, and for any type of therapy.[2 4 172]

Poor-quality medical products may arise from different origins.[5 173] For the purposes of this thesis, 'poor-quality' will refer to medical products that are either substandard or falsified, according to the WHO definitions of the terms, which are provided in table 4. The core difference between the two is intention.[5 10 103 174] Substandard medical products are registered by the NDRA and produced by a licensed manufacturer.[7 103 175] However, for some reason, the medical product is not fit for purpose at its point of use.[5 103] This may be due to the use of substandard components, an error or failing in the manufacturing process, or due to degradation following manufacture, for example.[5 10 50 103 176 177] Falsified medical products were not intended for the purposes of caring for the patient: they were created with the intention of deceiving detection for personal gain.[7 175 178] For example, a medicine that is falsified may contain *no* active pharmaceutical ingredient, a subtherapeutic amount (for the purposes of avoiding detection by chemical analysis), or it could be an entirely different medical product that has been re-packaged.[2 12 171 173 179 180]

Definitions of substandard and falsified medical products.[7]
Substandard medical products: Also called "out of specification", these are authorized medical products that fail to meet either their quality standards, or their specifications, or both.
Falsified medical products: medical products that deliberately and fraudulently misrepresent their identity, composition, or source.

Table 4: Definitions of Substandard and Falsified Medical Products.

Thus, although substandard and falsified (SF) medical products are both poor-quality and manifest similar problems, they have different causes, different routes to legitimate markets, and are anticipated to have different solutions.[7 103 173] For this reason, several papers have raised concerns with their amalgamation (i.e. into "SF" medical products), due to the confusion and distraction that this could create.[103 181] However, while it may be important to differentiate between these types of poor-quality product, it is noted that it may be currently unfeasible for many studies.[2 142 182 183] As previously stated, SF medical products may be indiscernible from medical products of sound quality (in their appearance and via chemical investigation) and, even if identified, may be indistinguishable from one another.[184] For social scientific research that examines *perspectives* (of users or procurers, for example), the distinction may be unnecessary and academic.

The difficulty of detecting poor-quality medical products frustrates estimates of their prevalence.[8 9 179 185-187] Indeed, the scale of the problem of SF medical products is, arguably, unquantifiable; not only is the accuracy of the original research uncertain (due to false negatives or positives), but its generalisability (to different markets, regions, time periods, and medical products) is questionable.[23 185] Despite this, numerous publications that discuss the problem of SF medical products in general terms reference some statistic regarding prevalence, but many fail to critically appraise the figure or the research upon which it is founded.[11 185] For example, I found that many papers quote the WHO's

press release that "*10.5% of medicines in low-income countries are estimated to be substandard or falsified*".[188] However, this claim may be highly inaccurate; it is extrapolated from studies in which the screening and testing technologies are prone to inaccuracies (which were gathered via literature review of data published between 2007 and 2016) and a database of non-random samples (gathered by regulators between 2007 and 2013).[10 11 185]

For patients or healthcare providers seeking actionable data to inform medical product purchasing decisions, statistical estimates offer little practical value.[8 29] No credible research claims to offer a reliable or specific estimate of the prevalence of SF medical products for a certain category, vendor, or location; decision-makers are blind to the scale of the risk.[185] Nor is there academic agreement about how screening and detection methods should be employed in a real-world setting, which would be helpful for the development of policies and procedures.[183 189 190] Therefore, while a raft of publications describe the consequences of poor-quality medical products and the importance of strengthening regulatory systems, currently data cannot inform a clinician whether a *specific* medical product, from a *specific* vendor, at a *specific* point in time will be safe and effective.[8 51 185] I will return to this literature gap in section 2.4.

2.3 The organisation and governance of the procurement of medical products for humanitarian health projects delivered by international non-governmental organisations.

2.3.1 Defining the scope of 'humanitarian health'.

Humanitarianism, as an institutionally organised endeavour, could refer to a complex array of different activities in a range of vastly different environments.[52 191-193] For example, the reconstruction of schools in rural Nepal following their destruction by an earthquake is, programmatically, quite different from advocating for a humanitarian corridor into the Occupied Palestinian Territories for the delivery of essential commodities.[53 194] However, at their core, both activities are focussed on the

welfare of people.[195] In reviewing the literature, I sought to understand the organisation and boundaries of humanitarian *health* activities, with the intent of informing my sampling frame and instantiating key terms. Despite being a relatively 'young' professional sector, I uncovered a gamut of grey literature, largely from UN agencies, that related to the definition, planning, expectation, coordination, and execution of humanitarian activities[5]. I noted that the health activities described in these publications could, broadly, be categorised into the following types: research, advocacy, development assistance and humanitarian aid. I will focus on the latter two as the former two are not of direct relevance to my study; research does not involve medical products of uncertain quality, and advocacy does not involve patient care.

Development assistance and humanitarian aid have distinct definitions but blurred boundaries.[196 197] Development assistance is frequently viewed as long-term activities that focus on enhancing national capacities and capabilities in the interests of systemic improvement and independence.[197 198] Humanitarian aid is often described as short-term specific 'relief' in the aftermath of an emergency.[195 199] An emergency in the humanitarian context could be defined as a natural or man-made event (such as an infectious disease outbreak, conflict, natural disaster, or hazardous spill) that overwhelms (some or all) of the national capacity to respond and care for the affected population.[200 201] However, emergencies do not end with the abruptness with which they may begin; there is no natural point at which a humanitarian aid project should become a development assistance one.[196 197] Consider the health needs that existed following the earthquake that devastated Haiti in 2010, or the 2014 Ebola outbreak in West Africa, or the Rohingya refugee crisis that persists today.[202 203] These events created immediate, disaster-related (mental and physical) health problems, but they were layered upon (and complicated by) chronic unmet health needs – and further compounded these systemic challenges.[202 204 205]

[5] For example, a list of publications from the United Nations (UN) Office for the Coordination of Humanitarian Affairs (OCHA) is available here: https://www.ochaopt.org/publications; websites of other UN agencies have similarly extensive libraries of publications.

In this matter, as with many such things, there is a difference between theory and practice.[32 206] *Theoretically*, humanitarian aid and development assistance differ in their duration, scope, and urgency.[197] However, they are merely conceptual constructs that have been designated to real-world problems and activities. In *practice*, events (and responses to them) do not necessarily fall neatly into one of these categories. Several authors have highlighted that attempting to dovetail humanitarian aid with development assistance does not merely present a conceptual problem; it creates two distinct infrastructures that compete for funding, authority, and prioritisation.[204 207] This tension has evolved from distinct perspectives on (and methods of) aid, into two distinct cultures, with differing mandates, priorities, partnerships, trajectories, funding streams, and traditions regarding localisation.[196 206 208] An example of this tension was the withdrawal of a prominent health charity from the World Health Summit in 2016; they objected to the attention on national resilience and 'development' activities, which they claimed undermined support for addressing 'humanitarian' issues.[209] An appreciation of this nuance is important for the collection and interpretation of data; to use appropriate language in interviews and to grasp the subtleties of the meanings and biases of interviewees.[66 90 210]

As I will describe, the QA requirements of bilateral donors were issued from "humanitarian" (as opposed to "development") governmental departments. However, with an appreciation of the aforementioned histories of these terms, one may surmise that the scope of those projects classified as "humanitarian" may extend far beyond emergency relief.[53 196 203] Therefore, this domain appears to offer the greatest potential variety for this exploratory study, whilst also 'benefitting' from the most potential tension (due to the intensity that results from urgency and constraints). I will define humanitarian health projects in broad terms (to avoid prematurely limiting findings) as: a package of organised healthcare that is delivered by a non-governmental organisation for the purposes of attempting to address unmet health needs.[92 205 211 212]

2.3.2 Humanitarian Health Supply Chains.

Though unquantifiable, the risk of sourcing substandard and falsified medical products is likely to be particularly high in humanitarian contexts due opportunity; it is characterised by a nexus of desperate need, increased spending (e.g. by aid agencies), and a reduced national capacity to disincentivise criminality.[7 175] It is estimated that about a quarter of the world's population lacks access to affordable, quality medical products, and that these people are disproportionately distributed in low- and middle- income countries.[213-215] If a disaster occurs, acute humanitarian needs are piled on top of the chronic ones.[42 202 203] Weaker regulatory and judicial controls inevitably cohabit these settings.[15 161 216 217] This does not cause poor quality per se, but it does create vulnerabilities that can be exploited by criminals, or organisations that prioritise profit over safety. The incentive to do so is the enormous size of the market: global pharmaceutical sales exceeded US$1.5 trillion pa in 2023 and development assistance for health was in excess of US$20 billion pa.[218-220]

Theoretically, an iNGO could quality assure medical products in the country in which they are operating, themselves. Informally coined "The Buyer Beware Principle", this would either entail evaluating the Quality Management Systems of each manufacturer, vendor, and handler in the value chain, or relying on the authorisation of an NDRA whom they trust, or a combination of the two.[7 100 221] However, in practice, these options are impractical due the resources required.[100 147 175 222-224] Ascertaining the veracity of an imported medical product that is supposedly authorised by an SRA (for example) is also problematic, due to a lack of critical and validated information.[5 137 161 175 225]

These challenges exist, in part, due to opaque and circuitous global pharmaceutical supply chains.[5 226-228] For example, consider a medicine that begins as disparate ingredients in separate manufacturing sites in China, before being combined into a "Finished Pharmaceutical Product" in India, which is labelled in Senegal, packaged in Malaysia, purchased in France via a Canadian broker, and imported to the destination country by a Dutch procurement agency, for onward distribution by various national vendors and pharmacies. With such complexity, it is highly unlikely that the procurer will be able to

obtain the information necessary to validate the medical products. [155 229-231] Therefore, at the point of purchase, an iNGO procurer is unlikely to be able to quality assure the medical product – no matter how many resources are brought to bear to evaluate it.

These difficulties mean that iNGOs who are concerned about medical product quality establish their own supply chains to import goods from markets or vendors that are regulated by SRAs.[20 199 232 233] However, studies concur that the dependencies of these extended parallel supply chains, and the unpredictability of the humanitarian projects that they serve, may undermine the smooth delivery of medical products to project sites.[20 234 235] For example, access to clinics may be hampered by poor infrastructure and insecurity. The size and needs of the patient population may vary with displacement, or community acceptance. The ability to recruit and retain staff with the necessary technical skills to manage medical products may be challenging due to education or intra-agency competition. All these aspects can burden the already substantial logistical effort needed to meet operational needs. Under these conditions, ensuring a ready supply of the intended (and urgently needed) medical products may be exceptionally challenging.[16 192 229 232]

When demand for a medical product exceeds its available supply a stock-out ensues.[19] The absence of medical products at the time and location that they are required can have far reaching consequences.[13 202 236-240] Not only can it have a deleterious impact on the health and wellbeing of the patient, their family and livelihood can become impoverished through loss of earnings and increased out-of-pocket expenses.[13 103] If it is a routine occurrence, it may also alter health-seeking behaviour,[103] leading patients to favour less well-regulated medical providers and drug vendors.[5 40 228 230 241] This can erode public health, the reputation of the iNGO, the morale of healthcare staff, and the integrity of local pharmaceutical markets (due to demand outstripping supply, thus increasing the incentive for criminal activity).[2 7 11 169 171 185 213 242] Therefore, there is often substantial pressure, from numerous actors, for iNGOs to avoid or resolve stock-outs with the utmost urgency.[13 192 229 243] However, a small pool of research indicates that iNGO health supply chains may be poorly equipped to respond to these demands.[16 243]

A wealth of publications indicate a prevailing sentiment regarding the unacceptability of compromising medical product quality,[5 17 50 51 156 227] which is reinforced through a small number of explicitly negative articles,[22 222 244] and an absence of sympathetic articles.[29] This may indicate an implicit norm amongst Global Health actors that it is unacceptable to compromise medical product quality. If this is the case, masked, false, or incomplete narratives may arise during the study in the interests of presenting socially acceptable appearances.[245-247] No academic papers were found that detailed how iNGOs address urgent stock-outs of medical products. However, a small but active topic of research offers insights into the choice behaviour of individuals sourcing medicines for personal use, in contexts where medicine quality is uncertain.[39 40 226 228 241 248 249] Here, Tibandebage et al's description of "*health as a relational activity*" is echoed in numerous findings, where the importance of trust in health care providers and systems is identified as a significant influence on individual decision-making.[40 226 241 248] Indeed, employing trust as a strategy to reduce complexity in uncertain or stressful situations is widely acknowledged.[248 250-252]

2.3.3 Policies regarding the procurement of medical products for humanitarian health projects.

Whether and how funding flows in support of humanitarian enterprises (and their health supply chains) is significant to a study of iNGO decision-making (and their procurement practices).[235 253 254] The power wielded by benefactors, and their ability to create or constrain opportunities, has been the subject of a rich and important vein of scholarship.[215 234 255-259] Although a review of this literature is beyond the scope of this thesis, I will highlight some points of general consensus that are pertinent to this study, before focussing on the medical product procurement policies of some donor institutions.

Economic control often translates into programmatic control. [235 254 260 261] Ineffective communication with (and accountability for) the population that a funder intends to help can mean that the scope and priorities of their programmes may reflect the interests of the donor, rather than the needs of the people.[153 207 253 262 263] Studies into the influence of power (particularly asymmetrical postcolonial

power) complement these insights, by highlighting the function of reliance and obedience in systems that cause vulnerability.[48 264-267] Numerous scholars have explained how this pattern of humanitarianism, which is often viewed as paternalistic and domineering, is a legacy and reinforcement of colonialist power and the global inequities that have arisen from it.[62 212 255 257 261 268 269]

I searched for documentation (i.e. grey literature, such as policies, procedures, or flow charts) or reports (i.e. academic literature, such as commentaries or original research) that explicated how an iNGO would respond to a stock-out in a humanitarian health project that is situated in a context in which the quality of available medical products is uncertain due to concerns for the NDRAs capacity. This search yielded no results. I then searched for policies and publications that would illuminate how iNGOs approached the routine procurement of medical products for humanitarian health projects more generally i.e. not in urgent circumstances. This search retrieved one paper, which summarised a system for quality assuring abortifacient medicines, developed by Marie Stopes International (a charity and commercial enterprise with a focus on reproductive health).[270] The timing of the paper (during an escalation of long-standing conflict regarding the moral and legal rights of abortion), its strong statements in support of public access to abortifacient medicines, and the affiliation of the authors to Marie Stopes International, suggest that the publication played a strategic role in a wider advocacy campaign.[271 272] The paper lacks significant technical depth and data regarding medical product QA, but it offers an overview of the iNGO's risk-based approach for the sourcing and pharmacovigilance of medicines used for medical abortion and, therefore, it is worthy of comment.

The paper describes a method of estimating and grading the risk of three criteria: the manufacturer, the batch of the medical product, and the attributes of the medical product.[270] The manufacturer is a key determinant of the quality, safety, and efficacy of a medical product;[6] its risk was evaluated according to its assessment by a "*stringent inspection body or MSI-approved auditor*". The paper does not detail the criteria used or the competencies required for independent inspections, nor does it list the "bodies" upon which it approves medical products (nor on what basis). The product dossier is

used to evaluate the quality, safety, and efficacy of a batch of medical products. The procedure for doing so and the qualification of the review are not provided. Finally, the risk that the medical product may pose to an intended patient if it is substandard is graded according to attributes such as route of administration and sterility requirements. These attributes seem logical rather than evidence-based and are not comprehensively listed in the paper. These factors are combined into an overall risk rating which, alongside the historic case load, informs a sampling strategy for the chemical analysis of batches. Testing methods and the selection of a laboratory are not described. Example cases of how this system has been used to identify substandard medical products are presented, but the paper does not attempt a systematic analysis of the effectiveness or limitations of the programme.[270]

While the paper lacks detail about the procurement and QA of medical products and only applies to a single category of medical products of one iNGO, it offers interesting insights and precedents. It reveals that iNGOs may conduct independent QA of medical products and that different medical products may be subject to different QA criteria. It also represents risk as a method of informing decision-making, and that medical products that are deemed to be "*very high risk*" may still be "*bought for an emergency*" (though the concepts of 'emergency' and 'high risk' are not instantiated, and who determines these situations is not stated). These insights raise questions regarding the transparency and oversight of iNGO activities, as well as the normative basis of their processes.[22 30 156 273 274] In this regard, it is noteworthy that policies were guarded and that no publications could be found that provided detail about how iNGOs select medical product suppliers, or about whether and what minimum quality criteria they apply in routine and urgent procurement circumstances.

Having identified the significance of financial oversight, I searched for donor policies that stipulate QA requirements for the sourcing of medical products by recipient iNGOs. I retrieved policy documents from the following donor organisations: The Global Fund,[275 276] the Bureau of Humanitarian Assistance of the United States Agency for International Development, (BHA-USAID),[277-280] the Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG-

ECHO),[281] and Unitaid[282]. Unitaid specifically stated that it "*aligned*" its QA requirements with The Global Fund and substituted policy detail for references to the latter's documentation. Therefore, I will only summarise the medical product QA requirements of The Global Fund, rather than of both organisations. One publicly disclosed discussion paper was found that described a review of donor medical product QA policies, which was commissioned by the World Bank in 2012.[283] The paper did not identify any additional donor organisations, and it referenced outdated policies, therefore I will not discuss it further.

To obtain a sense of the scale to which these policies applied, I looked for open-source financial data relating to their spending on medical products (though a detailed analysis is beyond the scope of this project). The Global Fund provided an online tool for data analysis, which indicated that its budget for "Health Products-Pharmaceutical Products", awarded to multilateral organisations, under grants that were active on 9 May 2024, provided a figure of nearly US$333 million.[284] Figure 2 refers (and indicates the filters that were applied). The BHA-USAID Annual Report of 2022 cited a global spend

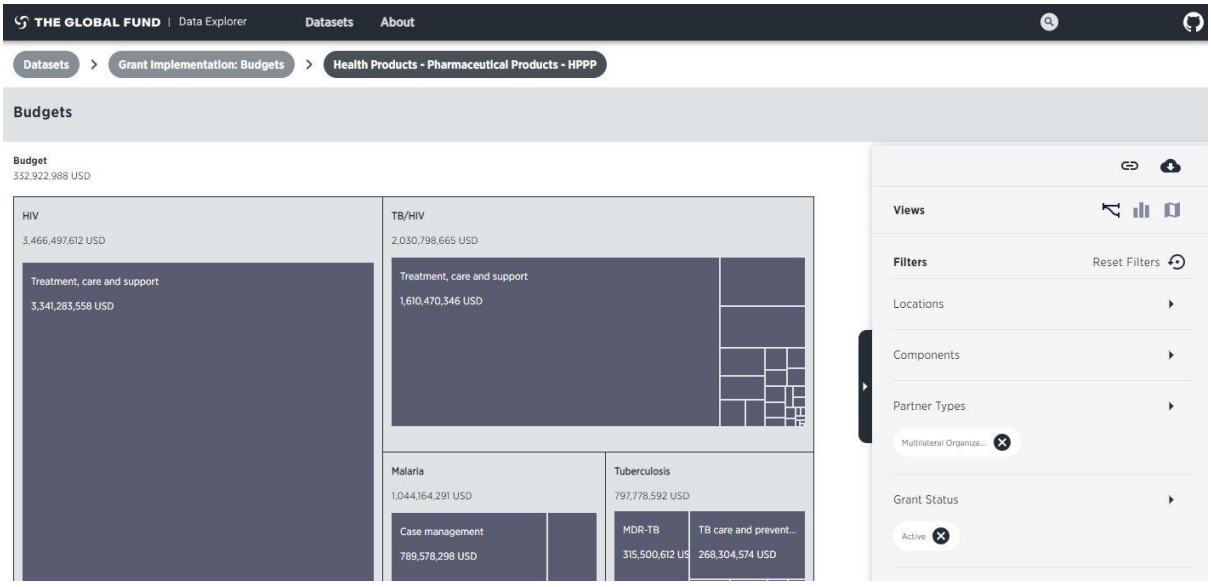


Figure 2: Global Fund budget data and search criteria.

of US$2.4 million on pharmaceuticals.[285] Although the European Commission has an online tool for analysing financial data, it was unfeasible to retrieve data that related specifically to ECHO's spending on medical products (rather than locations or recipients) with my available time and resources.[286] Data for Unitaid spending was not found (but a review of its 2021 financial report suggests that its budget for medical products was far more modest than the other three donors).[287]

A summary of medical product QA requirements is offered in figure 3. Regarding the scope of medical products for which the requirements applied, the bilateral donors (i.e. DG-ECHO and BHA-USAID) stipulated policy requirements to *all* goods that were purchased with their funds.[277-279 281]

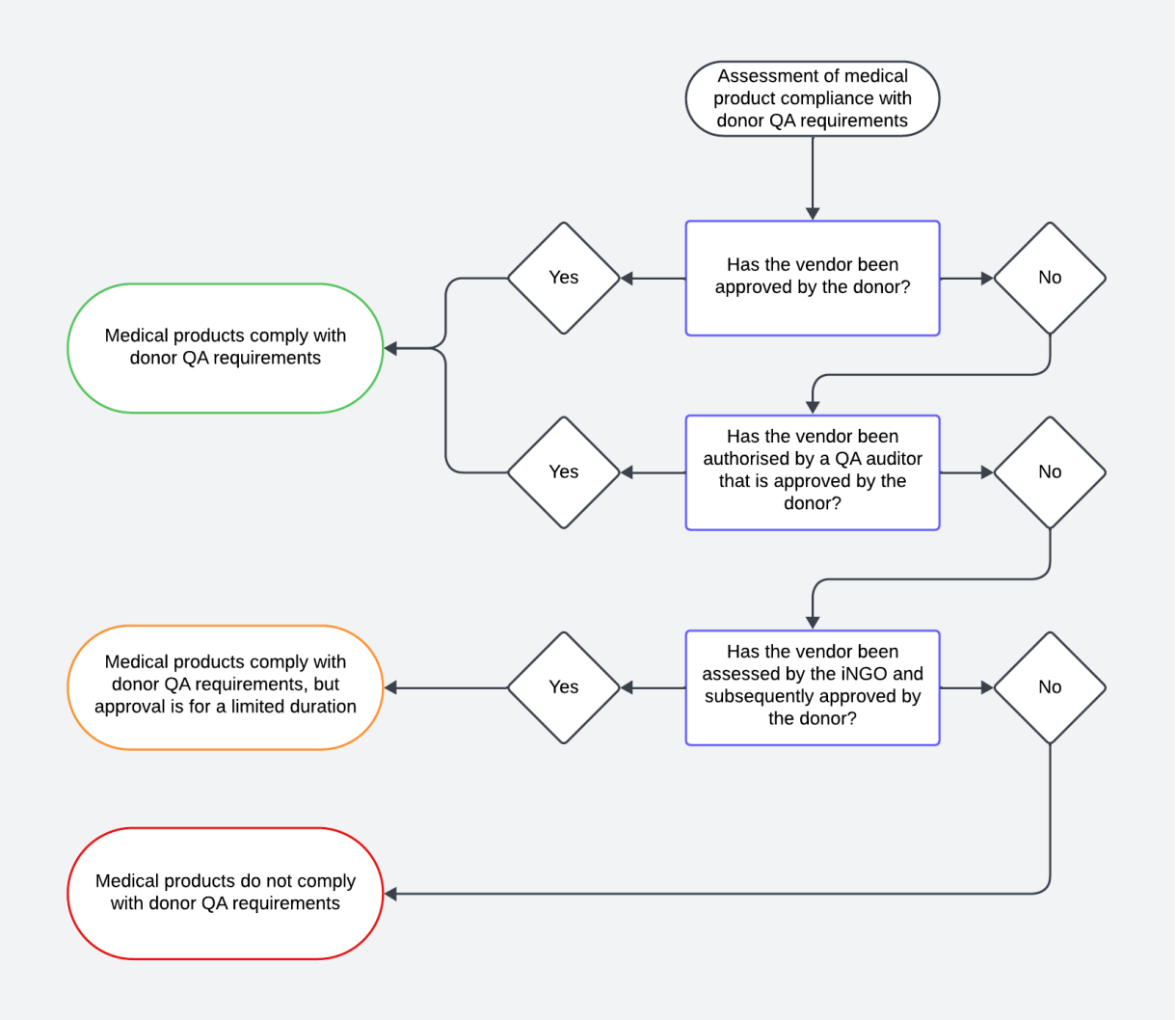


Figure 3: The approval status of medical products according to donor quality requirements.

The multilateral donor (i.e. The Global Fund) only applied heightened QA requirements to medical products that were associated with the treatment of its focal diseases (i.e. HIV/AIDS, malaria, and tuberculosis).[275 276] For all other medical products, the authorisation of the Host Government's National Drug Regulatory Authority (HG-NDRA) was permissible. It was unclear how much funding The Global Fund siphoned into medical products that were considered ancillary to their mandate, why they did so, for whom, and with what frequency. Therefore, it is not possible to comment on the practical significance of this disparity with available data (though I will comment upon the ethical

significance of it in the Discussion chapter.) I will assume that the majority of funding is dedicated to its "core" medical products and, therefore, proceed to focus on these QA restrictions.

The two bilateral donors maintained lists of "pre-approved" vendors; if the iNGO sourced from these suppliers then they did not need to offer any additional information regarding the quality of the medical products.[279 281] Several BHA-USAID documents listed the approved suppliers, but these were inconsistent. [277-280] Some vendors appeared on both DG-ECHO and BHA-USAID lists.[288] While criteria for approving vendors was provided, details of the assessments were not available and both organisations denied liability for the quality of medical products that were sourced from the vendors. No independent research was found that verified the Quality Management Systems of these vendors. No publications were found that scrutinised the impact of designating a small market of pre-approved vendors on other factors, such as medical product cost, availability, or acceptability.

All donors incorporated a system of reliance[6] for medical product QA, [141 144] in which the authorisations of certain institutions were accepted and compliant with QA requirements.[275 276 279 281 282] These institutions are listed in table 5 for medicines and medical devices. In summary, donor accepted QA auditors were either UN agencies or SRAs or, in the recently published Global Fund policy which made provisions for transition to the novel benchmarking system, WLAs. All documents stated the need to comply with national laws and legislation; however, for all donors the onus was on the recipient to do so. No guidance was offered regarding conflict between national rules and donor rules; and there was no stated requirement to comply with (or avoid undermining) national systems or cultures.

[6] Reliance denotes that one institution relies on the assessment and verdict of another; it is a common and accepted practice amongst national drug regulatory agencies.

Donor-accepted QA auditors for MEDICINES	Donor-accepted QA auditors for MEDICAL DEVICES
All donors accepted the following authorisations: • The WHO Prequalification of medical products programme; or, • A Stringent Regulatory Authority.	All donors accepted the following authorisations (and ISO 13485 recognition): • The WHO Prequalification of medical products programme; or, • One of the Regulatory Authorities of the Founding Members of the GHTF (i.e. Australia, Canada, EU, Japan, USA); or, • A Conformity Assessment Body recognised by one of the GHTF country funding members.
These donors had the following variances: • BHA-USAID also accepted UNICEF. • The Global Fund also accepted "WLAs, within their scope of listing."	These donors had the following variances: • ECHO also accepted UNFPA. • The Global Fund also accepted "WLAs, within their scope of listing."

Table 5: Summary of criteria for donor-accepted QA auditors.

All donors accommodated extraordinary approvals, in which the iNGO could contract a QA audit (or conduct their own QA audit) and submit the results for review by the donor.[275-279 281] The wording of these sections was often vague regarding the type of information required, how it would be assessed, and the competencies and qualifications of the QA auditor. This appeared to offer iNGOs a method for urgently sourcing medical products from national sources in a manner that complied with donor QA requirements. However, it also appeared to require conducting a QA audit which, as previously stated, has been suggested as unfeasible. A search was conducted to identify up-to-date qualitative data regarding the feasibility and methodology of urgent QA audits by iNGOs in humanitarian contexts, but none were found. No research could be found that studied how extraordinary approvals impacted the quality and availability of medical products, and patient outcomes.

2.4 Studies of the ethics of making difficult decisions in humanitarian contexts.

2.4.1 Decision-making and the humanitarian context.

Humanitarian contexts often involve compelling unmet needs, high stakes, inadequate resources, and time-sensitive decisions against a backdrop of inequity.[25 45 54 289] Moral theories that pursue ideals of fairness and justice may be unfeasible to implement when situated within a *non-ideal* quagmire of inequity;[290 291] thus, it is widely agreed that ethically complex situations are an "inescapable" reality for humanitarian aid workers.[25 54 292] Indeed, Slim argues that the greater the number of fundamental principles to which a humanitarian agency is committed, the more frequently their staff are likely to face ethical problems.[45] For example, a principle of protecting staff may conflict with preserving human life when operating in insecure environments.[45] For those working in health, it is common to have professional principles and standards, in addition to personal, cultural, or organisational ones. Thus, not only do humanitarian health workers face ethical tensions that are familiar to clinical practitioners across the globe, but they also contend with difficult decisions that arise from delivering healthcare in non-ideal contexts.[26 32 43]

In their literature review of "*decision-making at the sharp end*", Clarke and Campbell offer a "*sobering*" summary of humanitarian decision-making, which they describe as "*slow, dissociated from strategy, opaque, unaccountable […] informal, emergent, ad-hoc and reactive*".[289] Although they fail to consider the normative significance of this situation (and they also neglect research on this topic), they outline how non-ideal settings present profound challenges to decision-makers, which they categorise as: "*a large number of decisions with significant consequences*", "*urgent time pressures*", "*uncertainty about the current and future situation*", and "*high levels of stress*".[289] Based on their research, they conclude that humanitarian decision-making is largely arbitrary and intuitive. Although there is relatively little academic research into decision-making behaviour in humanitarian contexts,[289] there are numerous publications that investigate decision-making under similar circumstances in the fields of psychology and business management.[293-303] This literature tends to associate "crisis" decision-making with more

risk-taking, more reward-seeking and also finds that there tends to be a greater reliance on intuition.[85 295 301 304] However, these studies consistently indicate that the relationship between stress and decision-making is nuanced, being highly influenced by factors such as prior experience, time-pressure, and uncertainty.[294 299 300 305] These observations may be pertinent to humanitarian decision-makers; further research into these influencing factors may be beneficial to supporting and improving ethical, humanitarian decision-making.

During my research, I was curious about how to 'label' the decision that faced people who encountered an urgent stock-out in a humanitarian setting. I noted that papers in the fields of bioethics or social sciences that explored decision-making in non-ideal situations did not consistently use the term 'dilemma'. Moral dilemmas are defined by Beauchamp and Childress as "*a circumstance in which moral obligations [...] appear to demand that a person adopt each of two or more alternative actions, yet the person cannot perform all alternatives*".[28] Upon reflection and wider reading, I concluded that this definition would be too narrow to encompass all of the problems that might arise in my study, in which practical (non-moral) imperatives, uncertainty, or inescapable tragedy (for example) may also manifest difficult decisions.[25 43 45 54 292] Moreover, this definition of a moral dilemma would demand one to explain which moral values are in contention and how, to justify their use. In qualitative studies that are primarily concerned with human experience, such moral theory may distract from understanding the beliefs and perceptions of individuals who navigate these circumstances.[56 58 306] Thus, I searched for alternative labels to apply.

In the literature that I surveyed, I found that problems in humanitarian settings that were reported to be complex and morally uncertain or contentious by participants were captured with phrases like "*morally challenging*" or were described as "*difficult decisions*" in which there existed moral "*tension*" or "*uncertainty*", for example.[33 306-308] Slim adopts the term "*tough choices*" to accommodate situations that may "*masquerade as moral dilemmas*", noting the unlikelihood that humanitarian practitioners would make such theoretical distinctions.[45 306] In the domain of health, the emotional consequences of decision-making may be far greater due to the life-impacting stakes involved.[32 33 309 310] In this

regard, the term "*tragic choice*", originally coined by Calabresi and Bobbit, may be fitting as it draws attention to the emotional turmoil that can arise from desperate circumstances.[27] A translation of tragic choices into humanitarian health settings is offered by Hunt et al, as "*ones in which all options are morally problematic in some way and that, whatever choice is enacted, something of moral significance will have been lost*".[26]

It is normal to find such circumstances upsetting and for a decision-maker to experience psychological and emotional discomfort in reaction to it – a state that has been called "*moral stress*".[26 33 46 311] My exploration of literature into this phenomenon amongst humanitarian workers found that it largely originates in Jameton's observations of student nurses working in end-of-life care.[312] These individuals were described as experiencing "*moral distress*" if "*institutional constraints*" (such as policies and practices) prevented them from pursuing an action that they perceived to be morally right, or caused them to act in a manner that they felt was not in the best interests of their patient.[312] Before exploring moral stress in the humanitarian context, I will consider wider research on the decision-maker's position 'between' the patient and the institution, according to Jameton's definition, as my policy review suggests that this may be relevant to the decision of interest.

A great deal of research and thought has been invested into studying the choice behaviour of people who are situated in a position to care or protect another being, but who are compelled to act against their moral values by power, authority, or prevailing norms. For example, ground-breaking publications by researchers such as Arendt, Milgram, and Simon highlight how administrative systems, and a sense of "*obedience*" can induce immoral (and morally questionable) decision-making behaviours amongst the general population.[85 313 314] More recent studies on unethical behaviours within corporate institutions have highlighted its correlation with crises and have emphasized the influence of organisational culture in contributing to or protecting against these effects.[293 296 297 315] Indeed, in their detailed literature review on the topic, Christensen and Kohls remarked that "*unethical decision making often occurs in times of crisis*".[293] Other scholars note that unethical behaviour may be illustrated through passivity rather than decisive acts and choices.[297 298 316] For example, McGoey's

work on strategic ignorance predicts that some institutions will actively and preferentially remain ignorant of a problem to avoid responsibility for it, and to avoid dealing with it.[316] (This may be particularly significant to a humanitarian context in which uncertainties and unknowns abound).[308 317]

Returning to the concept of moral distress, Jameton's definition is widely criticised for being too narrow in scope, despite broad support for the idea that stress can arise from moral concern.[33 302 318] Studies that have explored the phenomenon in a humanitarian context have captured greater nuance in the causes and consequences of this human experience than being merely derived from institutional constraints.[25 43-45 307 311 319 320] For example, the work of Gustavsson et al have found that moral distress and wider psychological sequalae may manifest if moral stress is repeated, intense, or unresolved.[33] They describe these issues as potentially causing exhaustion, depression, and anxiety, or feelings of helplessness, frustration, and isolation.

Several studies name some form of institutional documentation (guidance, policies, procedures etc) as contributing to the problem – either due to its absence or due to its unfeasibility.[43 45 54 259 268 311] In terms of the absence of documentation, several publications have called for guidance, interventions, ethics training programmes, and follow-up care to help navigate the "inescapable" moral challenges that humanitarians face and the psychological harms that can result from them.[22 32 43 46 54 268 321] It is purported that tools that prepare aid workers for reaching ethical decisions when situated in non-ideal contexts may help with ameliorating uncertainty, improving staff resilience and recovery, and enhance the quality of ethical decision-making (although the heterogeneity of problems and their circumstances may make substantive guidance impractical).[22 32 33 45 46 305]

In terms of unfeasibility, many papers claim that policies (rules, principles, guidance, procedures etc) could contribute to the problem of moral stress if insensitive to the flexibilities and adaptations that may be required in non-ideal humanitarian settings.[45 54 269] The differential between what is procedurally 'required' and what is practically achievable can create morally challenging choices for individuals. For example, Hunt et al describe how expatriate clinicians may be forced to choose

between their professional codes of conduct (such as working within the scope of their clinical competence) and the exigencies of the situation (such as being the most qualified member of staff available to deal with a medical emergency with which they are unfamiliar).[43 320] Levine claims that these kinds of problems lie with universalism, and a culture that expects medicine to be mostly "*Western*".[322] However, the idea of cultural relativism can create moral discomfort due to the unjust inequities that may result.[43 322-325]

Beyond a normative debate of which standards should be upheld and to what extent, there is the question of who should decide them.[260 266 326] In Clarke and Campbell's review of humanitarian decision-making they note that "*an uneven distribution of power*" and the norm of centralised decision-making in iNGOs not only undermines the ability to gather pertinent and current information, but it also "*means that humanitarians are more sensitive to signals from donors […] than they are from people on the ground*". A host of research highlights that the unilateral determination of standards by Global North powers may represent a neocolonial domination of Global South epistemologies, which is interrelated to a neoliberal bureaucratization of aid.[212 269 327] For example, in a recent publication Sheather et al question whether the ethical guidance of iNGOs is motivated by a humanitarian concern for staff wellbeing or an example of cultural dominance that results in epistemological injustice.[321] Such commentaries build upon a growing body of scholarly thought that recognises the persistent legacies of colonialism in present day humanitarian aid.[92 153 261 327-329] The substantial power asymmetry between donor and recipient can result in the imposition of the dominant institution's cultural 'agenda' and implicit norms.[48 62 233 261 262 269 330 331] Scholars have noted that this can fail to meet the needs of communities in a manner that is acceptable to them, as well as perpetuating global inequities, concealing political or neoliberal objectives, causing cultural impoverishment, and controlling or redefining concepts, knowledge, and truth.[87 92 212 215 216 257 267 329 332-334]

I was curious about what this macro-level context might mean for the micro-level decision-making of humanitarians facing medical product stock-outs. As I will describe in the next section, I identified no literature on the ethics of this decision. However, I did uncover research into the significance of

proximity (between the decision-maker and patient or person in need) when responding to morally challenging situations, which I will outline here. From a practical perspective, studies tended to agree that bearing witness to need or suffering is more likely to provoke an emotional response in the decision-maker (than learning about it through other means).[37 299 311 335-337] This proximity (and emotional response) has been associated with moral concern and an increased likelihood for the decision-maker to act in a manner that is intended to help the patient or victim.

However, this is not a certainty; sometimes decision-makers may be observed to abandon or avoid the problem.[335 338] For example, some research suggests that morally stressful situations may cause decision-makers to 'shut down' and group membership may impede willingness to act.[297 304 338] Moreover, research into the phenomenon of 'compassion fatigue' has found that large or repeated pleas to assist humanitarian crises may diminish an agent's compulsion to act.[339] In general, empirical research of moral judgements note that distance is associated with a less emotional or compassionate response; those remote from a situation are more likely to apply rules and rational judgements and to "harshly" judge the actions of those who responded to the event.[311 340-342]

Perspectives on the ethical significance of proximity on moral obligation is debated.[336 337] It has been highlighted that proximity *seems* to matter, according to moral intuition.[337 341] An ethics of care approach argues that proximity manifests relational obligations.[37 59 343 344] This concept can be connected to broader philosophical thought on the nature of self and other and the moral duties that are inherent to this paradigm.[323 345 346] It can be argued that the intimacy of a relationship, particularly a caring relationship, manifests dependency (e.g. of the patient on their carer) and, therefore, confers moral obligations on the carer to act.[84 344 347 348] However, research into the ethics of vulnerability highlights that this is not necessarily a simple relationship in which the patient is vulnerable, and the carer is powerful.[347 348] For example, Kittay's observations of "*nested vulnerability*" highlights that being a carer may induce vulnerability, as well as carers being more likely experience vulnerabilities as a result of their own socioeconomic status.[348] This calls for a more holistic approach to interpreting the moral significance of vulnerability, and a consideration of how systems may contribute to the

risks and vulnerabilities of patients and their carers.[14 37 59 60 84] I will return to these ideas in the discussion, in Chapter 8.

Criticisms of an ethics of care approach – and the moral significance of proximity – are several.[59 83 323] For example, Singer famously claimed that our proximity to an "*evil*" should not determine whether we respond to it, arguing that one is equally morally obliged to act irrespective of physical distance.[349] While Kamm's detailed examination of the concept of moral distance contends that perhaps "*proximity matters as a heuristic device that correlates with morally significant factors, though it itself is not morally significant*" and proposes that "*salience*" may be a more valuable lens with which to consider moral obligation.[350] An issue raised against an ethics of care is its practical application to resource constrained environments.[59 60 83] Like the well-recognised tensions between public health and individual care, several scholars have noted that an ethics of care lies in tension with an ethics of justice.[59 60 83 325 330 351] While the former requires the carer to act in the best interests of the patient, the latter requires patients to receive equitable care. In non-ideal settings in which resource allocation is a concern (which at the time of writing is pertinent to almost any healthcare environment, not merely those in humanitarian health), the prioritisation of one patient's care may be at the expense of another and, therefore, result in the inequitable and unjust treatment of the patient population generally.[59 60 290 324 335]

2.4.2 Ethics of the prioritisation of medical product quality or availability.

I will now review papers that were more specifically related to the ethics of the situation of interest. Of these, I only identified one paper that acknowledged the tension that can exist between medical product quality and availability in humanitarian settings in normative terms[29] (although the unintended consequences of undermining medical product quality through pushing a Universal Health Coverage agenda is raised in non-normative terms in other papers).[30 156] Other than this, I found some papers that either consider the ethics of medical product quality or medical product availability. Next, I will

consider papers on these areas in turn (i.e. quality then availability), before summarising the paper that attends to both and reflecting on the implications for this study.

I uncovered two papers that present medical product quality in humanitarian settings as a *moral* concern.[22] [352] The first was a "*concept paper*" by the Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG-ECHO), which stated that funded iNGO's had an "*ethical and legal responsibility towards the beneficiaries to achieve quality assurance of medicines and medical supplies, to do the intended good and to prevent doing any harm*".[352] I believe that this may be the earliest open-source reference that frames medical product QA in humanitarian settings in ethical terms. The paper does not explain the normative basis for this claim and makes no further mention of ethics. However, the quoted statement infers that QA is founded on a moral principle of avoiding causing harm to patients. The paper, published in 2006, is around the time that ECHO introduced QA requirements for iNGOs and its stated objective is to review QA "*mechanisms*" in humanitarian aid.[352] [353] Therefore, it seems possible that the paper is akin to a business case that intends to influence change and promote support for novel procedures – and that one method for doing so is to state (unsubstantiated) normative claims to strengthen the argument.

The second paper, by Ravinetto et al, emphasizes the need for empirical bioethics studies to generate normative guidance for humanitarian procurers on the "*situation of multiple pharmaceutical standards*" – a reference to the different capabilities of NDRAs and the varying quality of medical products on their national markets.[22] Although they contend that failing to provide medical products in acute or life-threatening circumstances would be "*evil*", they do not clarify the meaning of this or the ethics of this position. Moreover, similarly to the ECHO concept paper, their normative claims appear to be biased in favour of arguing for enhanced QA measures (and targeted against counterarguments relating to the financial and administrative burden of QA). The largely one-sided commentary asks "*whether it could ever be ethically justified to compromise*" the QA of medical products. Applying the principles that were proposed as foundational to biomedical ethics by Beauchamp and Childress, they

conclude that compromising medical product QA is rarely ethically justified, as inequitable standards and avoidable harms contravene principles of justice, beneficence, and non-maleficence.[22 28]

Ravinetto et al's paper was used as an example of a disconnect between the theoretical importance of medical product quality and the practical constraints facing real-world clinicians in Hampshire et al's case studies of Ghanaian perspectives on "*pharmaceutical governance*".[31] They explain that the standards, processes, and expectations derived from ideal settings may be unachievable in humanitarian or resource constrained environments and highlight that a lack of guidance sensitive to non-ideal circumstances can lead to an ethical burden for those working in such contexts. These claims also support my criticism that the two papers on medical product quality (the ECHO paper[352] and that by Ravinetto et al[22]) do not attend to counterarguments for prioritising [46 321]medical product quality or attend to medical product availability as a moral concern.[269 321 329] Hampshire et al's observations also support the research that I outlined in the previous section, which connects untenable expectations to the manifestation of moral problems, moral stress, and tragic choices.[25 26 31 33]

Access to medical products in low- and middle- income countries garners considerable attention in academic and grey literature. Many publications frame the (non)availability of medical products as a threat to human health and the achievement of universal healthcare, thus underlining its ethical importance, representing it as a matter of social justice, and framing it as a human rights issue.[42 202 214 238 239 332 354-359] Indeed, several United Nations documents implicitly or explicitly enshrine access to medical products as a human right.[360-362] However, in my search I found no papers that attended to medical product availability as an attribute and that considered the extent to which it should (morally) be prioritised relative to competing concerns (such as quality).

Despite this, I found several papers that discussed difficult decisions that can arise from medical product shortages.[120 205 354 363-366] Publications that were focussed on medical product stock-outs in the resource constrained public health systems of low-income countries offered insights into the

tapestry of the problem.[365 367-372] I identified some ethnographic studies that drew attention to the challenges and pressures that are created by the absence of different medical products, in different health systems, for different patients.[118 371 372] These accounts often had unifying themes in spite of heterogenous circumstances. For example, a book by Wendland presented the experiences of medical students in Malawi as they struggled to access medicines, diagnostic equipment, and textbooks and a book by Livingston reflected on relationships on a cancer ward in Botswana in which the supply of medicines and availability of functioning equipment is unreliable.[371 372] Both underlined the terrible systemic inequities that manifest these circumstances, the tragedy for those who are victim to it, and the resilience and improvisation of healthcare workers that operate under such constraints.

Although I identified numerous publications that attended to the ethical considerations for resource allocation when demand exceeds supply (for example the prioritisation of vaccines)[364 373-376] I found only one that reflected on perspectives of the ethics of these decisions in humanitarian settings.[377] In their paper on "*rationing care in humanitarian and development work*", Sinding et al found that normative justifications for offering or withholding medical interventions were related to distinct conceptualisations of medical products.[377] Arguments for withholding care were often justified by a narrative that represented medical products as scarce commodities. Conversely, arguments for the provision of care were founded on narratives in which the medical products were objects of care and were essential to the act of caring. These observations chime with the research presented in the previous section regarding the potential for moral uncertainty or pluralism in non-ideal settings when evidence-based practices may be unfeasible (for example, ethical arguments of care versus justice in resource allocation).[59 83] Moreover, it highlights how minor differences in the conceptualisation of fundamental considerations may lead to major (and oppositional) differences in how options and moral obligations are perceived.[83 336 378]

As mentioned at the outset of this chapter, only one paper was found that identified the moral tension between medical product quality and availability in humanitarian health contexts. This paper,

written by me in the very early stages of this doctoral project, considers a wide range of "*dilemmas*" arising from uncertain medical product quality in humanitarian health.[29] One of these, which I call "*the unspeakable dilemma*", is pertinent to this review. It notes that compromising a medical product's quality and distributing it to a vulnerable patient seems unconscionable, yet this may be the only option available to decision-makers facing stock-outs in humanitarian contexts in which QA is unfeasible. I note that current discourse tends to focus on the need for quality, neglecting the normative significance of availability and alienating those who encounter the problem.[29]

2.5 Conclusion.

My review of academic supply chain literature identified that there is a likelihood of disruption to humanitarian health supply chains due to a reliance on importation, and an unpredictable context. However, my research into regulatory affairs found that sourcing medical products from humanitarian contexts presents a potential health risk to patients.[15 161 162 173 231] Therefore, I searched for policies and procedures that explain how iNGOs address urgent medical product stock-outs when the quality of those available is uncertain (and academic literature that might offer insight into this process). I found several donor regulations relating to the procurement of medical products but found that their requirements were unlikely to be feasible in a time-pressured, non-ideal setting. Indeed, these unrealistic medical product quality standards were identified as a problem by Hampshire et al due to the "*ethical labour*" that they engender.[31] Numerous papers in wider humanitarian ethics literature underlined that the expectation to apply norms and rules that are unfeasible in non-ideal contexts can result in tragic choices and experiences of moral stress and negative psychological and emotional consequences amongst aid workers.[26 33 45 54 292]

My review found no policy documents from iNGOs that were relevant to the topic. In academic literature, I found one publication that offered an overview of Marie Stopes International's risk-based approach to sourcing abortifacient medical products. This paper revealed that some iNGOs may adopt independent and self-regulating standards and procedures for navigating urgent stock-outs in

humanitarian contexts in which the quality of medical products is uncertain. Moreover, it presented the process as innovative, suggesting a lack of procedural consistency between iNGOs. Qualitative research into settings in which medical products are absent also highlighted that improvisation – and a deviation from evidence-based care – was common.[118 372] Calls for ethical guidance and training to support and protect humanitarian health workers in such circumstances was recognised in wider literature.[32 46 379] Moreover, Ravinetto et al's impassioned paper entitled "*quality medicines in resource-limited settings: the need for ethical guidance*" articulated the need for standardisation and guidance in this specific circumstance.[22]

Thus, I found a lack of practical and ethical guidance for humanitarian practitioners who encounter urgent medical product stock-outs and an indication that these measures are necessary for the wellbeing of those who encounter such problems.[26 33 289 308] Moreover, I identified that this issue demands attention because it presents serious concerns for patient care.[44 274] Research into decision-making in crisis settings suggests that those facing the problem may seek to avoid it or rely on intuition to respond to it, and that decisions may not be couched in ethical considerations.[31 293-295] Indeed, data generated from humanitarian settings indicated the likelihood of arbitrary decision-making and the potential for multiple, conflicting opinions regarding the morally apt course of action.[44 289 320] This raises the prospect that decisions about urgent medical product stock-outs in humanitarian contexts may be unethical, inconsistent, and inequitable and, therefore, represent a health injustice.[204 290 315]

In summary, my literature review uncovered no research into the normative tension between medical product quality and availability in humanitarian settings. I found that normative guidance for navigating the situation is urgently needed for the benefit of humanitarians and patients alike.[22 29 46] However, to develop guidance that is effective, feasible, and sensitive to practical constraints, we first need to understand the problem and to uncover the landscape of real-world systems and challenges that are significant to moral decision-making.[34 56 308 380] This is the research need that my study will address; I will gather empirical data relating to urgent stock-outs in humanitarian health contexts and

perspectives on the ethics of how this situation should be resolved. In the next chapter, I will specify my research aim and describe the methods that I will use to investigate them.

3

Methods.

3.1 Introduction.

In this chapter, I will detail and justify the methods chosen to address the research gap identified in the literature review. First, I will specify the overarching purpose of the study and my research questions. Then, I will describe and justify the method chosen to meet these aims, including a variety of study design options that were not pursued. Next, I will detail information pertaining to participants, including sampling frames, recruitment techniques, and communication strategies. I will then detail my data collection methods, followed by a description of the methods used for data analysis. The latter includes a positionality statement and reflexive practices that were adopted. The chapter concludes with an explanation of how findings are to be presented in the ensuing four chapters.

3.2 Aim of the study and its research questions.

In Chapter 2, I described how International Non-Governmental Organisations (iNGOs) often work in contexts in which medical product quality is uncertain, due to concerns regarding the Host Government's ability to regulate the national pharmaceutical market.[16 50 51] Some iNGOs rely on international supply chains to source medical products, but these may not be sufficiently agile or robust to deal with the demands of the context.[16 19] Informed by my experience as a Head Office pharmacist working in humanitarian health (see section 1.2), I noted that these issues could lead to situations in which difficult decisions between medical product quality and availability were needed. However, in my literature review I found no publications or grey literature that acknowledged this

specific issue and, consequently, there was no normative or practical guidance about how to navigate it.

My study will investigate this situation; namely, the decision facing an iNGO that urgently requires the replenishment of medical products for a humanitarian health project, but where the only immediately available medical products are of uncertain quality. My study aims to characterise this situation, and to describe the ethics of it, from the perspectives of those who have experienced it. To do so, I will focus on answering the following research questions, from the perspectives of participants:

1. What practical and ethical challenges are associated with this situation?
2. How are the quality and availability of medical products prioritised in this situation?
3. What norms, expectations, and other factors restrict or influence responses to this situation?
4. When determining how to respond to this situation, who represents the patient, who contributes to decision-making, who is excluded, and why is this the case?

3.3 Design of the study.

To adequately answer these research questions, I will require a methodological approach that is able to uncover human experience. Moreover, my chosen methods should be flexible and iterative so that they can accommodate and adapt to the unexpected findings that arise in exploratory research.[381 382] In this section I will describe and justify my chosen method and the study design considerations that arose before and during data collection.

3.3.1 Considerations arising in the selection of the chosen method.

I chose to adopt qualitative methods to investigate my research questions. A thick description of the experiences of stakeholders, their perspectives on the ethics of the problem, and their insights into

the systems and culture in which they operate will offer insights into the moral worlds of stakeholders; to understand what matters to them (and what does not), what influences them (and what does not), and the values that motivate them.[34 55 65 66 383] By collecting data on the situation within its real-world context, I can better understand the practical challenges, tensions, and opportunities that may exist, perspectives on their relative importance, and how intersecting inequities may amplify the problem.[34 35] Moreover, qualitative methods offer the benefit of flexibility and iteration, enabling emergent findings to inform and shape the design and direction of the study, which is highly desirable in the exploratory research of a novel subject.[66 381 384] I adopted the use of several qualitative methods, which enabled the triangulation of data.[385]

I considered several types of qualitative data collection techniques when designing the study. One-to-one in-depth interviews (IDIs) offered the opportunity to gather rich and detailed perspectives; furthermore, their confidentiality may help elicit views on sensitive topics (like the decision of interest).[66] I chose to employ them and use a semi-structured approach. The standardisation of questions can generate data that is more easily comparable, because how and when a question is posed can profoundly impact the response. However, allowing space for flexibility and adaptation during interviews is important for exploring new lines of inquiry and probing emerging perspectives that may not have been considered at the project's outset.[66 89 384 386] Sections 3.5.1 and 3.6.2 detail IDI sampling and data collection, respectively, and appendix C presents the topic guide.

Participant Observation (PO) can offer contextual insights and opportunities for stakeholder identification and relationships. For example, how are decisions made, who is present or absent, which matters spark debate, what conversations are held in the margins, and what motives underpin choices?[66 384 387] Although these insights would have been valuable for my study, the COVID-19 pandemic made observations in a physical place of work unfeasible, because the business of decision-making would be conducted remotely (through emails, instant messaging, and calls) and shadowing decision-makers would be impractical. Thus, I discounted this option.

I remained interested in the process of decision-making and postulated that, even if the final determination is shouldered by one individual, the proceedings may be collaborative or multidisciplinary in nature.[304 388] Therefore, as an alternative to PO, I considered running decision-making tasks with a group of participants that required them to reach a consensus regarding an urgent medical product stock-out scenario.[388-390] However, I shelved this idea as I realised that I would be unable to recreate the pressures that would arise in a real-world situation, such as the risk of patient harm or an impending deadline. Moreover, the data would reflect the decision of a fabricated committee, rather than responsible parties following an actual procedure, and thus may be misleading.[388 391 392]

Although I had concluded that 'observing' decision-making tasks in a research environment would be a poor substitute for using PO, my reading had led me to consider the use of vignettes in FGDs.[393-395] Vignettes are a hypothetical scenario; they can be employed as an elicitation tool in group settings, to facilitate debate and witness the social dynamics of problem-solving.[247 391 394-396] Responsive and additive comments *between* participants is possible in group-work due to the nature of their relationships, tacit knowledge of the decision-making context, and differing perspectives.[66] Therefore, I decided to use FGDs to collect data. Specifically, I would use vignettes with FGD participants to investigate relational dynamics and to gather perspectives on the ethics of options facing the iNGO decision-maker.[393-396] Sections 3.5.2 and 3.6.3 describe FGD sampling and data collection, respectively, and appendix C provides the topic guide.

I used informal conversations (ICs) and document analysis (DA) techniques to inform the design and direction of the study, but this data was not coded due to its voluminous, unstructured, and inconsistent nature.[397 398] Rather, IC and DA provided me with a contextual understanding of the world in which participants worked and assisted with topic guide development. I also used these techniques to validate my findings or, if this did not occur, to inform future sampling and recruitment.[66 89] I describe the collection, analysis, and application of ICs and DA in greater detail in section 3.6.4.

I focussed recruitment on participants who had experienced the situation (and therefore could offer personal perspectives on the problem) in a professional capacity, due to ethical concerns of discussing the topic with patients and caregivers, as explained in section 3.3.3.[399 400] I narrowed my sample population by using stakeholder mapping and theoretical techniques that considered the organisations in which the situation would occur with greater frequency and intensity.[401] Following this, participants were sampled in a gradual manner using stratified purposeful techniques (according to their role and their location) or snowball sampling techniques.[66 402] A principle of maximum variation was used to seek out disparate views and sampling frames assisted with recruiting a diverse cohort of participants.[384] Participant sampling and recruitment is described in section 3.5.1.

As my topic was large and unexplored, I decided to conduct five pilot interviews to grasp the broad dimensions of the subject, to focus my research, and to inform the sampling frame.[403] This is detailed in section 3.4. When analysing this preliminary data, I noted that some participants were uncomfortable or performative in responding to certain questions, and I sensed that some information was being concealed or misrepresented. Thus, I considered how to approach this topic more sensitively and, therefore, improve the quality of the exchange.[66 68 90] Effort was placed into engendering a space that felt safe for open dialogue in IDIs and FGDs, which is explained in sections 3.6.2 c) and 3.6.3 b). I also chose to employ a vignette method, as hypothetical scenarios are useful for gathering personal perspectives in a less direct or confrontational manner.[391 394-396] I will offer an overview of these next; a detailed account is provided in section 3.6 and the topic guides are in appendix C.

I used data collected in the pilot interviews to construct vignettes for ensuing IDIs and FGDs. This offered a sense of authenticity, whilst allowing flexibility to investigate specific topics of interest.[394-396 404] In IDIs I employed the vignette in stages.[395] First, I communicated a scenario in which a stock-out had occurred and asked participants to "think out loud" as they thought through the problem and the things that they might do.[388 390 392] (I emphasized that there were no right answers, comparing it

to the question of "what should I get for my niece's birthday?") This allowed me to observe the participant's priorities and factors that influenced them. The next stage of the vignette presented conflicting data from two sources, the Host Government and QUAMED (a widely respected Northern hemisphere charity that conducts Quality Assurance assessments) to specifically interrogate perspectives on expertise and reasons for them. Finally, I asked what a "good" decision looked like, to help transition to another topic and to better understand the explicit norms and values that guided their decision.

For FGDs, I wanted to create an environment in which participants could air and debate (potentially disparate) perspectives on the ethics of the situation, to gain insight into implicit norms and to observe how these were communicated and received in a multi-disciplinary context.[247 396 405] I was aware that FGDs had little time, several participants, and the need to overcome the social barrier of sharing sensitive information in a group-setting.[66 384] Thus, I presented the stock-out problem *and* the decision at the same time. I constructed the decision based on IDI data and its analysis.[391 393 404] I intended it to be extreme and controversial (though within the realms of what was feasible, to maintain authenticity), to encourage debate and to make explicit some emerging latent themes generated from IDIs.[395] I chose to present FGD participants with two separate vignettes, as this offered the opportunity to investigate and compare factors that had emerged as significant to decision-making.[404] I also decided to have multiple FGDs, as this would enable me to compare differences between groups. The options and process are described in section 3.6.3 b).

My analysis of data was loosely framed by an ethics of care approach, which is well-suited to interrogating the relational dynamics that surround decision-making in a caring context, and how power resides and impacts this paradigm.[323 343] My preferred method of data analysis was Thematic Analysis (TA) due to its suitability for inductive, exploratory research, its utility in identifying latent themes, and because it is highly accessible for novice researchers.[383] I considered numerous types of thematic analysis and trialled a codebook approach during the pilot phase of the study. However, I was unsatisfied with this analytical method, which views the individuality and subjectivity of the

researcher as a variable to be recognised and controlled, to achieve coding agreement between researchers.[64 406] I have personal experience with the research topic, as I outlined in Chapter 1; not only did I find accounting for my bias to be an unfeasible task, but I also felt that doing so would undermine data analysis.

During the pilot and its analysis, I found that personal experience of the decision, and the world in which it is situated, was helpful for connecting with participants and for interpreting their meaning. Therefore, I chose to adopt a reflexive TA (RTA) approach, in which the researcher assumes an active role in the interpretation of data and the generation of knowledge, due to my familiarity with the subject and the benefits that this offered.[71 72] This is described in section 3.7.3. During collection and analysis of data, I found that some topics were not openly spoken about (as evident in the void between speech and in the diplomatic application of 'business-speak'). Literature on discourse analysis helped me to adapt my approach and gain a deeper understanding of the meaning in these moments.[64 407] All themes and codes are summarised in appendix D.

Despite embracing the individuality of my analysis, I remained mindful of the potentially negative consequences of 'bias', such as assumption and misinterpretation. I sought to mitigate against this through reflexivity, to gain a better understanding of my positionality and how this was likely to impact my study, my interpretation of data, and my findings.[67 408] I incorporated structured reflexive practices into each data collection activity, and intentionally slowed the pace of my schedule to enable opportunity for this. I have outlined these practices in section 3.7.4, and I have provided a positionality statement in section 3.7.1.

3.3.2 Alternative methodological approaches that were discounted.

A range of methodological options were considered when designing the study. Reasons for their suitability and why an alternative method was deemed preferential are justified below.

3.3.2 a) Case study research.

My pre-pandemic project plans involved using multiple, comparative case studies to explore the problem and those affected by it.[409-411] During planning, it was estimated that each case (bounded as a decision-making event) would require interaction with ten to fifteen globally distributed individuals for its faithful construction, but potentially more, depending on findings. [409 412 413] This estimate was based on a purposive theoretical sampling exercise informed by stakeholder analysis (appendix B refers). The COVID-19 pandemic limited my research to remote data collection techniques, which raised questions regarding the feasibility of identifying suitable cases of this sensitive topic, identifying and accessing all relevant stakeholders, observing decision-making dynamics, and gathering a rich and honest description of the problem.[410 412 413] This suite of concerns undermined the suitability of case study research, within the time and resource constraints of a doctoral project.

3.3.2 b) Ethnography.

Ethnography has the potential to offer in-depth insights into lived experiences of the decision and its sociological context.[414-416] However, ethnographic research benefits from spending extensive time living amongst participants in a field setting, which was unfeasible due to pandemic travel restrictions.[417] It is noted that future research on the situation that focusses on a single organisation or health system may greatly benefit from this approach.

3.3.2 c) Phenomenology.

I considered conducting a phenomenological study of the decision using qualitative methods to build a common, positivist description of their occurrence and universal themes.[66 418] However, with no a priori scholarship on the problem (and how it may vary from case to case), it would have been necessary to compare phenomenological perspectives on a common case to ensure methodological

rigour.[66 419] This presented the same challenges as those previously described under case study research and, moreover, would have failed to satisfy the overarching aim of the study.

3.3.2 d) Mixed methods.

A sequential exploratory mixed methods design (of standard notation QUAL → quan) was considered.[420] The initial (and dominant) qualitative research strand would identify and describe the problem. This would inform the focus and content of the quantitative strand, which would explore the scope and generalizability of the findings.[381 421] However, the time and capacity constraints of a doctoral project meant that it was unfeasible to conduct a second strand of research (and incorporate the findings in a manner that was meaningfully additive), without diminishing the quality of the first strand. The DPhil uses a wholly qualitative approach and, as such, could be viewed as a starting point upon which to build a quantitative study.

3.3.2 e) Empirical bioethics.

Critical and normative reflection of the various ethical tensions that arise when medical product quality and availability are in conflict is urgently required. An empirical bioethics study that explores the strengths and implications of various arguments, within their real-world contexts, would guide future decision-making.[36 55 56 351 380] However, managing an integrated empirical bioethics study as a solitary and novice researcher, with the time-constraints of a doctoral project, was considered unwise.[55 422] This study therefore seeks to lay foundations for this future work.

3.3.3 Ethical considerations

A thorough assessment of risks and ethical concerns informed the design of this research project.[423 424] It received ethics approval from the Medical Sciences Interdivisional Research Ethics Committee

of the University of Oxford on 6th May 2021, ethics approval reference R75317/RE001.[425] Written consent was obtained from all interviewees and focus group attendees, and they were provided a detailed overview of the study prior to participation. These communications are detailed in section 3.5.4 and the appendices.

A primary ethical consideration was the risk of harm to patients and caregivers, if they were included in the sample set.[424 426 427] Although I was keen to speak with them about their perspectives on the quality and availability of medical products, I was concerned that raising awareness about these issues could impact anxiety, health-seeking behaviour, and aid worker security.[399 400 427] Therefore, I chose to limit my research to professional groups. A risk assessment for the latter identified several ethical considerations that, broadly, related to two concerns: participant distress and the inappropriate disclosure of data.[90 428] The sensitive nature of the research topic risked the psychological and emotional distress of participants when sharing regrettable incidents, but it also risked their reputation (and thus social or economic standing).[428-430] To mitigate psychological risks, I employed strategies to build trust and safety within the interview, prepared for how to respond to participant distress, and followed up with each interviewee after the research activity.[423 429-431] To mitigate reputational risks, I implemented a data management plan to ensure data security. I also anonymised data and used pseudonyms to safeguard participant confidentiality.[431-434]

3.4 Pilot study.

3.4.1 Overview.

The pilot study aimed to evaluate the aim, design, and instruments of the research, in addition to identifying my own training needs and exploring my positionality.[403] It ran for approximately seven months, from May to November 2021. During this time, I conducted data collection, transcription, and analysis. Following this period, I revised some aspects of the study (as I will explain below) and commenced data collection proper in February 2022.

3.4.2 Sampling.

The pilot needed to be small enough to be conducted within a reasonable timeframe, but powerful enough to elucidate insights about the decision of interest and the proposed methods of research and analysis. Upon consideration, and following discussion with my supervisory team, I decided to recruit five participants to the pilot study. I had determined that I would recruit participants working for iNGOs (via stakeholder mapping, as described in section 3.5.1 a)), but I had yet to confirm the roles to focus upon. I purposively selected participants for their significant experience with making sourcing decisions during stock-outs, and for their heterogenous careers.[401] [402] These included: a medical doctor, a pharmacist, and two logisticians, one with a Country Office background and the other from Head Office. I had hoped to recruit an operations manager as the fifth participant, but none who were accessible to me were available during the pilot phase. However, I identified (and recruited) an individual with operations responsibilities who worked for a prominent humanitarian wholesaler via snowball sampling.

3.4.3 Data collection and analysis.

Semi-structured in-depth interviews (IDIs) were conducted with each participant between 23rd May 2021 and 28th July 2021, which varied in length from fifty-two minutes to two hours and fifty-four minutes.[66] A reflexive memo of each interview was made within twenty-four hours (and compared with reflexive observations made before and during the call, as described in section 3.7.4).[69] Video and audio recordings of each IDI were used to create verbatim transcriptions (and noted significant non-verbal expressions, as described in section 3.7.3). Data was initially coded using NVivo software and analysed using codebook thematic analysis[7].[64] [435] Two transcripts were peer coded to review

[7] These were later re-coded using reflexive thematic analysis, as described in section 3.7.

consistency; the coding and analysis of several excerpts were discussed in small-group forums with peer doctoral researchers.[66] [406]

When the pilot phase was nearing a conclusion, I determined whether it would be appropriate to include this data in the dataset.[403] [406] I considered the quality, relevance, and comparativeness of data. Although the pilot had changed the study, I concluded that its data still offered a valid and important contribution because the preliminary findings of the pilot phase served as a foundation for later investigation and analysis, which would employ similar methods and sampling. Therefore, I chose to include these IDIs in the dataset and latterly analysed them using RTA.

3.4.4 Impact.

The pilot study had a profound impact on the focus and direction of the study.[386] [403] Decisions based on an analysis of the data and its collection methods included:

Research questions:

Research questions were narrowed to focus on the sourcing decision that arises in response to an urgent stock-out.

Topic guides:

Topic guide questions were introduced, altered, or removed according to the quality of data that they had produced and to reflect changes in the research questions. Based on findings, questions were generally changed to become less direct and to avoid the assumption that the participant viewed the decision as an ethically difficult one. For example, I employed a vignette in the IDIs to encourage discussion of a sensitive topic, as described in section 3.6 and the appendices.[391] [395]

Sampling:

Emerging data suggested that a participant's role or geography may be significant to decision-making. Sampling frames were adapted to explore this, as described in section 3.5.

Participant demographics:

I developed the participant demographics forms during the analysis of pilot phase data. I was guided by an emerging theme of relationships and an interest in the factors that may influence this.

Analysis:

Initially, all pilot IDIs were analysed using codebook thematic analysis. As section 3.7 explains, all data (including the pilot phase IDIs) were analysed using reflexive thematic analysis (RTA), which was considered more suitable, as described in section 3.3.[64]

3.5 Participants.

3.5.1 Sampling for in-depth interviews.

A summary of participants is available in appendix E. I used a range of sampling techniques to identify participants with experience of medical product stock-outs in humanitarian settings, and their organisations.[66 384 402 436] First, I used theoretical sampling (as explained in 3.5.1 a)), which was helpful for selecting an appropriate research context given the exploratory nature of the study.[401] Guided by emerging findings from the pilot phase, I then used stratified purposeful sampling techniques to identify potential organisations and people of interest, as described in sections 3.5.1 b) and 3.5.1 c), respectively.[66] Finally, I used snowball sampling techniques to reach beyond my own network, to identify potential participants (and their organisations) that may have valuable contributions and insights.

I recruited individuals directly (rather than via their institution), as I was interested in personal perspectives. Moreover, I anticipated that a participant's views of the ethics of the decision would represent the sum of their experiences rather than their iNGO's policy, and that it would be unfeasible to disentangle how different organisations and roles had shaped their view of the problem. Following a theoretical exercise to narrow down potential participants according to their professional experiences, I concluded that I would need two sets of sampling frames: one for the attributes of institutions at which an individual had worked and experienced medical product stock-outs, and one about the attributes of the participant themselves. These, described in section 3.5, were designed on a principle of maximal variation and recruitment continued to a point of data sufficiency.[402] [436] I will explain the two sampling frames in turn, though in practice this was not a sequential process.

3.5.1 a) Theoretical exercises conducted to select the research context.

To identify individuals who had experienced medical product stock-out problems, I sought to identify contexts in which it was, theoretically, likely to occur with frequency and intensity. First, I conducted a stakeholder analysis to map the landscape of actors that may influence the quality and availability of medical products at the treatment sites of patients in humanitarian contexts.[437] [438] Via this process and my conclusions, which are described in appendix B, I chose to focus on NGOs that directly procure medical products. This was because their decisions were significant to defining the physical properties of the medical product, and because my background offered access to a pool of individuals in this sector.

NGOs are a diverse category, varying in their size, donor, sector, culture, and footprint, for example. Through policy analysis, the analysis of data gathered during pilot phase interviews, and personal experience, I identified that certain 'attributes' may be likely to engender complex medical product stock-out situations (see Chapter 2.3.3). These are listed in table 6, alongside a justification for how they may complicate decision-making.

iNGO attributes	Justification
International	Participants from international NGOs may experience political pressures that differ to national NGOs, due to their 'dual' status in the Global Health community and in the nation, and because of the (probable) greater size of their awards.
Very large	Very large organisations tend to have greater wealth and resource, which may increase the complexity of decision-making by introducing options about resource allocation.
Multi-sector	The iNGOs that are not solely focussed on the delivery of health projects may have weaker health supply chain capabilities, or a culture that is less sensitive to the management of medical products. Also, they may have a greater variety of professional backgrounds working at them, thus a greater potential variety of opinion.
Humanitarian contexts	Humanitarian projects appeared to be subject to the most significant array of sourcing restrictions (compared with development assistance or emergency response), whilst also involving direct procurement and implementation. Thus, it was anticipated that the tension between quality and availability would be more apparent in humanitarian contexts, rather than emergency or development ones.
Quality Assurance Policy	As outlined in Chapter 2, it was noted that Quality Assurance policies may restrict and complicate medical product sourcing options.
Responsive, complex health services	It was hypothesized that resolving a stock-out problem would be more intense if the potential consequences were more severe. Thus, iNGOs were sought that offered responsive and complex health services for a range of patient populations.

Table 6: Sampling frame for criteria of iNGO at which a potential participant worked.

3.5.1 b) Sampling frames pertaining to the attributes of institutions for which the potential participant had worked and experienced medical product stock-outs.

The attributes listed in table 6, were used as a sampling frame for the iNGOs at which a potential participant had worked.[66 402 436] I sought to recruit individuals who had worked for an organisation that fulfilled *all* the criteria listed in the table. Initially I used internet searches and personal experience to identify potential iNGOs. Once data collection began, I used snowball techniques to

identify institutions of interest due to emerging themes, rather than strict adherence to sampling frame 'criteria'. This included organisations that were cited as particularly influential to the problem (such as certain donors), or that may give rise to disparate perspectives (such as iNGOs without Quality Assurance policies).

3.5.1 c) Sampling frames pertaining to the individual's attributes.

In the pilot interviews, I had purposively sampled participants from different Head Office roles, with a view to selecting one to focus upon. However, my analysis of pilot phase data identified an emerging theme that an interviewee's role may be important to their handling of a stock-out problem and that exploring these differences would be important for answering my research questions. My early hypothesis, informed by pilot interviews and my literature review, was that a participant's role changed the extent to which they were involved with patient care or fundraising and, potentially, their priorities. Rather than focussing on a single role I chose to adopt a stratified purposeful approach that would explore this idea (see figure 4).[66]

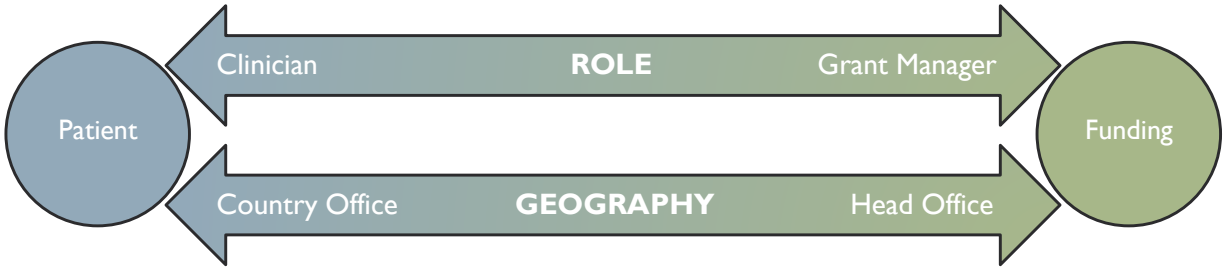


Figure 4: Illustration of stratified purposeful sampling strategy.

Initially, my strata in the 'role' category were clinicians, pharmacists, logisticians, Country Directors, and grant managers, based on my experience and preliminary analysis of interview data. However, I communicated with a team of grant managers and found that they had no professional interest in medical product stock-outs. Therefore, they were unwilling to be interviewed, and I surmised that little useful data would be generated. I also found it challenging to recruit Country Directors, which I

attributed to the busy nature of the role, the sensitivity of the topic, and my lack of direct access.[68 439] Instead, I sought to recruit individuals involved with operations generally, whose primary role was to support project implementation. Ultimately, the strata of the "role" category were clinicians, pharmacists, logisticians, and operations managers.

My preliminary findings from pilot interviews also suggested that there may be tension between Head Office and Country Office staff during urgent stock-out problems, and that they may have disparate perspectives. Therefore, rather than focussing on Head Office staff, I decided to recruit participants from either location. Emerging themes suggested that this 'geography' strata might echo the 'role' strata regarding the extent to which these locations were involved with patient care or fundraising, as illustrated in figure 4. During recruitment, however, I found that some participants did not fit 'neatly' into either category. For example, some participants were line managed by Head Office but were predominantly based in project settings, while others were based in Regional Offices. I defined a third strata in the geography category, to capture individuals that regularly moved or worked between Head and Country Offices and named it 'roving'.

3.5.2 Sampling for focus group discussions.

I aimed for FGDs to have three to six participants, to offer a rich yet manageable discussion with redundancy in case of last-minute dropouts.[66] First, I considered whether to establish the cohorts from different iNGOs or from the same iNGO. Although I felt that recruiting from different iNGOs may facilitate perceived equality amongst participants (and therefore fewer issues wrought from power dynamics), I thought that this was outweighed by the benefit of participants being from the same iNGO.[66 383 428] An emerging theme of IDI data was the influence of policy on decision-making. Therefore, I felt that a shared understanding of the policy context (no matter what that was) would be more efficient because it would allow the group to focus on the problem and avoid potential distractions about the nuances of rules or procedures.

I reached out for assistance in setting-up FGDs by using the IDI sampling frame pertaining to the preferable attributes of iNGOs as a purposive guide for who to approach. An individual who had been a participant in the IDI pilot phase felt that many people in their organisation would be interested in contributing to the study; their iNGO was experiencing widespread difficulties with sourcing medical products and stock-outs were frequently a problem. Having identified a suitable iNGO, I considered the composition of the group. I was sensitive to the real-world power dynamics that may manifest *between* participants and interfere with data collection.[66 428] Two aspects were of particular concern due to my analysis of IDI data: organisational hierarchy and technical knowledge.

In terms of organisational hierarchy, emerging findings (from IDIs and ICs) indicated that there was significant power asymmetry between Head and Country Office staff. I was concerned that mixing these participants in the same FGD would impact the data (because Country Office staff may feel uncomfortable with sharing disparate views in front of more senior, Head Office colleagues) and that it may present a risk to the careers and status of Country Office participants.[66 428] Rather than choosing one or the other, I decided to create two FGDs within the same iNGO, which were distinguished according to their geographical location: a Head Office group and a Country Office group. I hoped that this would allow me to gain a deeper understanding of intra-organisational conflict from *both* sides, as well as enabling a 'geographical' comparison of perspectives on the problem.

Regarding technical knowledge, my analysis of IDI data had shown that pharmacists played a pivotal role in gathering, analysing, and advising how to respond to medical product stock-outs in iNGOs (as discussed in the following chapters). Therefore, I was concerned that a pharmacist may overpower the discussion and heavily influence the contribution of other FGD participants, who may view the pharmacist as an expert and defer to their opinion.[66 391] Therefore, I chose to exclude this

professional group from FGDs.[8] As FGDs offer an excellent opportunity to explore disparate views, I considered how to achieve this through group composition. Emerging findings supported an early hypothesis that a participant's role was significant to their perspective of medical product stock-outs; therefore, I purposively sampled participants for the heterogenous roles listed in section 3.5.1 c).[402] [436] Operations managers proved difficult to recruit, so both groups were composed of a mix of clinicians and logisticians.

The participant who helped me to set-up the FGDs held a senior role with their iNGO's Head Office. For the Head Office FGD, I gave them the Participant Information Sheet (PIS) and Consent Forms and asked them to invite no more than six people, in a blend of roles, to consider joining the study. I requested that interested parties contact me directly so that I could confirm their *willing* participation, obtain consent, and to communicate about the research activity. For the Country Office FGD, I used a different approach to recruitment because I was concerned about being viewed as a Head Office representative or ally.[391] [395] [408] [428] Although I needed my iNGO contact to introduce me to Country Office staff (which they did via a short email), I was keen to lead the communication and to convey that I was independent. Therefore, I emailed Country Office participants privately to inform them about my study, share documentation, and to emphasize that contributions would be confidential. Some of these individuals were recruited to my study, and some connected me with colleagues whom I recruited (i.e. snowball recruitment).

I had initially intended to run a third FGD comprised of peripatetic emergency response members, to explore the difference that sudden onset disasters would have on perspectives about medical product sourcing decisions. The availability and responsiveness of these individuals was highly unpredictable due to the nature of their work. I ceased attempting to establish this FGD after two attempts had failed due to travel and operational needs. An opportunity arose to run an FGD with

[8] A pharmacist was unintentionally included in the Country Office FGD because his job title and role were "logistician". He did not have experience with Quality Assurance and his contribution did not appear to guide the opinions of the other participants.

students on a course at which I was a guest lecturer. I decided not to collect data from this activity due to concerns of the power asymmetries in a student-teacher setting, which may create unreliable results.[66 408 430] However, I presented the FGD as part of a teaching exercise and held a group discussion about the vignettes. This activity was recorded, with consent, and I used it to reflect upon my data and to validate findings. On consideration, I chose not to run further FGDs. The Head Office and Country Office FGDs had yielded a wealth of data and comparative insights that were sufficient for my study.[402] With the capacity constraints of a doctoral project, I chose to focus time and space on analysing and communicating these, rather than exploring a new 'dimension'.

3.5.3 Eligibility criteria.

Eligibility criteria were kept intentionally broad and permissive, to protect the exploratory nature of the study. Thus, the inclusion and exclusion criteria established prior to commencing data collection, listed in table 7, mostly focussed on practical constraints and research requirements.[430 433 440]

An individual is eligible for **inclusion** in the study if they are:	An individual will be **excluded** from participating in the study if they:
Willing and able to give informed consent for participation in the study.	Are unwilling or unavailable to participate in the study.
An adult aged 18 years or over.	Refuse to consent to a temporary audio recording of research activities.
Have experience with decisions relating to an urgent stock-out of medical products.	Are unable to connect to the online meeting software (e.g. due to a lack of internet connection).

Table 7: Participant inclusion and exclusion criteria.

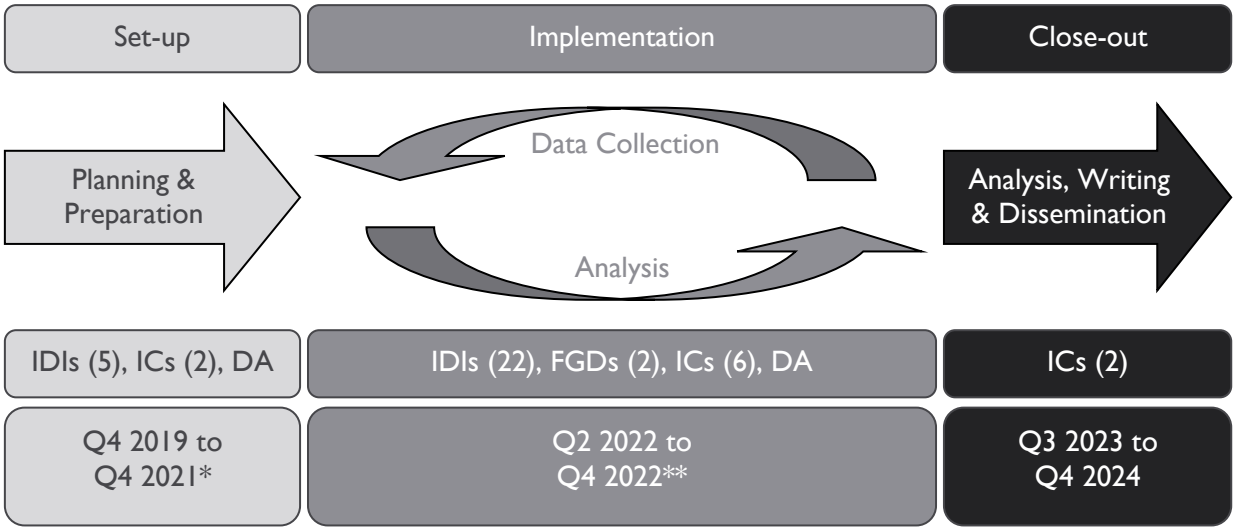
3.5.4 Written communication with participants.

I approached potential participants using social media (usually "LinkedIn") or, if an introduction was made by another participant, email. All invitations to participate in the study were accompanied by the relevant Participant Information Sheet (appendix F refers) and Consent Form (appendix G refers), which offered detailed and transparent information regarding my project and its data. The accessibility of these documents was maximised (to facilitate understanding) using Flesch-Kincaid readability checkers and feedback from lay persons.[441] If an individual agreed to participate, I communicated via email to coordinate a time for the research activity and to invite them to share any questions or concerns they may have. FGD participants were sent a copy of the slide deck presentation (appendix C refers) three days in advance of the research activity, alongside an explanation of what to expect on the day. I answered any questions and concerns via a short call or email, according to participant preference. Following an IDI or FGD, I sent out Participant Demographics Forms (appendix H refers) via email; this was shared *after* the research activity to avoid the risk of unconscious bias.[433 440]

3.6 Data collection.

3.6.1 An overview of research activities and their timing.

The project was organised into three sequential phases (figure 5 refers): set-up, implementation, and close-out, as per standard project management practice.[442] Set-up phase data collection activities involved pilot IDIs, Document Analysis (DA), and Informal Conversations (ICs), all of which informed study design and orientation. The bulk of data was collected during the implementation phase. No IDIs or FGDs were conducted during the close-out phase, which focussed on analysis and the write-up, although ICs helped to interpret findings.



* Parental leave (Q1 – Q4 2020)
** Sick leave (Q1 – Q3 2023)

Figure 5: Overview of study schedule and activities.

3.6.2 In-depth interviews.

3.6.2 a) Summary of IDIs.

Semi-structured IDIs were conducted with twenty-seven participants between 23rd May 2021 and 13th June 2022.[66] A summary of participants is available in appendix E. The five pilot interviews took place from 23rd May 2021 to 28th July 2021 (as described in section 3.4) and the remaining interviews were conducted from 28th February 2022 to 13th June 2022. On average, an interview lasted seventy minutes, ranging in duration from 34 minutes to 174 minutes. No participant was interviewed twice, though some were involved with other data collection activities (i.e. focus group discussions or informal conversations). Two individuals were interviewed together at the request of the participants themselves i.e. one of the IDIs consisted of two participants. Although I was concerned that one of the participants wanted to police the other (and this may have been the case to a certain extent), it became apparent that consent would not be proffered for separate interviews and insistence risked rupturing the nascent relationship.[66 90 430] With no other way to access pharmacists at that iNGO, and after careful consideration with supervisors, I agreed to hold the IDI with both individuals. In the thesis I term it a "joint IDI".

All interviews were conducted in an online setting.[443] [444] Audio and video recordings of every interview were used to create a verbatim transcript, annotated with any non-verbal communications that were considered significant.[445] [446] Field notes made during the interview were captured in a reflexive memo, alongside immediate interpretations of the data, within one day of the interview.[67] [69] (A fuller description of this reflexivity process is offered in section 3.7.4.) All interviews were informed by topic guides, as described below and in appendix C.

3.6.2 b) IDI topic guide.

A topic guide was used to structure IDI questions and to offer consistency between interviewees.[66] [89] [384] A semi-structured approach enabled me to probe unanticipated topics that arose during the interview and that could have relevance to the research. The topic guide was iterated during the study to adapt to emerging findings. The questions are listed in appendix C and a rationale for their inclusion and phrasing is offered below. In the following section, I describe various techniques that I employed to improve the quality and quantity of data collected.

The topic guide covered four 'grand tour' questions.[66] These were book-ended by opening and closing questions of a reflective and personal nature. The opening question asked the participant to reflect on how their career had influenced access to medical products. The primary aim of this question was to build comfort and confidence with the interview environment using a topic that the participant could speak on with ease (i.e. themselves).[90] [210] [386] It also situated the conversation within the research context and offered an insight into the interviewee's definitions of 'medical products' and 'access'.

The first grand tour question focussed on prioritisation, as the literature review and preliminary findings had identified that resource allocation was a highly relevant and morally challenging aspect to decision-making. To create safety, I acknowledged that the participant likely had more on their 'to do list' than time available and enquired as to how the participant prioritised activities. By openly

recognising the insufficiencies of the system, the question sought to obtain an honest insight into how the individual navigated the common problem of capacity constraint. Specifically, the question aimed to understand structural, procedural, and relational factors that influenced the individual.

The next two grand tour questions pertained to decision-making, which was explored by means of a vignette.[393] [394] [396] The participant was asked to "*think out loud*" about how they would "*handle*" a situation in which their iNGO's medical warehouse had been destroyed.[247] [390] [392] Once the participants had articulated their response, they were probed for how and why they would act. To follow-up, I asked what a "*good decision would look like*". This enabled a greater understanding of their values and beliefs in relation to the core ethical tension (of whether to prioritise availability or quality) and offered interesting insights into the differences between what they *would* do and what they felt *should* be done.[414]

The next 'grand tour' question, which elaborated on the vignette, sought to uncover the participant's beliefs regarding responsibility and authority, within the complex geopolitical context of humanitarian aid. Early findings from pilot interviews and grey literature identified the ethically fraught nature of governance regarding the quality of medical products that are intended for iNGO patients (see chapter 2.3.3). A scenario was described in which national vendors, all of whom were approved by the National Drug Regulatory Authority of the Host Government, were identified – but none of whom were approved under the iNGOs Quality Assurance policy. This conflict of authority was highlighted, and the participant was asked to choose between them.

The final grand tour question explored the participant's perception of the risk of substandard and falsified medical products, which was hypothesized to be pertinent to how the individual approached the decision. First, the participant was informed that, whilst reading, I had encountered the statistic that "*1 in 10 medical products in low- and middle- income countries are thought to be substandard or falsified*".[7] [188] The participant was simply asked, "*what are your thoughts about that?*"[210] This offered an insight into the participant's sense of threat of poor-quality medical products.

The closing question asked the participant to reflect on what guided their decision-making (although occasionally this question was skipped or curtailed due to time constraints). This question aimed to learn of the participant's explicit values, which could be compared with implicit values that were uncovered through earlier responses. It was considered highly appropriate as a closing question, as its reflective nature brought about a slower pace to the interview and avoided an abrupt ending.[66]

3.6.2 c) Techniques used to improve IDI data quality and quantity.

My interviewing style and the techniques that I describe here were heavily informed by reading instructional textbooks on Qualitative Research. Of these, Patton, Barbour, and Merriam and Tisdell were particularly influential.[66 89 384] Given the potentially sensitive nature of the subject, I felt that participant ease was essential for establishing an open dialogue. Thus, during data collection I took steps to reduce stress, create safety, and build trust.[386] I adopted numerous techniques to improve the quality and quantity of data gathered via IDIs, which were informed by literature and retrospective reflection on interviews (see section 3.7 for more detail on the latter).[67 69] Primarily, I focussed on relinquishing as much control as practicable, reducing unpredictability, and avoiding confrontation.[66 408 447] In addition to this I sought to generate engagement with the research topic, to mitigate the challenges of remote data collection, as well as to encourage thoughtful contributions.[383]

Relinquishing control:

Where possible, individuals were approached via LinkedIn (an employment-focussed social media platform), due to the cautious assumption that they would prefer to keep their involvement in the study distinct and discreet from their employed environment (i.e. their work email). I then asked participants to propose an email to continue the exchange. (The exception were snowballed participants, as this initial connection was made via an introductory email). This approach allowed participants to choose and control our method of communication. Although consent forms were

shared before research activities, the written consent of IDI participants was obtained *afterwards* to help the participant to feel in control.[66] Prior to recording (and taking verbal consent) with IDI participants, I reminded them that they would have the opportunity to reflect on the interview before deciding whether to consent to its use in the dataset. I also highlighted that their comfort was more important than answering questions; they were welcome to take a break during the interview, or chose not to answer a question, if they wished.

Reducing unpredictability:

All questions were phrased in an open manner and a conversational style to facilitate information sharing and rapport.[386] When moving from one topic of conversation to the next, I prefaced it with a short explanation about what would be asked and why. This avoided abruptness, allowed the participant to 'mentally prepare', and revealed my objective. This was intended to help the participant feel confident and like a collaborator, rather than wondering if I was trying to 'catch them out' or if I had a hidden agenda.[89 383]

Avoiding confrontation:

In the pilot IDIs, I asked the participant for examples of a stock-out situation and then we chose one to discuss. On reflection, I realised that this was quite a stressful task for the interviewees, who sometimes seemed flustered and groped for examples. Moreover, I noted that some participants were uncomfortable with my scrutinising a personal event.[68] Therefore, for later participants I presented a vignette that was constructed from data generated in the pilot IDIs and document analysis.[391 395] This technique enabled participants to engage with a sensitive topic in a way that did not feel personal to *them*, and without feeling confronted about their past choices.[391 395 396 404] Additionally, if challenging a participant's position, I usually tried to present the question as the opposing view of another participant. I might inform them, perhaps spuriously, that "*someone else I*

spoke to thought 'x'" and then invite them to comment. This helped to avoid direct confrontation and protected the researcher-participant relationship.[66 68]

Generating engagement:

Every invitation to participate included an explanation about why I was approaching that individual and the unique contribution that I believed that they could make to the study.[68 210] The style of this message was personalised to suit my relationship with them. I suggested to all participants that they meet me for their IDI in a private location in which they would not be disturbed.[415 440] Most joined the call from home, and several chose to meet on a day off from work. During the interview, I referred to the topic guide as little as possible, by committing it to memory and using an aide memoir of key words when necessary.[66 386] This enabled me to remain present and to look into the camera when speaking. I also tried to mirror the participant's language, or to reference their anecdotes, when speaking. I hoped that this would build rapport, create familiarity, and confirm my own in engagement and interest in the interview.

Whilst the participant was speaking, I was sensitive to my own behaviour and responses. I sought to adopt a neutral position that was accepting of any statement and that would avoid unintentional 'feedback' that influenced the participant.[66 90] However, I found that most participants expected me to offer some sign of comprehension or active engagement and would pause for this. I adopted a style that, I hope, projected empathy for their situation and curiosity about their perspectives, but that avoided agreeing or disagreeing with them or offering my own judgements. To do so, I consciously mimicked the participant's own behaviour, such as nodding or offering a monosyllabic interjection. Despite this, sometimes I used silence and stillness as a technique to encourage deeper thought or greater sharing. If I sensed that the participant was holding back, or mentally processing something, I would wait before asking another question.[386] If the interviewee appeared to need more time than a comfortable silence would allow (to articulate a thought or to build the confidence to share it) I used the excuse of referring to my notes.

3.6.3 Focus Group Discussions.

3.6.3 a) Summary of FGDs.

This doctoral project was constrained by travel restrictions and social distancing measures due to the COVID-19 pandemic, which restricted me to remote data collection methods. Unfortunately, at the time I could find very few qualitative studies in which FGDs were exclusively run remotely; publications about managing online interviews often focussed on how digital interactions might impede rapport with participants with few recent papers attending to FGDs on a digital platform.[431 433 443 444 448-450] Therefore, I chose to conduct FGDs towards the end of IDI research activities, which allowed the latter to inform the design and content of the former.

FGD Group	Number of participants	Roles
Country Office FGD	3	1 * clinician 1 * logistician 1 * pharmacist / logistician
Head Office FGD	5	2 * clinicians 3 * logisticians

Table 8: Summary of FGD participants.

Two FGDs were conducted online on 23rd and 25th May 2022 and both took around 90 minutes.[66] Sampling and recruitment are described in section 3.5, an overview of participants is provided in table 8, and a detailed summary of participants is provided in appendix E. As a summary, all FGD participants worked for the same iNGO, but they did not necessarily know each other before the interview. The groups were distinct in terms of geographical location and were composed with a mix of clinical and logistical roles. Audio and video recordings of the FGDs (created using Microsoft Teams teleconferencing software) were used to create a verbatim transcript, annotated with any non-verbal communications that were considered significant.[445 446]

3.6.3 b) Development of the FGD topic guide and techniques used to improve data quality and quantity.

This section describes the FGD topic guide and key decisions in its development. It is complemented by appendix C, which presents the topic guide itself and a brief description of each slide.

Following the success of using vignettes in IDIs, I chose to use them as a vehicle to encourage discussion in FGDs.[391 393 394 404] Early iterations of the topic guide used a vignette that represented the incredible complexity of the decision-making context, and tasked participants with reaching an urgent decision about how it should be resolved.[388] The scenario provided details of a humanitarian health project, its donor, the target population, the regulatory environment, sourcing options, the iNGO's significant relationships, and so on. However, after writing it I had concerns that this level of detail would be too time-consuming to discuss and too challenging to assimilate, as well as artificially leading participants to consider information because it was available and then miring them with minutia.[391 405] I decided to drastically simplify the scenario; instead of providing considerations, I would observe which ones arose.

Simplification of the vignette meant that I would have time to explore a second scenario with participants and thus the opportunity to explore dichotomous influencing factors, to investigate how perspectives agreed or diverged on a common theme. Options identified through preliminary data analysis included: response type (e.g. emergency vs development), beneficiary type (e.g. refugee vs citizen), medical product type (e.g. medicine vs medical device), type of care (e.g. preventative vs acute or chronic), and scale (e.g. small vs large stock-out). I found the latter to be of greatest interest, because it enabled an exploration of the tension between personal and public health, which was relevant to the concept of distance and proximity.[59 60 451]

The vignettes were constructed from anonymised IDI data and adapted to align with a location in which the participants' iNGO operated complex health projects (figure 6 refers).[391 394 395] They were

specifically designed to explore scale at opposing extremes, to assist with identifying how perspectives and norms might differ.[396] The first vignette focussed on a single patient who required a single medical product. The slide was designed to humanise the situation: the doctor is named, the condition and needs of the patient are articulated, and the image is of a person. The second vignette related to an inconceivable number of patients through the destruction of a medical warehouse. The slide was designed to avoid humanising the event: the image is of a location (rather than a person), the scenario does not reference names, roles, needs, or potential health impacts, and the description references financial data.

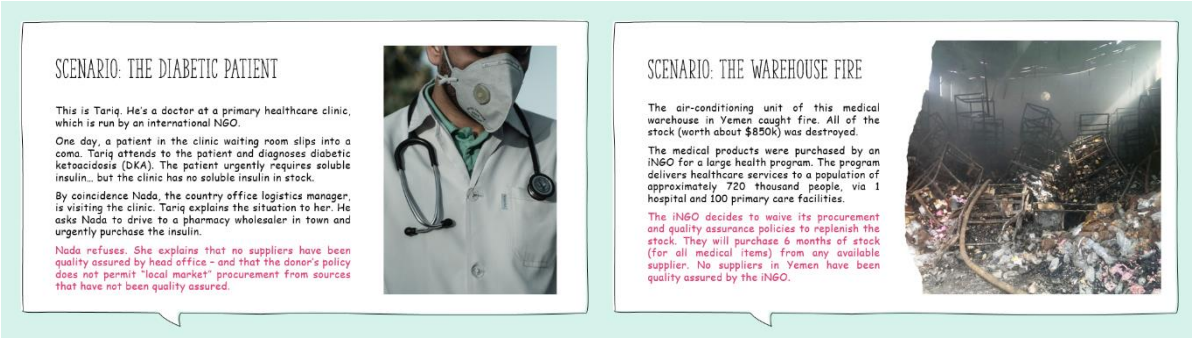


Figure 6: The FGD vignettes.

Whilst writing the vignettes I contemplated their purpose.[383] I decided not to use them as a 'task', as the FGDs were not a substitute for participant observation (as discussed in section 3.3.1). Rather, their role was to ground the discussion in a shared, imaginary situation, so that participants would be assisted in identifying their perspectives and articulating them with reference to an example.[391 395 396 404] Not only would this clarify communication, but it also made exploration of a sensitive subject far easier.[395 404] However, I remained concerned that participants would not have the confidence or time to voice their opinions during a 90-minute interview. To mitigate this, I chose to conclude each vignette with a (fictitious) decision that had been made; rather than asking participants how *they* would handle the scenario, I asked them to comment on the *decision-maker's* judgement.[383 388] To further encourage debate and discussion, the scenario's decisions were intended to be controversial (based on my analysis of IDI data). This format required less vulnerability and social risk on the part of the participant, whilst also generating impetus to discuss normative concerns. To ensure that all

individuals had the opportunity to speak, each participant was invited to make an opening comment regarding their understanding of the decision, before turning to plenary discussion.

I considered a range of options when planning on how to communicate the vignettes, including: actors, pre-recorded audio, email, video clip, and PowerPoint.[66 448] I selected the latter, as I assumed that it would be familiar to participants, would contribute to the ambience of a team meeting, and would allow me to share both written and pictorial information. Having chosen to use PowerPoint, I decided to use it to aid communication and structure throughout the FGD.[391] As shown in appendix C, the slide deck was used for my preamble, which described the purpose of the study, the significance of FGDs, the valuable contribution that the participants could make, and emphasized the importance of confidentiality and engagement.[386 428]

Many of the interview techniques used to create safety and encourage engagement in IDIs (section 3.6.2 c) refers) were also employed for the FGDs. Key differences included obtaining consent, sharing content in advance, and employing an 'icebreaker'.[386 428] In IDIs, I obtained written consent *after* the interview and offered participants an early opportunity to drop out. I considered whether this would be feasible for FGD participants. I concluded that it was impractical because the refusal of one interviewee could negate the use of a significant proportion of FGD data, which could disrupt the study and waste participant time.[66 423 428 430 431] However, I decided to share the FGD topic guide (i.e. the PowerPoint) three days in advance of the interview, alongside an explanation of what to expect on the day. I hoped that this transparency would help to reduce anxiety of the unexpected, increase enthusiasm for the discussion, and provide additional time to consider the vignettes.[383 428] Finally, to assist with building participant confidence, I invested about a third of interview time to an 'icebreaker' exercise, which involved short and thematic guessing games. These were intended to help participants to feel at ease within the group setting, to generate interest in the subject, and to orientate thinking around the risk of poor-quality medical products prior to commencing the group discussion.[386]

A summary and clarification of the vignettes presented by research activity.	
IDI	**The IDI warehouse fire scenario.** The participant is asked to think about the following 'out loud': "You work for a large iNGO. You receive news from a Country Office that one of their medical warehouses has burnt down. All the stock has been destroyed, and they are seeking approval to purchase it on the local market." When that discussion has concluded, I say something like: "I'd like to augment our scenario with Quality Assurance information that you've gathered from different sources. Let's say that the Country Office pharmacist has identified five potential suppliers. She has checked the credentials of these vendors with the national regulatory authority. All are of them have been recently inspected and are fully quality assured. However, QUAMED audited these suppliers and failed them. So, we have a difference of opinion here. Who is right?"
FGD	**The FGD warehouse fire scenario.** The air-conditioning unit of this medical warehouse in Yemen caught fire. All the stock (worth about $850k) was destroyed. The medical products were purchased by an iNGO for a large health program. The programme delivers healthcare services to a population of approximately 720 thousand people, via 1 hospital and 100 primary care facilities. The iNGO decides to waive its procurement and quality assurance policies to replenish the stock. They will purchase 6 months of stock (for all medical items) from any available supplier. No suppliers in Yemen have been quality assured by the iNGO.
FGD	**The diabetic patient scenario.** This is Tariq. He's a doctor at a primary healthcare clinic, which is run by an international NGO. One day, a patient in the clinic waiting room slips into a coma. Tariq attends to the patient and diagnoses diabetic ketoacidosis. The patient urgently requires soluble insulin… but the clinic has no soluble insulin in stock.

	By coincidence Nada, the Country Office logistics manager, is visiting the clinic. Tariq explains the situation to her. He asks Nada to drive to a pharmacy wholesaler in town and urgently purchase the insulin. Nada refuses. She explains that no suppliers have been quality assured by Head Office – and that the donor's policy does not permit "local market" procurement from sources that have not been quality assured.
In the thesis I will refer to these vignettes as "the warehouse fire scenario" and "the diabetic patient scenario". The context that I provide in the thesis will clarify whether the participant was presented the IDI or FGD version; they have been given the same title as they relate to the same incident.	

Table 9: Summary and clarification of vignettes presented to participant according to research activity.

3.6.4 Informal Conversations and Document Analysis.

3.6.4 a) Summary of Informal Conversations.

Informal conversations (ICs) were not planned, contrived, or anticipated; all took place in a relaxed, natural setting (face-to-face or via one-to-one videoconferencing) and were arranged for personal or professional reasons with friends and former colleagues. In this regard, I found that my insider-outsider positionality (section 3.7.1 refers) blurred the boundaries between 'my life' and 'my research'.[447 452] Over the course of my doctoral project, I frequently met with friends who worked in the humanitarian sector; inevitably, they would talk about what was going in their life and their work and, inevitably, I would reflect on how this related to my understanding of the research topic. I quickly realised that I needed to distinguish between 'people' and 'participants', to ensure methodological rigor and ethical integrity in clarifying what was 'life' and what was 'data'.[397 453 454] I deemed that a conversation had generated data of significance if it helped to answer one or more research questions, and if any of the following were true: it illustrated or refuted a finding, up to the point of data saturation; it offered a novel perspective on the problem or its context; it offered an insight that inspired a change in the study (such as the use of language or a new avenue for research).

I classified these unintended "revelatory moments" as informal conversations and included them in the dataset.[455]

A total of ten ICs were held with four different individuals during the study. Six ICs were with an IDI participant; two ICs were with an FGD attendee; the final two ICs were with two individuals who had no other involvement with research activities. Data generated in ICs were summarised in field notes, soon after the meeting. I did not code this data, due to concerns about validity and because it was not a transcript.[406] Rather, I mostly used this data for 'getting under the skin' of everyday lived experiences, like professional complaints, challenges, and relational tensions.[66] It informed my understanding of the context (which influenced iterations of the topic guide and sampling frame) and was used to validate my understanding and interpretation of findings.[456] On three occasions in the thesis, I supplement data gathered in a formal setting with short illustrations generated in ICs.

ICs can be ethically problematic in terms of transparency and obtaining informed consent; it was not practical for me to present consent forms and participant information sheets to 'people' before an IC.[397] [433] Instead, I retrospectively sought consent if, upon reflection, I considered that a specific story or information had generated data (according to my aforementioned criteria).[453] The outcome differed depending on the person and how I wanted to use the information.[454] For the two participants involved with IDIs or FGDs, I verbally asked for their permission to extend their written, informed consent to encompass the IC data (to which they agreed). I refer to the (anonymised) personal circumstances and experiences of one IC participant in the thesis; I obtained their written informed consent at a later meeting. Data generated with the fourth participant informed my topic guide – it was not explicitly used in the thesis. The participant stated their preference for giving verbal rather than written consent due to time and simplicity.

3.6.4 b) Summary of document analysis.

Document analysis was also an unanticipated and opportunistic method – some participants freely and unexpectedly shared the files listed in table 10. These files were too voluminous to code, and no documents are quoted or cited in the thesis due to confidentiality concerns. However, they offered detailed insights into factors that influenced decision-making and a greater understanding of how data was gathered and applied, including proxy indicators for risk.[398] I present my analysis of these findings in the vignette in Chapter 4 (see section 4.2.2). They also informed the development of topic guides and offered a method of data validation.

Summary of confidential documents supplied by participants	
Document description	Number of documents
Records of decisions pertaining to urgent medical product stock-outs.	37
Internal procedures for the procurement of medical products of uncertain quality.	2
Value for Money (VfM) assessments for the sourcing of specific medical products.	2

Table 10: Summary of confidential documents included for analysis.

3.7 Data analysis.

3.7.1 Positionality statement.

Reflexive Thematic Analysis (RTA) involves an "*artful interpretation*" of data by the researcher, whose individuality is viewed as integral to the analytic process, rather than a source of bias.[71 72] Thus, an appreciation of my positionality is essential to the reader's understanding and appraisal of this study's

findings.[67 456 457] This section describes my positionality, which would have undoubtedly shaped the dataset by impacting interactions with participants and my own understanding of those exchanges.[9]

To an academic audience, I am classified as having insider-outsider positionality.[447 458] I have been *inside;* I encountered the phenomenon of interest whilst working or consulting as a pharmacist at various iNGOs and would have been eligible to participate in this study. Yet I am also *outside*; I am an observer of people, their behaviours, and the invisible systems that contain them. This positionality statement will explore what being an insider-outsider has meant for me and the findings of this study.[408 452]

Being an insider gave me privileged access to a pool of suitable participants from which to recruit or snowball. It also meant that I was well-versed with the language of humanitarian health and with complex matters related to medical product quality. Speaking the same language as participants allowed me to be understood and communicate in a way that felt natural, which helped to build trust and momentum. It helped the conversation to flow, as I did not need to frequently interrupt participants. For example, when Olga[10] (IDI-671, donor, pharmacy) rhetorically asked "*Now, are we going too far with SRAs[11]?*" before continuing with her thoughts, I did not need to interrupt her to enquire about the acronym, or the controversy of its place in medical product Quality Assurance (QA).

However, for some participants, my familiarity with the space (or their knowledge of my background) was cause for reservation.[427] I witnessed how some participants would measure what they said, like Pete (IDI-499, iNGO, roving, operations) who abruptly stopped speaking in fear of "*raising a red flag*" to me. I realised that some participants assumed that, as a former pharmacist of an iNGO Head Office, I would frown upon their decision to source medical products of uncertain quality and, at first, they treated the interview as my test of their commitment to QA policies. These attitudes, in

[9] My appearance, for the benefit of those reading and critically appraising this study, is that of a slight, brown haired, cisgender woman of white Irish heritage. I speak with a South of England accent.
[10] All names have been changed. Appendix E refers.
[11] Stringent Regulatory Authorities: refer to the glossary or literature review for further information.

and of themselves, were insightful for understanding the taboo that might surround certain opinions.[459] However, they also required a great deal of tact and encouragement to shift the tenor of the conversation and to be viewed, to a certain extent, as an outsider. I feel no doubt that these interactions would have been different if I was 'just' a researcher.[68]

As an insider, I am well acquainted with the dizzying actors, systems and processes that might surround humanitarian health projects. I have written and advised on several policies, spending hours debating how decisions should be made, and by whom, as well as struggling to reconcile procedural tensions between what seems practical and what seems effective. These insights were a gift when creating the topic guide, probing participants during interviews, and searching for latent themes within the dataset.[452] For example, when I suspected that Ursula's (Joint IDI-460, iNGO, Head Office, pharmacy) enthusiasm for a novel system of classifying regulators was feigned, I was able to pose a question that interrogated her support for the initiative (see section 6.4.2).[12] This led to deeper insights regarding her perception of National Drug Regulatory Authorities.

However, spending years focussing on the creation of systems (specifically medical product quality management systems for Global Health charities), does not well equip one to objectively criticize them. To become an outsider, I attempted to disentangle myself by relentlessly questioning my thoughts, feelings, and responses to participants, as described in section 3.7.[447] I also deeply reflected on my identity and how this may have shaped my perspectives. Whilst working in the iNGO sector I had needed to be knowledgeable, opinionated, and decisive. However, as I picked at the epistemological and cultural foundations of my views, I increasingly saw ignorance and doubt as my goal. I have been ignorant, of course, but in *feeling* ignorant of what is right, in an ethical sense, I was able to approach the data with less presumption and greater curiosity.

[12] This exchange related to the Global Benchmarking Tool, a WHO initiative that plans to assess and grade the capacity of every National Drug Regulatory Authority. Chapter 2 refers.

As an insider I am intimate with the pressures and challenges of decisions that require medical product quality or availability to be compromised. I have been called to justify my decisions in-front of an angry (and predominantly male) auditorium. I have spoken with weeping clinicians about decisions and their outcomes. I have been hailed as wise and collaborative as many times as I have been condemned as stupid and inflexible. I have been thanked for saving lives and accused of being responsible for their loss. Therefore, I am well acquainted with the intangible aspects of the decision: its emotional turmoil that can feel impossible to bear, the exceptional loneliness that can accompany it, and the indifference of an organisation that permits its decision-makers to be targeted. None of my participants shared these kinds of experiences with me. However, when they spoke of their own difficulties I could empathise with their unspoken struggles and pain, which I witnessed in their silences, their hesitations, and their physical tension. I believe that this sensitivity helped me to create a safe environment for participants to share their stories, and that this is evident in the rich quality of my data.

Some of my negative experiences had also led to grudges against certain roles or organisations, which were unhelpful in seeing the subject matter clearly. I identified this anger during data collection activities. I actively worked on processing these feelings, as I viewed this as essential for becoming an outsider, by attempting to empathise with those roles and organisations that had been difficult to work with.[427] As well as being good for me, this helped with analysis. For example, it led to findings about vulnerability, some of which are described in the Discussion chapter. It was a stark awakening to find that some participants did not struggle with the decision at all, nor view it as an ethical problem. Blinded by my own feelings, I had assumed that these decisions were tough for everyone who faced them. Learning that Kamran (IDI-796, iNGO, Head Office, health) found these decisions to be "*easy*" was a revelation that led me to change the focus of the research and the way in which I presented the study to participants (see section 4.3.3 a)). I ceased referring to the decision as an "ethical" one and I explored perspectives on the ethics of the situation.

So, being an insider has been a double-edged sword; one that has helped to pierce to the heart of issues but has also blinded me into believing that sword-fighting is the only option.[408] Becoming an outsider has required a conscious unlearning and constant questioning. At the beginning of this DPhil project, I was nervous of my unconscious bias, fearing that my thesis would present a myopic account of a problem that reflected my privilege and, therefore, exacerbated systemic inequities. The reader can judge whether this is the case. However, I have also been able to harness my subjectivity to gain deeper insights of the dataset, using my discomfort and knowledge as a guide.[447]

3.7.2 Theoretical framework.

I did not closely adhere to a formal theoretical framework in the design of my study or the collection and analysis of its data, as I adopted an inductive approach that was responsive to emerging themes.[460] However, for the purposes of contextualising my findings, and for future research on the topic, it is important to clarify that my study has been broadly informed by feminist thought. Feminism offered a valuable platform for considering the myriad ways in which inequality and power(lessness) featured within my data.[461] [462] However, as feminism encompasses a wide (and sometimes conflicting) swathe of views, I will clarify some of the writings and distinct subaltern feminisms that were helpful to my understanding the phenomenon.

I was cognisant that the voices of patients and caregivers would be absent from my data (section 3.3.3 refers), but that the decision of interest concerned their lives. Literature on the Ethics of Care proved useful for focussing my analysis on the conceptual patient, and for examining what institutional norms and systems meant for patient care, agency, and representation.[14] [37] [343] In addition to being sensitive to micro-level interactions, my research led me to consider macro-level expressions of power that appeared tied to economic and political colonial histories.[257] [261] [463] Here, postcolonial feminism helped to unpack the complex heterogenous nexus of relationships that converged on the iNGO (for example, between Head and Country Office, or Host Government and donor).[463] [464] A theme consistent to both patients and iNGOs was that of vulnerability, as I will

explain in Chapter 8. Although an understudied area, writings on the ethics of vulnerability (which draws upon feminist theory) offered a deeper understanding of perspectives on what it means to be vulnerable and the possible moral obligations of others in response to this.[38 84 347]

3.7.3 Reflexive thematic analysis.

My method of data analysis was Reflexive Thematic Analysis (RTA), as explained and justified in section 3.3.2, which was largely guided by the publications, website, and instructional videos of Braun and Clarke or those who critiqued their work.[64 71 72 383 465] Here, I will describe how I engaged with, analysed, and organised the data, to identify the themes and patterns that are presented in the thesis. I commenced data analysis at the outset of data collection, and it continued throughout writing the thesis.[66] A summary of final codes and themes are in appendix D.

The audio and video of all IDIs and FGDs were recorded and used to generate a transcript that captured speech verbatim and simplified actions.[66 446] Efforts were made to capture all vocal sounds, such as uttered hesitations, half-spoken words, sighs, and laughter, for example. I recorded significant changes in volume (i.e. whispering or shouting), as well as emphasis, a mid-sentence change of subject, and short pauses (using italics, ellipsis, and a full stop between parentheses, respectively). A simplified summary of non-verbal communication that appeared significant, including gestures and postural changes, was documented in-line with the text, within curly braces.[13] This method of transcription was adopted to record *how* something was communicated, rather than simply *what* was communicated, to signpost possible emotions that were elicited during the exchange and, therefore, to facilitate analysis of meaning and identification of subtext.[445] Figure 7 provides a transcription example; see the front matter for the key to my transcription shorthand.

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[13] This notation system was informed by the Jefferson notation system for conversation analysis, but simplified to make it more accessible to any reader. See reference: 445. Bolden GB, Hepburn A. The Conversation Analytic Approach to Transcription. In: Sidnell J, Stivers T, eds. The Handbook of Conversation Analysis. Chichester: Blackwell Publishing 2012.

> *KE: There's a difference of opinion there, between the SRA and the, kind of, local drug regulatory authority. […] Who is right in, in, in your understanding?*
> *R: {long pause, sways on seat, fidgets in chair throughout this whole response} Yeah, no. That's, um, (.) that's a difficult question.*

Figure 7: A short example of transcription, capturing speech and non-verbal communication.

Transcription offered an excellent opportunity to get close to the data.[383 446] I transcribed the pilot phase IDIs, while a (university approved) third party drafted transcripts of all other interviews. The latter provided a 'raw' transcript that I comprehensively revised to correct errors and gaps, to add the 'non-speech' details just described (such as gestures and hesitations), and to anonymise the text. This necessarily slow and detailed process facilitated engagement with the data and ample opportunity for reflection; I captured these thoughts using the "comments" function.[446] Comments were deleted upon finalising the document; those specific to the participant were transposed to the reflexive memo and more general analysis was catalogued in an analytic journal (section 3.7 refers to both).[69]

As well as identifying codes, I attempted to understand each participant's story and familiarise myself with the data.[66 466] I listened to the audio recordings of interviews whilst going about daily life. Repeated playbacks helped me to 'get to know' each participant and their perspectives on the problem. I found that listening to participants with contradictory views back-to-back was helpful and that different settings (e.g. shopping or dog-walking) might spark new insights. In addition to using transcription and reflexive practices, I made extensive use of tools that allowed me to easily manipulate data.[457] This included using white boards, online kanban boards (I used "Trello"), and sticky notes. I would use these to re-arrange and categorise quotes or concepts that arose in the pilot interviews, to help interpret their latent meaning and consider how to label it. I would then compare these preliminary findings with my outputs for other interviews. This recursive process informed – and was informed by – coding exercises.[72 383 457]

I conducted line-by-line open coding of all transcripts using NVivo.[71 72 457] During this process I was sensitive to the aim and objectives of the study; for example, I was sensitive to expressions of difficulty, distress, or tacit beliefs, due to my interest in the ethics of the problem. As my process was inductive, the codes and their thematic categories evolved throughout analysis; I added, removed, combined, and changed codes (and sub-codes) as I uncovered patterns in the data and better understood how they were connected.[72 457 460] These emerging findings sometimes led me to reevaluate my research objectives, topic guides, and literature reviews; due to the flexibility of qualitative methods, this might (re)inform my codes, themes, and sensitivity to patterns in the data.[66 383 456] For example, preliminary observations of knowledge gatekeeping led to my interest in decolonial studies; this led to my interest in relational dynamics and expressions of power or vulnerability in the dataset and, ultimately, findings of epistemological inequity (as discussed in section 8.4.2).[265 467]

During data collection and analysis, I became interested in absences: in what was not said. I found that a substantial amount of meaning (regarding the problem and the people involved with it) was communicated in pauses, was implicit, or was performative.[66 384 446] I found literature on discourse analysis helpful for informing how to uncover hidden meaning in these instances.[64 407] For example, I paid close attention to exchanges that caused an interviewee to change their manner and used codes to help track and interpret them. For example, my code "diplomacy" highlighted speech that was uncharacteristically business-like and more performative in nature. When this arose, I considered the nature of the performance – who was the audience, what was the narrative, how did the speaker wish to be perceived, and what was backstage?[246 468] I also conducted detailed analysis of specific terms that appeared burdened with latent meaning.[71 457] For example, the phrase "local market" was an informal but ubiquitous term that implied more than just geography; I explored who used it, who did not, and what the phrase substituted. Findings are presented in Chapter 6.

At various points, I sought feedback from peers, qualitative researchers, and humanitarian practitioners regarding codes and themes.[406] For example, extracts of two pilot phase IDIs were coded by three fellow Ethox DPhil candidates; two different IDI transcripts were explored with two researchers who had experience in Global Health and Qualitative methods; thematic excerpts were shared with a group of PhD students of different disciplines and nationalities. I also presented my preliminary findings to the Humanitarian Health Ethics working group and received helpful feedback.

I refined and defined codes and themes using various tools and methods that assisted me in gaining a deeper understanding of areas of interest.[72 457] To reveal similarities in participant perspectives and beliefs according to positionality, I linked, coded, and analysed data from participant demographics forms (see appendix H) in NVivo. I complemented this with codes and links that represented key relationships and dynamics between participants or organisations. For themes that were huge, housing many infrequent codes that seemed distinct but interconnected (e.g. "uncertainty" and "influencing factors"), I used mind-maps. I found their non-linear format helpful for building connections and re-categorising data. Once all transcripts had been coded, I abandoned NVivo (as it struggled with lag when amending or re-categorising codes) and used sticky notes (figure 8 refers). This tool offered great flexibility in revising codes, refining themes, searching for a consistent thread in the data, and organising content into chapters for the write-up.[72 457 466]



Figure 8: Sticky notes used for refining themes and organising chapters.

3.7.4 Reflexive practices.

At the commencement of the study, I researched the significance of positionality in qualitative research, with a particular focus on literature pertaining to the insider-outsider. This led me to develop my own positionality statement; I did so prior to data collection, returning to it throughout the study to adapt and reflect, using it as a tool for better understanding myself, in relation to the research topic.[447 452 458] When I identified RTA as my analytic method, I also decided to embed reflexive practices throughout data collection (as I will explain below). I felt that this would help me to improve data analysis, engagement, and rigor, by having a better awareness of the origins and basis of my interpretations, as well as offering a technique to dwell on the potential significance of interactions.[72 408 447 454 465] In addition to interview-triggered reflexivity, I kept an analytic journal using Microsoft OneNote, which allowed me to log my analysis, ideas, and decisions.[69]

I conducted reflexivity exercises before, during, and after each IDI and FGD, which I captured in a participant-specific memo.[67 69] I developed a template as a guide for this, which I will describe here. Before the interview I considered the participant: I journalled my historic and recent relationship with them, why I invited them to participate, and how I felt about meeting with them. Based on this, I jotted my expectations for the interview, which helped to identify and scrutinise preconceptions, as well as pinpointing the interviewee's unique value to the study. During, I largely focused on conducting the interview. However, I used a field book to note down the physical environment of both the participant and me (that could have impacted what was said and how), strong feelings that I had to their responses, and key observations. I used the latter to inform the longer prose that I wrote immediately after the interview, which documented impressions about the interaction and its implications for future data collection.[447 454 456]

Post-interview, I also reflected on the following five areas. The first was data quality; I considered whether the way in which I phrased questions or spoke with the participant could have influenced their responses, to what extent, and how. Second, I reflected on my own positionality; in particular I

noted what had felt uncomfortable or awkward, and reflected on why that was the case.[447 452 454] Third, I thought about broad themes that had emerged from the discussion and how this connected to interviews with other participants. Fourth, I considered how the interview might inform the topic guide, sampling, literature searches, and future research activities. Finally, I reflected on my capability as an interviewer and considered ways to improve.

3.7.5 Presentation of analysis in the thesis.

Empirical findings are presented in chapters four to seven, which are based around the four main themes that I identified during my analysis: the problem, power through policy, procurement and prejudice, and proximity. Most of my analysis is presented using participant quotes, which are embedded in an explanation of my interpretation of their meaning, their significance, and how they connect.[72] The language that I use largely remains faithful to that used by participants, rather than specific dictionary or academic definitions. I detail the meaning, ambiguity, and inconsistency of these terms (according to participants) within the empirical chapters. Despite this, I avoid adopting two terms that I found troubling due to their colonialist connotations: "beneficiary" and "local market".[92 467] Both terms were widely used by many participants; you will find them in quotes in the thesis and my direct references to them. However, as the words that we use and the definitions that we ascribe to them can shape our thinking and our reality, I avoid their general use due to the inequities that they may perpetuate.[87 91] Instead, I adopt the terms "patient" and "national market", respectively.

I also present findings using a vignette, in Chapter 4, to describe the decision of interest and its context.[70 469] This technique allows me to communicate the complexity of the situation, and its plethora of actors, in a manner that does not overwhelm the reader; rather, it efficiently offers a rich understanding of the data and serves as a foundation to deepen these insights in future chapters. Whether presenting data as quotes or via a vignette, it should be noted that I describe the situation as it *is*, rather than making ethical claims for how it *ought* to be.[470] Future normative studies are required for the latter.

3.8 Conclusion.

In this chapter I have articulated the focus of my study and the methods that I will use to examine it. Methods and techniques used for data collection and data analysis were constrained by the COVID-19 context, informed by literature, and iterated based on a pilot study, emerging data, and reflexive practices.[384] [456] These choices were informed by – and impacted – sampling frames and the participants who formed the focus of this study. In the following four chapters I will present my empirical findings.

4

Introducing 'no stock, high stakes' problems.

4.1 The 'no stock, high stakes' problem, and participant reports of its occurrence.

4.1.1 The phenomenon of 'no stock, high stakes' problems within the context of this study.

When I spoke with her, Skye[14] (IDI-101, iNGO, roving, pharmacy) had recently returned from Ethiopia, where her international Non-Governmental Organisation (iNGO) managed several large health projects. Her organisation imported medical products from international sources and then shipped them to each project site because "*local drugs*" were not compliant with her organisation's Quality Assurance (QA) policy. (My study purposively sampled participants from iNGOs with similar practices, and their donors, as described in Chapter 3). During our exchange, she wondered:

> *What if the import laws change? What if the stock gets held up at customs longer? We shouldn't be deciding between "we'll close all our services" or "we'll buy local drugs" and that is the literal conversation we would have to have. It wouldn't be like, "We'll plug the gap with stock from the [Ministry of Health], like, we'll go and approach them". We'd just be just, like, "Oh my God! Do we close the programme until the drugs come? How do we manage it?"*
>
> **"Skye": IDI participant 101, iNGO, roving, pharmacy.**

Skye's iNGO placed strict stipulations around the sourcing of medical products to ensure their safety and efficacy and thus protect the health of the patient. Medical products that did not comply with these QA requirements, such as those available from the Ministry of Health of the Host Government, were treated as being potentially harmful by the organisation's decision-makers.

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[14] Names have been changed. Appendix E refers.

Rather, Skye's iNGO sourced from international vendors. As a pharmacist, she was concerned by the fragility of this arrangement and cited two scenarios in which disruption of these extended health supply chains could feasibly occur and be beyond the iNGO's control: new importation requirements and customs delays. This experienced humanitarian explained that this would result in a stock-out (i.e. the absence of medical products at the treatment site) and a terrible choice: source "*local drugs*" of uncertain quality that may injure the patient population, or "*close the programme*" due to an inability to provide medical aid. The former risked harming patients whilst striving to help them; the latter risked abandoning their care and bearing witness to human suffering. I will term this a 'no stock, high stakes' problem: a situation in which essential medical products are absent, the only immediate replenishment options are of uncertain quality, and in which the lives and livelihoods of patients are perceived to be at risk.

4.1.2 Participant insights into the prevalence of 'no stock, high stakes' problems.

In my interviews, participants indicated that 'no stock, high stakes' problems were a familiar part of their professional lives, occurring "*three or four times a month, at least*" ("Kamran": IDI-796, iNGO, Head Office, health) and would be "*repeating itself again and again*" ("Pete": IDI-499, iNGO roving, operations). Participants from donor organisations, who had oversight of iNGO requests to urgently source medical products from an unplanned vendor, all agreed that they were a common occurrence: "*we are confronted with that all the time*", ("Jan": IDI-886, donor, health); "{*exaggerated nodding*} *I have some example – some bad example*", ("Olga": IDI-671, donor, pharmacy); "*what do you do in these scenarios? Unfortunately, those come up all the time*" ("Liam": IDI-764, donor, pharmacy). Moreover, when I posed the warehouse fire scenario[15] to In-Depth Interview (IDI) participants, and asked them if it felt like a feasible problem for discussion, nearly everyone offered an affirmative response and many divulged that they had had a similar experience:

[15] A scenario in which a warehouse that stores an iNGO's medical supplies has burnt down, causing massive stock-outs. Summarised in Chapter 3 and detailed in appendix C.

KE: All of the [warehouse] stock has been destroyed […] Before we jump in, (.) does that scenario sound like it would be feasible to you?[16]

The burning of warehouse is feasible. No doubt. No doubt at all.

"Farid": IDI-267, iNGO, Country Office, logistics.

{interrupting} Yep.

"Pete": IDI-499, iNGO, roving, operations.

Yes. *I mean it's a completely, er, real example.*

"John": IDI-284, iNGO, roving, pharmacy.

That, that happens. {smiling} […] We don't have the very much stable, er, energy, source of energy, electricity.

"Arjun": IDI-147, iNGO, Country Office, logistics.

We had such a, an instance {laughs freely} occur (.) in my time in [my iNGO]. Yeah, yeah. A, er, a warehouse burnt down and that was certainly a, a realistic issue.

"Noah": IDI-586, iNGO, Head Office, pharmacy.

That so many individuals (from diverse organisations, roles, countries, and project sites) shared the view that the destruction of a warehouse that stored medical products was a feasible occurrence in a humanitarian setting suggests that it is a recognised issue. Beyond the difficult problem that it creates for decision-makers, it has a profound and terrible impact on access to healthcare for affected communities. Some participants, usually with gravity and uneasiness, shared that they had witnessed widespread stock-outs and disruption to the availability of essential healthcare services. For example, a patient-facing clinician gave the following response to my question regarding the feasibility of the warehouse fire scenario in a Focus Group Discussion (FGD):

Not the, the fire in the warehouse part, but complete lack of medications in a, in a health facility – something we have, we face, like, er, (.) very frequently, in the contexts I work in. […] There are no

[16] Although the quotes are listed consecutively, it should be noted that this data was gathered from separate interviews.

> *other facilities nearby, there is no other access to health services, and then you go and visit health facility, which is completely (.) empty. […] {long pause} There are staff, there are some equipments that are there, but no medication. So, I have seen… Er, several, er, occasions, I've faced such, er, incidents.*
>
> **"Jabari": FGD-113, iNGO, Country Office, health.**

Jabari was an experienced medical doctor who had frequently witnessed the wide-scale lack of medical products in remote communities that were unable to access other healthcare facilities. In this situation, patient-facing participants like Jabari are unable to do their job; with no available treatments, they are forced to neglect the needs and ailments of the population. Such 'witness' reports signpost both the diversity and prevalence of 'no stock, high stakes' problems amongst the sample set (i.e. grant-reliant iNGOs working in humanitarian health settings, whose donors stipulate medical product QA requirements). For example, it may be initiated by a single patient in need of a single medical product, or it may manifest from the devastation of a warehouse that affects an entire community. My findings indicate that certain factors (such as donor QA requirements, which are the focus of the next chapter) exacerbated the complexity of the problem, and a participant's perspective of what should be done. Having illustrated that it is a recognisable and not infrequent phenomenon, I will now situate the 'no stock, high stakes' problem in its broader context.

4.2 An illustration of a 'no stock, high stakes' problem, and its context.

4.2.1 Rationale for presenting findings as an illustrative vignette.

The presentation of my analysis in this section takes the form of an illustrative vignette, constructed from this study's dataset and its analysis, to present the reader with an example of how, why, and where the 'no stock, high stakes' problem might occur. It describes a situation in which an iNGO's health supply chain is disrupted, whilst located within a country with a weak drug regulatory capacity. Ensuing tension between medical product availability and quality is heightened by additional sociopolitical pressures (such as the donor's QA requirements) and ambiguous responsibility for

decision-making. The sequence of events is based upon a case detailed in internal decision-making documents that were shared by a participant (see section 3.6.4). However, aspects have been adapted using other data that was collected during the study, to create anonymity and to highlight key facets of the problem, culture, or context.

As discussed in the methods chapter of this thesis, vignettes are particularly well-suited to the holistic presentation of complex qualitative findings.[70 395 469] Many interviewees acknowledged the intricate and inevitably politicised nature of their work, which relied on *international* supply chains, to deliver aid from *international* donors, to meet *internationally* agreed objectives, within States that had an under-resourced government and, possibly, political instability. The situation was described as "*geopolitical*" ("Justin": IDI-696, iNGO, Head Office, logistics), a "*political chessboard*" ("Hugh": IDI-269, iNGO, roving, operations), "*very complicated [… and] changeable*" ("Genevieve": joint IDI-881, iNGO, Head Office, pharmacy), and a reflection of "*power dynamics*" ("Ahmed": IDI-790, iNGO, Head Office, pharmacy). The socio-political web described by participants is pertinent to understanding the 'no stock, high stakes' problem and how it influenced those who experienced it, because it shaped and confined the decision-making context with rules, expectations, and norms. It is anticipated that the following vignette, and the data presented within it, will offer a rich and immersive understanding of the phenomenon of interest, serving as a touchstone for exploring and discussing the boundaries and architecture of 'no stock, high stakes' problems in future chapters. It is followed by a short description of its construction, and an accompanying commentary that draws attention to some of the key actors, challenges, and narratives that appear within it.

4.2.2 An illustrative vignette of the 'no stock, high stakes' problem, and its context.

"Mansoor's Year"

Due to concerns with corruption and capacity of the State's government, iNGOs were contracted to provide healthcare services for thirty-one of Afghanistan's thirty-four provinces between 2001 and

2020. It was known as the System Enhancement for Health Action in Transition (SEHAT), or 'Sehatmandi', project[17]. Interested iNGOs would bid for the opportunity to provide a basic package of health services to the population of one or more provinces and, if successful, they were awarded a multi-year contract that was funded by a consortium of Northern hemisphere donors. The following fictitious case, based on real-world events, follows a Country Director, Mansoor, for one year as he attempts to implement the Sehatmandi project with a challenging and uncertain health supply chain.

– Autumn –

Mansoor works for a Northern hemisphere iNGO as the Country Director of projects in Afghanistan, the largest of which is the delivery of healthcare to a remote province under the Sehatmandi project. The province serves a population of approximately one million adults and children via clinics, primary healthcare centres, and a hospital. Unfortunately, the project is on the brink of failure; Mansoor's team have been waiting for nearly eight months for their re-supply of medical products, and they now face many shortages.

Although some of the delay has been caused by difficulties with planning and budgeting for a twelve-month order of medical supplies, the greatest frustration has been with Afghanistan's importation regulations. Each item requires a variety of certificates for medical product quality and authenticity. With great effort and expense, certificates for about a third of the items have been obtained. However, suppliers (and their manufacturers) are generally unwilling to furnish exceptional documentation for a small-scale customer and for some items, particularly medical devices, the certificates do not even exist. Therefore, despite all the medical products being of sound quality, Mansoor's team is unable to prove this via the mandated documentation. He is concerned that this infraction will impact his iNGO's designation as a Sehatmandi partner, or their authorisation to operate within Afghanistan.

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[17] The Sehatmandi project is explained on Afghanistan's Ministry of Public Health website, here: https://moph.gov.af/en/sehatmandi-project (accessed 6th June 2024).

Mansoor arranges a series of meetings with Afghan governmental departments to explain the situation and to seek exemption from the documentation requirements of their imported medical products. The National Drug Regulatory Authority, which participates in a regulatory system strengthening programme and is partnered with the Food & Drug Administration of the United States, is unwilling to acquiesce to this request. Not only would such permission undermine its efforts with tracing medical products, but it would also create a dual standard that is difficult to justify with other procurers. "*Regulation is our business, not yours*", they state. The Ministry of Economy, which is indifferent to matters of Quality Assurance, is eager for funds to be invested into the national pharmaceutical market, rather than being lost to international vendors. Finally, the Ministry of Public Health, which manages the Sehatmandi project, underlines the importance of continuous access to healthcare services across the provinces. They conclude the meeting by reminding Mansoor that there are many eager applicants for the Sehatmandi project and, if necessary, the grant of fifteen million US dollars will be reallocated to a competing iNGO.

Mansoor is familiar with these competing iNGOs, most of whom do not have quality standards for sourcing medical products. The iNGO that he works for has a strict QA policy in place, which ensures that all medical products are sourced from a supplier with 'trusted' credentials. He fears that a competing iNGO would indiscriminately source medical products from the national market based on price. The threat of poor-quality medical products is deemed exceptionally high in Afghanistan due to conflict, crime, corruption, and extreme temperatures. Therefore, he worries that the reallocation of the Sehatmandi grant would place patients in severe danger from substandard or falsified medical products.

Yet, Mansoor believes that there are a few 'credible' organisations, like his own, that work within Afghanistan. These 'peer' organisations have a reputation for strong international health supply chains and have near-identical policies for medical product QA. He approaches these Northern hemisphere agencies for an unofficial loan of essential medical products, which his iNGO would then replace on

receipt of their long-awaited shipment. Technically, his iNGO is not legally authorised to receive and supply medical products in this manner, but he knows that this is just to prevent private trading and a distortion of the national pharmaceutical market, and so he interprets that the law does not apply.

Unfortunately, no iNGO can help Mansoor on the scale that he needs. The most promising offer is from a UN agency, which can donate three Interagency Emergency Health Kits[18]. The donation would be simultaneously meagre and excessive. The volume and type of products would be insufficient for the scale and breadth of the Sehatmandi project, but also it would contain many superfluous 'emergency response' products that would present a healthcare waste management challenge. Despite these issues, Mansoor decides to accept the assistance.

– Winter –

Mansoor is now unable to reach many of the Sehatmandi project's agreed targets due to stock-outs; under the advisement of his health advisor, he believes that the only remaining solution is to source medical products from the national market. He hopes that, with the support of the pharmacist at Head Office, his team will be able to identify a reasonable 'local market' supplier. His procurement staff warn that this course of action risks disallowances and financial penalty from donors; however, it would allow the programme to continue and, crucially, it would protect his national staff. Not only would it safeguard their jobs, but it would also lessen the security threat that they face. Many of their clinics are situated in Taliban-controlled areas where stock-outs, and the inability to treat ill-health, is not tolerated. Death-threats and the raiding of clinic supplies has become increasingly common.

Mansoor submits a request to the Regional Director to purchase three hundred thousand US dollars' worth of medical products on the Afghan national market. They escalate it to the Global Operations

[18] These are standardised kits of medical products that have been developed by the World Health Organization to address the health concerns that commonly arise from humanitarian emergencies or natural disasters. See: https://www.who.int/emergencies/emergency-health-kits for further information.

Director, who escalates it to the CEO. The CEO seeks technical input from the Head Office pharmacist and Legal Counsel. The pharmacist describes the risk of substandard and falsified medical products and the impact that this could have on public health. The lawyer highlights the reputational risk of distributing poor-quality medical products and adds that, as the company's QA policy is aligned with that of major donors, waiving it could have severe ramifications for the organisation's future funding opportunities.

As the CEO holds a degree in international development but no formal health qualifications, she seeks the advice of the Risk Committee. She calls upon the pharmacist to summarise the risks of, and mitigation measures against, substandard and falsified medical products. The pharmacist explains the potential consequences of poor-quality medical products to individual and public health, but they are unable to quantify the risk. There is no data about the prevalence of substandard or falsified medical products for this province, nor about how different medical products are affected. They have obtained some reports about national suppliers from peer iNGOs, but the data is several years old, incomplete, and based on cursory investigations. There is no reliable information about manufacturers, and they have been unable to verify the provenance of medical products from any national vendor. The pharmacist concludes that they cannot endorse medical products to be sourced on the national market based on the exceptional scale and the perceived risks.

The CEO deliberates for three weeks (with extensive internal and external consultation) before announcing a decision. Based on the committee's holistic risk assessment, she instructs Mansoor's team to source three months' worth of medical products on the Afghan national market. She tasks the Head Office pharmacist with selecting the national suppliers for this procurement and for overseeing the roll-out of "*all possible*" mitigation measures. Concomitantly, she draws supply chain staff away from other regional desks, to re-allocate them to the task of gathering the documentation needed to import quality assured medical products into Afghanistan.

Following this decision, it takes almost ten weeks for the medical supplies to reach the clinics. This included a statutory four weeks for advertising the tender, two weeks of site visits to gather QA data for the pharmacist, another two weeks for them to analyse it, then ten days to agree contracts and arrange deliveries. The purchase was funded from the iNGO’s limited reserve of unrestricted funding. (The project’s donors were approached for financial support, but they would not authorise a spend that was not in compliance with their own spending requirements.) As requested by the committee, the Head Office pharmacist produced a new pharmacovigilance policy to share with donors. This document, which outlined how the iNGO would mitigate the risks of sourcing poor-quality medical products, was endorsed by the legal team and the medical director. In practice, many of the measures proved unfeasible for Mansoor and his team to implement.

– Spring –

The shelves are now visibly full, but it is not known for certain what is inside each box. This problem is made apparent when three young children die at the iNGO’s hospital facility. Each patient had had pneumonia and had received amoxicillin suspension. With no funds for, or access to, a Quality Control laboratory that can forensically analyse the medicine, the cause of death is uncertain. The attending medical team suggest disease progression, perhaps due to antimicrobial resistance, or maybe a falsified product with insufficient active pharmaceutical ingredient. The pharmacist speculates that substandard manufacturing practices may have led to a contaminated product, in which case additional medicines from the same vendor may be affected. The batch of amoxicillin suspension is recalled, and, at great expense, a QA expert is sponsored to urgently identify a new supplier.

Relations with the Ministry of Public Health and provincial communities are now at a fever pitch, inflamed by the incident and the lengthy stock-outs. Mansoor has moved the health director and his family away from the province and back to Kabul, for their safety. He has also arranged for the CEO and a donor representative to meet with the Afghan government, to advocate for an exemption from importation regulations. He is hopeful that they can pressurise the government into allowing an

exemption, for which a precedent has already been set by UN agencies and prominent international health NGOs.

– **Summer** –

International procurement remains a lengthy, expensive, and time-consuming exercise but, following the high-level meeting, Mansoor's team successfully negotiated the importation of a large shipment of medical products. Last night, however, all this stock was lost in a fire that consumed the medical warehouse. Mansoor is uncertain of the cause but, in his incident report to Head Office, he states that the blaze was started by a faulty air-conditioning unit. This is feasible; the warehouse did not comply with Good Distribution Practices and was poorly maintained due to a lack of funding. When they submitted a proposal for the Sehatmandi project, his team removed all support costs from the application and even underquoted other aspects. They had little choice: competition for the grant was fierce and its bilateral donors wanted all costs to be directly attributable to patient care, as this is what their voters 'back home' expected. In private, Mansoor wonders whether the fire was a warning, perhaps from the government, or from the Taliban, or from a disgruntled community.

When he eventually receives it, the report from the QA expert does not recommend any national suppliers. However, it does stratify them according to risk and identifies potential sources for most of his project's medical products, but "*only if absolutely necessary*". As Country Director, Mansoor believes that it *is* necessary and that the risk is justifiable. Therefore, he seeks permission to source from these vendors on a permanent basis, alongside a hollow commitment to implement all measures laid out in the pharmacovigilance policy. Conversely, the Head Office pharmacist draws attention to the weaknesses of the expert's rapid audit, the pervasive risks that a poorly regulated pharmaceutical market presents to public health, and the futility of the proposed mitigation measures. The Risk Committee convenes once again to debate whether to source potentially poor-quality medical products, or whether to abandon the project (and its patients) entirely.

– End –

4.2.3 About the illustrative vignette and its construction.

Real-world data gathered from interviewees, the confidential records that they shared (see section 3.6.4), and my analysis of policy (see chapter 2) was used to construct the illustrative vignette. However, the vignette is not intended to offer a template of the 'no stock, high stakes' problem. Its purpose is to present an example of it in a real-world setting, to illuminate the complexity of the constraints, relationships, and responsibilities that may magnify the difficulty of an already ethically troubling decision. Participants reported that the type of medical product, its quantity, the donor, the existence of referral options, the iNGO's relationships, the scope of the project, the country, the pharmaceutical market, even the weather, were potentially significant to decision-making. Indeed, situational variety was observed to frustrate the creation of procedural documents to guide decision-making. For example, one policy-writer informed me that "*it's extremely difficult. […] Whether it makes sense that you really need those drugs at that facility in Syria, or whether you can really wait two weeks, […] I think that it can't, that can't be written down in a policy*" ("Lynn": FGD-385, iNGO, Head Office, health). Therefore, while some aspects of the vignette are true, some are incorporated from different experiences; however, all themes remain faithful to this study's dataset. This section explains key decisions that were made to either preserve or adapt data when constructing the vignette.

The location, Afghanistan, was selected due to its complexity. It is a landlocked country that experienced extremes of temperature, had borders that could not be patrolled, and had a disjointed infrastructure. This environmental complexity made the regulation of medical products exceptionally challenging. The vignette is set before the Taliban gained control of the State (in 2021), but during their existence, in a politically complex environment that many associated with corruption and conflict. This setting offered the opportunity to showcase extreme risks related to staff safety, as well as a strained relationship with the Host Government. At the time of the vignette, Afghanistan was still a political priority for many powerful States, who had currently or recently supported a military intervention there. In an expression of soft power, Afghanistan received a substantial amount of humanitarian aid, which created an institutionally complex environment. Many iNGOs, working on

many projects, funded by many donors, operated in the country. This allowed the duality of iNGO relationships to be highlighted, which were observed to vacillate between cooperation and competition in a crowded context.

The vignette's Global Health actors were chosen and characterised to reflect the organisations that were most frequently mentioned by participants and an interpretation of their feelings towards them. For example, many interviewees described an iNGO's vulnerability to the rules and whims of its donor or Host Government, and the impact that this had on 'no stock, high stakes' behaviours: "*the donor, kind of, [makes] a difference in terms of the way that you (.) would respond*" ("Elliot": IDI-668, iNGO, Head Office, operations), and "*you feel that yourself, you cannot confront the MoH [Ministry of Health], because they may be very aggressive and defending*" ("Ikolo": IDI-359, iNGO, roving, health). It is also the reason that communities and local groups are intentionally absent from the vignette (they were not mentioned by any participant) and why the patient is written into the background. Interviewees would relate practical and logistical challenges with clarity and attention, against the backdrop of an ever-present, amorphous, and homogenised patient group that required their care and protection.

The project, Sehatmandi, is genuine.[471] It was identified via document analysis of confidential reports shared by a participant[19]; it was selected because many participants (and their respective organisations) have been involved with it (and, therefore, it will not undermine participant anonymity). The project also offered the opportunity to describe the 'no stock, high stakes' problem on a huge scale. It was noted that participants were able to recall events that involved a single medical product with clarity but would describe stock-outs of incomprehensible magnitude more vaguely and, sometimes, dispassionately. The vignette, in part, sought to offer a concrete example of the enormous and desperate stock-outs that participants referenced (the warehouse fires, the bombings, the blockades, the supply chain failures, and the interminable bureaucracy) but that they did not depict in human terms during interviews.

[19] The participant and the document cannot be named to protect anonymity, but an overview of document analysis is provided in section 3.6.4.

The vignette's minor events and timelines are wholly constructed from data collection and its interpretation. For example, it was Martin (IDI-231, iNGO, Head Office, pharmacy), a QA pharmacist, who shared that, "*There was, um, a local production of amoxicillin suspension and the, the reason why I was there, is that three kids died after receiving a, a local source.*" Meanwhile, the problem about whether to accept inappropriate Interagency Emergency Health Kits was described by Guy (IDI-775, iNGO, roving, operations), an operations manager, who stated that "*seventy percent of what came was very useful, because [the project] had lost nearly everything, but the rest of it was never going to be useful and was just a storage problem*". It was the roving pharmacist, Skye (IDI-101, iNGO, roving, pharmacy) who raised concerns about the readability of her iNGO's policies. She felt that they were not "*understandable, and accessible, and functional in the field*", but rather were a "*legal*" exercise intended to "*protect us from litigation*".

Mansoor's iNGO viewed the medical products from national vendors as lacking any QA. This reflects that most participants would entirely disregard any information created by the Host Government, due to the belief that "*a lot of the countries where we work, the government's opinion isn't worth (.) the paper that it's written on*" ("Pete": IDI-499, iNGO, roving, operations). Instead, participants would seek preexisting data generated by a 'trusted' iNGO or third party. (Chapter 6 offers a detailed analysis of participant perspectives on medical product QA knowledge producers.) Regardless of the data obtained, or lack of it, differing professions were observed to differ in their opinion of how to resolve a 'no stock, high stakes' problem.

> *As the health coordinator, I will argue for buying [uncertain medical products in 'no stock, high stake' problems], and then I'm sure "Youssef" [(FGD-554, iNGO, Country Office, logistician)] will be arguing against it. So, at the end of the day, er, the, yeah, the Country Director would be the one would decide.*
>
> **"Jabari": FGD-113, iNGO, Country Office, health.**

This quote informed the professional tensions depicted in the vignette. Health professionals like Jabari (who were 'close' to the patient and their care) would often readily choose to source medical products of uncertain quality when faced with a 'no stock, high stakes' problem, while their logistics

colleagues, like Youssef, (who were responsible for ensuring that procurement complied with legal and procedural requirements) were often less willing to do so. I will explore this in Chapter 7.

Jabari reported that such conflict, which was evident during both Focus Group Discussions, was arbitrated by a more senior decision-maker in real-world settings: "*the Country Director would be the one would decide*". This approach was common, but nuanced, across the dataset. In some organisations technical personnel made the decision, while in others it was handled by someone from an operational background. However, as in the vignette, most participants made clear that the decision would be made by a senior person, remote from the project site, using their best judgement, and without recourse to the Host Government or the patient community. Chapter 7 touches upon how the locus of 'no stock, high stakes' decision-making was reported to influence attitudes to sourcing medical products of uncertain quality (with less proximity being associated with less urgency and a greater concern for policy compliance). In the next section, I will attend to these differing positions and examine the ethical values that underpin them.

4.3 Participant perspectives of 'no stock, high stakes' choices.

4.3.1 A summary of definitions and the participants that are referenced in this section.

Having introduced the 'no stock, high stakes' problem and its real-world context, as presented by those I interviewed and the documents that they shared, I will now examine the difficult choice that befalls the decision-maker: whether to source medical products of uncertain quality and risk that they harm patients, or whether to abstain from doing so and disrupt access to essential healthcare services. Ethical tension exists because medical product *quality* and medical product *availability* are both essential to the wellbeing of a vulnerable population; but, in a resource constrained and uncertain humanitarian context, the prioritisation of one inherently means the compromise of the other. Participants described the problem as "*tricky*" ("Ikolo": IDI-359, iNGO, roving, health; "Claudette": IDI-933, vendor, pharmacy), "*complex*" ("Liam": IDI-764, donor, pharmacy), "*very difficult*" ("Florence": IDI-462, iNGO,

Head Office, health), "*horrible*" ("Elliot": IDI-668, iNGO, Head Office, operations), and "*terrible*" ("Nikolas": IDI-458, donor, policy). Signs of discomfort (including heavy sighing, head shaking, ear-pulling, looking away, speaking quietly, and nervous laughter) were also common. These comments and behaviours signalled participants experienced difficulty and uncertainty in navigating the moral complexity of 'no stock, high stakes' problems. In this section, I will present the perceived moral values (a personal sense of right and wrong) and moral obligations (a personal sense of responsibility to fulfil or refrain from a task according to how one applies their moral values to a task or event) of participants. Three anonymised participants will serve as primary vehicles for this (mirroring the decision-making dynamic described in the previous section): an operations executive, a medical doctor, and a logistician.

Elliot (IDI-668, Head Office, operations), a European operations executive, was a senior decision-maker with a long career in humanitarian operations, formerly in project sites and latterly in Head Office roles. Geographically, he was far-removed from the patient; yet his responsibilities were focussed on project delivery and, emotionally, he strived to overcome physical distance by this litmus test: "*"Is this right for the people receiving this (.) service?" Whatever [the decision] is, […] that's always been front of my mind*". His voice has been selected because, although most interviewees recognised the ethical tension between medical product quality and availability, few were so articulate, candid, and expressing of vulnerability in explaining their decision. He situated himself within each scenario for an extended period without seeking to avoid, change, or solve it; whereas many participants refused to reach a final decision, or would substantially alter the conditions of the scenario, in an apparent effort to avoid emotional discomfort. By allowing me to witness his struggle and isolation, both in reaching a decision and in bearing the consequences of it, Elliot offered an excellent insight into his experience of the difficult choice.

Kamran (IDI-796, iNGO, Head Office, health) was a senior medical doctor based at Head Office, originally from South Asia, with a background in health system strengthening. The health projects of his Northern Hemisphere iNGO were largely dependent on the grants of donors, who stipulated QA

requirements for the sourcing of medical products. While his early career as a clinician had been 'close' to patients, for many years he had focussed on developing governance frameworks and policies at Head Office. He proudly told me of his achievements in this regard: "*None of those standards or procedures existed before [I arrived]. All of that is in place now. We've just gone through an inspection earlier this year: {grinning} we've passed*". Kamran has been chosen to articulate arguments for abstaining from sourcing medical products in 'no stock, high stakes' problems because (excepting for participants from donors) his views were the most absolute of the sample set, and because he spoke with compelling certainty.

Rohan (IDI-502, iNGO, Country Office, logistics) was a national member of logistics staff whose work in South Asia was "*totally dedicated for the [refugee] community*", whom he served via supporting numerous humanitarian projects. The major donors of his Southern Hemisphere iNGO did not require additional QA for medical products; therefore, he was physically 'close' to the patient and procedurally unobstructed in his task. He has been selected to present the view that medical product availability should be prioritised in 'no stock, high stakes' problems, because his utter surety and unusual degree of passion offered an insight into the underlying values that may have motivated his convictions.

4.3.2 Perspectives on the moral implications of risks and consequences of a 'no stock, high stakes' problem.

Elliot (IDI-668, Head Office, operations), the operations executive who focussed on patients whilst being geographically remote from them, reported having considerable experience in handling 'no stock, high stakes' problems, which he referred to as a "*moral dilemma*". His description of the information that he would seek, the likely challenges that he would face, and the ethical concerns that he would have (both for sourcing medical products of uncertain quality *and* for suspending the health project) was so richly detailed that it was obvious that he had thought deeply about similar issues on many occasions. During our conversation, he summarised his understanding of the problem:

> *In certain situations, you've got (.) critical needs, er, presenting themselves, and the only option you have is to provide medicines for those people from a supplier where you don't have as much assurance as you want. That, that's, that's where the 'moral', kind of, boils down to. Do, do you go with {large inhale} (.) that, you know, that supplier, that drug, or not?*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

He described the 'no stock, high stakes' problem as a life-threatening situation in which patients required care, but where the only available treatments were of uncertain quality and, therefore, were potentially harmful. Throughout the exchange he appeared to use the terms "*moral*" and "*dilemma*" interchangeably to describe his feelings of uncertainty about what the ethically 'right' course of action was. He believed that he *should* help to save lives, but also that he *should not* harm patients. Therefore, he was unsure whether to "*go with that […] drug, or not*", because only at the point of administration would he learn whether it would cure or kill the patient.

His answer to the warehouse fire scenario was unusual compared with that of other IDI participants, as he did not express an observable preference for whether to source medical products of uncertain quality. Therefore, I asked him, "*Which side do you come down on?*", and he gave the following response (redacted for brevity):

> *Er. {long pause, looks away, long inhale} I mean, {exhales} my, my instinct is always to do something. […] You know, I think earlier on, I, I might think, "Well, {sighs} you know, these guys are gonna die anyway, so let's try and, you know, there's a chance we might be able to help them". Um. I don't know if I'd go that far nowadays; I think I'm older and sort of more cautious. […] Essentially you are still faced with that situation where they're probably gonna die, (.) anyway. Er, so is it worse to try? You know, to take a chance that you might stop that (.) with a, a fake drug, potentially? Or, you know, give them something that speeds up their demise in some way? Um, yeah. {blows out through pursed lips} It's, it's bloody hard. I, I think I, I, I don't know if I'd go there, these days. I, I might just take the view that {raises hands in a "don't shoot" gesture} they're gonna die anyway, and I'd rather not be part of speeding that up.*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

Elliot's unflinching account offered a vivid insight into his lived experience of a 'no stock, high stakes' decision. He described the ethical tension of the "bloody *hard*" problem that simultaneously motivated him to act *and* abstain when faced with life-threatening need. He also portrayed the extraordinary difficulty of weighing the consequences of either choice, which may be mundane, desirable, or terrible. This matrix of choice and consequence is illustrated in figure 9.

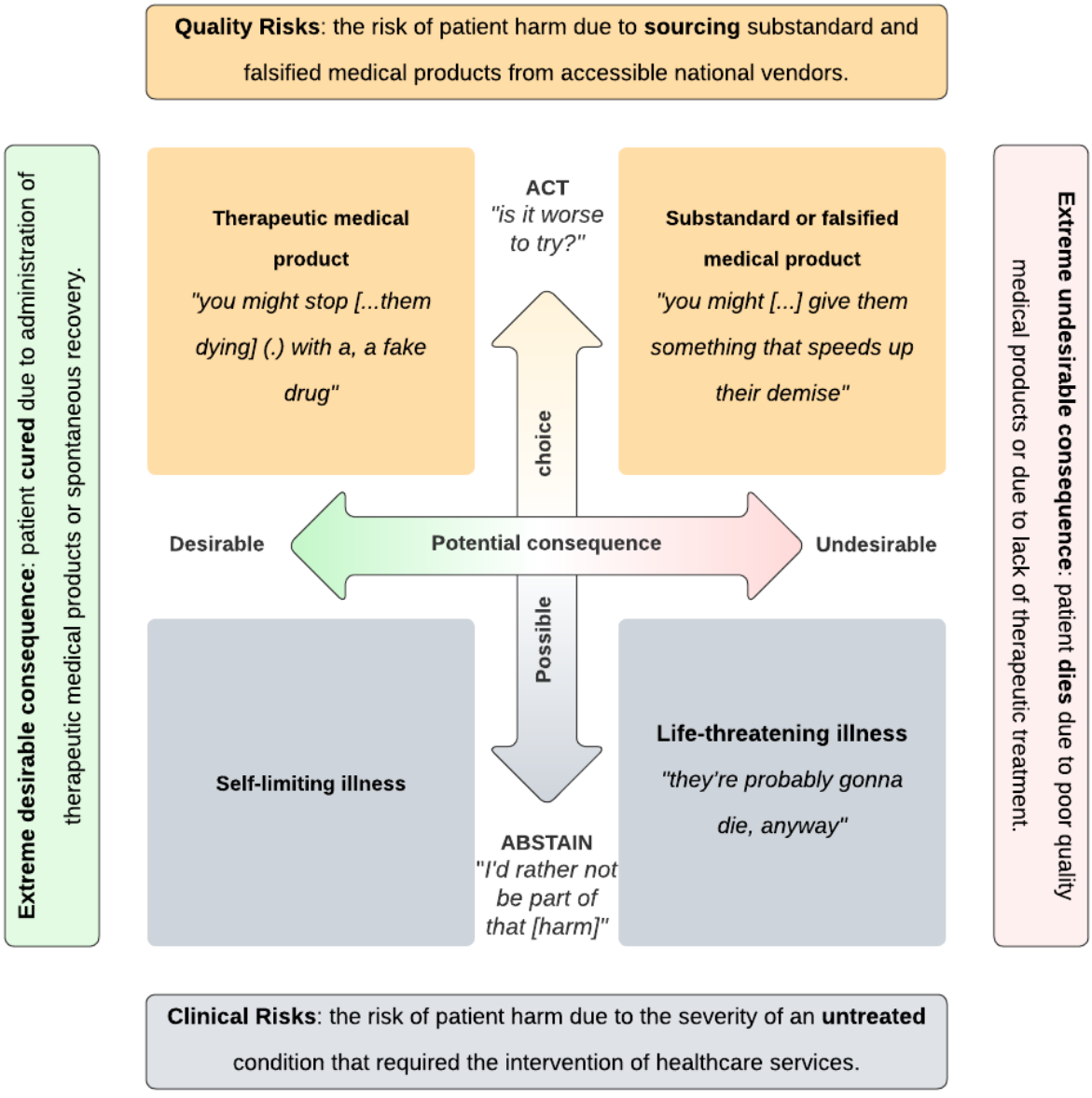


Figure 9: Act or abstain; tragic or mundane? A matrix of the possible choices and their potential consequences in a 'no stock, high stakes' problem, brought to life by the words of "Elliot".

Elliot's "*instinct is always to do something*": he described a compulsion to act, to try to save lives (represented in the top half of figure 9). However, his will "*to try*" and "*take a chance*" was repeatedly

disturbed by his uncertainty of the outcome, because his choice risked sourcing substandard or falsified medical products. His concerns were twofold: he was uncertain of the likelihood of sourcing poor-quality medical products, and he was uncertain of the potential severity of the impact that these may have. His description of the potential consequences was akin to a grim lottery; if successful, he "*might stop*" death (the top left quadrant) or, if not, he might "*speed up their demise*" (the top right quadrant). These outcomes are at either end of a scale of severity. One can assume that between these polar extremes lie more moderate outcomes: for example, disability or unfettered disease progression.

Like all participants in this study, Elliot considered a spectrum of potential consequences that might arise following an act of sourcing medical products of uncertain quality. However, the assessments of these consequences were based on a perception of the risk of patient harm due to substandard and falsified medical products. During a 'no stock, high stakes' problem these risks are not *known*, they are *perceived*. Therefore, if participants did not perceive there to be a risk of poor-quality medical products, their concerns regarding the potential harm of intervention would be extinguished and they would experience no "*moral dilemma*". Findings that participants varied in their interpretation of the risk of substandard and falsified medical products, and their willingness to tolerate them, are described in Chapters 5 to 7.

The bottom half of figure 9 represents the choice to abstain from sourcing medical products of uncertain quality. Elliot's justification was that he would "*rather not be part of*" an intervention that might hurt a patient; an intuition that is evocative of a common norm, that it is wrong for one person to harm another. The spectrum of potential consequences of this choice related to the risk of patient harm due to the severity of an untreated condition that required the intervention of healthcare services. Patients with self-limiting illnesses (the lower left quadrant) are absent because they did not initiate *moral* concern or a sense of crisis. Participants implicitly characterised the 'no stock, high stakes' problem as concerning patients with "*critical needs*" that were "*gonna die*" (the lower right quadrant). The bluntness with which Elliot repeated this statement was unsettling, yet effective, in

capturing the awful and alarming urgency of the situation. Participants were observed to differ in their interpretation of which medical products were urgent, as well as the degree of suffering that they were willing to tolerate. These findings are detailed in Chapter 7.

When Elliot wrestled between his certainty that patients will die without his aid and his concern that his intervention may hurt them, we observe his uncertainty: not only in navigating the risks associated with either choice, but also in discerning the boundaries of his own responsibilities towards them. Interviewees who were motivated by conflicting responsibilities (i.e. to assure both the quality *and* the availability of medical products) were observed to experience far more uncertainty during our discussion of 'no stock, high stakes' problems than those who felt compelled by only one, or neither. Like Elliot, these interviewees tended to be professionally responsible for service delivery but geographically remote from the project site. As I will explain in Chapter 7, interviewees who were focussed on policy-compliance were observed to preference the choice to abstain, whereas those focussed on patient care generally chose to act when facing a 'no stock, high stakes' problem. The only participants that did not exhibit a sense of responsibility for either were from donor organisations, which I will explore in Chapter 5.

Like all participants who felt a morally responsible for maintaining medical product quality *and* sustaining medical product availability, Elliot experienced uncertainty but reached a decision by considering the risks of either choice, debating his obligations in relation to them, and then distancing himself from one of the potential outcomes. Next, I will explore perspectives on how a 'no stock, high stakes' problem *should* be resolved via two participants who were similarly confident but opposing in their views.

4.3.3 Perspectives on moral values and moral obligations in response to a 'no stock, high stakes' problem.

In this section I present an analysis of two conflicting moral obligations that appeared to motivate participants in response to 'no stock, high stakes' problems. A moral obligation is an individual's

sense of responsibility to fulfil or refrain from a task according to how they apply their moral values to a task or event. Moral values refer to an individual's intrinsic sense of what is the right or wrong thing to do, in a normative sense. This section reflects participant perspectives and observations of what ought to be done, according to their moral values, as conveyed by the interviewee and analysed by me.

4.3.3 a) Participant perspectives on the ethics of the decision to abstain from sourcing medical products of uncertain quality.

Kamran (IDI-796, iNGO, Head Office, health) was a senior decision-maker for 'no stock, high stakes' problems at his iNGO, where he was based at the Head Office and charged with ensuring patient safety via the development of governance frameworks. He shared that he regularly received requests to source medical products of uncertain quality from project-based staff – and that he regularly received complaints if he did not approve them. He related one such encounter to me and described his response to Country Office staff, in which he "*calmly*" explained his "*rationale*" for refusing their request:

> *We are trying to save children's lives. We are trying to save mothers' lives. We are trying to provide health service to affected communities in a crisis setting. We're not trying to harm them. And if you are sourcing blindly from, ah, from entities that we don't know that, that are quality assured, you will end up harming them.*
>
> **"Kamran": IDI-796, iNGO, Head Office, health.**

Kamran spoke of "*harm*", a morally and legally loaded word that is evocative of Hippocratic principles.[472] Using repetition as a rhetorical device, he also humanised that risk of harm by conjuring the imagery of mothers and children: population groups that are usually viewed as innocents who should be protected from generalised harms and threats as a matter of priority. For Kamran, sourcing medical products of uncertain quality did not harbour a variety of *potential* consequences; he was unequivocal in asserting that harm *would* result from "*sourcing blindly*". Moreover, he emphasised his statement by directing it in the second person: "*you will end up harming them.*"

His speech was dramatic. Dramatic speech is not usually employed to describe quotidian decisions or procedural doctrine. It suggests that he was defending a deeply held belief; a moral value that was threatened. A review of the quote indicates that this moral value probably centred on "*not trying to harm*", because he referenced the morally repugnant act of knowingly harming vulnerable groups via the administration of injurious compounds. Based in Head Office, Kamran would not be a prescriber or administrator; however, his quote indicated that he viewed his decision as an extension of that act. Therefore, the moral value driving his decision to abstain from sourcing medical products of uncertain quality could be phrased as, "I ought not harm patients".

During a 'no stock, high stakes' problem, either choice may cause patient harm. For Kamran, this was administration of potentially injurious compounds; thus, he expressed a moral obligation to quality assure all medical products. He stated: "*it is our responsibility as a service provider to adhere to our bare minimum standards of safety and quality*". He described his commitment to comply with medical product QA standards, because he perceived that this would assure their safety and efficacy. Although the definition, measurement, and application of "*minimum standards*" were disputed amongst participants, they all recognised the importance of quality standards for medical products. Therefore, motivated by the perceived moral value that he ought not harm patients, Kamran felt that he had a moral obligation to quality assure medical products.

> *The risk [of sourcing poor-quality medical products], I think, is too much. You end up harming children instead of saving lives. And that's, that's a bigger problem for all of us. I mean, I would be implicated as well, if I'm saying 'yes' to it. So, I wouldn't say 'yes' to those items because we're not, er, confident of the quality of those products.*
>
> **"Kamran": IDI-796, iNGO, Head Office, health.**

When he spoke of a "*bigger problem for all of us*", he shared his belief that his iNGO would be responsible for patient harm resulting from neglect of the perceived moral obligation to be "*confident of the quality of*" medical products before sourcing them (and referenced his personal sense of responsibility by stating that he "*would be implicated*"). The nature of this perceived responsibility appeared to be moral rather than legal; in our wider discussion, he was concerned with damage to

his iNGO's "*reputation*"[20] (due to social disapproval for reneging on QA commitments) but made no mention of legal ramifications.

To whom, specifically, Kamran felt responsible was ambiguous. He asserted that sourcing substandard and falsified medical products would have an "*impact […] on our service delivery for that local community, the relationships with the local authorities, with the government, with our peers, the reputation, the donor*". It seems unlikely that he would feel *morally* responsible to all these groups for his perceived moral obligation to quality assure medical products sourced by his iNGO. Rather, he probably listed the groups from which he expected reprisal if poor-quality medical products were administered, because he perceived that they had some expectation regarding medical product quality. The groups listed are consistent with the finding that an iNGO is subject to polycentric governance of ambiguous hierarchy and that, during a 'no stock, high stakes' problem, they may present the decision-maker with conflicting expectations. I will explore the power-vulnerability dynamic of these relationships (and the influence that they may have on resolving 'no stock, high stakes' problems) in the Discussion chapter.

Although Kamran described a moral obligation to assure medical product quality, he was not absolute in his prioritisation of QA requirements:

> *We're not (.) managing risks [of sourcing poor-quality medical products] by stopping service delivery. {laughs} So, the solution is not to stop that medical procurement; it is to enable that risk management and mitigate it as much as possible.*
>
> **"Kamran": IDI-796, iNGO, Head Office, health.**

Kamran joked that "*stopping*" health services would avoid the need for "*medical procurement*" and therefore be an effective way to manage the risk of poor-quality medical products; patients would not receive potentially harmful treatment, because they would receive *no* treatment. His laughter, which was somewhat hollow, signposted the complaints that he had referenced earlier: that his

[20] An iNGO's concern for reputation should not be underestimated; charitable organisations are entirely reliant on external support for financing their operations.

decisions to abstain from sourcing medical products of uncertain quality had impeded "*service delivery*". Perhaps this joke was his rebuttal to his critics via an acknowledgment that *both* medical product quality *and* medical product availability were crucial to patient care (though he did not comment on the *extent* to which one should be prioritised over the other). The controversy of Kamran's decisions (and that he chose to compromise QA procedures under certain conditions) highlights the complexity of the problem and signposts the existence of some other, incompatible moral value or obligation, which I will attend to next.

4.3.3 b) Participant perspectives on the ethics of the decision to source medical products of uncertain quality.

Rohan (IDI-502, iNGO, Country Office, logistician) a logistician from South Asia, had formerly worked for a Northern hemisphere iNGO with QA policies that had restricted the sourcing of medical products (which reflected the stipulations of their major donors). At the time of our interview, he was employed by a Southern hemisphere iNGO that had "*no separate policy for pharmaceuticals procurement*". I was interested in how these different bureaucratic contexts would shape his perspective of the 'no stock high stakes' problem. At both organisations he had been a national member of staff whose role had been to procure, store, and deliver medical products. Although his profession did not involve patient contact, at both iNGOs he had worked directly with clinicians, and he had routinely visited the health clinics of project sites.

Policy-focussed participants, like Kamran, had advocated for medical product quality but had acknowledged the need for availability; conversely, patient-focussed participants, like Rohan, tended to prioritise medical product availability, but were still painfully aware of the risk of poor-quality.

> *Once I supplied poor-quality of medicine product. That can be very harmful for the, for the beneficiaries. Even they, in some cases, are taking the medicine, and the children can be (.) died, or it can be a risk.*
>
> **"Rohan": IDI-502, iNGO, Country Office, logistics.**

Rohan spoke of the terrible consequences that can occur following the administration of substandard or falsified medical products, sharing an incident in which they had been sourced for a health project that he had supported. However, it was unclear whether patients had died following this event, or whether he had reflected on the problem and identified that this was a potential risk. Either way, this experience led him to encourage his iNGO to establish medical product QA processes.

> *There should be a separate [procurement] policy, you know? Medical procurement is not similar to the procurement of* books*. […] There is a risk. Very high risk.*
>
> **"Rohan": IDI-502, iNGO, Country Office, logistics.**

Rohan felt that medical products should have a distinct procurement policy, because of the exceptional risks that they can pose to patient health. He presented this case to his "*management*", who stated that although they "*agreed on [his] points*", they viewed "*the cost of consultant, cost of visit*" to be excessively "*high and time-costly*". Rohan felt that this resistance would "*be improved if donor can convince them*", explaining that the time required to quality assure vendors was incompatible with his iNGO's short-term grants from donors:

> *The project timeline is very short; three months, six months, one year is maximum, basically. […] Donor do not bother about such prequalification [of medical products…]. They emphasize on burn rate, basically.*
>
> **"Rohan": IDI-502, iNGO, Country Office, logistics.**

Rohan explained that there was insufficient time to arrange and conduct "*prequalification*" (activities that shortlist vendors who meet minimum medical product QA standards) for short-term health projects. Furthermore, his iNGO's donors were disinterested in these activities; instead, they encouraged "*burn rate*", the rapid spending of donated funds. These statements are consistent with findings (presented in Chapter 5) that donors can have a powerful influence on 'no stock, high stakes' decision-making, and its context.

Rohan was sensitive to the risk of sourcing medical products of uncertain quality, to the extent that he was motivated to attempt organisational change. However, despite this knowledge, and his

personal experience of the consequences, he supported the sourcing of medical products of uncertain quality in 'no stock, high stakes' situations:

> *I have to continue my support to the key beneficiaries. This is my motto. This is my mission. I cannot withdraw support from them. So, as I have the opportunity, so I'm, I have to ensure their support. This my key task, or key job. I am bound to support them.*
>
> **"Rohan": IDI-502, iNGO, Country Office, logistics.**

His intense and personal language appeared to hail from internal convictions; he gave the impression that opposing them would be a violation of his moral values. He was certain and unhesitant when he shared his belief that he must ***continuously*** "*support […] beneficiaries*" if he was able to do so ("*as I have the opportunity*"). It transcended a simple eagerness to be a 'good' employee: this was his "*motto*", his "*mission*", his "*key task*", he was "*bound*". These statements reflected his perceived moral obligation: that he must ensure uninterrupted health supply chain "*support*". Indeed, he later reiterated that he would not "*follow the route of 'stop procurement'. […] I will ensure the support, be at any cost.*" His depth of conviction was such that he would choose to prioritise the availability of medical products, no matter the "*cost*".

Rohan did not explicitly share the perceived moral value to which his commitment related. However, it is reasonable to assume that he recognised that stopping procurement would lead to a disruption of health services, and that this would deleteriously impact health outcomes. It appears that the moral value driving Rohan's actions were the same as Kamran's: I ought not harm patients. However, although both individuals were driven by comparable moral values, and recognised the potential for patient harm in either choice, they differed in their conceptualisation of the action and its subject. Rohan viewed the withdrawal of support as actively (rather than passively) causing harm and, when faced with a 'no stock, high stakes' problem, chose to source medical products of uncertain quality to ensure medical product availability, as this would ensure that patients could continue to receive essential healthcare services. I will explore perspectives on acts of harm in greater depth in the discussion.

4.3.3 c) Evidence of conflict between the two perceived moral obligations.

These perceived moral obligations, to sustain medical product supply but also to fulfil QA procedures, were incompatible with one another in a 'no stock, high stakes' situation. Therefore, unsurprisingly, evidence of struggle and conflict was found in the dataset. Sometimes this conflict was internal to a single person, as witnessed with the Operations Executive, Elliot (IDI-668, iNGO, Head Office, operations), who wrestled with the incredible stakes and uncertainty of the problem. Sometimes, the conflict was inter-disciplinary (such as between the health and supply chain professionals), or international (such as the complaints of Country Office staff to the Head Office decision-maker). In Chapter 7, I will explore how role and location could impact a participant's proximity to the patient, and their perspectives on prioritisation during decision-making, in greater depth.

While the disagreements described in interviews appeared quite civil, sometimes conflict was emotionally charged. For example, one participant felt "*sad*" ("Lynn": FGD-385, iNGO, Head Office, health) about 'no stock, high stakes' decisions that they believed were wrong and another found it "*easy to get angry*" ("Pete": IDI-499, iNGO, roving, logistics). Some participants described being the target of strong emotions. For example, a pharmacist who had spearheaded the creation of medical product QA policies at several organisations, and which had resulted in operational "*constraints*", told me that, "*{laughs} I have never been a very popular colleague. {laughs} Usually people hate me. {laughs}*" ("Martin": IDI-231, iNGO, Head Office, pharmacy).

On analysis, it was noted that distress and rancour were more likely if the participant lacked decision-making power *and* if they perceived that the conflicting opinion arose from ulterior factors that they deemed to be unethical. For example, this was evident in my discussion with Noah (IDI-586, iNGO, Head Office, pharmacy). As a Head Office pharmacist, he had developed and implemented QA policies at his iNGO, but these had increased the time, expense, and complexity of project implementation. He told me of "*that constant friction between someone who's responsible for ensuring that [the QA] standard is upheld, and, um, and this, like, really important imperative of the organisation to be*

viable". He shared that recommendations to abstain from sourcing medical products due to the risk of poor-quality would be met with questions from decision-makers like, "*What is quality? Oh, how many people are actually dying from using these products?*" Clearly agitated by this memory, I asked him:

> *KE: Do you feel like you were forced to, um, implement decisions that you felt were (.) 'wrong'?*
> *Noah: {long pause, stretches word} Yes.*
> *KE: Yeah?*
> *Noah: Yeah. Definitely. Definitely. […] Like, this (.) is (.) wrong. […] We're going to try and mitigate your wrong decision by putting in all these other things in place, which we know people aren't going to adhere to anyway. There was a lot of stuff that seemed really wrong, for sure.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

This exchange offered a valuable insight into the moral world, and workplace conflict, of individuals concerned with medical product quality in humanitarian health projects. Like all participants, Noah demonstrated that he was willing to source medical products of uncertain quality in a 'no stock, high stakes' problem, *if* he felt that the risk of doing so was justified by the "*clinical risk*" presented by the stock-out. Therefore, he did not disagree with the concept of compromising medical product QA and told me that "*ninety-nine percent*" of these situations "*are grey*", with no definitive 'right' answer. Yet, he was emphatic that "*a lot of stuff […] seemed really wrong*" and was distressed to the extent that he "*fell out with the organisation*" and, ultimately, resigned.

To understand this incongruence, let us consider Noah's characterisation of his iNGO's decision-makers. He depicts them as boorish and supercilious, undermining the significance of his concerns with the question of "*what is quality?*" The purported enquiry, "*how many people are actually dying?*", framed them as spectacularly unfeeling to the potential suffering of patients, whom they conceptualised as numbers – and were willing to experience loss for the sake of project 'viability'. He seemed to view them as apathetic to patient harm with the revelation that mitigations were employed despite knowing "*people aren't going to adhere to*" them. This suggested deception: performative conscientiousness with self-serving motives. In summary, Noah paints a picture of a repugnant decision-maker whose actions were not commensurate with the moral value that one ought not to harm patients. Perhaps his depiction was accurate. Or, perhaps, the decision-maker was

doing their best to ensure medical product availability in a very challenging situation. Either way, Noah's distress did not arise from the decision, per se; it arose from his perception that it was driven by factors that were not ethical, or patient focussed.

The converse was also evident. One participant reflected on how the decision to abstain from sourcing medical products might feel from a patient perspective:

> *I'm sitting in the clinic and the doctor's like, "Meh! Your child's got neonatal sepsis, but I've got no antibiotics for them. You can try and take them to the hospital; it's four hours in a […] minibus thing, but that's up to you.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye was a 'roving' pharmacist with extensive experience of working in humanitarian health project sites. She used a fictitious interaction between a doctor and their patient to powerfully convey the real discomfort that she felt with decisions that undermined medical product availability for life-threatening illnesses.

Shortly after this statement, Skye shared her view that Country Office staff should handle decisions because "*when you deal with the [Head] office, they don't think about the patient. The focus is on the quality piece and ensuring the drug is of quality, not what is going to be the end outcome for this particular patient*". Therefore, the doctor in this quote is allegorical. They were not a patient-facing clinician; rather, the quoted "*doctor*" represented the Head Office decision-maker, whose "*focus*" is on medical product quality. Skye evaporated the vast distance between decision-maker and patient to imagine the humanity of the confrontation. By depicting a healthcare professional who was callous to the fate of a seriously ill child and indifferent to the fears of their caregiver, we learn that she did not perceive this choice to be an ethical one.

4.4 Conclusion

In this chapter, I have presented my analysis of the 'no stock, high stakes' problem; a term that I coined to describe a situation in which an iNGO procurer is unable to guarantee the quality *and* availability of medical products for a humanitarian health project and must choose between them. Compromising availability was perceived to undermine access to therapeutic care and present the risk of unmitigated ill-health. Compromising QA processes was perceived to increase the risk of administering potentially harmful or ineffective medical products. Ethical tension exists because both options carry the potential for patient harm; the decision-maker is compelled to source medical products of uncertain quality *and* to refrain from doing so. I uncovered that this situation was deeply morally problematic for participants – not only due to their normative uncertainty, but also because of the constraints placed on them by policy, authority, and access to resources.

Through close examination, I revealed that participants who reached different conclusions to 'no stock, high stakes' problems may still be driven by the same moral value: "I ought not harm patients". This principle could not necessarily be fulfilled, because either of the available choices held the potential for harm. Thus, in response, some participants were observed to differentiate the options according to whether they perceived that they would be actively causing harm, or whether it would occur (more) passively. There were differing interpretations of active harm, as I will detail in the discussion, with some viewing it as the act of withdrawing care and others perceiving it to be the act of administering poor-quality medical products. This led to participants with different perceived moral obligations (of replenishing medical products from an unproven vendor or complying with QA requirements, respectively), and thus different responses to the 'no stock, high stakes' problem.

Moral distress and conflict were reported by numerous participants. Sometimes interviewees characterised the decision-making of others as morally wrong, especially if they perceived that it was motivated by factors that were extraneous to patient care, such as reputational or financial concerns. As I will explain in the next chapter, these concerns were closely tied to the iNGO's commitments

to their donor and, specifically, how the donor restricted and controlled the sourcing of medical products. Understanding this backdrop to the decision-making context, and the impact that it was observed to have on the norms and culture of ‘no stock, high stakes’ problems, is essential to understanding the real-world pressures of those who experienced it.

5

"If it's our funding, then it's our policies": participant perspectives on the quality assurance of medical products for the humanitarian health projects of grant-reliant international Non-Governmental Organisations.

5.1 Introduction.

In the last chapter, I described a situation that I have termed a 'no stock, high stakes' problem, in which an international Non-Governmental Organisation (iNGO) procurer can secure *either* the quality *or* the availability of medical products for a humanitarian health project, but not both. I provided an analysis of participant perspectives on the ways in which the problem might manifest, mapped its features and the complexity of the moral landscape that iNGO decision-makers must navigate. I also introduced the ways that those who experience the problem have differing perspectives about what should be done. In seeking to understand these perspectives three key themes emerged via my analysis of the data: policy, procurement, and proximity. In later chapters, I will attend to how participants made sense of their choice, highlighting patterns and differences in how they estimated, perceived, and tolerated risks to patient harm, by examining their perceptions of (mis)trust (chapter 6) and their proximity (chapter 7). However, an understanding of the policy context is required to appreciate how participants understood and prioritised risks, because this shaped the cultural norms and defined the constraints of the system in which decision-makers operated. Thus, in this chapter, I will focus on policies and examine perceptions regarding quality requirements for the procurement of medical products for humanitarian health projects.

Before proceeding, I will define and instantiate terms relevant to this chapter. As explained in Chapter 2, Quality Assurance (QA) is a method for assessing the safety and efficacy of a medical product by verifying that its manufacture and subsequent handling has complied with minimum practice standards.[6] However, this is distinct from the phrase 'quality assured', which was generally used by participants to describe a medical product whose source was compliant with their organisation's QA policy. These policies largely mimicked those of donors who were significant to the iNGO, as I will illustrate in section 5.3. Participants tended to use the term 'donor' to indicate an organisation (or a consortium of organisations) that grant an iNGO monetary funds to execute an agreed project.[21]

As presented in Chapter 2, donor QA requirements tended only to permit iNGOs to spend funds on medical products that have been evaluated by an 'authority' that was approved and deemed competent by the donor. For medicines, this system largely relied on the 'competent approval' of National Drug Regulatory Authorities (NDRAs) that had been designated as Stringent Regulatory Authorities (SRAs)[22]. (An NDRA is essentially a governmental department that is mandated to control and regulate the quality of medical products that are manufactured in, or imported into, a country. Some NDRAs are SRAs; these are a shortlist of NDRAs that have been deemed capable to fulfil this task. Chapter 2 refers). Policy analysis indicated the unlikelihood of a Host Government having a donor approved NDRA, which had ramifications for 'no stock, high stakes' decision-making. (The term 'Host Government' will be used to refer to the body that governs the State in which the iNGO's health project is situated). I was unable to discern a specific term for an NDRA that was not an SRA from my data (which was a sign of the othering of these institutions, as I will explore later). Therefore, I will refer to the NDRA of the Host Government as the 'HG-NDRA'.

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[21] It should be noted that donors to whom participants referred usually had QA requirements that restricted the sourcing of medical products due to my study's sample and focus, as described in section 3.5. This is not necessarily the case in real-world settings. I consider the implications of this (and other limitations of the study) in section 8.5.

[22] Arguably, the acronym "SRA" is viewed as outdated in Global Health – in Chapter 2 I explained that it is being superseded with a new 'system'. However, SRAs were found to be an organising concept, widely and currently used by interviewees and donor policies. My use of "SRA" in this thesis reflects its use by participants.

I will structure the chapter around the three important sub-themes that emerged during analysis. In the first part, I will present perspectives regarding an HG-NDRA's ability to reliably quality assure medical products. In the second part, I will provide an analysis of why and how donor QA requirements controlled medical product quality for humanitarian health projects, from a participant perspective. In the final part, I will explore responsibility for the QA of medical products for the humanitarian health projects from HG-NDRA, donor, and iNGO participant perspectives.

5.2 Concern for the quality of medical products from countries that do not have recognised Stringent Regulatory Authorities.

5.2.1 The historical emergence of medical product quality as a matter of concern for sourcing medical products for humanitarian health projects by grant-reliant iNGOs.

Two of the participants in this study were European pharmacists with specialist interests in medical product QA, whose long careers had facilitated the formation and dissemination of medical product QA requirements for iNGO procurers across numerous Northern Hemisphere organisations. They were Martin[23] (IDI-231, iNGO, Head Office, pharmacy) and Yolande (IDI-133, iNGO, Head Office, pharmacy). Their words will be used to illustrate the findings of my analysis regarding the emergence of medical product quality as a matter of concern for humanitarian health actors, and the corresponding evolution of donor QA policies in response to this.

Martin was an exceptionally experienced QA pharmacist, who had worked and consulted for many iNGOs, UN agencies, and donors. He estimated that "*until the mid-90s, {nods} there, there, there were no real concern for quality*". He believed that because "*pharmacists were totally absent*" from many

[23] Names have been changed. Appendix E refers.

Global Health organisations[24], there was a "*kind of a naivety*" in which medical product "*quality was assured, er, somewhere, somehow, by somebody. You know? And it was not their role to, to control that, er, quality of, of the [medical] products*". This was echoed by Yolande, a similarly qualified QA pharmacist, who stated that, "*the quality, er, was not, {unfurls hand} was not an issue, er, ten years ago. […] Medicines were assumed to be of good quality.*" Martin viewed the HIV/AIDS[25] crisis as the watershed of the emergence of concern for medical product quality amongst Global Health actors:

> *I think [medical product QA] is, um, {short sigh} probably related to, to access to HIV / AIDS treatment. […] There was an issue on access [to medical products…] and the solutions were, (.) {shakes head} obviously, with generic manufacturers [who were]* not *assessed by, you know, the, the, the regulatory authorities that we usually refer to, like US FDA or the EMA.*
>
> **"Martin": IDI-231, iNGO, Head Office, pharmacy.**

Martin pinpointed the HIV/AIDS crisis as a moment of collective awareness amongst iNGO pharmacists regarding the risk of substandard or falsified medical products. He explained how the highly publicised public health crisis, in which access to HIV/AIDS medical products was a key concern, generated an outpouring of financial aid, an increased demand for pharmacotherapy, and, consequently, a proliferation of novel generic manufacturers. The NDRAs of America (the US FDA) or Europe (the EMA), which Martin and his colleagues trusted, had not approved these manufacturers. They did not trust the HG-NDRA to assure medical product safety and efficacy (for reasons I will detail later). Therefore, they faced the challenge of navigating pharmaceutical markets that they viewed as "*unregulated*", with the knowledge that any wrong decision may receive explosive, international media attention. In response, a small group working with similar Europe-based organisations, "*started developing procedures and, and tools to, to try to mitigate the risks*". They also began actively campaigning for other Global Health actors to adopt similar approaches to medical product QA.

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[24] Few iNGOs or donors employed pharmacists at their Head Office location in the early nineties. It is likely that the role and number of pharmacists in humanitarian aid has also been influenced by a shift in QA policies, but this is beyond the scope of this study.

[25] Human immunodeficiency virus / acquired immunodeficiency syndrome.

Yolande, who was heavily involved with such campaigns for decades, said that this task "*was not easy*":

> *They say, {gestures 'flipping a table'} "No! […] I'm fed up with, er, with your speech about quality! Let, er, let, er, me doing my job!"*
>
> **"Yolande": IDI-133, iNGO, Head Office, pharmacy**

International NGOs were initially unwilling to establish medical product QA procedures, because the increased costs and bureaucracy were barriers to the implementation of their health projects.

Yolande and other QA pharmacists adapted their messages and refined their target audience to improve engagement. She reported that focussing on the risk of patient harm was a more successful approach to organisational change: "*first, [was] for us to convince that there […] were risks and, um, then to convince that we cannot continue and, er, in this direction*". Then, she attempted to raise support for medical product QA by spotlighting the potentially dire consequences of sourcing substandard or falsified medical products, arguing that "*if it's not good medicines, it's better not to give them*". Fear of these risks was evident in the dataset. Many participants used intense language when considering the "*minefield*" ("Ikolo": IDI-359, iNGO, roving, health) in which "*you're potentially killing people*" ("Guy": IDI-775, iNGO, roving, operations) by sourcing medical products of uncertain quality. As a result, "*everybody's terrified*" ("Pete": IDI-499, iNGO, roving, operations): they're "*scared to do harm*" ("Skye": IDI-101, iNGO, roving, pharmacy) because "*the harm that that would do (.) is just sort of (.) incredible*" ("Taylor": FGD-121, iNGO, Head Office, logistics).

In terms of the target audience, donors became the focus of Martin's campaigns for adopting QA procedures. This was because grant-reliant iNGOs "*had to comply (.) with the QA policy*" of the donor, "*because otherwise they would not get the money*". This leverage was used to influence the rapid and widespread adoption of QA policies amongst iNGO recipients. For example, following the creation of Global Fund's QA policy "*suddenly QA was, you know, a key issue in the procurement of, um, health products in, in humanitarian, er, programmes*" for grant-reliant iNGOs, who needed to adopt replica QA policies to remain eligible for funding. Having considered the historic emergence of medical

product quality as a concern in HG-NDRA countries, in the remainder of the chapter I will present current perspectives.

5.2.2 Participant perspectives on the National Drug Regulatory Authorities of Host Governments.

Jan (IDI-886, donor, health) was a European medical doctor who had extensive experience of working in humanitarian health settings (including complex emergencies in Fragile States[26] and areas affected by conflict), with various Northern hemisphere iNGOs and donors. At the time of our interview, he held a senior role, overseeing a large portfolio of humanitarian health grants that had been awarded by his employer, a large, bilateral donor. His statements captured the typical positionality that was observed amongst donor participants and that was echoed by many participants based at an iNGO Head Office. However, I found Jan's style untypical because he was so unabashed in stating the norms and biases that were subtle or concealed by other participants. For this reason, I will use Jan's words to illustrate my analysis of these findings.

When I posed the warehouse fire scenario[27] to Jan during an In-Depth Interview (IDI), I noted that his response was entirely focussed on the actions of foreign, multinational, humanitarian aid agencies; he did not comment on the interests or capabilities of national actors. I wanted to explore the reasons for this without direct confrontation, so I said:

> *The iNGO comes to you and says, […] "We need to buy (.) on the 'local' market. We've spoken to the National Drug Regulatory Authority, they're all approved vendors, all of the medicines are registered nationally." What would be your response to that?*
>
> **Question posed to "Jan": IDI-886, donor, health.**

[26] Fragile States fail to fully meet the needs of their citizens due to gaps in their security, legitimacy, or capacity, for example. For further information, see https://fragilestatesindex.org/

[27] A scenario in which a warehouse that stores an iNGO's medical supplies has burnt down, causing massive stock-outs. Summarised in Chapter 3 and detailed in appendix C.

My question emphasized the legitimacy of the medical products that had been identified by the iNGO (by stating that they were registered[28]), and the legitimacy of the vendors that stocked them (by sharing that they were approved by the HG-NDRA), to explore how Jan valued these endorsements. I indicated that these sources were acceptable to both the iNGO and the HG-NDRA, to uncover how he would support or resist this motion, as it would require flexibility in his application of donor quality requirements. He responded with:

> *Oh, well it's very clear, because we are confronted with that all the time and that's what we have in our policy. Uh, {shrugs} sorry. But, if you're gonna procure locally, I don't care what the National Drug Regulatory Authority says. […] {shrugs} Huh, yeah? {laughs} This drug regulatory authority, they don't, they're not {laughs} to be the same. They're not the most serious ones. Huh? Er. So, I don't care. […] How you gonna ensure the quality of those drugs? […] Good luck, huh? Because how are you gonna identify the people who gonna be able to come and check the documents, the type of drugs that they are procuring? […] You're not gonna be able to keep the same level of operations.*
>
> **"Jan": IDI-886, donor, health**

Jan explained that his donor organisation did not accept QA approvals of the HG-NDRAs due to concerns regarding capacity; they would require independent verification by a third-party that were acceptable to the donor. However, as I will explain in Chapter 6, this was perceived to be unfeasible for 'no stock, high stakes' problems, so Jan glibly offered the iNGO "*good luck*" with this endeavour. Indeed, he felt that the only solution would be for the iNGO to reduce their "*level of operations*". His proposal (and the attitude with which it was delivered) used his own organisation's QA requirements to define the decision-maker's terms of engagement, as well as distancing him from responsibility for resolving the issue (which fell outside such terms). I will explore perspectives on responsibility in section 5.4.

An interpretation of Jan's underlying beliefs is just as revealing as an analysis of the content of his speech. He repeated that "*I don't care what the National Drug Regulatory Authority says*". He laughed

[28] Broadly, a registered medical product is one that has been authorised by the NDRA for sale within the country or region of their jurisdiction. See glossary.

with incredulity that an HG-NDRA verdict, which he perceived as "*not the most serious*", could be relied upon – even though the country in which the scenario took place (and therefore the identity of the HG-NDRA) was not defined. I observed that this attitude was pervasive amongst interviewees who were not involved with patient care and who were policy-focussed (such as donors and many iNGO Head Office staff). However, I noted nuance regarding *why* they disregarded HG-NDRAs.

Some participants overlooked HG-NDRA knowledge due to concerns for regulatory effectiveness.

> *Look at, er, Togo and Denmark. It's the same [size] population. In Denmark, the Danish Medicine Authority is more than 400 persons, (.) working only on QA. In Togo, there are nine. Nine person! What can you do, you know? The challenges are even bigger in Togo because it's open borders. Medicines are coming from everywhere, and, and… Yeah. It's, it's impossible.*
>
> **"Martin": IDI-231, iNGO, Head Office, pharmacy**

Martin, who had described the emergence of medical product quality concerns in the wake of the HIV/AIDS crisis, felt that NDRAs differed because of capacity. To illustrate his example, he selected a high- and low- income country (which he claimed had a similar size population[29]); however, as I will highlight in the discussion, the differential was extreme and, perhaps, an unfairly skewed representation of HG-NDRAs. The disparity, a ninety-eight-percentile difference in human resources, was exacerbated by Togo being landlocked and surrounded by other poorly regulated countries. Martin explained that if he sourced medical products on the Danish market, where all items were assumed to meet with minimum QA standards, he may decide what to buy according to price; however, on the Togolese market, he would feel obligated to conduct an independent QA assessment to choose "*the least worst*" vendor.

Martin felt that standards for medical product QA were "*almost universal*" between NDRAs (i.e. SRAs and what I have termed HG-NDRAs), but "*at the same time, […] they are complex to implement, they*

[29] It appears that the population of these two countries was similar around 2003; however, Togo has experienced a more rapid increase in its population since then (see https://database.earth/population/togo). The staffing numbers of NDRAs is not open-source data. Despite these factors, the point that the participant is trying to make via this comparison is clear.

are complex to verify, and, and, it has an impact on the prices." Therefore, "*in countries like Brazil, India, China, Ukraine[30], (.) the regulators would tell you, "Okay. I know what I need to ask to assess and to prove the efficacy and safety of a, of a product, but it's too costly, so I would not require it."*" These four middle-income countries highlighted the tension between national priorities (such as economic growth or a war effort) and investing in regulation. This framed NDRA staff as 'doing their best' with the resources that they had; a perspective that, perhaps, came from his familiarity and proximity with an array of global NDRA auditors and regulators. I noticed that most QA pharmacists who participated in this study agreed with this view; that NDRA capacity was a sliding scale. However, interviewees without these experiences tended to assume that inferior moral standards, competence, or education were to blame, as I will explain next.

The pervasiveness of corruption was a common perception amongst participants who were geographically remote from the project site. For example, a logistician from a wholesaler based in Europe claimed that vendors in non-SRA countries were "*little criminals*" ("Viktor": IDI-626, vendor, Head Office, logistics), and argued that this was why his organisation did not "*by default accept the local NDRA approval, (.) because it has shown to be either corrupt, {stretches word} or (.) um, allows for (.) a bit lower standards than we would allow*". A pharmacist focussing on QA policy at an iNGO Head Office also viewed the supply chain as a target for corruption. With a cautious use of terminology, she told me: "*The risk you have when you are in country, er, (.) more corru- {pauses, smiles} less transparent than other, er, is […] because [the registered medical product] has been smuggle in the country*" ("Genevieve": joint IDI-881, iNGO, Head Office, pharmacy). The problem that they are highlighting is that if bribery were used to circumvent importation regulations, it would be impossible to differentiate between legitimate, registered medical products and illegitimate, smuggled ones.

Participants from the Focus Group Discussion (FGD) with iNGO Head Office interviewees perceived that "*corruption is another big part of [importation challenges] in some of these countries*"

[30] This interview took place shortly after the outbreak of the Russia-Ukraine war.

("Derek": FGD-969, iNGO, Head Office, logistics). For example, Derek claimed: "*I have met politicians in Africa who have made those choices*", to take "*political […] backhanders*" in return for the approvals necessary to sell or import medical products. Parodying these "*politicians*", he stated: *"my morals say, "Somebody died – that's okay. If lots of people die – it is back in my head'"*". This opinion, that some "*Africa[n]*" politicians had a threshold of lives that they were willing to trade in return for political gain was met with either agreement or non-complaint by the other FGD members, who either nodded or were silent.

The same FGD group discussed an importation challenge in Yemen that had resulted in a 'no stock, high stakes' problem. While some viewed this issue as an indication of corruption, one participant thought "*it's about power and control*":

> *It's just about controlling us and telling us what to do! {laughs while other participants nod} Instead of, you know, us being able to do whatever we want to do. We're, we're outsiders. I mean the big NGOs were, w-, were, you know, American, Scandinavian organisations that aren't Yemeni (aren't Middle Eastern even) and so, there's, I think there's a need or a desire to influence and control us, in ways that are possible. {laughs}*
>
> **"Taylor": FGD-121, iNGO, Head Office, logistics.**

Taylor, a logistician based in the Head Office of a grant-reliant iNGO, routinely navigated the importation requirements of different countries; she was responsible for sourcing medical products from Europe and coordinating their distribution to humanitarian project sites. She viewed Yemen's importation regulations as a desire to "*influence and control*" iNGOs *specifically*, rather than a desire to control their borders *generally*. She framed importation restrictions as an overt and targeted flex of Host Government power, situating it within a broader struggle by highlighting that Yemen is "*Middle Eastern*" and the iNGO was an "*outsider*".

In contrast, national staff tended to feel that "*we really need to work with the, er, with the [Host] Government*" ("Arjun": IDI-147, iNGO, Country Office, logistics), despite difficulties with them. For example, one clinician told me of his experiences with a "*health zone*" manager who had found expired medical products in the pharmacy and had accused his team of "*giving poison to the population*" ("Ikolo": IDI-359,

iNGO, roving, health). He explained that the MoH relationship was tense and capricious because they "*think that you are plenty millionaires*". He described how his iNGO "*had to defend, so, {waves arms upwards} at different layers*" of the Host Government. As he did so, unlike participants from geographically remote roles, he appeared to differentiate between the State (because "*you (.) tell yourself that the government will not give something that will be killing its own population*") and one of its employees. I also noted that none of the participants who were national staff used the term "*corruption*" in relation to a Host Government.

National staff also tended to describe national vendors with far greater granularity and perceived them differently than those who were geographically remote. For example, when exploring 'no stock, high stakes' problems from their perspective, national pharmacists and logisticians would often detail the pharmaceutical manufacturers in their country: their number, their products, their certifications, who their customers were, which ones they would trust, and those they would not. Although all participants acknowledged the risk of substandard and falsified medical products, national staff treated the problem as a navigable reality; in contrast, non-pharmacist Head Office staff often depicted the problem as an absolute inevitability. This difference was particularly apparent between two participants that oversaw the procurement of medical products in their respective organisations. Farid (IDI-267, iNGO, Country Office, logistics), a member of national staff, described his strategy of "*having a cup of tea*" with selected vendors "*once in a year*" to negotiate prices and build relationships. This was suggestive of an entirely different worldview to Viktor (IDI-626, vendor, Head Office, logistics), the Head Office logistician who had informed me that national vendors were "*little criminals*".

5.3 Donor quality requirements as a method of controlling the sourcing of medical products for humanitarian health projects of grant-reliant iNGOs.

5.3.1 Perspectives on the purpose of donor medical product quality requirements.

As previously explained, concern for medical product quality led to several organisations adopting stipulations for their QA (which is a method for confirming the safety and efficacy of a medical product by verifying that its manufacture and subsequent handling has complied with minimum practice standards). In this section I will focus on the QA requirements of donors, which had a substantial impact on the resolution of 'no stock, high stakes' problems and complicated the decision-making context by challenging HG-NDRA authority. Their explicit purpose was captured in comments like, "*[they are to] meet safety and quality standards, which hopefully translates into, you know, quality products that are utilised in the [iNGO] programming*" ("Liam": IDI-764, donor, pharmacy). However, although patient safety was the overt reason for donor QA policies, many participants from donor organisations would allude to ulterior motives when probed. It was noted that these would differ depending on whether the interviewee was referring to themselves or the organisation; therefore, in what follows I will do the same.

For participants working at donor organisations, QA restrictions were not merely passive boundaries; they were tools of instruction, with which they could attempt to effect global change.

> *I think one of the things that we always hoped that, you know, {smiles} I can't say whether it's happening or not, is that if several organisations or groups or, you know, governments, or what have you, sort of banded together around this issue of quality products; if we all are enforcing the same thing, at some point, does the system (.) have to level itself up, in order, you know, to, to make that happen? […] If we continue to push the global (.) community to have these standards – and to enforce them – then I think our hope is that, at some point, it will get better.*
>
> **"Liam": IDI-764, donor, pharmacy**

Liam (IDI-764, donor, pharmacy) was a pharmacist with a donor organisation who "*ensures that the, the pharmaceuticals that are procured, are in-line with [our] policy*" and, therefore, had in-depth technical knowledge of medical product sourcing restrictions and how these applied to 'no stock, high stakes' problems. As he told me about the impact of his role, he seemed hopeful and proud of his mission (enforcing policy) and idealistic about the impact that it could have (safer medical products on a global scale). However, he also conveyed struggling against some form of resistance when he described the effort of "*banding together*", of "*pushing*", and of "*enforcing*". A policy-writer from a different donor organisation shared these views, stating that he "*always felt good that we were one of the very few donors that were imposing obligations on our partners*" ("Nikolas": IDI-458, donor, policy). These sentiments framed such 'enforcers' as guardians of a universal standard, perhaps even the protectors of an ideal, in the "*hope*" of global and systemic change.

However, the same participants depicted *institutional* motives for medical product QA with far less magnanimous language than their *personal* agendas. For example:

> *It's one of those stories that I, I've never researched, to actually go to the root of, to find, but I've always heard and believed it's true; is that, the reason that [my organisation] has such strict policies about pharmaceuticals is because, um, you know, I think, (.) sort of, whatever I've heard is that, I think, I think in the seventies, there were some funded pharmaceuticals that were either of low quality, or falsified, or something that, that caused harm and, in fact, death.*
>
> **"Liam": IDI-764, donor, pharmacy**

This report echoed the analysis presented earlier in this chapter of how medical product quality emerged as a concern around the time of the HIV/AIDS crisis. However, while this interviewee's personal motivation was to *achieve* something (better quality medical products across the world), he perceived that his organisation's agenda was to *avoid* something ("*harm and, in fact, death*" due to substandard and falsified medical products). His tale appeared difficult to share. His exaggerated disfluency of speech ("*um, you know, I think, (.) sort of, whatever I've heard is*") was, perhaps, a prevarication from the story's uncomfortable conclusion and a desire not to advertise the error. This is suggestive of a culture that is intolerant of harm caused by poor-quality medical products but, compared with previous dialogue about enforcing policy, one that is relatively accepting of potential

harm caused by the non-availability of medical products. I will explore this observation further in the Discussion chapter.

Concern for the patient was not the sole purpose of donor QA requirements; to some extent, they were also driven by a concern for reputation, litigation, and status. The policy-writer who had "*felt good*" about "*imposing obligations*" told me of the "*scandal*" and "*reputational issue*" that would arise from quality "*problems with medicines [that were] paid with our money*" ("Nikolas": IDI-458, donor, policy). He did not refer to the health impact of *not* sourcing medical products of uncertain quality during our interview. Another saw QA requirements as "*a guarantee*" that, if compromised, "*has a lot of influence, and can impact a lot on your notoriété. […] Reputation*" ("Olga": IDI-671, donor, pharmacy). This finding was not limited to donor participants. Interviewees from iNGOs also tended to view "*inappropriate medical products*" as "*a bigger [journalistic] story, for sure*", and therefore a greater threat to the iNGO's reputation, "*'cause if there are no medical products there is nothing to report on. {laughs}*" ("Hugh": IDI-269, iNGO, roving, operations). Generally, only participants in patient-oriented roles raised medical product stock-outs (rather than quality concerns) as "*an unacceptable level of risk - not just to beneficiaries, but also to the organisational reputation*" ("Pete": IDI-499, iNGO, roving, operations).

5.3.2 Perspectives on the enforcement of donor medical product quality requirements during 'no stock, high stakes' problems.

I was curious about how donors enforced QA requirements amongst their grantees, and any flexibilities that they offered during 'no stock, high stakes' problems. The simple answer was:

> *If it's our funding, then it is our policies.*
>
> **"Liam": IDI-764, donor, pharmacy.**

All donor participants were unequivocally firm and inflexible in asserting that iNGOs must adhere to donor's rules and standards whilst in pursuance of grant-funded health projects. Recipients "*will have to follow the QA policy of the donor*" ("Olga": IDI-671, donor, pharmacy); "*it's very clearly written in our, in our*

guidance that […] the regulatory agency, it has to be a level 'whatever'" ("Nikolas": IDI-458, donor, policy), because we "*don't care what the [HG-NDRA] says*" ("Jan": IDI-886, donor, health). Ultimately:

> *If you don't fulfil the rules, you do not comply with the rules, then we get the money back.*
>
> **"Nikolas": IDI-458, donor, policy.**

Participants explained how funds that had not been spent in compliance with donor sourcing requirements may be identified via financial audit and reclaimed. Several interviewees referred to this as a 'disallowance', therefore I will do the same. Participants from iNGOs confirmed this practice; sharing, for example, that donors "*would say, "Okay, you made a mistake. You procure products that are not complying with the QA policy. Please, give back the money*" ("Martin": IDI-231, iNGO, Head Office, pharmacy).

Participants from iNGOs felt that the possibility of disallowances were "*concerning*" for iNGOs because they "*would have to give back the money afterwards*" ("Martin": IDI-231, iNGO, Head Office, pharmacy). This meant the use of precious *unrestricted* funds (usually reserved for 'keeping the lights on' and contingencies[473]) to finance the reparation. One iNGO participant offered a personal example to explain the impact that this could have:

> *[My organisation] had to pay back two, I think it was two hundred thousand [US] dollars. […] I think it, it was a kind of {raises hand above head in a claw shape} alarm for the management of [my organisation] that they, you know, they cannot make mistakes. They had to understand and to, to apply the QA policy of the [donor].*
>
> **"Martin": IDI-231, iNGO, Head Office, pharmacy**

This excerpt occurred within a broader discussion in which Martin, the QA pharmacist, described his difficulties in implementing a QA policy at his large iNGO. His arguments for patient safety were "*unpopular*" due to the constraints that they placed on procurement. However, this large disallowance shifted the priorities of his managers and heralded a significant change to the organisation's governance framework to one that replicated the QA requirements of the donor.

Disallowances were an even greater disincentive for small, grant-reliant iNGOs. During an informal conversation with an IDI participant (i.e. data gathered outside of the recorded interview), I was

asked for advice regarding a challenging US $600,000 procurement of medical products for a humanitarian health project. Like "*Mansoor's Year*" (see section 4.2.2), the iNGO's European suppliers were inaccessible due to extensive importation delays, but national vendors were not permitted because of quality concerns, as the HG-NDRA was not recognised by donor QA policy. Moreover, the timeframe was urgent: a clinical colleague had informed them that "*people will certainly die*" without the immediate implementation of the health project. They seemed conflicted: they were compelled to urgently source medical products of the best available quality on the national market but were unwilling to contravene the donor's quality requirements to do so. I learned of their grave concern that disallowances would threaten the stability of the entire organisation. They explained that "*we can't afford a disallowance*" because the iNGO lacked sufficient unrestricted funding to repay the donor. Moreover, their CEO was anxious that outstanding (disallowance) debt could result in other projects being terminated, or the iNGO being blacklisted from future grants, or the whole organisation going into administration. Therefore, a "*moratorium*" had been placed on "*waivers*" (permissions to waive QA requirements to enable national procurement.)

They were visibly upset as they contended with a "*hopeless*" situation, trapped between the Host Government's importation regulations and the donor's quality stipulations. During our call, they concluded that sourcing medical products (and delivering the health project) was "*not possible*" and, therefore, they would try to change the grant to an education project. This unwilling abandonment was an indication that they felt that they lacked decision-making autonomy: the choice between sourcing medical products of uncertain quality and the potential foreclosure of an international health charity was not, really, a choice at all. This power asymmetry, between donors and grant-reliant iNGOs, was highlighted by Ahmed (IDI-790, iNGO, Head Office, pharmacy), a pharmacist who worked in advocacy.

> *iNGOs, first and foremost, in order for us to operate, we need grant finance. Or we need grants, essentially. And so, donors; they play the music, and you, you know, (.) they decide what, what the, the pace at which you're dancing. So, that is controlled by donors, whether we like it or not.*
>
> **"Ahmed": IDI-790, iNGO, Head Office, pharmacy.**

Ahmed worked in advocacy; he was familiar with reading and navigating strategic relationships. His role relied on his perspicacity; his ability to pinpoint a donor's "*agenda*" and uncover mutually beneficial actions that could ameliorate global inequities in access to quality medical products. This quote was taken from a response to my observation, at the end of our interview, that donor medical product quality requirements appeared to heavily influence 'no stock, high stakes' decision-making. He took a bird's-eye view, which was typical of him, connecting QA requirements to inter-agency "*power dynamics*". His description of the relationship between grant-funded iNGOs and their donors was reminiscent of marionettes: the donor, hidden behind the curtain, controlling the iNGO, dancing upon the world stage.

He proceeded to speculate about the "*agenda*" of donors and their policies, which contrasted with the altruistic and reputational claims that they presented:

> *I think everyone has an agenda. […] You know, is [the donor agenda] rooted in purely, kind of, egalitarian purposes? Or is it rooted within their, kind of, national security? Is it rooted in, kind of, foreign policy? Some kind of historic, um, colonial, kind of, er, legacy? There's a rationale behind why a lot of these governments are operating within a country.*
>
> **"Ahmed": IDI-790, iNGO, Head Office, pharmacy.**

Ahmed inferred that "*national*" interests or "*colonial*" legacies, rather than "*egalitarian purposes*", offered a more compelling explanation for a donor's presence in humanitarian settings. I will reflect on this perspective in the Discussion chapter, and how donor requirements were reported to impact medical product availability in 'no stock, high stakes' problems. Next, I will explore perspectives on responsibility for medical product quality.

5.4 Perspectives and observations on responsibility for the Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs.

5.4.1 The Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs: the Host Government National Drug Regulatory Authority (HG-NDRA) perspective.

Having spoken with iNGO and donor staff, I was keen to explore an HG-NDRA auditor's experience of donor quality requirements. I spoke with Babiker (IDI-814, regulator, pharmacy), who had had an extensive career as the head of an NDRA in Northern Africa. I told him that I had noticed that the opinion of a 'donor-approved' QA auditor may conflict with the opinion of an HG-NDRA auditor. He gave the following, impassioned response:

> *Patients' health is the responsibility of the government, rather than the NGO themselves. Legally, ethically; […] this is a responsibility of the government. If the government decided to authorise {holds up phone as a prop} this product (.) for each patients, from this local company? In my opinion, it is not a right of the (.) donor to say, "No, this is not safe for your patients. We need to bring to you a safe, high-quality products", because it is the responsibility of the government. […] And I talk to them. I say, "I am responsible for the safety of our patients, for the health outcomes, because this is government, this is not you." {long pause, shakes head, looks down}*
>
> **"Babiker": IDI-814, former regulator and head of a North African NDRA, pharmacy.**

Babiker repeatedly asserted that, "*public health is the responsibility of the government*". By extension, he viewed assuring the safety and efficacy of medical products that circulate within a State's borders as the responsibility of the HG-NDRA. He emphasized that the HG-NDRA was "*legally*" and "*ethically*" "*responsible for the safety of our patients*". He claimed that the HG-NDRA had legal responsibility because, as well as being responsible for QA, it drafts government legislation to control and regulate medical products. His claims regarding ethical responsibility were less obvious, but perhaps reflected a government's duty of care for the health of its population. By clarifying that responsibility 'belonged' to the government and "*not you*", he signposted the competition that he had experienced in assuring the quality of medical products – and that it was unwelcome.

I asked this former head of an HG-NDRA how iNGOs would respond to claims that medical product QA was the responsibility of the Host Government. He told me:

> *They say, "We procure for number of countries. So, we cannot, you know, tailor our procurement just to fit with [your country]." […] Then they said, also, they have their own regulations to buy from certain suppliers. […] So, this is two main reasons they, they always brought to our discussion.*
>
> **"Babiker": IDI-814, former regulator and head of a North African NDRA, pharmacy.**

Babiker was informed that iNGOs adopted a global approach to medical product procurement, which did not accommodate national sourcing strategies, and that they were required to procure from specific suppliers. (This is a reference to a short-list of vendors that are pre-approved by donors, which I described in Chapter 2).

I asked him what would happen if he "*put his foot down*" and attempted to enforce his authority as a regulator:

> *The government at the higher level intervene […saying,] "This is donations. We have got, say, if you have good relations with this NGO, this will help us." […] The government, you know, the donors (.) like, er, fill a gap for them.*
>
> **"Babiker": IDI-814, former regulator and head of a North African NDRA, pharmacy.**

Babiker was instructed by senior government officials to waive regulations for iNGOs because their donations could "*fill a gap*" that the State could not.

On analysis, an imprint of Babiker's experience was observable in the transcripts of iNGO and donor participants. For example, the invisibility of the HG-NDRA was evident in comments that characterised "*national procurement*" as being "*without any quality assurance*" ("Taylor": FGD-121, iNGO, Head Office, logistics). The perceived inferiority of HG-NDRA activities was evident in the way in which iNGOs held an expectation that they should be allowed to circumvent importation requirements:

> *We really focus a lot, we put a lot of efforts in negotiating with the authorities [for exemption from importation restrictions]. […] We are very, er, respectful (or we try to be really respectful). […] We're working (.) really globally. We, we, can't really go and assess the market for each, for each place and to buy locally – that would require immense resources. And then we try to […] reassure*

> *them (.) that the quality standards that we're applying are really high […] international quality standards.*
>
> **"Ursula": joint IDI-460, iNGO, Head Office, pharmacy.**

Ursula (joint IDI-460, iNGO, Head Office, pharmacy) explained that the needs and resources of an iNGO (who "*can't really go and assess the market […] for each place*") were consistently afforded primacy; the impact on HG-NDRA systems and resources were overlooked. The approach that she described seemed patronizing and performative; it entailed "*carefully explaining*" the nature of the "*really high […] international quality standards*" to the HG-NDRA, rather than confirming acceptability to the Host Government or engaging with their wider concerns.

This justification for an exemption overlooked the HG-NDRA's claims for authority and control:

> *{large inhale} The real issue is […] medicines (.) on the market without authorisation. […] The issue is not the quality assured medicines they brought in. […Medicines without authorisation] will negatively, negatively impact on the regulatory systems, (.) because you cannot differentiate {gestures pointing at different 'boxes' of medicines on his desk} "This is from this NGOs. This is from this NGOs. This is from smugglers. This is from counterfeiters. From where this is?"*
>
> **"Babiker": IDI-814, former regulator and head of a North African NDRA, pharmacy.**

Babiker's resistance to iNGO's importing medical products was not on grounds of quality; it was because it undermined regulatory controls. He reported that iNGO medical products that lacked a "*market […] authorisation*" were indistinguishable from those that were a result of criminal activity. He also shared that it created a "*double standard*" that disadvantaged national vendors and complicated relationships with them. Ultimately, however, he was unable to refuse due to "*government at the higher level*". This powerlessness was leveraged by some iNGOs, as evidenced by this senior logistician:

> *We've had to get [the donor] in the room to say to the Ministry of Health, "They are not allowed to do this with our money." So, we've had to get that backing, in order to have that stick, to say, "You have to allow us to buy this." And I've been in that situation multiple times. So, we've, we've tried to use the carrot and the kind of rational (.) argument, and it sometimes doesn't happen, and we have to bring in the sticks.*
>
> **"Derek": FGD-969, iNGO, Head Office, logistics.**

Derek (FGD-969: iNGO, Head Office, logistics) was responsible for the development and enforcement of medical product QA policies. He explained that his iNGO leveraged the political power of its donor to coerce the HG-NDRA into ceding regulatory controls, and to obtain approval for the importation of medical products that otherwise would have been disallowed by the government. By using a 'carrot and stick' imagery to describe the interaction, he depicted the donor as dominant, the HG-NDRA as bestial, and the outcome as inevitable. I will reflect on these power dynamics in the Discussion chapter.

5.4.2 The Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs: the donor perspective.

None of the interviewees from donor organisations with whom I spoke disputed the claim that the HG-NDRA was legally responsible for medical product regulation. Indeed, both donor pharmacists reinforced this:

> *Ultimately the, the legal authority is the national regulatory authority, and they are, have their sovereign right to regulate the products that are circulating within their country.*
>
> **"Liam": IDI-764, donor, pharmacy.**

Although donor participants recognised the legal responsibilities of an HG-NDRA, they did *not* agree that the HG-NDRA should be ethically responsible for the quality of medical products procured by grant-reliant iNGOs.

> *It, it's a question of responsibility. […] The NGO […] are not responsible if there is anything that will happen [because of poor-quality medical products]. The responsible will be the regulatory authority because they are the one who took the responsibility to put the drug in the market. Then, as an NGO, er, not ethically, but legally, you are covered.*
>
> **"Olga": IDI-671, donor, pharmacy.**

This donor participant used anticipated blame for patient harm (due to substandard and falsified medical products) as a guide for who she believed had legal responsibility for medical product quality: the HG-NDRA, because they "*put the drug in the market*". However, it is interesting to note that in

the quote she makes an important distinction between legal responsibility and ethical responsibility. She, like most iNGO and donor participants, suggested that the iNGO held ethical responsibility for ensuring that the medical products procured and used in their health projects were of sound quality.

This perspective was echoed by another donor participant. I informed him that some interviewees from iNGOs viewed medical product QA as an HG-NDRA responsibility and, therefore, felt that it was acceptable to buy nationally when faced with a 'no stock, high stakes' problem. As I spoke, he made a shocked exclamation and physically swatted at the air, as if to banish my words. He then withdrew into his chair, with his eyes closed and his head in his hands. Before I could finish, he interrupted me:

> *No, no. No, no. {flushed cheeks} But, I've never heard of this! I mean, I mean how could you say this? […] It's very clearly written in our, in our guidance that, you know, (.) if [iNGOs] want to trust the regulatory agency, it has to be a level 'whatever'[31]. So, I mean [iNGOs] are very much aware. They work in this environment, so they know that there's so much corruption, and it would be crazy, (.) um, if they were trusting the, the er, the national authorities.*
>
> **"Nikolas": IDI-458, donor, policy.**

Note how this response spotlighted the risk of poor-quality medical products in a 'no stock, high stakes' problem but was insensitive to the risk of absent medical products (as documented in section 5.3). This was common amongst participants who lacked proximity to the patient. Nikolas' (IDI-458, donor, policy) emotive response suggested that my proposal conflicted with his ethics which, perhaps, would be: 'procurers should be responsible for the QA of medical products that they procure'.

Donor participants were observed to apply two different arguments for their authority to supersede the responsibilities of HG-NDRAs. One was financial: "*if it's our funding, then it is our policies*" ("Liam": IDI-764, donor, pharmacy). The other was ethical: that it would be unethical to rely on an HG-NDRA, if that body was perceived to lack the capacity or integrity to discharge their responsibilities. However,

[31] This refers to the World Health Organization (WHO) system of WHO listed authorities (WLAs), which grades NDRAs into four maturity levels. Chapters 2 and 6 refer.

these participants did not assume responsibility for QA activities themselves. They all claimed that their donor organisation was responsible for defining the standard, but none of them claimed responsibility for its execution.

> *When [iNGOs] come to me with this, with this request [to source medical products of uncertain quality] I say, "Listen, I'm here from [my High-Income Country]. Sorry, I've never been there. I don't know what the situation [is like], how it is. I just cannot, cannot give you the green light to buy from this local supplier, because I have no clue. Sorry. […] Listen, I don't want to know anything." So, in the end, it, we give the responsibility to the [iNGO] when they buy local. You understand?*
>
> **"Nikolas": IDI-458, donor, policy.**

Nikolas, like all donor participants, delineated a distinct boundary between responsibility for *setting* medical product quality standards, and for *enacting* medical product QA in 'no stock, high stakes' problems. Indeed, he attempted to distance himself from any personal responsibility for the decision or its outcome, stating that he didn't "*want to know anything*" about it. In fact, when facing a 'no stock, high stakes' impasse, donor participants shared that they would prefer to "*re-dimension*" the project's scope or objectives ("Jan": IDI-886, donor, health), or even to relinquish part of the project to another donor ("Liam": IDI-764, donor, pharmacy), rather than to relax their own quality requirements. This suggests that they also perceived that they were not responsible for medical product availability in 'no stock, high stakes' problems.

5.4.3 The Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs: the iNGO perspective.

5.4.3 a) Tensions emerging from two incompatible sets of restrictions for sourcing and moving medical products.

Host Governments control the importation of medical products to regulate quality and to protect certain economic interests (e.g. manufacturing). Methods for doing this include checking the quality and documentation of incoming consignments, only permitting a specific list of medical products to

be brought in and reviewing evidence for medical products that are not on this list. This may slow or even interrupt the flow of goods. The medical product quality requirements of donors meant that iNGOs relied upon the importation of medical products from vendors that had been approved by the donor or had been approved by an auditing body that was acceptable to the donor. Interviewees reported that these rules applied to any donated funds, irrespective of location. Many grant-reliant iNGOs centralised sourcing and applied these rules across the organisation. Challenges arose for iNGOs when their expectations for sourcing medical products *internationally* conflicted with an HG-NDRAs *national* regulations and priorities.

> *The [national] authorities won't let us import anaesthesia medications. We can't get them in. So, we can only buy them from the local market, and we have, er, a programme that's funded under [donor name redacted] (which of course has no rules about, er, where we can buy these items). And I think we are faced with now a real (.) dilemma, (.) because we can't meet our own internal policy to provide these items, but we're kind of… (.) There's not many other partners who can either. So, y-… {gestures juggling} How, how do we work?*
>
> **"Lynn": FGD-385, iNGO, Head Office, health.**

In this quotation, Lynn divulged a live 'no stock, high stakes' problem that was clearly distressing to her. Her iNGO and "*many other partners*" were unable to "*import anaesthesia medications*", but *national* sourcing would conflict with their "*own internal policy*", which was designed to meet the requirements of their strictest donor. Although the donor of *this* health project had no QA requirements, Lynn felt obligated to comply with the policy. However, this approach would undermine the availability of health services and therefore she was "*afraid of then losing our, you know, [legal] status with the MoH [Ministry of Health]. We're… We, we lose our programming, and not just for that donor, but perhaps much more broadly.*" In other words, the Host Government could rescind her iNGO's permission to operate as a legal entity in the country.

I suggested that Lynn's iNGO was caught between incompatible medical product quality requirements and importation regulations, but she did not view it this way:

> *How is this linked to corruption? […] There's obviously some reason why they're saying you can't import anaesthesia. There's no, like, there's no logical, technical reason why you wouldn't be able to*

> *do so. I think that that… I mean we import it in other countries. So, (.) why? And what do we do about it? […] I think it's a, it's a huge conversation. And the amount of power that the government wield in this is {long pause} quite a, {nods} quite substantial.*
>
> **"Lynn": FGD-385, iNGO, Head Office, health.**

Lynn blamed the HG-NDRA for her iNGO's inability to import anaesthetics. Moreover, she was disconcerted by "*the amount of power that the government wield*", a verb suggestive of offensive action and conflict. She did not view the restriction as reasonable, or even as legitimate, speculating that it was "*linked to corruption*". These suspicions chime with the findings presented in section 5.2.2, that many Head Office participants (i.e. those who lacked proximity with the country and its government) perceived the HG-NDRA as corrupt. They also indicate that the speaker viewed the iNGO as responsible for medical product quality and the HG-NDRA as a barrier, rather than an arbiter, of it.

5.4.3 b) Participant perspectives on whose knowledge was permitted for the Quality Assurance of medical products for the humanitarian health projects of grant-reliant iNGOs.

Skye (IDI-101, iNGO, roving, pharmacy) was a highly experienced humanitarian pharmacist, who had worked for numerous iNGOs, implementing many projects, in several countries, and who was very open during our two-hour interview. She was born and raised in a high-income country, was line managed by her iNGO's Head Office, but had spent most of her career working with Country Office staff in humanitarian contexts. "*I sit on both sides*", she stated, referencing these working arrangements and the schism between Head Office and national staff, that will be presented in more detail in Chapter 7. This experience of "*both sides*" seemed to give her a critical objectivity of QA policy that was unusual amongst participants. She attributed sourcing restrictions to a generalised mistrust of the HG-NDRA: "*we […] don't trust them*". Skye felt that:

> *We do have a double standard and a bias towards what we know. And I guess this is the whole Global North and South problem. We're biased and we think our way is the right way, and everything we have is better.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Echoing the words of Babiker (IDI-814, regulator, pharmacy), Skye highlighted a "*double standard*" in medical product QA, in which iNGOs "*don't trust locally produced certificates, […] whereas [European suppliers] basically never provide us paperwork, and we don't care! {laughs}*". Unlike most international staff, Skye viewed this as an aggrandizement of the "*Global North*" and a "*bias*" against the QA knowledge producers of the Global South.

I wanted to explore the potential that attitudes towards medical product QA for humanitarian health projects, in which "*Global North*" donors and "*Global South*" HG-NDRAs were in conflict, was influenced by "*bias*". This topic was sensitive; therefore, I wanted to confront the issue without confronting the interviewee. Therefore, I revised my topic guide, by presenting IDI participants with the following augmentation to the warehouse fire scenario[32] after they had finished sharing their thoughts.

> *I'm just going to augment our scenario then, a little bit, before we leave it and move on.*
>
> *Let's say the Country Office pharmacist has selected five different vendors that are in the country. (.) Um, QUAMED [a donor-approved auditor] has said that they can't support or recommend any of those five vendors. However, each of those five vendors have been approved and authorised by the National Drug Regulatory Authority and all of them offer registered medicines.*
>
> *{long pause}*
>
> *So, this is something I think about a lot, because there's a conflict here. QUAMED is saying, "No", whereas the NDRA is saying, "Yep, good to go."*
>
> *{long pause}*
>
> *Who would you say is right?*

Example IDI question, exploring attitudes towards who should determine medical product quality.

[32] A scenario in which a warehouse that stores an iNGO's medical supplies has burnt down, causing massive stock-outs. Summarised in Chapter 3 and detailed in Appendix C.

QUAMED is a charitable organisation aiming to improve access to quality medical products, to which many participants referred. One of their initiatives is to inspect "*local market*" vendors and to conduct (donor-recognised) QA audits on behalf of their paying iNGO members. I described a situation in which vendors that had been approved by the HG-NDRA were not recommended by QUAMED. I pointed out this "*difference of opinion*" and asked the interviewee, "*who would you say is right?*". By framing the question in this manner, I made explicit the conflicting opinions between national and international staff, and between the HG-NDRA and foreign auditors.

Many participants who were remote from the context, such as donors and iNGO policy makers, were discomforted by this question. For example, immediate reactions included:

> *{a few moments of silence and then an awkward high-pitched laugh} Um. {long pause, smacks lips}*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

> *{long pause, sways on seat, fidgets in chair throughout whole response} Yeah, no. That's, um, (.) that's a difficult question.*
>
> **"Olga": IDI-671, donor, pharmacy.**

> *{leans back, tenses arms, raises eyebrows, loud exhale} Oh! That's (.) difficult! {smiles, long pause, then laughs nervously} Um. {long pause}*
>
> **"Liam": IDI-764, donor, pharmacy.**

> *{long pause} That's a sensitive topic. {long pause, laughs, flushes, rubs throat}*
>
> **"Ursula": joint IDI-460, iNGO, Head Office, pharmacy.**

My interpretation of this awkwardness was that, by recognising that the HG-NDRA *had* an opinion (and that it conflicted with that of the donor approved auditor), I had framed QA procedures as a *choice* requiring justification, rather than an undisputed *truth* regarding expertise. This inability to form an immediate response, which was common amongst policy-focussed participants, suggested that their beliefs about responsibility for medical product QA were implicit: they knew *what* they thought, but not necessarily *why* they thought it. However, one participant was able to explicate why he trusted QUAMED's opinion over that of the HG-NDRA – as well as why my question had made him feel uncomfortable.

> *{looks away, raises eyebrows, clenches jaw} Yeah, I know. Um. And, you know, increasingly, in the last few years, we're, we're rightly uncomfortable with that kind of situation, where we're saying, "We know better." Um, er, I find it hard though, 'cause […] I don't think the, sort of, guilt of colonisation, and, you know, and decolonising aid […] should be mutually exclusive with being able to say, "We've learnt all of this over the last hundred, two hundred years, you know, of Western medicine. […] This is what we know, and this is what we can bring to the, to the table".*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

Although Elliot felt what he referred to as 'colonial guilt', he also sought to justify his perspective that "*we know better*" by arguing that QA policies recognised institutions that he felt benefitted from "*two hundred years, you know, of Western medicine*". This implied that the "*West*" had a richer history of achievement in the discipline of medicine *and* that it afforded a present-day auditor with technical superiority due to the privilege of their national status. These sentiments were shared by another Northern hemisphere participant, but in a rather blunter manner:

> *The obvious answer is that QUAMED is right. You need to defer to that (.) opinion because, ah... {long pause} Yeah, I mean, a lot of the countries where we work, the government's opinion isn't worth (.) the paper that it's written on.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

In contrast, national staff were generally less shocked by the question of "*who is right?*". They were also more willing to consider the HG-NDRA's opinion *and* to question the suitability of QUAMED's opinion. For example, a clinician from Central Africa told me that he would "*abide by the government because, er, NGO, they are not there for long*" ("Ikolo": IDI-359, iNGO, roving, health). A logistician from South Asia told me that medical product QA "*must be the role of the government*", noting that "*the recommendations from the QUAMED […] may not be applicable in our coun-, local context*" ("Arjun": IDI-147, iNGO, Country Office, logistics). Other national staff acknowledged the heterogeneity in HG-NDRA capacity, stating that their decision "*would depend on the context*" ("Farid": IDI-267, iNGO, Country Office, logistics) or by offering their appraisal of a specific "*government regulatory authority technical expertise in this field*" ("Ishaan": IDI-476, iNGO, Country Office, pharmacy).

5.4.3 c) One participant's reflection on responsibility for compromising the Quality Assurance of medical products for humanitarian health projects of grant-reliant iNGOs.

Most participants focussed on who should be responsible for *assuring* the quality of medical products for the humanitarian health projects of grant-reliant iNGOs. Having presented these views, I will conclude by examining the words of a participant who looked at the problem differently. Martin (IDI-231, iNGO, Head Office, pharmacy) reflected on who should (or should not) be responsible for *compromising* medical product quality on behalf of the patient.

> *What do you know, eh? Actually, how do you measure your responsibility in the spreading of resistances to, to amoxicillin, if you select a poor source of amoxicillin? How will you, er, size-up your responsibility in the spreading of cancer, if you purchase antihypertensive products that are banned in Europe, but you will purchase for Argentina, or for El Salvador? How do you measure that? We know that it is identified as (.) an important risk in the EU, and you, with zero knowledge, you consider that it's not so important for the population of El Salvador, or DRC, and you decide yourself to select a source, that is not, erm, you know, bullet-proof? We know that, that the risk of, of contamination by, er, carcinogenic products in that category of product is huge. And you consider that it's not so important? Ah! For me, that's terrible. It's (.) totally impossible for me to understand that. You? As a European, (.) being in, in your comfort, (.) you decide what is appropriate? What level of risk you will take for a population, knowing that risk? That's terrible, for me.*
>
> **"Martin": IDI-231, iNGO, Head Office, pharmacy.**

Martin, the highly experienced QA pharmacist that we met at the start of this chapter, questioned the status quo of 'no stock, high stakes' decision-making, in which remote, non-technical iNGO staff "*decide what is appropriate*". He did not suggest that medical product quality should not be compromised; rather, he asserted that it should not be compromised by "*a European, (.) being in, in your comfort*" of a geographically remote context. This perceived lack of contextual expertise was compounded by a perceived lack of technical expertise ("*zero knowledge*") and his concern that decision-makers were insensitive to the risk of "*substandard products that are everywhere – but it's not spectacular*" (such as antimicrobial "*resistances*" and the "*spreading of cancer*"). (Although these issues do bear a 'spectacular' burden on healthcare providers,[11] Martin meant that their ingestion does not

result in an immediately "*spectacular*" injury to the patient that would alert the clinician to a medical product quality concern. Rather, the deleterious health effects of poor-quality medical products may be unknown, or unknown for many years.) I will return to participant perspectives on expertise and who should make 'no stock, high stakes' decisions in Chapter 7.

5.5 Conclusion

Participants interviewed for my research described how iNGO medical product QA originated in the HIV/AIDS crisis, due to concerns regarding the quality of medical products from markets that were not regulated by NDRAs designated as 'stringent'. These concerns persist; as does the binary categorisation of 'SRA' and 'not SRA', which was observed to inform the worldview of many participants. I will focus on this in the next chapter. The enforcement of a secondary set of restrictions (donor sourcing requirements in addition to HG-NDRA importation regulations) was found to complicate, intensify, and even create, 'no stock, high stakes' problems. The heart of this appeared to be deeply held and conflicting opinions regarding who should be responsible for the QA of medical products for the humanitarian health projects of grant-reliant iNGOs. However, the concept of responsibility was also multi-faceted; participants distinguished between types of responsibility (such as legal or ethical), and between specific activities (such as defining requirements and executing tasks). Ultimately, donors were found to have the power to dictate who was responsible for medical product QA. In the next chapter, I will describe the difficulty that participants faced when sourcing medical products from the national market, due to the perceived risk of substandard and falsified medical products and the unfeasibility of applying donor QA requirements to non-ideal settings.

6

"It's SRA or it's not SRA": participant perspectives on the risk of substandard and falsified medical products from unknown sources in 'no stock, high stakes' problems.

6.1 Introduction.

In this chapter, I will focus on how participants navigated 'no stock, high stakes' problems in the absence of systems that would usually support them: QA systems to select suppliers and health supply chain systems to deliver goods. I will begin by describing participants' beliefs regarding the quality of medical products that may be available to them in a 'no stock, high stakes' problem. These sourcing options were either borrowing from peer agencies or buying from national vendors. Then, I will describe how participants were found to lack ethical guidance when considering these sourcing options. Finally, I will present participant perspectives on QA knowledge producers when evaluating and selecting suppliers from HG-NDRA regulated markets in urgent stock-out situations, and how this tended to align with social trust rather than data quality.

6.2 Participant perspectives on their sourcing options in 'no stock, high stakes' problems.

6.2.1 Participant perspectives on borrowing medical products in a 'no stock, high stakes' situation.

In my interviews with them, participants typically perceived there to be two options for sourcing medical products in a 'no stock, high stakes' problem: borrowing or buying. This participant, who had

substantial humanitarian health supply chain experience, summarised these options (and their challenges) as follows:

> *The first thing would be to find out who else has got similar kinds of supplies in a country that we could draw from. Maybe it's [WBN[33]], maybe it's [ZNZ], maybe it's (.) others doing similar kinds of programming. Ahm. Maybe they could tide us over while we organised (.) an international (.) procurement. Ahm.*
>
> *And the (.) other obvious question, probably before that, would be, well, what country is it? Do we have any credible suppliers in country? Ahm. If we haven't approved them, do other organisations (.) have evidence of having done some sort of process with them that we could, (.) that we could use to assure ourselves that it's safe. Ahm. So, those are the two options basically.*
>
> *Are we looking at what, (.) what really is the state of the local market? And is there any evidence that there is a safe (.) procurement route there? Er. Assuming that there isn't, (ah, {half laughing whilst speaking} which is usually the case), um, then we'd be, yeah, we'd be looking to borrow and, and fast track international, ahm, air freight.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

When Pete[34] (IDI-499: iNGO, roving, operations) told me about sourcing options for 'no stock, high stakes' problems, he opened with borrowing supplies from other humanitarian agencies rather than seeking "*credible suppliers in country*". He laughed at the unlikelihood of the latter; had medical products of acceptable quality been available, there would not have been an urgent stock-out problem. Like most participants, Pete would borrow medical products as an interim solution, whilst seeking a rapid resupply from QA policy compliant vendors. This kind of interagency assistance was so common amongst participants that it was tantamount to a default response. Almost every interviewee from an iNGO informed me that they would "*swap*" ("Skye"), "*borrow*" ("James", "Hugh", "John", "Pete", "Jan", "Guy", "Derek"), request a "*loan*" ("Farid", "Ahmed"), or "*seek support*" ("Ishaan"), from other aid agencies, when facing a 'no stock, high stakes' problem.

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[33] The names of humanitarian aid agencies have been replaced with a random three letter code for anonymity.
[34] Names have been changed. Appendix E refers.

Donor participants also endorsed this approach. For example:

> *Your patients, er, they will need drugs immediately and those drugs can only come from somebody else's warehouses. […] [Sourcing from global suppliers], that's gonna take you some time. {laughs} I can tell you. It's not gonna be, it's not gonna be quick. And in the meantime, you have to be covered by somebody else. {long pause}*
>
> **"Jan": IDI-886, donor, health.**

Jan, an experienced medical doctor who worked for a bilateral donor, felt that borrowing was the only feasible option in an urgent stock-out situation. He spoke of the tremendous difficulty of rapid resupply in a complex humanitarian environment using the established health supply chain. A challenge that he perceived to be so great that he laughed at the enormity of it, and the time that it would take.

However, views differed on the likelihood of being able to borrow medical products from another aid agency. Some participants were confident that another organisation could "*provide this [loan of medical products] for the time being and, also, if they get the same incident then we will, er, er, give them [medical products]*" ("Ishaan": IDI-476, iNGO, Country Office, pharmacy), while others didn't "*think many iNGOs would, would very, very easily give up medicine, to be honest*" ("James": IDI-137, iNGO, Head Office, logistics). These opposing perspectives may be attributable to the 'intimacy' of interagency relationships experienced by either speaker. The first, Ishaan, was a national pharmacist supporting a massive and complex health project, working closely with other iNGOs. He routinely coordinated with them in a shared effort to positively impact the same humanitarian crisis and was able to name his counterparts at peer organisations. The second, James, was a Head Office logistician with no such ties. In his early career he had worked at very remote project sites and, after his move to Europe, his interagency interactions were limited to "*conference calls*". These perspectives on the likelihood of borrowing medical products differed, but both may have been accurate. It is possible that iNGOs were more willing to share medical products in an emergency setting with a familiar counterpart to whom they felt connected, rather than for disparate projects between relative strangers.

Only one participant explicitly raised concerns about the risk of poor-quality medical products if sourced as a loan from another aid agency.

> *At one side we are trying to save lives, but another side we are, I mean, making them compromised, because the source, supply chain, we don't know about these products, from where they are coming. […] Individuals came out having their gifts, um, medicines gifts from the [iNGO] organisations, although apparently, they are looking very attractive, but, er, I mean, what kind of products they are supplying? From where they are coming? Is there any, I mean, supply chain maintained, right from the supplier, er, from the pharmaceutical company until the time (.) they are being handed over to you? We don't know.*
>
> **"Farid": IDI-267, iNGO, Country Office, logistics.**

Farid (IDI-267, iNGO, Country Office, logistics) was a senior member of national staff responsible for the policy-compliant procurement of medical products in his iNGO's Country Office in South Asia. Although he felt that there was "*no other solution*" than to "*borrow*" from other iNGOs that "*have the same standards as you*", he was uncomfortable with his lack of knowledge about them. Skye (IDI-101, iNGO, roving, pharmacy) also questioned whether it was appropriate:

> *"Oh well, we'll trust that, those people more because they're an iNGO." Why would we trust an independent iNGO, that we have no idea what they're doing, more than we would trust the government that we can go and read their drug policy and see what their legal requirements are?*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

This experienced humanitarian pharmacist found it "weird" that her iNGO would "*trust an independent iNGO*" but would disregard the legitimate "*national supply chain*". Note that she was comparing iNGO medical products with those from the national supply chain that provisioned the *public* health system (and therefore had the greatest level of regulatory control); she was *not* comparing them to private, national vendors.

Despite these misgivings, she told me of an experience of "*trying to swap*" medical products between different iNGOs during an emergency response: "*"You've got AL [an antimalarial], but you don't have pregnancy tests, but I've got lots of pregnancy tests, but no AL." You know? "Can I juggle these around?"*" She then made a statement that surprised me:

> *Within the iNGO circuit there, there was an illegal drug trade happening. And we knew it. In terms of government legislation, it was clearly illegal.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye believed that the loan of medical products between iNGOs was illegal trading because, in many countries, the sale and distribution of medical products (for purposes other than administration to, or use by, a patient or caregiver) is regulated. Therefore, she thought that the trading of goods between iNGOs would likely contravene legislation pertaining to the control of medical products. Although Skye felt that iNGO staff "*knew*" of this illegality, no other participant made such claims. If other participants believed that "*the iNGO […] drug trade*" was illegal, it seems reasonable to assume that far fewer participants would have mentioned that they borrowed stock (for fear of reprisal) or would divulge that it was not permitted. The freedom and regularity with which it was mentioned suggests that either the practice is not illegal, was only illegal in some settings, or that other participants did not realise that it was illegal.

6.2.2 Participant perspectives on buying medical products from the national market in a 'no stock, high stakes' situation.

In Chapter 5, I described attitudes to the HG-NDRA. Unsurprisingly, these perspectives aligned with sentiments about national markets regulated by HG-NDRAs. For example:

> *Your medical warehouse burns down. You've got no way of getting more international quality assured drugs in. You know, the local market is horrendous. […] So, then, then you're trying to figure that out.*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

Elliot conceptualised two 'markets' for medical products: international and local; perceiving the former to be inaccessible during 'no stock, high stakes' problems, and the latter to be unreliable. This distinguished geographical location from the perspective of the country in which the health project was situated: "*international*" referred to vendors that were external to the State's borders, whilst "*local*" denoted national vendors. However, the terms were also observed to hold an implicit

meaning, relating to trust. Elliot, like most participants, did not mean *any* foreign vendor when he spoke of "*international*" sources; he was referring to "*quality assured*" vendors that were trusted to provide safe and effective medical products because they complied with QA requirements. Conversely, "*local*" inferred "*horrendous*"; it did not mean national vendors that had received endorsements from a donor-approved auditor, for example.

Youssef (FGD-554, iNGO, Country Office, logistics), an experienced Country Office logistician, explained:

> *Who is the regulatory authority, okay, who is issuing that [approval]? So, if it is considered as a stringent, okay, approval regulatory authority, that is fine. And if their, their products are locally sold in the market, this is something, you know, like, acceptable.*
>
> **"Youssef": FGD-554, iNGO, Country Office, logistics.**

Youssef explained that a national vendor with SRA approvals was compliant with medical product quality sourcing restrictions. However, participants did not appear to have a term for these 'local' in a geographical sense, but not 'local' in a quality sense, medical products. Perhaps, as explained in the previous section, due to the unlikelihood of such endorsements.

So, the "*local market*" was seen as the antithesis of a trusted market: it was almost universally used to describe suspicion and danger by participants in my interviews. Sourcing from this "*horrendous*" market (based solely on HG-NDRA approvals) was viewed as "*a really terrible idea*" ("Olivier": FGD-751, iNGO, Head Office, logistics), a "*last resort*" ("Ahmed": IDI-790, iNGO, Head Office, pharmacy), and "*a big, big, big, big, big compromise*" ("Youssef": FGD-554, iNGO, Country Office, logistics). However, because the term related to an interviewee's trust or suspicion of vendors, participants differed in how they applied the concept to real-world settings.

The location of the warehouse fire scenario[35] was intentionally withheld during In-Depth Interviews[36], yet it was normal for interviewees who were geographically remote from the setting, or who were unfamiliar with it, to reference grave concerns with the "*local market*" without asking where it was. One donor participant clarified her view that "*"local manufacturer", meaning in Africa*" because "*there is higher risk of producing a substandard medicine in a country where there is no, um, means, financial means*" ("Olga": IDI-671, donor, pharmacy). These 'remote' participants often perceived *any* country (or, indeed, continent) in which an iNGO might deliver a humanitarian health project to be synonymous with the risk of poor-quality medical products, because of their concern for HG-NDRA capability. However, this tended not to be the case for participants who were familiar with sourcing medical products from the "*local market*" (such as pharmacists involved with procurement, QA, or supplier selection). These participants tended to apply the term differently, viewed nuance within the concept, and had a different relationship to the risk that it posed.

For example, I spoke with a national member of staff who was a pharmacist experienced in the procurement and QA of medical products. During our discussion, he appeared to make contradictory comments regarding the "*local market*". First, he stated that, "*we are procuring from [my country's] local market*" and estimated that "*falsified medicines procurement is {shakes head} very, very low chance*". However, later he stated that, "*[on] the local market, […] there is a huge risk to purchase falsified medicines*". I pointed out that this seemed to be inconsistent and asked him, "*What does 'local market' mean to you?*", to which he replied:

> *'Local market' means, that, er, retails shops. […] There are many retail shops who actually know from where the fabricated medicines are manufactured. Knowing this matter, they are procuring this and storing this in their retail shop.*
>
> **"Ishaan": IDI-476, iNGO, Country Office, pharmacy.**

[35] A scenario in which a warehouse that stores an iNGO's medical supplies has burnt down, causing massive stock-outs. Summarised in Chapter 3 and Appendix C.
[36] Though not in Focus Group Discussions.

According to Ishaan, the "*local market*" meant shops that had intentionally bought and sold falsified medical products, thereby not only knowingly risking the health of patients, but also abetting organised crime. His use of the term "*local*" differed depending on the context of the discussion: it could mean 'national' (as he initially named his country in relation to it), or it could mean something akin to 'untrustworthy' (as he used it in relation to obviously nefarious vendors). His first usage drew upon a dictionary definition of 'local', differentiating it from 'international'. The second usage reflected how Ishaan had internalised the cultural *intention* of the word "*local*", making sense of it according to his own worldview. He applied the derogatory moniker of "*local*" to those vendors that fulfilled the cultural subtext of its definition according to his own perceptions.

Some participants who were familiar with supplier selection in humanitarian contexts saw nuance *within* the "*local market*": some vendors posed a greater threat of substandard and falsified medical products than others. A common view was that the length of the health supply chain correlated with the risk of substandard and falsified medical products and, therefore it was preferable to be "*closer to the source of the product*" ("Justin": IDI-696, iNGO, Head Office, logistics). One logistician told me that he "*won't buy from the pharmacy on the corner. So, that's a definite. I will go to wholesalers and distributors - or manufacturers, preferably*" ("Justin": IDI-696, iNGO, Head Office, logistics), and a pharmacist shared that "*there's very few instances I'd be like, […] "Go to a pharmacy shop and buy it"*" ("Skye": IDI-101, iNGO, roving, pharmacy). An emergency response pharmacist from East Africa was even more specific, stating that the risk of poor-quality medical products was "*higher if you go into*" certain shops, listing those without "*qualified*" pharmacists, "*internet*" stores, or vendors in markets with "*porous borders*" ("John", IDI-284, iNGO, roving, pharmacy). While another felt that political instability may make some parts of the "*local market*" even less appealing: "*where there is a war […] or, in a big country, a more instable part*" ("Genevieve": joint IDI-881, iNGO, Head Office, pharmacy).

These participants also tended to have more confidence in their ability to navigate the risks of the "*local market*" than non-technical interviewees.

> *I have been in so many countries (and difficult ones, sometimes, in, in war conditions – like in DRC[37]), and it's always possible to, to find something that will not be (.) too risky, I think.*
>
> **"Martin": IDI-231, iNGO, Head Office, pharmacy.**

Martin, like most interviewees who had the skills and experience to "*assess*" the "*local market*", was confident in his ability to identify sourcing options that he perceived to be an acceptable risk, *if* he had sufficient resources and time to do so. This was generally not the case amongst participants who lacked this profile (such as health or operations staff), who feared that any vendor on the national market would "*end up harming [patients]*" ("Kamran": IDI-796, iNGO, Head Office, health).

Some participants believed that there was a reputational risk associated with sourcing medical products from the national market *at all* – not just in instances where harm occurred. One Head Office pharmacist asserted that "*good management is the basic thing not to go for local procurement*" ("Genevieve": joint IDI-881, iNGO, Head Office, pharmacy). Here we observe her bias against "*local*" vendors and surmise that sourcing from them was perceived to be because of an error, or poor "*management*", rather than by choice. She went on to state:

> *{Gestures 'a small amount' by pinching her finger and thumb together} We had, er, twelve <u>percent</u> of local procurement! […] Some [regions] mu-, er, better than others, some worse. […] In some country we are obliged to do the local procurement.*
>
> **"Genevieve": joint IDI-881, iNGO, Head Office, pharmacy.**

Genevieve's views were typical of policy-focussed participants, who characterised national spending as an undesirable event. Thus, she sought to distance her iNGO from responsibility for some "*local procurement*" by stating that it had been "*obliged*" by the Host Government. Another Head Office pharmacist echoed these sentiments, stating that those facing 'no stock, high stakes' problems "*will procure locally, […but] this will never happen if you had a strict criteria, I mean, in your QA policy*" ("Olga": IDI-671, donor, pharmacy). She perceived that those who "*procure locally*" did so due to recalls (or other medical product quality concerns), but that the iNGO could (and should) have avoided these by competent QA procedures.

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[37] The Democratic Republic of Congo.

Other Head Office participants sought to excuse "*local market*" purchases, as if there were stigma associated with the act.

> *It might be that we, you know, borrow some from [an iNGO], or (which we've done before). But, yeah. I mean, often it gets to the point where it's, actually, we can't serve our needs with those options – and so it comes to buying in the local market. […] You don't have a choice. You just have to. You have to go to the local market.*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

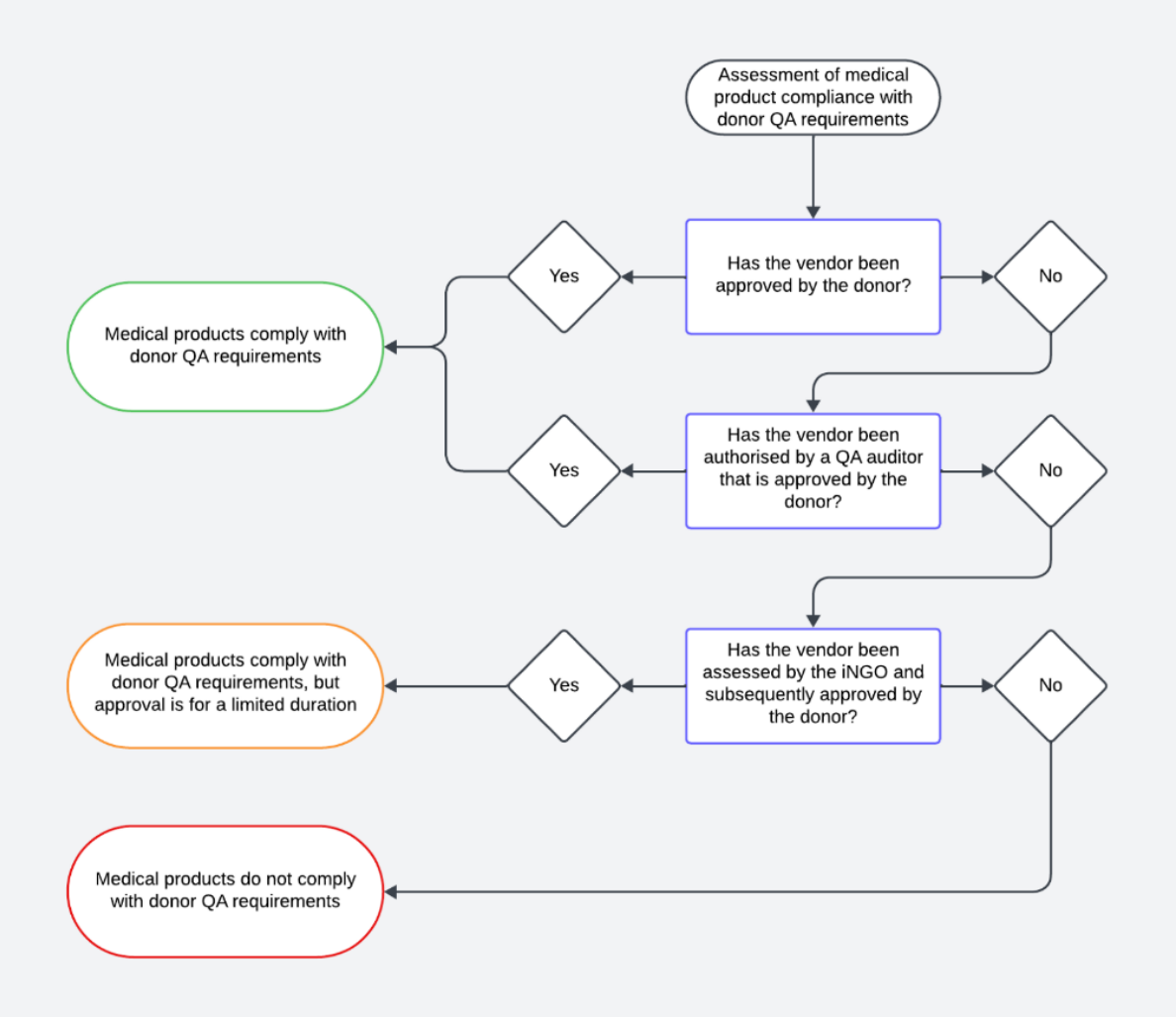
This exchange concluded a wider discussion, in which Elliot was asked to "*think out loud*" about how he may respond to the IDI warehouse fire scenario. He became uncomfortable, fidgety, and hesitant, when speaking of "*buying in the local market*". He stressed *thr*ee times that he felt obligated to do so ("*You don't have a choice. You just have to. You have to go to the local market*"), suggesting that he saw this decision as controversial or regrettable and in need of justification. These statements were in stark contrast to his nonchalance of sharing that he may "*borrow some*" medical products from an iNGO (whom he named but has been redacted for anonymity). He was relaxed and matter of fact in revealing that borrowing medical products from another iNGO was a viable option to "*serve our needs*"; an option that he evidently perceived to be more acceptable than buying on the "*local market*".

6.3 The lack of ethical guidance for iNGOs urgently sourcing medical products from unproven national vendors for humanitarian health projects.

6.3.1 Perspectives on the unfeasibility of complying with donor medical product quality requirements in 'no stock, high stakes' problems.

I reviewed the content of donor quality requirements for sourcing medical products in Chapter 2. Although I will not revisit this information, I have repeated the summary illustration below (figure 10, which was first presented in section 2.3.3) to offer a background to my analysis, and to help engage

with the findings presented in this section.



KEY.
Reliance Method: the iNGO procurer *relies* on the quality assurance of a donor-approved organisation and can **proceed** with sourcing.
DIY Method: the iNGO procurer conducts or contracts the quality assurance investigations themselves and must **wait** for donor review before sourcing.
Not recognised: the iNGO is not permitted to use donor funds to source from these vendors, without additional endorsement from an approved QA auditor.

Figure 10: A 'traffic light' summary of the QA auditors able to approve a vendor according to the medical product sourcing requirements of donors.

Similarly to these policies, most participants categorised medical product quality into two groups: those approved by a Stringent Regulatory Authority (SRA) or equivalent[38], and those that were not.

[38] See Chapter 2 for a detailed explanation.

> *Any product that is WHO prequalified, or authorised by SRA, would be no risk. Well, I mean, limited risk.*
>
> **"Olga": IDI-671, donor, pharmacy.**

> *If we have a supplier which is not approved by any other UN agency, and it's not SRA, then they would, like, to go and audit themselves, to approve them.*
>
> **"Claudette": IDI-933, vendor, pharmacy.**

> *{Gestures "top shelf" by raising up a flat palm} Our top on the on the quality manual is always the, um, SRA-approved product. […] We put that alongside the WHO prequalification mechanism.*
>
> **"Viktor": IDI-626, vendor, logistics.**

An array of participants expressed trust that medical products "*authorised by SRA would be no risk*" and explained that this also applied to "*the WHO prequalification mechanism*" and "*other UN*" agencies. However, several participants communicated that it would be unfeasible for an iNGO to obtain these validations during a 'no stock high stakes' problem. This pharmacist from a donor organisation, whose role was to ensure policy compliance, explained why this was the case:

> *If you […] choose to procure through one of these [donor approved] vendors [i.e. the 'green light' Reliance Method depicted in figure 10], you don't have to submit any additional, you know, quality assurance documentation about the vendor. But […] those can't always meet the needs of every single situation. And so, we have a process open where partners can, um, provide documentation to have a non-[approved] source approved to utilise our funding [i.e. the 'amber light' DIY Method illustrated in figure 10]. […] That can be a very time-consuming process, it can require a lot of documentation, and there's no way to guarantee (.) what kind of timeframe that decision can be made in.*
>
> **"Liam": IDI-764, donor, pharmacy.**

Liam had demonstrated an in-depth knowledge of his organisation's sourcing policies. When I asked how an iNGO procurer might comply with medical product quality requirements during a 'no stock, high stakes' problem he described two methods, but explained that neither was suitable. Relying on donor-approved vendors (the 'green light' Reliance Method in figure 10) would not "*meet the needs*" of an urgent stock-out situation. As this method did not offer a comprehensive supply chain solution,

an ad hoc approval process had been established (the 'amber light' DIY Method from figure 10). However, he acknowledged that this process was "*time-consuming*", high-effort, and not time-bound.

Numerous iNGO participants voiced concerns regarding the feasibility of the 'DIY Method'. For example: it "*takes too long, it's totally confusing, and then they say "no" anyway*" ("Justin": IDI-696, iNGO, Head Office, logistics); "*doing the prequalification of the, the suppliers locally; {shakes head} it takes a lot of energy*" ("Ikolo": IDI-359, iNGO, roving, health); it would cost "*a few million*" Euros to audit and approve "*suppliers around the world*" ("Pete": IDI-499, iNGO, roving, logistics). Indeed, one highly experienced QA pharmacist, with a wealth of experience in both organising and conducting QA audits, entirely dismissed the notion of using the 'DIY Method' during a 'no stock, high stakes' problem:

> *I didn't bring that [DIY Method] up as a possibility because it's very unlikely you'd be able to do that in the short time frame that, you know, you need to get medicines back up and going in the programme. By the time, you know, by the time you could actually have an audit carried out, you can probably already get your medicines resupplied by the international wholesaler.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

This statement was intended to highlight the redundancy of the DIY method for 'no stock, high stakes' problems, as it was perceived to be too slow, but also emphasized that the process of importation may be protracted (as depicted in Mansoor's Year, Chapter 4).

6.3.2 Participant concerns regarding a lack of practical guidance in response to 'no stock, high stakes' problems.

Many interviewees seemed lost when deliberating 'no stock, high stakes' problems.

> *I'm thinking back to the (.) particular medical procurement policy. […] It made everybody understand that (.) they couldn't go shopping for drugs, um, in Eastern Congo. Um. So, yeah. It's... That was clear. Um. (.) What was less clear, perhaps, was the policy on how to (.) expand our supplier list (.) in a (.) achievable way. I think people (.) felt crippled by the complexity of it and weren't able to, (.) to do anything.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

Pete was an operations manager with a logistics background and a wealth of experience in supporting the delivery of humanitarian health projects. He expressed his frustration that he found iNGO policies for sourcing medical products to be complex, and that they offered no practical guidance for situations that I have termed ‘no stock, high stakes’ problems.

I was curious as to how participants who had responsibilities relating to QA policies, such as donor staff and iNGO policymakers, would determine medical product quality in a ‘no stock, high stakes’ situation. This donor participant listed the QA knowledge producers from their policy:

> *Either it's WHO prequalified, or it's what we call SRA-approved. […] Then, this list, um, are available for, um, limited category of product: ARV, malaria, TB, reproductive health. […] There are some, er, also website like, um, on the manufacturing side that have been inspected by Europe or whatever.*
>
> **“Olga”: IDI-671, donor, pharmacy**

Olga was a senior pharmacist with a wealth of QA and supply chain experience. First, she explained how she would remotely ascertain the quality of a medical product during a ‘no stock, high stakes’ problem using policy-compliant sources of information. Then, she searched for other sources of information that would be accessible at the point of purchase:

> *Now, if you, if you don't have this information, then you can go to… {long pause} Alors, er, how to, to know, um, {scratches head} outside of this, {laughs} who, which supplier is procuring this drug? {long pause, shrugs} […] {throws up hands} I don't know!*
>
> **“Olga”: IDI-671, donor, pharmacy.**

After some time, and after some literal head scratching, Olga threw up her hands and declared, “*I don’t know!*” Her inability to advise how to obtain and use information about the quality of a medical product in a ‘no stock, high stakes’ problem suggested that her organisation did not concern themselves with this challenge.

Justin, an iNGO policymaker, was similarly perplexed. I asked Justin (IDI-696, iNGO, Head Office, logistics) how he would judge the quality of a medical product at the point of procurement in a ‘no stock, high stakes’ problem and he replied:

> *{long pause, shakes head} The reality is I wouldn't have a clue. And, like, that is the reality. Like, I would look for branding, for Western brands – but all that can easily be faked. I would look for […] national regulatory authority stamping – but all of that is easily faked. There's no easy way of doing it. What you are trying to do is look at the source where you're procuring it from and having some confidence or not in where you're procuring it from.*
>
> **"Justin": IDI-696, iNGO, Head Office, logistics.**

Justin "*wouldn't have a clue*" how to ascertain the quality of a medical product from an unknown vendor in a humanitarian context. However, this comment did not reference his knowledge per se; he was a senior and experienced logistician with a wealth of experience in sourcing medical products and had contributed to developing his iNGO's QA policy. This comment referenced his perception of the circumstances. Justin felt unavoidably ignorant of the chemical nature of the medical products (the quality of their constituents, their provenance, their supply chain environment, any possible concealed dangers) because, even if information was obtained, he was not confident in its veracity and rigor. He eschewed visual inspection because "*brands*" and "*stamping*" and "*all of that is easily faked*". He referred to the need for QA (in which you evaluate "*the source you're procuring it from*" and its journey thereafter) but lamented that "*there's no easy way of doing it*" at the point of purchase in a non-ideal setting. However, despite the risk of sourcing medical products of uncertain quality, and that this course of action may tarnish his iNGO's social standing, he shared that "*we all buy locally when we need to.*" Next, I will explore how he, and other iNGO participants, estimated medical product quality during 'no stock, high stakes' problems.

6.4 Participants' perspectives on estimating the risk of poor-quality medical products from unfamiliar national vendors during 'no stock, high stakes' problems.

6.4.1 Participant perspectives on information from international organisations when responding to 'no stock, high stakes' problems.

As presented in section 6.3.1, it was extremely challenging for iNGOs to obtain actionable data regarding the provenance and handling of medical products during 'no stock, high stakes' problems;

trusted SRA data was unavailable, they lacked the time and resources to generate their own data, and they did not trust the data from HG-NDRAs. Therefore, participants were observed to seek out pre-existing knowledge for decision-making, from familiar sources.

> *I'm thinking about reliance mechanisms? […] So, have we gone and visited, have we done, have we done a pre-qualification process or, um, for any medicine suppliers, um, that are available to us before? Like have we gone and looked at their warehouses, er, at their storage and distribution systems? Or - has somebody else done it? […] I would also be trying to link up with other organisations who are, who operate in the country – maybe similar to us, but who do do more local procurement, um, and learn from what they know. […] Maybe QUAMED has carried out assessments of suppliers in that, er, in that country and done a local market assessment and, and we have, might have, they would have access to information on suppliers from, um, through QUAMED work.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Like many interviewees, when Noah considered how to obtain pre-existing information about national vendors to assist with 'no stock, high stakes' decision-making, he categorised data into three discrete sources self, peer, and QUAMED (a charitable organisation aiming to improve access to quality medical products). At this point in our conversation, he overlooked HG-NDRA data.

First, Noah contemplated his own iNGO: "*have we done a pre-qualification process or, um, for any medicine suppliers?*" This supports document analysis, which revealed that 'no stock, high stakes' problems may be a recurring issue in some iNGO projects (due to seasonal epidemics or, as depicted in "Mansoor's Year", long-term importation challenges, for example). Second, he wondered about "*other organisations*", whom he clarified as those who were "*similar to us*". Reaching out to "*peer*" humanitarian organisations was a common concept with different interpretations, as I will explain later. Third, he considered whether QUAMED may have "*done a local market assessment*".

In the following sections, I will present an analysis of perspectives on data obtained from peers and QUAMED[39]. Then, I will explore participant perspectives on HG-NDRAs and whether to differentiate between them. To do so, I will present attitudes on the WHO-listed authority (WLA) initiative described in Chapter 2, which benchmarks NDRAs. Finally, I will return to Noah who, much later in our discussion, reflected on why he had initially overlooked HG-NDRA data for 'no stock, high stakes' decision-making.

6.4.1 a) Participant perspectives on medical product quality information from "*peer*" iNGOs.

When describing their handling of a 'no stock, high stakes' problem, several iNGO participants made vague comments about "*buying from a place that is recognised and reputable by some of my peers, or other agencies*" ("Justin": IDI-696, iNGO, Head Office, logistics). They would ambiguously gesture towards "*somebody*" ("Hugh": IDI-269, UN, roving, operations; "Elliot": IDI-668, iNGO, Head Office, operations) to rely on when facing a challenge in the delivery of their humanitarian health project, often claiming those somebodies as "*similar*" ("Noah": IDI-586, iNGO, Head Office, pharmacy), "*partner*" (IDI participants "Arjun", "Martin", "Hugh", "John", "Noah", "Elliot", "Ahmed", "Kamran"), or "*peer*" (IDI participants "Ishaan", "Guy", "Ahmed", "Kamran", "Justin").

It was common for participants to characterise the "*peer*" iNGOs with descriptors like, "*reputable*" ("Guy": IDI-775, iNGO, roving, operations), "*credible*" ("Pete": IDI-499, iNGO, roving, operations), "*robust*" ("Kamran": IDI-796, iNGO, Head Office, health), and "*trusted*" ("Ahmed": IDI-790, iNGO, Head Office, pharmacy). Earlier in the chapter, I reported that a participant wondered why her iNGO would "*trust an independent iNGO, that we have no idea what they're doing?*" ("Skye": IDI-101, iNGO, roving, pharmacy). I recalled this question when speaking with participants and wondered the same. Therefore, repeating the language of their own statement, I would ask questions like, "*what makes another agency "credible",*

[39] Readers are directed to Chapter 5 section 5.2.2 for perspectives on HG-NDRAs as a QA knowledge producer.

in your eyes?" Often the interviewee would appear surprised and uncomfortable with the question, and uncertain of the reason. For example, immediate responses included:

> *{raises eyebrows, smiles, flushes a little} Yeah, good question. Umm. {long laugh, some gurning} I mean… {long pause} Yeah, I mean, from a technical perspective, I can't, I don't have the answer.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

> *{long pause} Yeah. {covers mouth with hand, looks up} That's, that's… {laughs} That's a good question.*
>
> **"Ahmed": IDI-790, iNGO, Head Office, pharmacy.**

> *Yeah, so… Yeah. {shifts on seat} Good question.*
>
> **"Guy": IDI-775, iNGO, roving, operations.**

The participants exhibited physical signs of discomfort and seemed awkward. I interpreted that my question had revealed an unconscious bias, hitherto unconsidered and difficult to immediately explicate with defensible evidence.

Instead of descriptors, some participants would offer one or two example organisations when referring to "*peers*". For example:

> *Has ZNZ[40] bought this in the country? Has WBN bought it in the country? Has OJN even bought it in the country? […] I'd ask ZNZ, or WBN, which would be the obvious ones. Or QXL, or OJN, or AEH, or even NII, or those.*
>
> **"Justin": IDI-696, iNGO, Head Office, logistics.**

> *Can we find it from somewhere else? Like ZNZ, or one of the other medical, medical NGOs – DPV or somebody like that?*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

> *Is ZNZ operating in-country [… or], you know, BOR?*
>
> **"Ahmed": IDI-790, iNGO, Head Office, pharmacy.**

[40] The names of iNGOs have been replaced with three letter codes for the purposes of anonymity.

When explaining who they would approach for support, these participants substituted an example iNGO for an explicit description or explanation, thus signposting tacit knowledge about their attributes or status. Sometimes these perspectives were woolly, (shown by instances of hesitancy, like "*OJN even […] or even NII*"), suggesting that they were defining this status in the moment. Indeed, one policymaker told me that "*there is this, this (.) flexibility there, […] it is slightly open-ended*" ("Kamran": IDI-796, iNGO, Head Office, health).

I noted that a small number of organisations were respected and cited by a variety of participants (for example, each of the previous quotes referred to the organisation pseudonymised as 'ZNZ'). However, sometimes opinion conflicted. For example, one national pharmacist was happy to approach "*many iNGOs, (such as WUK, VCD, er, and, er, QXL, […] also ELN)*" ("Ishaan", IDI-476, iNGO, Country Office, pharmacy), while a Head Office doctor in the same organisation felt that "*maybe I wouldn't trust ELN, at this stage. {laughs}*" ("Kamran": IDI-796, iNGO, Head Office, health). One roving pharmacist from an iNGO informed me that she didn't believe that *any* iNGO had the "*proper technical capacity*" to evaluate medical product quality ("Skye": IDI-101, iNGO, roving, pharmacy). A doctor from a donor organisation held similar concerns, stating that "*for most NGOs, it's impossible. […] They don't have the capacity, you know?*" ("Jan": IDI-886, donor, health). He felt that there were "*two organisations that do have that [QA] capacity*": 'ZNZ', which was mentioned by several participants and 'KID', which was mentioned by no one else.

On analysis, participants who trusted another iNGO were found to do so according to familiarity and positive impression. For example, one participant chose to "*reach out to, to gather health and logistic cluster*"[41] information during a 'no stock, high stakes' problem; he explained that he had worked alongside these members and, over time, had developed confidence that "*they have the same*

[41] The "Cluster Approach" is a United Nations Office for the Coordination of Humanitarian Affairs (OCHA) method for coordinating groups of humanitarian organisations who are responding to the same emergency and working on the same activity (such as health, logistics, shelter, or nutrition). See reference 1. Office for the Coordination of Humanitarian Affairs. OCHA on message: the Cluster Approach. In: OCHA, ed., 2012.

standards as" his iNGO ("Farid": IDI-267, iNGO, Country Office, logistics). Another participant echoed this statement, but named Cluster membership as a single aspect of a network of ties:

> *You've been here [in-country] for 35 years, working. You, you know, you run ten clinics. (.) I know you from, {shakes head} both socially, er, you know, I just see, see your staff socially and I know that you're a player. I see you at the Health Cluster meeting, or the whatever, the health working group meetings.*
>
> **"Guy": IDI-775, iNGO, roving, operations.**

Guy valued a sense of community. He explained that his trust for another iNGO would evolve from long-standing relationships and a common purpose, offering insight into his experience of working and socialising within a humanitarian context as an Operations Manager.

Ahmed (IDI-790, iNGO, Head Office, pharmacy) also used his professional experience as a framework for determining trust. Just like Guy, he felt that "*working relationships often have a big influence*" and shared a preference for "*long-standing partners*", because he felt that "*trust*" needs to "*develop over time*". However, as his career path was quite different, he valued different attributes. Ahmed had not worked overseas or in an emergency response; he worked in advocacy, regularly attending high-level meetings with a cohort of Global Health actors whose mission was more policy-focussed. This background was evident when he shared that he would trust "*big, internationally recognised iNGOs*" who worked "*within the kind of pharmaceutic space*", particularly if they were "*seen as a kind of thought leader*".

Ahmed stated that he would not be comfortable using QA information from "*a locally registered NGO, which may have the same operations*" as his own, because they would not be "*held by the same kind of donor dynamics*" (a reference to the donor sourcing restrictions discussed in Chapter 5). He believed that these would provide "*checks and balances*", so "*we can, to some extent, trust that they have the same rigour in terms of procurement mechanisms and same rigour around Supply Chain Management*" (IDI-790, iNGO, Head Office, pharmacy). Other participants also stated that their knowledge of an iNGO's "*quality assurance process*" ("Justin": IDI-696, iNGO, Head Office, logistics) or "*medical logistics system*" ("Hugh":

IDI-269, iNGO, roving, operations) would inform the institutions that they would approach for vendor information in a 'no stock, high stakes' problem.

6.4.1 b) Participant perspectives on medical product quality information from QUAMED.

Several geographically remote participants (i.e. iNGO international staff or from donor organisations) referenced the work of QUAMED when explaining how they might determine whether (or where) to source from the national market. For example, "*we've always relied on QUAMED*" ("Pete": IDI-499, iNGO, roving, operations); "*have I got any [vendors] that [QUAMED] recommend in the country? Cos if I have, I'll go straight to them.*" ("Guy": IDI-775, iNGO, roving, operations); "*ideally you get QUAMED in and you do some sort of, you know, nice review*" ("Elliot": IDI-668, iNGO, Head Office, operations). In 'no stock, high stakes' situations, in which information is scarce, and the risks are uncertain, these participants valued QUAMED data and used it to inform their decision-making.

> *We look, er, for validation from, not only from QUAMED (so, 'has there been a local market assessment?', or 'have these suppliers been validated by QUAMED?') but also from, er (.) FDA[42], or WHO. So, there's a long list of options, five different options, including the last one is, so, other international NGOs.*
>
> **"Kamran": IDI-796, iNGO, Head Office, health.**

Kamran described his iNGO's hierarchy of trust for various QA knowledge producers, which he had developed. The most trusted of the "*five different*" categories were SRAs, QUAMED was somewhere in the middle, and at the bottom were "*other international NGOs*". These preferences were common amongst geographically remote interviewees. So too was overlooking the knowledge of HG-NDRAs, which were generally homogenised and mistrusted by these participants and their organisations.

Kamran's response suggested that data were differentiated according to their source (rather than some other factor like type, age, or method of collection, for example). He also inferred that

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[42] The Food & Drug Administration. The speaker's statement infers that they are referencing the US-FDA, which is recognised as an SRA in donor sourcing policies.

different data types were available from the same organisation (by separately citing QUAMED's "*local market assessment*" and their supplier validation). I wondered how this data differed, so I asked Noah (IDI-586, iNGO, Head Office, pharmacy), a participant who was familiar with QUAMED services, to explain these two types of investigations. He explained that "*validated by QUAMED*" meant that the vendor had received a "*two- or three-day audit*". He felt that this was akin to an investigation by an NDRA. Regarding the other investigation he told me:

> *They'll just do, like, a half to one day technical visit and that just gives you enough of an understanding of their basic operations. And that's much more palatable for a company to accept. "Um. Okay. Well, it's just a half a day, or a full day. Like it's not a full, it's not a full audit." As soon as you say 'audit', it makes people scared.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

This "*local market assessment*" was a compromise. A vendor might refuse an audit (due to the resources required, or because they were "*scared*" of inspection), but they were perceived to be more likely to accept a "*half to one day technical visit*". Although this was insufficient to comprehensively scrutinise the vendor and the quality of their medical products, it afforded QUAMED the opportunity to gather *some* data. This would suggest that, to some extent, assessments were informed by the auditor's impression of the vendor, according to what they had witnessed in a cursory visit.

Nikolas (IDI-458, donor, policy), a policymaker for a bilateral donor, had concerns about QUAMED's "*local market assessments*".

> *Well, {shaking head} I'm always caught, you know, between the wall and the sword. […] First, for me, there is an issue [of doing local market assessments]. I mean it's a big issue, you know? […] [QUAMED] have two types of audit. One which is super light. So, they go by these vendor, they spend, I don't know, four or five days and they visit different suppliers. And then, they spend some hours with them (three, or four, or five hours) and then they say, "Okay, this looks good. Okay, fine." Then they have a little bit more in-depth audits, er, where they, kind of, analyse a little bit more in detail if they comply.*
>
> **"Nikolas": IDI-458, donor, policy.**

Nikolas articulated his concerns about the quality of QUAMED local market assessment data, and its suitability for informing 'no stock, high stakes' decisions. Although he wanted to facilitate access to medical products, he felt uncomfortable with "*super light assessments made by, by QUAMED*", in which iNGOs would "*spend half a million on medicines*" based on data that was collected over only "*three, or four, or five hours*". He told me that his concerns were twofold. First, this was "*a breach of the principle of competition, because what, what they do is they choose {gestures stabbing motion with finger on table} with their finger some suppliers which seem to be okay*". Nikolas felt that this was inappropriate in terms of fairness (particularly given the size of spend), stating that "*it should be an open competition restricted with […] entities which are compliant with certain capacities*". Second, he raised concerns with the quality of the data. He felt as though "*we cannot actually rely 100%*" on the accuracy of the information, because "*basically (.) assessments […] are not renewed every, for instance, two or three years*".

6.4.2 Participant perspectives on estimating the capability of an HG-NDRA for the purposes of reliance on their QA data.

At the beginning of this section, Noah (IDI-586, iNGO, Head Office, pharmacy) "*was thinking about reliance mechanisms*" in response to a 'no stock, high stakes' problem. This included using data from QUAMED and other humanitarian agencies. Later in our interview he revisited the problem and shared that, ultimately:

> *The decision about all this might be like "Okay, well, here we are. All we need to do is accept that we're going to rely on the measures of, you know, the quality assessment that the National Regulatory Agency has done, um, because we think that they're not terrible. {laughs}*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Noah judged the extent to which he could trust an HG-NDRA's "*quality assessment*". If he felt that the risk of poor-quality medical products was tolerable, it opened a selection of national market vendors rather than restricting his iNGO to vendors that had been assessed by QUAMED, or who were known to another iNGO.

I was curious as to what informed Noah's opinion about an HG-NDRA and so I asked, "*How do you go about, um, evaluating the N[D]RA of the country that you're in?*" He responded:

> *How would I evaluate them myself in my head {laughs} is, is, is a reasonable question!*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Noah's 'evaluation' of an HG-NDRA was arbitrary and subject to bias. He proceeded to describe his professional experience of engaging with various HG-NDRAs. As he did so, it seemed that he was trying to understand *why* he had certain impressions of certain HG-NDRAs, as if considering this for the first time.

It seemed that this reflection, and this new awareness, was important to Noah because he returned to the subject of bias at end of our conversation. Having thanked him for the interview, he belittled his contribution and his "*Eurocentric view*". He shared his opinion that people like him, with "*white privilege*", lacked an understanding of "*what's true and what's needed on the ground*" and, as a result, "*there's just so much inequality of medicines*". I asked him for recommendations of who to speak with, who may have a different view, and our conversation turned administrative. Once again, I moved to wrap up the interview, but he returned to the subject of bias:

> *I'm just thinking on the Eurocentric thing. […] The NGO usually gets things from the international wholesalers: it's quality assured, all that stuff. I'm not confident about that premise. […] Ghana and Tanzania and, and Kenya […] (and, you know, even Uganda) like, they've got lots of products on their market that are not great. But their, their standards of what they're registering are really strengthening, really improving a lot. […] [International wholesalers] don't apply an equivalent standard to what you'd get in, in Tanzania. Like, they don't. So, we shouldn't be just assuming that "Oh, they're good, they're fine." And that is like, yeah, we should be doing more local procurement.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Noah questioned the "*premise*" that "*international wholesalers*", who were based in countries that had SRAs, should be automatically accepted. As they purchased stock globally and for export only, he was concerned that these medical products would not be regulated to the same standard as those that were destined for a European population. (Several pharmacists shared these concerns. However, as

these findings relate to international procurement they are beyond the scope of this research and will not be presented in this thesis.)

In addition, Noah conjectured that international wholesalers would not necessarily "*apply an equivalent standard to what you'd get in, in Tanzania*". He was not saying that he trusted the quality of medical products from countries regulated by (what I have termed) an HG-NDRA; indeed, he acknowledged the risk that some medical products "*are not great*". However, he did raise concerns about inequality. First, regarding the inequitable quality of medical products in humanitarian health; the medical products distributed by export-only international wholesalers who cater to humanitarian aid agencies may be of inferior quality to those on the national market of *both* the dispatching SRA *and* the recipient HG-NDRA. Second, regarding the inequity of assumptions about vendors according to nationality, which may impact both medical product quality and availability. He asserted that "*there needs to be a big shift towards*" conducting "*more local procurement*" but recognised that "*how that happens is a long story and a complicated, er, complicated thing, for sure*".

These remarks were unusual compared with the views of most other participants (or even the rest of his own interview). No other participant stated that their estimation of an HG-NDRA's capability would inform their decision of whether to source medical products of uncertain quality in a 'no stock, high stakes' problem. For the most part, as explained in Chapter 5, participants tended to think that either the authority of the HG-NDRA should be respected regardless of their capability, or that the opinion of the HG-NDRA was immaterial. I spoke with one donor participant who felt that this needed to change:

> *Of course, {rolls eyes} the [donor QA] policies refer to "Stringent Regulatory Authorities", or SRAs. […] I think I'm really interested to see how the WLA system[43] works out, that gives us maybe more*

[43] A World Health Organization (WHO) initiative to benchmark the maturity of an NDRA against key indicators, for specific product categories, and so to rank their performance into listed authorities. Chapter 2 refers.

> *of that breakdown of information than we've had before, because we have always worked off, you know: "it's SRA or it's not SRA."*
>
> **"Liam": IDI-764, donor, pharmacy.**

With a roll of his eyes, Liam gestured that he viewed his organisation's use of the SRA designation as outdated (Chapter 2 refers). He was frustrated with the bluntness of "*it's SRA or it's not SRA*" and expressed curiosity about the more granular "*WLA system*", which he hoped would enable him to respond with "*more than a "yes or no"*" to iNGO procurers.

Mention of the WLA system was rare amongst participants; it was only referenced by pharmacists and none of them appeared willing to utilise it (and its benchmarking ratings) when considering 'no stock, high stakes' problems. I was curious as to why this was the case because it seemed like it had the potential to dramatically ease the frequency and tension of 'no stock, high stakes' problems in some countries. I explored perspectives on the system with two international QA pharmacists from an iNGO:

> *KE: Nigeria recently reached [maturity] level three and so, some organisations I speak with say, "Okay, well that's acceptable for us and now we can buy in Nigeria."*
>
> *Genevieve: {exaggeratedly shaking head to indicate disagreement}*
>
> *Interviewer: Okay, Genevieve, you're shaking your… Okay. Interesting.*
>
> *Genevieve: {shakes head vigorously} No! {laughs}*
>
> **"Genevieve": joint IDI-881, iNGO, Head Office, pharmacy.**

Maturity level 3 is defined by the WHO as a "stable, well-functioning, and integrated regulatory system".[159] Genevieve immediately and emphatically disagreed with the notion of sourcing from a country based on its maturity level or WLA status. Her colleague (who had insisted on being present and conducting the IDI jointly) elaborated:

> *No. […] {long inhale, hunches shoulders} I, I, I think Nigeria maybe at some point, (er, definitely not tomorrow), progressing into that. […] We did a few [QA] audits in Nigeria (.) some years ago (.)*

> *and, er, and we selected the ones that were at the {gestures 'high level'} highest level. […] {laughs} Actually, most of the times were not possible, {self-correcting} er, positive. And when they were, they were positive, they were really, er, borderline.*
>
> **"Ursula": joint IDI-460, iNGO, Head Office, pharmacy.**

Note that this pharmacist's opinion of Nigeria's NDRA was guided by "*a few [QA] audits in Nigeria some years ago*". Both interviewees appeared very resistant to the idea of reconsidering their opinion based on the WLA system.

6.5 Conclusion.

In this chapter, I described how participants attempted to navigate uncertainty when seeking sources of medical products. I explored how familiarity shaped participants' perceptions of the risks of substandard and falsified medical products, and their willingness to trust an institution as a source of goods or data. Participants generally relied on familiar institutions (such as QUAMED) and concepts (such as SRAs), while refusing opinions that were viewed as external (such as HG-NDRAs) or novel (such as the WLA system). These perspectives were often justified with personal experiences and overlooked criticisms or evidence that countered them. These views reflected the participant's proximity to the QA knowledge producer; they were more likely to trust systems that they were 'close' to and reject those that were new or unfamiliar. Next, in my final empirical chapter, I will explore factors that influenced a participant's proximity to the patient, and how their positionality could shift their sensitivity to certain risks and their willingness to source medical products of uncertain quality. In Chapter 8, the discussion, I will examine the concept of proximity further.

7

"The risk, you could argue, is the right thing": an examination of factors that influenced participants' willingness to take risks when responding to 'no stock, high stakes' problems.

7.1 Introduction.

7.1.1 Characterisation of 'no stock, high stakes' problems as a conglomeration of risks.

For many years, Pete[44] (IDI-499, iNGO, roving, operations) had supported the delivery of large, logistically complex health projects of international Non-Governmental Organisations (iNGOs) in countries with onerous humanitarian and political challenges. As a manager who had fulfilled Head Office roles, he had worked closely with Quality Assurance (QA) pharmacists and was well versed in the risks of substandard and falsified medical products. However, he was also highly sensitive to the humanitarian health needs of patients (and the potential tragedy of stock-outs), due to his extensive experience of working at project sites. He described 'no stock, high stakes' problems as "*really hard*": "*it's about wanting to do the right thing. […] I don't think it's something that we, I think, that you can really call easily.*" So, it was unsurprising that he was visibly tense, and expressed strong emotion, when sharing his own experiences of delivering humanitarian healthcare within the constraints of QA policy restrictions:

> *{looking down} You go to a field office, and you can visit the pharmacy, and you see that they're out of (.) ahm, lifesaving drugs that you know children need in villages around the district. And we*

[44] All names have been changed. Appendix E refers.

> *haven't got it, ahm, because (.) we're being very, very careful. It's easy to get angry and decide that we need to take a risk.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

Pete's anger was an obvious undercurrent throughout our entire conversation, evident by his agitation, long pauses, and carefully measured speech (and possibly stoked by speaking with me: a former humanitarian pharmacist, who had implemented QA policies in iNGOs). However, he was not "*angry*" with QA restrictions per se; rather, he was troubled by the *extent* to which they were applied.

On the one hand, he had claimed that "*it's not aid if you don't know it's safe*": he felt that an iNGO was not offering "*aid*" if there was reasonable doubt that it may harm, rather than help, the patient. Indeed, he had stated:

> *I don't think that we (.) really have any scenario where we should be {sharp intake of breath} ahm, (.) distributing stuff that we haven't got, ah, {long pause} our own assurances.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

He felt that his iNGO was obligated to assure the quality of medical products sourced for humanitarian health projects. However, almost immediately, he countered this assertion with:

> *{looking down, speaking quietly} Ahm. {very long pause} When you, when you've got a team (.) outlining (.) the impact of not doing it [i.e. sourcing medical products], ahm. {long pause} It's, it's a certainty. It's not, it's not a risk. You've got a certainty of people (.) being sick, or, (.) potentially even children dying. Ahm. Then sometimes, (.) the risk, (.) you could argue, is the right thing.*
>
> **"Pete": IDI-499, iNGO, roving, operations.**

Yet, on the other hand, he was concerned that the requirements would restrict the availability of "*life-saving drugs*" and result in "*people being sick or potentially even children dying*". When reflecting on the choice, he inferred that his iNGO was excessively averse to medical product quality risks and expressed the wish that "*sometimes*" they would "*decide that we need to take a risk*" to source medical products of uncertain quality.

These perspectives on patient harm, and behaviours to act in avoidance of it, were explored in Chapter 4. In that chapter, I presented two interviewees that were certain of their (opposing) choices (yet acknowledged occasion for the alternative). In contrast, Pete was *un*certain of what "*the right thing*" to do was and vacillated between sourcing "*lifesaving drugs*" of potentially poor-quality and "*the impact of not doing*" this. This statement makes the 'no stock, high stakes' problem appear to have a binary solution: to source or not to source? However, the emotional turmoil and nuance of the exchange indicated that the reality was far messier: it was a decision about how much to risk, to whom, for how long, and on what authority.

The use of risk as a conceptual way of making sense of the 'no stock, high stakes' problem was typical amongst all participants. This QA pharmacist explained how he used risk in decision-making:

> *[Decision-making] would involve […] working out what our options are, then kind of doing a risk assessment of what those, what those options are, um, and then making the decision. Then, to go ahead with the local procurement, um, according to the, the lowest risk option of what those options were. Um, and then saying "Okay, well these are the risks that we're taking on. How are we gonna mitigate, you know, what can we do to mitigate those risks? Um, and how long do we have to accept this risk, you know, this heightened risk for?"*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Thinking about the decision in terms of its perceived risks allowed Noah to conceptualise the problem, as well as to organise, evaluate, compare, and communicate the possible options. Many participants took a similar approach. For example: "*you have to* balance *the pros and cons of the risk or benefit of us procuring, or not*" ("Kamran": IDI-796, iNGO, Head Office, health); "*it's always a* balance *of risk, essentially*" ("Elliot": IDI-668, iNGO, Head Office, operations); "*[it] is a sort of risk analysis*" ("Ishaan": IDI-476, iNGO, Country Office, pharmacy). These statements depict the choice, not as a dichotomy, but as an effort to find a solution that correlated to a risk preference, along precarious spectra of interconnected risks, and with no certainty of the outcome.

7.1.2 Participant proximity and its influence on risk perception.

This chapter presents an analysis of the role played by the use of the concept of risk in participant accounts of the 'no stock, high stakes' problem. My use and definition of this word will mirror that of Pete and Noah who, like all other participants, broadly applied it to mean 'the potential for negative sequalae'. Where relevant to the analysis of this chapter, I will reference risks that were explored in previous chapters, including: the risk of injury to the patient due to substandard and falsified medical products or lack of access to treatment (which I covered in Chapter 4), the risk of financial ruin of the iNGO due to disallowances (which I detailed in Chapter 5) and I will present risks to the individual (such as threats to safety, career, and social inclusion). Throughout this chapter I will explore how participants varied in their sensitivities and tolerances of certain risks, and how this influenced their decision-making. When I analysed the risk-related concerns of participants, a pattern emerged. I found that, when faced with a 'no stock, high stakes' problem, some participants concentrated their attention on the welfare of the patient and tended to voice their concerns predominantly around these risks. I will refer to this as being 'patient-focussed'. Other participants spoke more emphatically and for longer about complying with QA policy requirements. I will refer to this as 'policy-focussed'. Many participants, but not all, exhibited a preference for patient-focussed or policy-focussed concerns during interviews.

As I will present, it was generally the case that patient-focussed participants prioritised, and were more sensitive to risking, medical product availability; they tended to be more willing to accept risks related to sourcing medical products of uncertain quality. Conversely, policy-focussed participants often prioritised, and were more sensitive to risking, medical product quality; they appeared more tolerant of risks relating to the availability of medical products. When analysing the attributes of patient-focussed and policy-focussed participants, I identified a common theme: proximity. As explored in Chapter 2, the definition (and significance) of proximity in ethics is debated. My use of the word denotes a (potentially multi-factorial) connectedness that one person has for another being. I will examine proximity in greater depth in the discussion chapter.

In this chapter, I will explore three attributes that emerged as influenced by a participant's proximity to the patient: product, profession, and place. First, I will explain how an interviewee's perception of a medical product's urgency and importance could influence the type and scale of risks that they took (or avoided) and the speed with which they acted. Second, I will offer an example of how an interviewee's profession could influence their priorities and frank risks they experienced via a close examination of logisticians. Third, I will dwell on the significance that participants gave to a person's 'place' in the organisation, which I will consider in terms of status, seniority, and physical location. These findings are intertwined with tensions and mistrust that was observed between Head and Country Office respondents, as many iNGO participants perceived that 'no stock, high stakes' decision-making differed between these two cohorts. Therefore, in anticipation of this section, I invite the reader to pay close attention to participant descriptors whilst reading this chapter, and to whether a speaker is based in Head Office, Country Office, or roves between the two. More detailed attributes for each pseudonymised participant is available in table 18, Appendix E

7.2 Product: how participant perceptions of the medical product influenced their risk sensitivities and proximity to the patient.

7.2.1 The perceived importance of medical products and its influence on participant risk sensitivities.

Ikolo (IDI-359, iNGO, roving, health), a highly experienced medical doctor, vividly described the potential consequences of a stock-out:

> *In a malaria setting, if you stay out of stock for a week, you've lost maybe ten children.*
>
> **"Ikolo": IDI-359, iNGO, roving, health.**

Ikolo's illustration of the potential human cost of supply chain failures in humanitarian contexts was extreme: he referenced a vulnerable population, with a life-threatening illness associated with low-income contexts, that can be cured with cheap, yet irreplaceable, medical products. His example was not merely about the importance of medical products; it served to underline the injustice of 'no

stock, high stakes' problems, in which "*lost*" patients reflected global inequities and iNGO priorities. I will return to this in the discussion.

The potential significance of malaria and the importance of its curative agents is irrefutable. So, consider: what if the conditions of this case were altered? One intuits that a lack of cough syrup would not incur the same sense of crisis, or feelings of distress, as a stock-out of antimalarials. However, what about medical products that fall in between those that are lifesaving and those that are trivial? The variety of medical products needed for a humanitarian health project can be vast, spanning, for example, medicines for mental health conditions, chronic diseases, and surgical anaesthesia, or medical devices for laboratory tests, assisting respiration, or delivering infusions. In this section, I offer an overview of factors that can lead a medical product to be perceived as important, and how this influenced the sourcing behaviour of participants.

7.2.1 a) Perceptions of clinical risk and medical product importance.

Noah (IDI-586, iNGO, Head Office, pharmacy), a QA pharmacist, regularly received calls about medical product stock-outs. He explained that one of his first tasks would be:

> *Categorising the importance of the different medicines, clinically, in terms of their risk. Um, so, it's a risk management kind of process, of saying "Okay, what's the higher risk products here that we <u>really</u> need to focus on?" Um, because we probably won't be able to focus on everything fully.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Like many participants, Noah categorised medical products according to their perceived 'clinical importance' when handling diverse stock-outs. He used his professional judgement to predict the potential medical consequences for prospective patients of each stock-out (due to deleterious consequences for patient or public health) and prioritised the medical products accordingly. His tolerance for the perceived risks associated with poor availability were *greater* for lower priority medical products. However, this was not because he deemed them unimportant per se, but because his capacity (which, presumably, fluctuated with circumstance) was limited. Similarly, Noah was more

tolerant of the perceived risk of poor-quality medical products if they were perceived to harbour a significant 'clinical' risk to the patient.

7.2.1 b) Perceptions of reputational risk and medical product importance.

Having told me of his use of clinical risk as an arbiter of importance, Noah (IDI-586, iNGO, Head Office, pharmacy) then explained how these considerations were layered onto the expectations of his iNGO. He informed me, much later in our conversation, that medical products that were perceived to be significant to the organisation's "*mission*" (to tackle a named condition), were subject to heightened sourcing restrictions.

> *The most important […] was the stuff that really was, revolved around our mission of what we did as an organisation. […] The next level [of medical products…] was important in providing our services, but more supporting. […] The first tier, a lot of that stuff was, we were managing, um, supply of a lot of those products centrally, internationally, in the organisation. But that second tier was really about locally procured products, in particular.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Noah's iNGO was more sensitive to the risk of poor-quality medical products if it was perceived that this could impact the organisation's brand and reputation. They were more tolerant of this risk if the medical product was viewed as ancillary. These sensitivities were reflected in QA policy and in procurement practices. "*Mission*" specific medical products were sourced "*internationally*" (i.e. from international vendors) and managed "*centrally*" (i.e. by the Head Office). All other medical products were sourced by Country Office teams from their respective national markets and "*how they actually did that in practice, I, I, would have differed from country to country.*"

One of the organisations that Olga (IDI-671, donor, pharmacy) had worked for also focussed on tackling a specific disease and had a similar QA policy.

> *QA policy is, er, very permissive for certain category of product. […If] the volume will be low, then, […] quality criteria will be more, more, um, permissive. […] Big volume, big impact on our*

> *reputation, then high [QA] criteria. And for me, ah, {points at chest} this, personally I, I don't find it super ethic.*
>
> **"Olga": IDI-671, donor, pharmacy.**

Core medical products that were needed for the pursuance of the organisation's objective to eradicate a specific disease were subject to "*high [QA] criteria*". The organisation was highly tolerant of the risks presented by stock-outs for these medical products because, purportedly, it was extremely sensitive to the reputational risks of being associated with harm caused by substandard and falsified medical products. However, she explained that the "*QA policy is very permissive*" for other medical products, regardless of their perceived clinical significance or perceived risk of poor-quality. For example, she believed that for "*co-trimoxazole*[45]*, there is, the, the risk [of being substandard or falsified] is higher, for sure, let's say, globally*", but her former organisation had no quality requirements for it.

While Olga felt that her former organisation's approach to medical product QA was unethical, Noah felt that it was practical. Noah had developed his organisation's QA policy *himself* and explained the rationale behind it. He told me that, eventually, he aspired to "*apply minimum standards for quality*" for all medical products (and "*also, you know, a pharmacovigilance system*"). However, quality requirements "*added extra, a lot of extra complexity […] that makes [procurement] more difficult*", a lot of "*extra work […] that was tricky*" for clinicians, and it created a "*quality versus price dilemma*" due to the finances required for the implementation of QA audits. He told me that "*any time you wanna introduce something new in a big international organisation, in each individual country, it's* hard*. It's really hard.*" This "*tiered*" system, which focussed on a handful of "*the most important*" medical products, was practical; it was more palatable to "*Country Directors*" and more manageable for him (because "*you're only (.) really (.) one person and trying {short laugh} to spread that out.*")

[45] Cotrimoxazole is a combination antibiotic used in the treatment of common bacterial infections such as pneumonia.

7.2.1 c) Perceptions of evidence-based medicine and medical product importance.

Different perceptions of the relative importance of a medical product could lead to unpleasant confrontations, as attested by Skye (IDI-101, iNGO, roving, pharmacy), who conflicted with an expatriate clinician during an emergency response:

> *[It is] an ethical dilemma where you're like, well, this medicine isn't on our list [of medical products that are essential for the health project], but we're going to get it flown over with [the iNGO] because one of the doctors has complained (.) loud enough […] They get snotty, they yell. […] If they can't have the medicine they want, they make threats about "well, if somebody dies this is your fault". […] You know, we have a perfectly acceptable alternative, I just think you personally prefer to give, you know, the majority of patients, let's say, diclofenac over ibuprofen. And it's like, there's very limited indications that you would be like, "Yes, this is essential and … {leans forward and raises eyebrows} nobody's going to die". {laughs}*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye described the bullying that she had experienced when overseeing the procurement of medical products during an emergency response. For her, the importance of an additional medical product was weighed against the negative impact that it would have on the agility of her iNGO's mobile clinic and, therefore, their ability to respond to an unfolding emergency. With this approach, the availability of medical products for the individual were in tension with their availability for the population. Even with seemingly banal medical products (or perhaps because of it) she had experienced disagreements of shocking intensity, like ibuprofen (which was on the iNGO's "*list*") and diclofenac (which was not, but which had been requested by a physician)[46]. Skye experienced an "*ethical dilemma*" when weighing the importance of these two drugs; significant resources were required for getting an exceptional item "*flown over*" (i.e. a chartered flight), which she perceived to be wasteful and unnecessary. Yet, by maintaining her position, she risked significant social and professional pressure.

[46] Ibuprofen and diclofenac are non-steroidal anti-inflammatory drugs. They can be used as a simple analgesic, but their selection may be viewed as significant when prescribed for inflammatory disease, or where the patient is undergoing significant bone healing.

Let us imagine the possible risks perceived by the medical doctor in this scenario, to speculate why they were sensitive to a stock-out of diclofenac. If we assume best intent on the part of the doctor, we must also assume that she believed diclofenac to be superior to ibuprofen for her patient(s) and, thus, believed the "*list*" to be inadequate for their needs. This did not equate to the life-threatening clinical risks that were described earlier, but rather to concerns for suboptimal care. She was unable to prescribe the medical product that she believed to be best suited to the patient according to current evidence and, under different circumstances, might be received in her own country. Perhaps this inequity of differing standards conflicted with her ethics, and she used her status to escalate her clinical concerns, to redress perceived systemic barriers that she felt were undermining the quality of patient-centred care. Moreover, perhaps suboptimal prescriptions also conflicted with her professional code, representing legal risks to her practise.

7.2.1 d) Perceptions of status and medical product importance.

Skye (IDI-101, iNGO, roving, pharmacy) dwelled on this experience as she described being "*stuck in the middle*" between doctors and patients, in relation to 'no stock, high stakes' problems. This statement characterised doctors (who she viewed as "*loud*") as having priorities that were distinct from patients (who she saw as "*quiet*").

> *The doctors […] complaint is much louder than the complaints of the patients who aren't getting, you know, the right paracetamol. They've got one that dissolves in your throat. […] How do we weigh up the complaints of the patients? […] People just don't complain as a patient. And particularly in a humanitarian crisis, I think you feel a lot less empowered to say something and a lot more (.) grateful for what you can get.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye's observations highlighted that people differed in their opinion of which medical products were important – but that the needs and preferences of patients may be unvoiced or unheard in a humanitarian crisis. She depicted those with status and privilege as voicing "*loud*" complaints, capable of influencing the risk sensitivities of those around them; she characterised patients as "*less*

empowered", passive recipients who were unable to effect change. I am unable to comment on how patients perceived medical product importance, as none were interviewed for this study[47]. However, because few participants mentioned patients (or caregivers, or the community), data suggests that their preferences were not well represented and that they lacked an active role in decision-making.

7.2.1 e) Perceptions of poor-quality risks and medical product importance.

The perceived importance of ensuring that a medical product was available was in tension with the perspective that its quality was important. If participants perceived QA restrictions to be less applicable or significant to a certain medical product, then they were generally comfortable with sourcing it from a national vendor. This behaviour was evident if the interviewee thought that it was unlikely for a particular medical product to be substandard or falsified – or if they were unconcerned by the potential harm that would be caused by a poor-quality medical product.

> *[It] doesn't mean all those [substandard and falsified medical] products are (.) {searches for word} bad. […] It might not be working 100%, but it works 95% {long pause} of its intended form. […] If you take paracetamol – whether there's 500 mg active ingredient in there or 450 (.) {pulls face} (.) {shaking head} You won't, you won't notice the difference. […] It's not, it's not life threatening. Whereas, if you have other products, erm, where you get an overdose, or an underdose, it does.*
>
> **"Viktor": IDI-626, vendor, logistics.**

Viktor contrasted poor-quality paracetamol tablets to "*certain vaccines*"; he informed me that the latter would have a more deleterious impact if "*something went wrong with the production*". Several participants made similar statements during data collection. For example: "*insulin […] wouldn't have the most negative effects, if it was made {gestures quotes} "wrong" – {laughing} in my non-expertise opinion!*" ("Taylor": FGD-121, iNGO, Head Office, logistics); "*latex gloves [… or] any face covering will be helpful, so, even if it doesn't meet with the specifications that [the vendors] claim it does*" ("Kamran": IDI-796, iNGO, Head Office, health). These participants were less sensitive to the risks associated with poor-quality if

[47] Intentionally, due to ethical concerns, as explained in Chapter 3.

they trusted the medical products and thus were more accepting of national sourcing. These participants suggested that some medical products were inherently 'safe', either due to their unlikelihood of being poor-quality, or because they perceived them to pose a tolerable threat if they were substandard or falsified.

7.2.2 The perceived urgency of medical products and its influence on participant risk sensitivities.

If the perceived (un)importance of a medical product meant that an iNGO planned to source it from the national market, another debate arose: with what *urgency* should this occur? Ahmed (IDI-790, iNGO, Head Office, pharmacy), a pharmacist, explained that there was a tension between time and process, because rapid sourcing usually meant compromising information gathering:

> *You have to balance what is, what is the optimal, kind of, process, versus what is timely. […] Having done all the checks that you, you would feel comfortable with, going for locally sourced manufacture – locally sourced, kind of, product – versus waiting 'X' amount of days.*
>
> **"Ahmed": IDI-790, iNGO, Head Office, pharmacy.**

Neither importing a medical product that complied with the iNGO's QA policy, nor conducting a QA audit was "*timely*". However, most participants did not "*feel comfortable*" with sourcing medical products from an uncertain supplier with zero checks. The balance between a timely response and an informed choice was arbitrary during 'no stock, high stakes' problems, according to Ahmed. What a participant found "*comfortable*" when considering the urgency with which a stock-out should be addressed existed along a spectrum of *discomfort*; discomfort of their ignorance of the safety and efficacy of available medical products, and discomfort of the possible and perceived suffering being endured by patients who were waiting for the medical product. However, as I will present, a history of differing perspectives on urgency sometimes bred intra-organisational conflict and mistrust.

Policy- and patient- focussed participants tended to prioritise time and processes differently (except for lifesaving medical products, as I will explain in the next section). When I asked, "*what would you say a 'good' ['no stock, high stakes'] decision looks like?*", patient-focussed participants usually prioritised

the need for a rapid decision: "*I think the good decision is what will permit the population to get quick access to drugs*" ("Ikolo": IDI-359, iNGO, roving, health), "*providing immediate help to the communities that need them should be paramount*" ("John": IDI-284, iNGO, roving, pharmacy). However, policy-focussed participants consistently offered 'knowledge' as the hallmark characteristic of 'good' decision-making.

> *I think a good decision, in this case, would have to be […] getting the most information that you can and making (.) the best decision that you have, based on that, what is probably going to be limited information.*
>
> **"Liam": IDI-764, donor, pharmacy.**

> *A good decision would involve […] assessing possibilities. […] Then to go ahead with the local procurement, um, according to the, the lowest risk option of what those options were.*
>
> **"Noah": IDI-586, iNGO, Head Office, pharmacy.**

Pharmacists, like these two participants, tended to prize knowledge that related to the quality of the medical product (which was evident from the broader context of the discussion.) Their descriptions of "*information*" would often narrowly focus on technical data garnered from supplier assessments. This tended not to be the case for policy-focussed participants who were non-pharmacists:

> *There should be, you know, like a lot of consultations […] other than making like a blind turn into decisions.*
>
> **"Youssef": FGD-554, iNGO, Country Office, logistics.**

> *Literally: {gestures using an abacus} you do your table, and you do all your, kind of, probabilities and likelihood – and then you get the emotional one and you say, "The emotional impact of not doing this." {long pause} And you do include that. In the end you use a judgement call. […] Most decisions should be human.*
>
> **"Derek": FGD-969, iNGO, Head Office, logistics.**

Non-pharmacists were more likely to approach decision-making via "*a lot of consultations*" and to consider "*the emotional impact*" of their perceived options. These differences may reflect different styles of problem-solving arising from differing epistemological backgrounds, or it may be that the pharmacist's role in 'no stock, high stakes' decision-making was to input their analysis into group consultations (thus the quotes may have reflected different stages of collaborative decision-making). Therefore, despite their agreement that information (and process) was essential for making a good

decision, policy-focussed participants appeared to disagree on what constituted 'data' and how it should be applied to the problem.

Either way, my analysis of participants' comments was that policy-focussed respondents generally lacked the urgency exhibited by patient-focussed participants when faced with a medical product stock-out. For example, Justin (IDI-696, iNGO, Head Office, logistics), a policy-focussed participant, quite bluntly described the extent to which he was willing to tolerate patient "*suffering*":

> *I would try everything to get the drugs, if it was going to cost people's lives. […] If it was a drug that wasn't going to cost lives but will bring a little bit of suffering, I would probably hold out a bit longer. […] I don't think… Across the board there isn't consistency in this – and even within organisations, there isn't consistency.*
>
> **"Justin": IDI-696, iNGO, Head Office, logistics.**

Justin's sense of urgency was related to how urgent he perceived the medical product to be, according to predictions of "*severity*" of consequences if the condition was left untreated. I found his candour unsettlingly vague: how much suffering, for how many lives, was equivalent to how much more time? Of course, these factors were not quantifiable – they were perceived, subjective, and complex. It was unsurprising, then, that he reported a lack of "*consistency*" regarding the time taken to reach a decision.

Many patient-focussed participants were frustrated about the time their iNGO took to reach a 'no stock, high stakes' decision. Ishaan (IDI-476, iNGO, Country Office, pharmacy) acknowledged that medical product "*quality is important*" but felt that Head Office "*should expedite*" their decision-making.

> *For this long time, we have suffered from this [time taken to reach a decision], because until we are getting the final decision, we are not able to supply these medicines or the medical consumables to the beneficiaries or our health posts.*
>
> **"Ishaan": IDI-476, iNGO, Country Office, pharmacy.**

Ishaan expressed frustration at the time taken to receive a 'no stock, high stakes' sourcing decision from his Head Office. Sometimes the wait was extreme. For example, I learned through an informal conversation with James (IDI-137, iNGO, Head Office, logistics) of a nine-month delay to an iNGO's

medical product sourcing, which was attributed to repeated requests (from Head Office staff) for information to be gathered or clarified (by Country Office staff).

When I asked Ishaan "*what are they doing?*" (referring to the purpose of the "*review process*" by "*central office*"), he responded:

> *Er. {laughs freely and for a long time} That's actually a hard question! I don't know how they [i.e. Head Office] add value for all these cases.*
>
> **"Ishaan": IDI-476, iNGO, Country Office, pharmacy.**

Ishaan was amused by my question because I had assumed that the process held some meaning, whereas he did not perceive that it contributed anything of "*value*". Indeed, he told me that the purpose of "*the control mechanism and, er, policy*" was to "*ensure value for money*" and to protect "*the reputation*" of the organisation. This meant that he had "*suffered*" in wait for a process that he found neither helpful, nor perceived to be primarily motivated by care for the patient.

These sentiments were echoed by another patient-focussed participant, who shared an example of a very time-sensitive stock-out:

> *That patient would have died if we hadn't bought insulin locally. And yet, if we'd followed our policies and procedures it would have led to the death of the patient, because we would have had to fill out a form, get all the batch and expiry information, send it, wait a week to get the outcome back.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye shared her view that her iNGO's system was geared towards safeguarding medical product quality rather than availability. To emphasize her point she offered the example of insulin, which had been immediately required for the treatment of diabetic ketoacidosis[48].

Another participant was similarly disenfranchised. Martin (IDI-231, iNGO, Head Office, pharmacy) spoke not only of information being prioritised over the urgency of medical products, but also over their

[48] This experience informed the creation of the diabetic patient scenario used in the FGDs. Chapter 3 and appendix C refers.

quality. As a Head Office QA pharmacist, he was responsible for gathering and analysing data relating to the perceived quality of the medical product and offering his expert judgement to senior decision-makers. He relayed that, during 'no stock, high stakes' problems, they might wonder, "*"Okay. Maybe we should use the same sources as another organisation, so we should not take the decision ourselves."*" He viewed the use of data from "*peer*" agencies as decision avoidance and had challenged this practice:

> *I told them, "Yes, but I know that those sources are not complying with the, with the standards of the WHO. So, it's the same question [of risk]." {replying as if the senior decision-maker} "Yeah, but in that case, it, it won't be our responsibility." […] {speaking as himself} So, you see the level of courage, huh? {laughs}*
>
> **"Martin": IDI-231, iNGO, Head Office, pharmacy.**

Martin claimed that his organisation had selected vendors that had failed QA audits, if they perceived that they could deny responsibility for poor-quality medical products. Reports from other participants lent weight to view that the (hidden) purpose of the process to gathering information was to alleviate organisational risk, rather than being motivated by a concern for patient welfare. For example, this policy-focussed logistician informed me that a 'good' 'no stock, high stakes' decision involved "*documentation!*" She elaborated:

> *{emphasizing every word} Katherine! Write things down! Whatever it is. Make sure that it is written down and can be referenced in the future.*
>
> **"Taylor": FGD-121, iNGO, Head Office, logistics.**

This answer did not focus on what made a 'good' decision for the *patient*; rather, it offered an insight into her perception that, "*in the future*", she would need to explain the decision (perhaps to mitigate legal threats or the risks of disallowances that were explored in Chapter 5.) "*Documentation*" was essential because "*one wrong decision […] could end up resulting in you losing your licence to operate*" ("Ahmed": IDI-790, iNGO, Head Office, pharmacy) and "*endanger […] your future work*" ("Guy": IDI-775, iNGO, Country Office, operations). These perceived risks made data collection (and investing time in knowledge generation) important.

Taylor (FGD-121, iNGO, Head Office, logistics) also shared that a medical product's urgency could be determined by factors that were unrelated to the patient:

> *The {gestures quotes} "concept" of emergency can get lost in an organisation that's grant funded, like us. A lot of times we consider "urgency" and "emergency" as something different than "lifesaving". So, its donor-driven grants are ending, um, need to spend money, that kind of thing. And that's used (the term "emergency" is used) for that more often than, um, you know, lifesaving need based on disaster, outbreak, or something like that.*
>
> **"Taylor": FGD-121, iNGO, Head Office, logistics.**

Taylor thought that urgency to source medical products was more frequently related to donor deadlines than patient need, suggesting that underspend was resolved by procuring consumables (e.g. medical products), regardless of their significance to the patient. It was unclear whether such a bookkeeping "*emergency*" involved sourcing medical products of uncertain quality.

Some policy-focussed interviewees gained comfort from process when facing difficult 'no stock, high stakes' problems. However, these processes were not the external-facing QA policies that mirrored donor requirements and WHO recommendations. They were processes for when QA was unfeasible, to help decision-makers respond to 'no stock, high stakes' problems. No policymaker that I spoke with was willing to "*share*" these "*internal*" documents ("Ursula": joint IDI-460, iNGO, Head Office, pharmacy) that were "*owned by the organisation*" due to "*legal*" and "*media*" concerns ("Kamran": IDI-796, iNGO, Head Office, health). However, one of them was willing to broadly (and proudly) explain the process that he had devised for his iNGO:

> *[The pharmacists] provide a whole paragraph, or two paragraphs, of each of the items. (Or for each of the line, in fact, because there's an Excel sheet.) So, these are all of the items that are requested and there's, there's, there's, lots of columns of the source and everything. And, and so, they will fill out that whole sheet. And based on that reasoning, or based on that validation, they would say [the sourcing parameters].*
>
> **"Kamran": IDI-796, iNGO, Head Office, health.**

This policy-focussed, Head Office clinician also appeared in Chapter 4 (section 4.3.3), in my exploration of the ethics of abstaining from sourcing medical products of uncertain quality. He, like

many other interviewees who were troubled by compromising QA policies, embraced technocratic procedures. The process seemed comforting to Kamran, though he later admitted that "*we have never had [the process], er, validated*". He also shared that the data inputted into the "*excel sheet*" might include self-assessments from vendors (raising concerns regarding a conflict of interest) and lists of vendors used by other iNGOs (that did not detail which medical products, when, or under what circumstances). Thus, Kamran's description of a "*robust process*" in which decisions were not "*subjective*" because they required pharmacists to complete "*lots of columns of the source*" and "*a whole paragraph*" for each medical product seemed bombastic; he seemed focussed on confidently reassuring me that his iNGO was behaving responsibly but was unwilling to share the procedure or recognise any limitations of it.

I spoke with a patient-focussed pharmacist who had previously worked at Kamran's iNGO, and she offered me her perspective of the process:

> *I need to submit the country of manufacturer, the brand name, the pack size, the batch, and the expiry of the product that I'm going to get. There's this massive table and you just… Like, you have to have a really strong IT system to be able to get that information to begin with. And so, it's not even practical to get the information, now that we need to be able to get local procurement approved. And realistically; if I sent through a list of… say it's an emergency and I send a list of a whole procurement load, so say 100 items, you cannot tell me that in a suitable timeframe somebody is going to go through and individually check each batch and expiry.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

The wealth of data that was a source of pride for the policy-focussed Kamran (IDI-796, iNGO, Head Office, health) was seen as an overwhelming burden by patient-focussed Skye (IDI-101, iNGO, roving, pharmacy). She explained the challenge of data management in humanitarian settings and the unfeasibility of the information gathering process during emergencies. She perceived that time spent following "*policies and procedures*" was motivated by a wish to "*cover our arses, rather than looking at how do we deliver something safely for patients*".

7.2.3 The concept of 'lifesaving' medical products.

Participants tended to depict 'no stock, high stakes' problems as those concerning 'lifesaving' medical products, characterising them as both irrefutably important and exceptionally urgent. This conceptual category of medical products tended to unify policy- and patient- focussed participants alike, both of whom became sensitized to patient risks and were more willing to tolerate risks associated with poor-quality. For example: "*the ultimate objective is to save the precious lives and, er, if the, the, the products are not up to that 100% standard (which are in advanced countries), but they can still save lives, we should be flexible to have those*" ("Farid": IDI-267, iNGO, Country Office, logistics); "*if the medicine is really require for the lifesaving of any, er, people, […] our first priority should be – must be – that timely supply of the medicine. […] Things like the quality […are] the secondary priorities in that context.*" ("Arjun": IDI-147, iNGO, Country Office, logistics).

Most participants found 'no stock, high stakes' decisions to be simpler for 'lifesaving' medical products. This participant summarised why:

> *If the person is going to die anyway, the risk becomes easier to take. Because it is "do nothing they die; do something, they could die, they could live." That's an <u>easy</u> kind of risk-based choice.*
>
> **"Derek": FGD-969, iNGO, Head Office, logistics.**

Like many interviewees, Derek (FGD-969, iNGO, Head Office, logistics) took an odds-based approached the problem. He compared the potential worst-case outcomes for the patient for each choice and selected the option that he perceived to offer the greatest probability that "*they could live*". By focussing on a single risk (the likelihood that the patient will "*die*") and simplifying his options (to "*do nothing*" or "*do something*"), the decision became "*easy*" for him.

Several interviewees adopted this approach. For example, Jabari (FGD-113, iNGO, Country Office, health) echoed the same line of thinking:

> *[If] we are not a hundred percent sure that the medication is of very good quality – at least the possibility, the probability of this drug saving the patient […] is better than not giving the patient any medication – because that, for sure, would lead to a more dangerous complication.*
>
> **"Jabari": FGD-113, iNGO, Country Office, health.**

Another participant offered an illustration of this decision-making in practice:

> *We had this last year with antivenom, (.) for snake bites (.) in South Sudan. And we said, "Yes. Go and buy it. Go and buy it on the local market", we didn't have it in place, "because (.) it will save the life." You had to take that risk. {long pause, clenches jaw, shrugs, throws up hands} I don't know! I don't know if that was right or wrong, but to me that was the right decision.*
>
> **"Lynn": FGD-385, iNGO, Head Office, health.**

Snake antivenom typified a "*lifesaving*" medical product (examples of which also included antimalarials, adrenaline, insulin, and amoxicillin suspension). They belonged to different therapeutic categories, but all were medicines, and all had the potential to radically reverse a life-threatening condition.

When Lynn (FGD-385, iNGO, Head Office, health) considered buying snake antivenom, she was not simply applying the "*do something […] they could live*" approach that was adopted by her colleague. It was an act of hope, in which she claimed that taking this risk had secured patient survival: "*go and buy it on the local market […] because it will save the life*". This kind of faith was relatively common amongst patient-focussed participants, irrespective of role or location (although no pharmacists aired such views). However, despite initially equating the act of 'sourcing' with the outcome of 'saving', she remained uncertain as to whether it was "*right or wrong*", describing it as a "*a real dilemma*".

There was one instance of 'lifesaving' being used to argue *against* taking risks associated with sourcing medical products of uncertain quality:

> *They said "no" last year to adrenaline (.) for local procurement. […] "The patient will die, so if we give them bad adrenaline {furrows brow} they're still going to die; we haven't impacted the outcome."*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye described a "*local procurement*" request for adrenaline (for the management of anaphylaxis) for an upcoming Yellow Fever vaccination campaign[49]. She was clearly bemused at the Head Office decision to refuse the application. Her explanation was reminiscent of the previous odds-based calculation, which compared the probability of patient survival and selected the option with the perceived greater chance of a positive outcome. However, this decision-maker was concerned with the probability of a fatally unsafe medical product. If this was a risk, they (reportedly) chose to abstain from sourcing the medical product, no matter the need, which was justified by arguing that they had not caused a *more* negative outcome.

Although this could simply be an outlying opinion, this approach is not morally intuitive, nor does it align with any other empirical data collected in this study (regarding decision-making flexibility when faced with urgent need). Therefore, it warrants deeper consideration. It is possible that the decision-maker was influenced by undisclosed risks. For example, maybe they were concerned that unused "*bad adrenaline*" would be siphoned into general circulation after the campaign, thus risking (non-iNGO) patients, where the impact could not be tracked or mitigated. Or perhaps they weighed the relatively low risk of anaphylaxis against the perceived risk that it would be used when not indicated. This would mean the administration of a medical product of uncertain quality to patients that were not in life-threatening danger: a different normative paradigm and one with which the decision-maker may not have been comfortable.

7.3 Profession: how a participant's profession could influence their prioritisation and preference of risks using the case example of logisticians.

One of the Focus Group Discussion (FGD) scenarios was a warehouse fire (Chapter 3 and appendix C refers); a terrible incident in which several months of stock for an entire provincial health system

[49] Anaphylaxis is a risk with many vaccines. The incidence of anaphylaxis with Yellow Fever vaccine is estimated to be around 1.3 patients per 100,000 doses: https://travelhealthpro.org.uk/media_lib/mlib-uploads/full/the-green-book-chapter-35-yellow-fever-march-2024.pdf

was destroyed. Taylor (FGD-121, iNGO, Head Office, logistics), a policy-focussed logistician, was incredulous of the scenario's Country Director's decision to "*indiscriminately purchase three months' worth of medical products*":

> *Like, donor rules, compliance… Um, you know, especially at a scale that big. […] More than a million dollars' worth of purchasing that could potentially be disallowable, could potentially be bad product. I mean, and the harm that that would do (.) is just sort of (.) incredible. And without any assessment? Without any quality assurance? I just, I don't… There is just nothing to that scenario, {laughing} that that's the way you should go! I mean, I'm not saying you, like, you shouldn't do any national procurement in that scenario. Yes, you should. But you should take a couple of steps! {laughs}*
>
> **"Taylor": FGD-121, iNGO, Head Office, logistics.**

Like many policy-focussed participants, Taylor emphasized the risk of sourcing medical products of uncertain quality and the perceived importance of organisational processes. Her first concerns were "*donor rules*" and policy "*compliance*" rather than patient care, and she implicitly disregarded the knowledge and approval of the Host Government's National Drug Regulatory Authority (NDRA). Yet, note that she agreed that the iNGO "*should*" proceed with "*national procurement*". She, like all participants, recognised that medical products were essential to the delivery of health services. However, as presented in the previous section, Taylor viewed the "*steps*" of gathering and analysing data to be essential to decision-making. Indeed, questioning her own sense of urgency, she acknowledged that "*probably there's lifesaving things in here*", but she also felt that "*you can't directly connect it*" to the patient or "*somebody [who] was going to potentially die.*" I will reflect on how circumstances such as this, which obscured a participant's view of the patient, undermined proximity to them in the discussion chapter.

These statements reinforce the findings of the previous section but are included here to explore them from another angle: profession. There were numerous instances of participant agnosticism to the perceived importance or urgency of a medical product. Those from iNGOs, who did so on grounds of "*donor rules*" and procedural "*compliance*", predominantly stemmed from a single professional group for whom 'no stock, high stakes' tensions were observed to be especially intense.

Logisticians were responsible for managing the health supply chain (and thus the availability of medical products at the health clinic) *and* for ensuring that procurement practices complied with organisational policies, donor rules, and national legislation. Moreover, they lacked the clinical knowledge to interpret the significance of a stock-out for themselves. The following quotes from logisticians (of various iNGOs, geographical locations, and seniority) showcase that, unlike other iNGO participants, they were unlikely to be influenced by claims of medical product importance or urgency. I will also explore the professional challenges that this engendered.

Youssef (FGD-554, iNGO, Country Office, logistics) was guided by the rules and regulations of their iNGO and the boundaries of their designated authority:

> *I will not go for, for, for waiving of the quality assurance requirements and do the, do the purchases from the local market.*
>
> **"Youssef": FGD-554, iNGO, Country Office, logistics.**

As we spoke, he reminded me of a sailor navigating the "*doubtful*" pharmaceutical market with utter faith in the guiding light of his organisation's "*quality assurance requirements*". At no point did he question whether the policies were appropriate. If the requirements were satisfied (or an exemption from them was permitted by the "*Country Director*") then that was "*fine*"; if not, he was "*not obliged to compromise the quality*" of medical products, which may cause "*the situation or condition of the patient*" to worsen.

Logisticians often vocalised a commitment to procedural compliance but, as explained in Chapter 5, it was unfeasible to meet donor QA requirements during 'no stock, high stakes' problems. In these circumstances, they lacked familiarity with the nature of the medical product and its significance to patient care, which sometimes strained their relationship with clinical colleagues (who tended to be patient-focussed):

> *The part that will bubble up is that you're having a health expert talking to a logistician. […] None of us know what insulin does, or cannot, can do to harm a person if it's not (.) made right.*
>
> **"Taylor": FGD-121, iNGO, Head Office, logistics.**

As Taylor considered the diabetic patient scenario,[50] she described a difficult power dynamic that she felt could arise due to a knowledge divide between a "*health expert*" and a "*logistician*". Logisticians were the gatekeepers to procurement: they controlled what was sourced and how. However, they were ignorant of clinical matters and were unable to reach their own conclusions regarding whether *this* situation met the conditions of a legally, procedurally, or morally justifiable deviation from policy (and assumption of associated risks). Thus, logisticians depended on the guidance of "*health experts*" but did not necessarily trust them, because they were motivated by different concerns and vulnerabilities.

> *I can think of a couple of scenarios where […], as a logistician working in DRC, or working in CAR[51], where the physician said, "That's urgent. Go get it." And then when I check with HQ and ring somebody up they're like, "That's not really that urgent." I can think of one or two scenarios like that. I had the wherewithal to ring up HQ – and I was the white person, so it was easier to ring up HQ and ask.*
>
> **"Derek": FGD-969, iNGO, Head Office, logistics.**

Derek, who had worked 'on-site' in humanitarian health locations in his early career, mistrusted the judgement of the national "*physician*" on "*a couple*" of occasions. Upon receiving a request to circumvent QA policy on the premise of clinical need, he "*had the wherewithal*" to "*check with HQ*". His short statement brings a host of relational dynamics into stark relief, and how they can influence medical product quality and availability. Not only was his handling of the 'no stock, high stakes' problem influenced by who he trusted (which itself may have been informed by his unconscious bias, perceptions of expertise, and norms regarding prioritisation), but it was also shaped by his privilege. As "*the white person […] it was easier to ring up HQ*" to seek advice. This discrimination, in addition to the inference that Head Office overturned the request, provide an insight into intraorganizational power asymmetries. I will return to these matters later in the chapter and in the discussion.

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[50] A scenario in which an unconscious diabetic patient urgently requires insulin, but none is available at the clinic. Summarised in Chapter 3 and detailed in Appendix C.
[51] The Democratic Republic of Congo (DRC) and the Central African Republic (CAR).

James (IDI-137, iNGO, Head Office, logistics) related an incident in which operational colleagues were "*pushing for doing things quickly*". This meant that there was insufficient time to "*buy them [i.e. medical products] the proper way*". His Country Director asked him to explain his "*refusal*" to purchase the medical products, to which he replied:

> *I'm refusing to buy them for the Deputy Country Director. But you're the Power of Attorney: you have the legal responsibility for everything. So, if you tell me, if you tell me that you will sign your name on it, and say that you understand that this is a potential financial loss to the organisation (because it won't pass an audit), and it's a potential risk to the organisation ('cause we wouldn't be able to do all of our usual due diligences), then, yeah – I'll prepare a contract for you. But I'll do it for you, 'cause you're the, you're the person who's legally responsible.*
>
> **"James": IDI-137, iNGO, Country Office, logistics.**

James, like most logisticians, fulfilled the role of procedural guardian for his team and was tasked with ensuring that "*due diligences*" were followed to protect their organisation from legal and financial risk. The ramifications of bypassing these processes were made explicit by Olivier (FGD-751, iNGO, roving, logistics), who stated that "*complying with the [QA] process*" was essential for Country Office logisticians because "*deviations from the process are seen as reasons for fraud, or corruption, and losing your job*". However, as evident in James' statement, "*refusing to buy*" medical products that "*won't pass an audit*" sometimes conflicted with prevailing norms (for medical products perceived to be lifesaving, for example) and led to social and professional risks.

An instance of this was observed during an FGD in which four of the five members had emphatically spoken in support of sourcing insulin for a diabetic patient experiencing a medical emergency. The fifth member, Olivier (FGD-751, iNGO, roving, logistics), appeared nervous as he began a response that contradicted that of his peers – and was met with shock by the other members:

> *Olivier: {sharp inhale, appears tense} Yeah. So, the… {smiles} To be, to be unpopular. {short, nervous laugh}*
> *Lynn: {places hand over mouth in surprise}*
> *Taylor: {places head in hands}*
> *Derek: {suddenly sits upright, frowns}*
>
> **"Olivier": FGD-751, iNGO, roving, logistics.**

Olivier offered a "*a counterargument*" that focussed on health risks to the patient and possible security consequences to clinic staff. His colleagues responded with comments that questioned his ability to work in a team, his priorities, and his credibility: "*I know that's not our policy [but…] we have to have more than a, "No! Can't do it.""* ("Florence": FGD-462, iNGO, Head Office, health); "*I feel sad that decision is driven by compliance to a policy*" ("Lynn": FGD-385, iNGO, Head Office, health); "*I think good logisticians in the Aid sector, […] learn all of the rules very well, so you know how far you can bend them without breaking them*" ("Derek": FGD-969, iNGO, Head Office, logistics). Olivier visibly disengaged after these comments (by looking at his phone) and did not speak for the remainder of the FGD without prompting. These interactions shed light on the possible personal risks of voicing unpopular opinions (and the disincentives for doing so).

In many of these interactions, displeasure is aimed at the logistician. However, Pete (IDI-499, iNGO, Head Office, operations), the Operations Manager and former logistician who opened this chapter, felt that it reflected the 'system':

> *{long pause, becomes subdued} If you make people work within a, a policy that doesn't (.) allow them to deliver, ahm, their programmes (and their programmes are, (.) sort of, in some cases life and death), then (.) that puts people in, in a really difficult spot. Ahm. And that's where sometimes the wrong decisions get made, I guess. Yeah.*
>
> **"Pete: IDI-499, iNGO, roving, operations.**

Pete viewed QA "*policy*", rather than the people who enforce it, as being responsible for compromising the availability of medical products in 'no stock, high stakes' problems and spoke of the distress that this creates for those torn between the two. Like for Arjun (IDI-147, iNGO, Country Office, logistics), who shyly made the following request after I presented him with the In-Depth Interview (IDI) warehouse fire scenario[52]:

> *Um… {looks away} If I, um, {shifts on seat} um, don't consider myself as a, er, as a [iNGO] employee? {smiles}* ***KE: Sure! {smiles} Yeah, you don't have to.*** *If I consider myself from*

[52] A scenario in which a warehouse that stores an iNGO's medical supplies has burnt down, causing massive stock-outs. Summarised in Chapter 3 and detailed in Appendix C.

> *different, different, er, um, role, then I, definitely, will, um, er, procure the medicines from, from the, er, local, um, manufacturers. That's to, to get the things as soon as possible.*
>
> **"Arjun": IDI-147, iNGO, Country Office, logistics.**

Noting the tension between time and knowledge, Arjun went on to outline how he would "*get [supplies] as fast as possible within the minimum time frame. Then other remaining quantity, we can take much more time to get the more, much more analysis, more evaluation on the quality aspects, and all those things*". His emphatic speech indicated that he saw this as the ethically right course of action; however, these comments represented his personal views. Had he answered as an "*employee*", his response and priorities would have differed. He did not comment on his feelings regarding being forced to follow priorities that differed with his own, though this is a situation that is well-researched as causing moral distress (Chapter 2 refers).

7.4 Place: participant perceptions of distance on priorities and risk preferences, and the intra-organisational conflict that this engendered.

7.4.1 Participant perspectives on distance.

Many patient-focussed participants believed that physical distance was significant to how 'no stock, high stakes' problems were resolved. Like Skye (IDI-101, iNGO, roving, pharmacy), who believed that remote decision-makers were unlikely to act in the perceived best interests of the patient:

> *These decisions are all being made by people who either haven't worked in the field or haven't worked in the field for a very long time, and I think that the patient gets forgotten.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye claimed that "*the patient gets forgotten*" by those in Head Office because they are unsighted and obscured by a host of competing responsibilities, such as "*the quality piece and ensuring the drug is of quality*". She felt that "*the further you get away from the field, the more we're concerned about risk and liability and the legality side of things and the less it feels like we're concerned about the actual patient.*" She concluded that "*the system is inherently dangerous, because it is taking the decision-making too far away*"

from the patient (and those that were witness to the needs of the patient), which created a system focussed on the application of QA policies.

The observation that physical remoteness of a decision-maker led to emotional remoteness from the patient was reinforced by Elliot (IDI-668, iNGO, Head Office, operations), who reflected on his personal difficulties with empathising with a 'no stock, high stakes' situation. I asked him what guides his decision-making, and he replied:

> *What guides it, I think, is, is always, "Is this right for the people receiving this (.) service?" […] And it's, it's very easy to lose that, the longer you're out of a country programme context. You know, sitting in an ivory tower somewhere, and all you're thinking about is systems, and regulatory things, and all that kind of thing. It's quite easy to lose that, but I've always tried to keep that, somehow. You know is… "How would I feel if this was me?"*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

When Elliot, a patient-focussed participant, reflected on being situated "*in an ivory tower*", he used imagery that spoke of more than just a lack of *physical* proximity. An ivory tower is a symbol of privilege and opulence that is starkly different to the humanitarian environment. This called Elliot's ability to comprehend the austerity of the context into question and depicted his lack of *narrative* proximity (i.e. his ability to connect with the patient's story). Ivory towers are also a marker of power and status that contrast with the characteristics of those requiring aid. This cast doubt as to whether Elliot could identify with the patient's situation, thus highlighting the lack of *emotional* proximity between those who make decisions and those who are affected by them. Elliot explained that he sought to mitigate his distance by an exercise in empathy and by envisioning himself as one of the "*the people*": "*how would I feel if this was me?*"

7.4.2 Perspectives of Head Office participants on where 'no stock, high stakes' decisions should be made.

When I asked Elliot (IDI-668, iNGO, Head Office, operations) where 'no stock, high stakes' decisions should be made (in an organisational sense), his answer aligned with his views on physical distance: "*in terms*

of decision making, […] obviously, it needs to be as local as possible". One of the reasons that he offered for persisting in handling the problem himself, at Head Office, was perceived obligation:

> *I think, sometimes, when you're an international 'leader', sort of, forced to make a decision, you kind of feel like, sometimes, I think you're feeling like you're, you're doing it because nobody else can do it, or you know, is doing it. Um. And that's why it's come to you to, to make that decision.*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

This patient-focussed executive (who depicted the uncertainty of 'no stock, high stakes' problems in Chapter 4) felt that decisions were intentionally and preferentially escalated by Country Office staff (who wished to avoid them), rather than due to policy or authority. His statement echoed my observation that many IDI participants appeared unwilling to reach a decision in the warehouse fire scenario. For example: "*I wouldn't want that to be my decision in the end. {Laughs} I'd be trying to punt that up to someone more senior.*" ("Guy": IDI-775, iNGO, roving, operations); "*[there are] black holes of decision-making where […] no one's (.) qualified to make a decision or **allowed** to make a decision*" ("Skye": IDI-101, iNGO, roving, pharmacy). However, this view contradicted the statements of many Country Office staff, as I will present later. Given his sentiments and status, I found it interesting that Elliot (IDI-668, iNGO, Head Office, operations) did not *expect* Country Office staff to reach a decision but, rather, accepted the role of decision-maker. This (and the participants' avoidance of answering the scenario), suggested that the problem was viewed as difficult, contentious, and multidisciplinary; a problem that could not be (easily) delegated and whose escalation was justified.

In my study, interviewees from Head Office roles were reticent to relinquish control of 'no stock, high stakes' decisions, as they were uncertain whether Country Office staff would reach a solution that they deemed satisfactory. Elliot was "*hopeful that we can create*" capacity for "*local*" decision-making, but felt that it would need training and tools to create it:

> *{sighs} If you equip these guys on the ground in the right way, with the right training, […] and trust, you know, trust that you've got very good people there. And make sure that you're developing them, and, you know, and developing the next generation after them.*
>
> **"Elliot": IDI-668, iNGO, Head Office, operations.**

Elliot's top-down approach to "*the right training*" involved equipment and Head Office-devised development. Many Head Office participants that I spoke with agreed with the *concept* of decentralised decision-making. They also tended to think that national staff should undergo training before being considered suited to handling 'no stock, high stakes' problems (but did not mention that this was necessary for Head Office staff).

When I asked FGD participants from the Head Office group "*what role should [the Country Office] have in decision-making?*", they offered the following insights:

> *I mean, {laughs} Lynn, how, how enthusiastic would you be about countries taking decisions on the technical elements (.) of pharmaceutical evaluations? {laughs} I mean, I, you know, at the moment, perhaps, a little bit less enthusiastic about it (.) is maybe fair to say?* ***Lynn: {emphatic nodding}*** ***Yes.*** *Over time, basically, I think, you know, you would want to empower countries, and you'd want them to be able to take informed decisions about what it is that they are doing. Er. And I'm not sure if that's there. […] Some countries are very good at it, some countries aren't.*
>
> **"Olivier": FGD-751, iNGO, roving, logistics.**

Olivier characterised Head Office decision-makers as more knowledgeable educators, who would "*empower countries […] to take informed decisions*". This was common amongst international staff, and in keeping with attitudes towards HG-NDRAs (as described in Chapter 5).

Lynn (FGD-385, iNGO, Head Office, health), the clinician to whom Olivier directed the comment, agreed. She elaborated that the perceived deficiencies of Country Office technical expertise related to "*capacity*" (because "*in some countries we've got five pharmacists – in other countries we have none*") as well as "*the maturity of the, of the system and the people that are, that are interacting with that system*". The word "*maturity*" is multifaceted; in this context it educed being embedded, experienced, wise, and stable, but Lynn's meaning was ambiguous. Her colleague followed-up with a more explicit assessment:

> *We have different dynamics in our different country (.) programmes, depending on the leadership there and, and as Lynn said, the staffing and their seniority or their experience. […] We are {gestures a concertina} centralising ['no stock, high stakes' decision-making…] – and that might*

> *loosen up later on as we get more comfortable, and people understand […] the policy. But, yeah. So, I think it differs country by country. {long pause} There are, there are some wild ones! There are some people that think they can just make the decisions (.) {shakes head} themselves – and they don't fully understand the implications of those decisions.*
>
> **"Taylor": FGD-121, iNGO, Head Office, logistics.**

Taylor felt that many Country Office staff could not be trusted to reach judicious 'no stock, high stakes' decisions. A fourth member of the group also had reservations about entrusting national staff with decision-making because he believed that "*out in these developing economies*", the "*morals are quite different*". He felt that:

> *The value of an individual life in some cultures is less than it would be in our moral compass. (.) And people are making decisions, they are making decisions related to their moral compass. […] I do think that's, there's a difference between the HQ, (especially the Western HQ) driven policy and the local interpretation of how to use it. […] Most individuals would probably try and solve the problem. Whether they would solve it right or not is a question.*
>
> **"Derek": FGD-969, iNGO, Head Office, logistics.**

I will dwell on the prejudice of this statement (and cross-reference it to numerous other quotes in the thesis) in the Discussion chapter. Derek felt that Country Office staff could not be trusted to solve 'no stock, high stakes' problems because their ethics would be likely to diverge from that of the iNGO Head Office and its policies. At present, without normative research, there are no objectively "*right*" 'no stock, high stakes' decisions; therefore, I interpreted this statement to mean that Derek believed that national staff may "*solve the problem*" differently to him.

7.4.3 Perspectives on whether national staff require protection from the challenges and consequences of 'no stock, high stakes' decisions.

These statements, which questioned the educational, emotional, and moral suitability of national staff to handle 'no stock, high stakes' problems, were not the overt reasons supplied for centralising the decision. Many Head Office participants, from several different iNGOs, stated that national staff were not granted decision-making authority for their own protection.

> *[The pharmacist] have to be expat, [i.e. an expatriate] just to keep the distance and just to be, let's say, um, um, be out of their conflict of interest. […] We have a national staff, er, as a deputy (or let's say assistant) of this person, which is not assistant or deputy because it's less important. […] Sometime you are to go to discuss with [national drug regulatory] authority; sometime it's better to send a local, […] but at the same time we need to be careful, because this person can be under pressure – and if there is something maybe (.) complicated to say, huh, it's much better if it's an expat. But as [our iNGO], we needed to protect the local staff, because they are pharmacist.*
>
> **"Genevieve": joint IDI-881, iNGO, Head Office, pharmacy.**

Genevieve perceived "*distance*" to be important. However, unlike previous statements, distance was *positive* and was a product of nationality, rather than a variable trait or physical location. By giving national staff the role of "*deputy or, let's say, assistant*", she argued that her iNGO "*protected*" them from becoming embroiled in political risk, because "*if they have something to, to say against to [the iNGO], he can always say, "He's my boss. She's my boss. Talk with her. Talk with him*". This was perceived to be important for protecting their "*future*" as a "*registered pharmacist*" in the country, a statement that implicitly characterised the national "*authority*" as revengeful.

However, Genevieve's statements were intertwined with an ulterior concern that, perhaps, prevented promotion: that "*local staff*" may come "*under pressure*" during negotiations with the government (for the controversial importation permissions described in Chapter 5) and would face a "*conflict of interest*" (between the objectives of the iNGO and the career prospects of the individual). She appeared to attempt to balance these remarks with statements that her iNGO "*give a lot of importance to*" national staff, particularly during supplier assessments, because they "*speaks the languages*" and "*knows the market*". (These narrow 'recognitions' of importance are associated with epistemological inequity and neocolonialism,[467] as I will touch upon in the Discussion chapter). It was noted that this approach was not informed by context: it was a blanket "*policy of [her iNGO]*".

One policy-focussed participant felt that national staff also needed protection from the perceived *consequences* of 'no stock, high stakes' decisions, citing the importance of avoiding poor-quality medical products due to the threat of physical reprisal. During the diabetic patient scenario, Olivier (FGD-751, iNGO, roving, logistics) defended his unpopular views (that I described in section 7.3) by

exclaiming: "*What happens if the person then dies […] and then the next day that person's entire family and extended family come over and burn down the office, because you were seen to be the one who gave them rubbish medicine?*" Perhaps this candour was induced through duress; few other participants were so outspoken, but another participant signposted that these views were common in her iNGO:

> *This assumption that we make that we will be harmed if a patient comes to harm. Like, our staff will physically be harmed. […] That concept that we're just instantly assuming that other people are more savage, essentially. That, you know, people will not understand a properly worded disclosure about an incident. That they will just turn around and, like, attack our staff or, you know, someone will be murdered because of these slip-ups.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye believed that Head Office decision-makers assumed that communities and the Host Government "*people are more savage*" – a statement loaded with colonial history (and possibly intentionally so, given the broader context of our discussion). She shared that this fear had led her iNGO to choose not to disclose an incident involving poor-quality medical products to the Host Government and community affected by them. However, she acknowledged that physical threats were occasionally a problem in certain contexts: "*I guess there was some issues in Afghanistan that were more valid.*" Yet, for her, this was a reason to hand over decision-making authority, rather than to control it:

> *It's easy for us to make a decision [at Head Office] to say, "Oh no! Afghanistan, they can't buy anything locally!" But we're not the ones that are going to get shot at the end of the day and we don't necessarily have that knowledge […] so I feel like local level [decision-making] is better than central level.*
>
> **"Skye": IDI-101, iNGO, roving, pharmacy.**

Skye viewed contextual knowledge to be crucial for decision-making in high-threat environments. An example of a life-threatening security risk was shared by Yazhu (IC-450, iNGO, Country Office, pharmacy), from a time when he was a member of national staff working in a Fragile State. His role involved the assessment and selection of vendors, where national procurement had been permitted by Head Office. He described being offered bribes from local militia in return for selecting certain vendors; he

was concerned that accepting inducements would harm patients and that refusing them would harm his family. He claimed that he declined all offers. He is now living as a refugee.

I wondered how other national staff felt about their protection at the expense of decision-making authority. I informed the focus group of Country Office participants that participants had told me that "*people in Head Office have to make the decisions, so that our Country Office staff aren't targeted, or threatened, um, by decisions that might not be (.) agreed with by the national government, or by patients and beneficiaries – and if something goes wrong, we want country office staff to be able to say, you know, "It's not our fault. It's people at head office.'*". When I asked, "*What are your thoughts on that?*" there was an immediate change in the atmosphere; the participants were obviously uncomfortable. Omar (FGD-209, iNGO, Country Office, pharmacy), a relatively junior pharmacist, looked away from the camera, covered his mouth with his hands, and laughed nervously when invited to speak. He did not offer an opinion. Youssef (FGD-554, iNGO, Country Office, logistics), an experienced logistician, hunched his shoulders and, with some encouragement, made an abstract reference to, "*the most important thing is what are our internal policies.*" The most senior member of the group, Jabari (FGD-113, iNGO, Country Office, health), offered the following assessment:

> *{sharp inhale} Ah. {shakes head} I mean, it… I don't know how much risk it is to make this decision. […] It depends on the context, but at least from the countries I worked in, yes, there is government, er, would put pressure on you to procure locally. They put a lot of bureaucratic processes to limit the number of, like the, er, importation. Er, but they will not really directly threaten you like, er, physically, er, because you make that decision.*
>
> **"Jabari": FGD-113, iNGO, Country Office, health.**

Jabari acknowledged that political pressure may occur during 'no stock, high stakes' problems, but stated his view that physical threats were unlikely in many contexts. He continued, "*if the Country Programme team felt that that specific NGO, in that country programme, felt that that is a risk, I think, yeah, that decision may be right.*" Here he has emphasized that a specific context may warrant measures to protect the safety of staff but, crucially, highlighted that this should be identified and requested by "*the Country Programme team*".

7.4.4 Perspectives of Country Office participants on where ‘no stock, high stakes’ decisions should be made.

Jabari (FGD-113, iNGO, Country Office, health) was a medical doctor from Central Africa with a wealth of international humanitarian health experience in patient-facing roles, from numerous iNGOs. Unlike many participants, his responses consistently and explicitly focussed on the best interests of the patient (according to his own opinion) and were remarkably bereft of concern for organisational culture and policy. When he spoke, he seemed self-assured and open to debating with other members of his FGD. His views on proximity and decision-making during ‘no stock, high stakes’ problems aligned with the perceptions of most other Country Office participants (and conflicted with most from Head Office). His confidence and clarity make him well-placed to illustrate this position:

> *Leaving the decision completely to people in headquarters, er, would really disarm the [Country Office] staff, because they are the ones who are seeing these beneficiaries and seeing things physically. […] Reading about it from email or, er, from a report is completely different. So, the same people who have argued against [sourcing medical products of uncertain quality] when they are away (like, from a distance), might argue, er, for it, when they see the actual beneficiary. So, er, I think, er… Yeah. Um. (.) If you're in the field, you, if you see these, er, beneficiaries, you would, you would, you would compromise a lot of things, because you just wanted to save all their lives – and the decision should be, er, based on saving lives.*
>
> **“Jabari”: FGD-113, iNGO, Country Office, health.**

Jabari felt that place was important; he felt that witnessing patient suffering would compel Head Office staff to “*compromise a lot of things*” related to medical product quality requirements. His statements made several assumptions and inferences. First, that Country Office staff would choose to source medical products of uncertain quality, and that this course of action was in the interests of – and would – save lives. Second, that Head Office staff would refuse to source medical products of uncertain quality and that, rather than being driven by a concern for patient wellbeing, this was because they prioritised organisational risks. Third, he believed that these conflicting views resulted from distant decision-makers having a reduced capacity to empathise with the patient, and that patient-focussed individuals (i.e. who prioritised patient “*lives*”) should handle the decision.

Therefore, he surmised that 'no stock, high stakes' decisions should be handled by Country Office staff who have witnessed the problem.

Youssef (FGD-554, iNGO, Country Office, logistics), a *policy*-focussed interviewee in the same FGD, agreed with his conclusion:

> *Decision-making between the Country Office and the decision-making between the Headquarter; here, the most important things need to be taken into consideration is that "who has the better understanding of the context?" […If] I'm only relying on the informations that I'm just getting from the meetings, or from the emails; […] that will not give me, er, a very better understanding. […] If I have that ground reality, and I have been to the missions, so, I will be more, better positioned to do, to make that decision, than someone sitting on top of me somewhere outside of the region, and have never been to the area, or never have been to the region.*
>
> **"Youssef": FGD-554, iNGO, Country Office, logistics.**

For Youssef, "*the most important thing […is] "who has a better understanding of the context?"*" Yet, he did not feel that *anyone* based in the Country Office should make the decision. How could they, he wondered, if they had "*not been […] into the health facilities where we are working, […] and to the warehouses which we are supporting, […and] into the camps where we have a lot of interventions*"? His statement depicted a layered and diffuse organisation, which dissolved the binary perspective of Country Office *or* Head Office. For him, the closer to the situation the better, because of the advantages and insights of contextual expertise.

Another type of expertise was referenced by participants: technical expertise. As previously stated, many Head Office staff perceived themselves as possessing superior technical expertise to Country Office staff *and* Country Office staff being insufficiently trained to handle the decision. Ishaan (IDI-476, iNGO, Country Office, pharmacy), like many other participants who were national staff, disagreed.

> *We have the expertise. So, it's doesn't require to send this to the centre or region. For example, in [my country] context you have the pharmacist. You have the tender specialist. […] The manager procurement have the experience, because he, he is, he or she is around twelve/fifteen years he*

> *have spent with this procurement process. He knows the [country] context. He knows the [country] procurement law. He knows the [country] government structure, infrastructure.*
>
> **"Ishaan": IDI-476, iNGO, Country Office, pharmacy.**

Earlier in this chapter, Ishaan had described how he "*suffered*" while waiting for 'no stock, high stakes' decisions from Head Office, which he felt did not add "*value*". It is unsurprising, then, that he felt that these problems should be handled by him and his colleagues. Not only did he highlight the technical capabilities of his team, he argued that they were *more* suitable to handle the decision than Head Office, citing greater experience and superior contextual knowledge.

7.5 Conclusion.

In this chapter I uncovered how participants' relationship with risk was central to the way in which they understood and responded to 'no stock, high stakes' problems. I described how they differed in their anticipation of how different risks might threaten the patient, the organisation, and themselves. I explained that participants differed in their sense of responsibility for addressing perceived risks, and in their beliefs about how to address them. I noted that participants varied in their prioritisation of risks, their sensitivity or tolerance of them, and the extent to which they were willing to take them – and that this could be influenced via circumstance. I identified several of these influencing factors and selected three to present in this chapter: product, profession, and place. Throughout the chapter, my analysis suggested that these three factors all related to a participant's proximity to the patient – to the sense of connectedness that the participant felt to the patient and their needs. Factors that strengthened connectedness generally led to an increased willingness to tolerate the perceived risks of acting in the patients perceived best interests. Often these participants chose to prioritise the availability (rather than quality) of medical products, to varying extents. Conversely, I found that factors that competed with the perceived best interests of the patient – or conspired to 'obscure' or dehumanise them – tended to result in more reluctance to source medical products of uncertain quality.

A consequence of different proximities, and thus different priorities, was its impact on intra-organisational conflict. I described some of the dynamics of 'no stock, high stakes' decision-making; that many Country Office participants viewed those in Head Office to be overly policy-focussed and excessively tolerant of the risks associated with stock-outs, while many Head Office participants viewed those in Country Office positions to be cavalier in their tolerance of the risk of poor-quality medical products and inadequate to the task of 'no stock, high stakes' decision-making. I found an incongruence between where the seat of decision-making lay (mostly with Head Office) and where many participants felt that it should reside (generally decentralised and 'close' to the problem). While both Head and Country Office participants supported the idea of decentralising 'no stock, high stakes' decision-making in theory, the former were reported to escalate the problem in practice, whilst the latter expressed unwillingness to cede power and control. Having presented an analysis of the data in chapters 4 - 7, in the next chapter I will examine a theme that is woven throughout them and discuss the implications of my findings. In my discussion I will explore proximity, and its profound impact on trust, power, and patient care in 'no stock, high stakes' problems.

8

Discussion.

8.1 The patient gets forgotten.

In this doctoral research I have identified, analysed, and detailed a previously undocumented ethical problem. The situation that I have termed a 'no stock, high stakes' problem presents the decision-maker with a tragic choice, because all feasible options carry the risk of patient death and personal sacrifice.[26 27 292 309] The decision is complicated by "unknowable uncertainties" like, will this drug kill or cure my patient?[301 317 474] And by moral uncertainties like, to what extent is the availability of a medical product more important than its quality, and how does this equation shift over time or according to patient need and vulnerability? Moreover, it raises normative questions like, who has the moral authority to make this decision and to take risks on behalf of the patient?[475-477] The enormous stakes inevitably heighten the emotions that surround the decision.[33 294 300] During my study, participants exhibited hope, fear, desperation, and moral stress, and found different ways to cope with it; some avoided it, some took unilateral action, and some imagined that things were different.[33 297 298 338] Currently there is no normative guidance regarding how to respond; participant decisions were arbitrary, inconsistent, and conflicted (both in terms of internal wrangling and between professionals).[289 293]

However, as I will explore in this chapter, somewhere amongst all the wrangling and debating "*the patient gets forgotten*" ("Skye": IDI-101, iNGO, roving, pharmacy). Patients that are human, dignified, and equal were absent from 'no stock, high stakes' decision-making; rather, in my study, patients were often conveyed as an abstract concept and a legitimising purpose.[48 49 478] (Section 7.2, for example.) I found that systems operated in a manner that neglected a patient's personhood, translating them into

a financial estimate of spending that might be disallowed under the donor's grant and re-imagining them as passive receptacles of aid.[62 269 479] These systems were unbalanced in terms of resolving the 'no stock, high stakes' problem: they valorised medical product quality and overlooked the significance of medical product availability. (As evident in section 5.3.2, for example). Accountability for how these decisions impacted patient care appeared to be lacking and largely self-regulated.[266 326 480] This was further compounded by opaque processes and undisclosed outcomes. Indeed, without feedback on how 'no stock, high stakes' decisions affected patients and communities, their voicelessness and invisibility were cemented.[14 62 348]

In this chapter, I consider my findings in the wider scope of humanitarian health and within the broader landscape of academic research. In the first part of this chapter, section 8.2, I reflect on factors that impacted a participant's connectedness to the patient (at an individual, micro-level) and how this could influence their perspective on the ethics of the problem.[336 337 341 343 350] Here, I draw upon research into proximity to offer insight into 'no stock, high stakes' choice behaviour. Then, in section 8.3, I consider what these findings indicate about organisational, meso-level relationships. Informed by research on relational vulnerability, I propose a model of interdependencies in which the international Non-Governmental Organisation (iNGO) is subject to a complex web of poly-governance in a dominant neoliberal frame that disincentivises patient-focussed care.[83 84 266 334 346 347 481] In section 8.4, I dwell upon the inequities and injustices wrought by this system on patients, their caregivers, and their State.[92 255 260 324 482] Like all research, this study and my findings are subject to limitations, which I outline in section 8.5. Finally, in section 8.6, I offer recommendations for action and further research.

8.2 Caring and proximity: how risk sensitivities and tolerances differed according to the proximity or obscurity of the patient in 'no stock, high stakes' problems.

8.2.1 A balance of risks.

In section 7.1, I described how some participants perceived there to be a conglomeration of potential risks that were in tension with one another during 'no stock, high stakes' problems; the choice to avoid or reduce one perceived risk possibly enhanced the risk of some other undesirable consequence. For example, the risk of disallowances was perceived to increase when a decision-maker sourced medical products that did not comply with donor quality requirements, and thus was in direct tension with the perceived risk of patient harm due to untreated health conditions. (See section 5.3.2). The urgency of sourcing was in tension with the time needed to research sourcing options; thus, arguably, the number of patients at risk of a stock-out (resulting from the duration of the problem) was in tension with the perceived likelihood of sourcing poor-quality medical products (though this may be a non-linear relationship). (See section 7.2.2). Personal circumstances added yet more complexity to the decision-making crucible, shifting the experience and perception of threat with security, career, and reputation concerns. (For example, 4.3.3 c).

The ultimate decision depended on the sensitivity of that participant, at that time, to various risks, and the extent to which they were willing to tolerate them; a sensitivity that was modulated by their proximity to the patient.[59 336 340] I will turn to the imagery of a balance to explain this in greater depth, as several participants referred to 'no stock, high stakes' problems as a "*balance of risk*", or similar (like Elliot in section 4.3.2). Thus, imagine a scale, or weight balance, like the one depicted in figure 11. Either side represents the participant's choice: whether to source a medical product of uncertain quality, or whether to abstain from doing so, when navigating a 'no stock, high stakes' problem. In a sense the decision is binary: the decision-maker will buy



Figure 11: Image of a weight balance.

medical products, or they will abstain from doing so. However, if choosing to source medical products of uncertain quality, there is enormous potential variation (for example, which medical products, from where, how many, and for how long?) Therefore, the decision is also scalar, depending on the extent to which the decision-maker is willing to take risks. Let us imagine that this is indicated by the angle of the beam.

It is the decision-maker's task to place weights upon the balance. In this conceptual model, the weights represent perceived risks. Participants varied in where and whether they placed the weights. For example, some participants viewed a risk as irrelevant (like the conflicting perspectives on security threats that I outlined in section 7.4.3). Sometimes participants felt that a weight was relevant, but that it was not their responsibility to burden it (for example, in section 5.4 I presented differing views on who was responsible for medical product quality assurance).

To add further complexity, it was also the decision-maker's responsibility to assign each weight with a mass. The mass represents the significance of each risk but, unlike tangible weights, this was perceived, estimated, and arguably unknowable. Therefore, participants were guided by the prominence that it appeared to have to them, from their position, and according to their experience and worldview.[315 342 481] Sometimes weights were fully or partially obscured from certain positions and decision-makers would rely on witness reports to gauge them. (As depicted in section 7.2.2). For example, staff working in project sites may have minimal interaction with the donor or their policies, whilst Head Office staff may not have visited the project site and its patients. Therefore, iNGO staff relayed information to one another, describing the risk from their own perspective. (This was particularly evident in confidential records of decisions, the findings of which are presented in section 4.2.2). This introduced a social aspect to decision-making, in which the credibility, reasoning, and agenda of the 'observer' were interpreted by the decision-maker when considering how and whether to apply the information, in addition to interpretating the risk itself.[39 226 241 249 314 483] (For example, in Chapters 6 and 7 I described the epistemological gatekeeping of knowledge regarding medical product Quality Assurance (QA) by some Northern hemisphere participants). Next, I detail how

proximity to the patient influenced choice behaviour through altering their perception of and sensitivity to various risks.

8.2.2 Proximity, obscurity, and concern for the patient.

In Chapter 7, I presented three attributes that were found to influence a participant’s ‘no stock, high stakes’ choice (product, profession, and place) by modulating their sense of connectedness to the patient. Attributes that improved a participant’s metaphorical or actual ‘sight’ of the patient’s circumstances tended to increase sensitivity for patient wellbeing; consequently, decisions were more likely to be grounded in what were perceived to be the patient’s best interests.[37 311 337 342 343 350] I termed this being ‘patient-focussed’. Patient-focussed participants often prioritised medical product availability; they usually chose to source medical products of uncertain quality in ‘no stock, high stakes’ problems. Conversely, if attributes ‘obscured’ the patient from the participant’s view then they were generally less sensitive to risks that they perceived may harm the patient, and they tended to dwell on risks that were not directly attributable to the affected population.[60 83 314 481] I labelled these participants as ‘policy-focussed’ because I found that their concerns chiefly related to non-compliance with QA policy. Policy-focussed participants often prioritised medical product quality; they were usually more tolerant of stock-outs than patient-focussed participants and articulated greater aversion to sourcing medical products of uncertain quality. (See section 4.3.3 for a summary of these views).

Many participants felt that geographical remoteness was the primary attribute in determining whether a decision-maker acted in the patient’s best interests. (As outlined in section 7.4.1). Several patient-focussed participants argued that those in Head Office were disconnected from the patient and overly tolerant of perceived risks of patient harm; many believed that if policy-focussed participants were to witness patient need, then they would better appreciate the detrimental impact of medical product stock-outs, and all other concerns would be rendered insignificant. These assertions align with prominent theories of proximity and moral distance, which claim that those who

are unable to witness the outcome of their decision are more likely to be comfortable with verdicts that detrimentally impact patient care (than those who are in proximity to the patient and the decision's consequences).[340 342 349 350 484]

However, my analysis indicated that physical location did not offer a consistent relationship to connectedness and choice behaviour. For example, some Country Office participants were policy-focussed, and they were situated closer to the patient than any patient-focussed participants from a Head Office. (Some logisticians in section 7.3, for example). In their theoretical research into the distance effects of moral reasoning, Nagel and Waldmann note that physical location may be conflated with other morally relevant attributes.[336 342] These conclusions support my own analysis; participants in Head Office roles were more likely to have responsibilities that involved creating or enforcing policies than those in Country Office positions, whilst those in Roving or Country Office positions were more likely to be involved with the clinical care or operational delivery of the project than those at Head Office.

In section 7.3, I examined the role of logisticians to illustrate how professional responsibilities could shape a participant's proximity to the patient. Logisticians were not inured to patient wellbeing, yet nearly all these participants prioritised QA policy compliance over clinical need. These concerns were not necessarily driven by a lack of physical proximity to the patient; rather, the prominence of competing concerns obscured the interviewee's view of the patient.[85 314 315 378] Some participants with a logistics background reported that the removal of policy requirements (or the punitive reprisals for non-compliance) would be sufficient to re-focus them on the perceived needs of the patient and, moreover, to alter their response to a 'no stock, high stakes' problem (like Arjun in section 7.3). It is feasible that a participant's moral proximity was impeded when their professional responsibilities were in tension with what they perceived to be the morally appropriate course of action.[38 39 260 297 311 337 338 485 486]

Regardless of place or profession, nearly all participants became patient-focussed if they perceived a medical product to be "*lifesaving*". This is, perhaps, because the term creates a narrative proximity, promoting understanding of the situation and empathy with the patient.[311 337 338 341 486] The title is value-laden; it acknowledges the human life ("*life*saving") for whom the medical product is intended, inferring that the decision-maker's action will determine the patient's fate. Paradoxically, narrative proximity was often undermined by scale.[296 339] Although large stock-out events (like the warehouse fire scenario) could have involved many "lifesaving" medical products, FGD participants were *less* compelled to prioritise their availability and these discussions tended to be less patient-focussed. (Examples woven throughout section 7.2). The reasons for this could be three-fold. First, greater stock-outs will involve greater spending and, therefore, policy-focussed concerns are probably more prominent.[48 263] (The vulnerability model presented in section 8.3 offers insight into the drivers of this). Second, the scale of the problem could interfere with a feeling of connectedness with the patient, because of the difficulty of conceptualising individual patients rather than a faceless mass.[313 339 349] Third, perhaps some participants were overwhelmed by the problem and distressed by their inability to resolve it; research has identified that avoidance and a reduced willingness to respond is associated with stressful circumstances.[33 297 338]

The narrative proximity afforded by the clarity of a lifesaving medicine was lost for medical products that were not deemed "lifesaving". This was because patients were largely discussed in terms of the absent medical product; with this lens, the situation is automatically dehumanised, impacting empathy, connectedness, and proximity.[269 487 488] Moreover, when debating how to respond, the perceived and relative significance of the medical product's indication was used as a proxy for patient need. (See section 7.2.1). This reduces the affected patient to a single caricature of need that does not account for comorbidities, prognoses, treatment preferences, and familial responsibilities, for example.[479] Nor does it consider the broader healthcare burden that may result, and how this impacts communities or national health systems.[326 489] For example, learning about a stock-out of an analgesic does not provide one with knowledge about patient suffering, nor the risks that they might take to alleviate it.[60 61]

'No stock, high stakes' decisions were largely made by those in Head Office. Some of these participants attempted to mitigate their distance by visualising 'a' patient, by recalling past experiences, or by imagining a loved one as the patient.[295 336 340 490] These techniques served to humanise the patient, promote empathy, and engender a connectedness that, sometimes, resulted in patient-focussed decision-making. However, for policy-focussed participants, this was not the case. These participants lacked physical proximity to the patient, their moral proximity was obscured by competing responsibilities, and their narrative proximity was undermined by communication conventions, which were inadequate for conveying the particularities of the patient.[335 337 338] As a result, they were less likely to display connectedness and empathy for the patient, more likely to tolerate perceived patient harms, and were more sensitive to organisational risks.[296 315 340 487] Yet, let us assume that no participant viewed their decisions as immoral. Proximity to the patient altered a participant's conceptualisation of fundamental aspects of 'no stock, high stakes' problems (like the patient, acts of harm, and minimum standards), leading to different perspectives on the ethics of the decision.[45 59 292 302 350 490] I will examine these next.

8.2.3 How proximity to the patient influenced the choice behaviour of participants in 'no stock, high stakes' problems.

8.2.3 a) <u>How conceptualisation of the patient differed according to proximity to the patient.</u>

Participants differed in their view of when 'people' became 'patients' and how their responsibilities to either one differed. (For example, compare participant statements in section 4.3). For patient-focussed participants, the concept of the patient commonly related to the population living within a catchment area. Their expressions of care tended to encompass perceived and anticipated needs, which might accommodate referral options and risks following patient discharge. Some policy-focussed participants seemed to have a narrower definition of the patient, which related to people receiving care at the iNGO health facility. The latter distanced the iNGO from responsibility for

availability. (After all, ‘people’ who lack access to medical products are disadvantaged members of a population with unmet needs enduring a humanitarian crisis; they are not ‘patients’ who have a right to healthcare that is being denied).[49 329] Yet, this is not necessarily to say that a participant’s drive to help patients reduced with distance; rather, findings from my study suggested that participants with different proximities (and different foci) conceptualised ‘the patient’, their rights, and how best to care for them, in different ways.

Policy-focussed participants tended to take a strategic view of ‘no stock, high stakes’ problems; their concept of ‘the patient’ was not limited to the project site in question. They commonly argued that prioritising medical product quality avoided ‘disallowances’ (section 5.3.2 refers), which prevented economic damage to the iNGO. This protected patients beyond the project in question (both in the future and in other locations) because it safeguarded funding. This concept of ‘the patient’ represented the entire reach of the iNGO, with poor judgement potentially threating other projects in that country, or with that donor, or for the whole organisation.[59 83 486] Patient-focussed participants tended to use simplistic and short-term probability estimates to reach a decision in the perceived best interests of the project’s population (like in section 7.2.3); however, policy-focussed participants tended to act conservatively to maintain organisational stability, in the perceived best interests of “the many” current and potential patients served by the iNGO.

Yet, similarities remained. Most participants I spoke with in my study, whether based in Head or Country Office, did not routinely interact with patients or their caregivers. As such, when discussing ‘no stock, high stakes’ problems, they could not personify the patient with facts such as name, clinician, condition, or other identifiers. Indeed, many participants did not communicate about people as individuals in human terms; they spoke of an absent medicine, a disallowance risk, an epidemiological estimate, or a vendor’s quote, for example.[335 488] Patients were often a vague (albeit an urgent and constant) backdrop to interviews, rather than assuming a real and complex shape.[329 486 491] In this dehumanised state, what emerged (or, rather, what remained) was an idealised and simplified version of ‘*a* patient’.[329 486 491] The idealised patient did not have treatment preferences,

comorbidities, hypersensitivities, social circumstances, religious beliefs, or cultural traditions, to consider. They lacked specific or awkward demands and were constantly ready to receive whatever aid was gifted upon them; they were vulnerable and grateful. The patient, as a concept, was always remembered and was the driving force of humanitarian industry. The patient, as a human, was forgotten. In section 8.3, I will relate this concept of the patient to the iNGO's legitimate purpose and examine the interdependencies between 'people in need' and the business of aid.

8.2.3 b) How perceptions of patient harm and moral obligation differed according to proximity to the patient.

In section 4.3.3, I described participant perspectives on the ethics of 'no stock, high stakes' problems. I explored opposing views using the words of two interviewees, both of whom were certain and passionate in their beliefs, which enabled a detailed analysis of underlying values and perceived obligations. Interestingly, both were strongly motivated by the will not to harm patients; however, their differing positionalities led them to different interpretations of which choice constituted an 'act' of harm, and which choice led to harm for which they did not feel directly responsible. When facing a 'no stock, high stakes' problem, individuals chose to act in avoidance of the greatest perceived harm, rather than pursuing the action of the greatest perceived benefit. [336] [340] [481] Perspectives on what constituted the greater act of harm differed according to the interviewee's proximity to the patient. Let us re-visit patient-focussed Rohan (IDI-502, iNGO, Country Office, logistics), who was responsible for the uninterrupted supply of medical products in his Southern hemisphere iNGO (which did not have a QA policy) and policy-focussed Kamran (IDI-796, iNGO, Head Office, health), who was a medical doctor based in Head Office (and was the author of his iNGO's QA policy).

Like most patient-focussed participants, Rohan tended to prioritise medical product availability. He viewed the choice to abstain from sourcing medical products of uncertain quality as tantamount to neglect; he perceived that he would be responsible for causing harm that befell patients who were unable to access healthcare because he had 'failed to act'. He told me that he refused to "*withdraw*

support". The word "*withdraw*" in this statement is important; Rohan delineated a difference between passively withholding aid for a person in need and, in his view, actively reneging on a pledge to provide care to a dependent party with whom there was a pre-existing arrangement.[377] Moreover, he did not perceive that he would be directly responsible for the harm caused by poor-quality medical products, which he viewed as a responsibility of the Host Government. Rohan's positionality led to moral proximity with the patient and a perceived moral duty to avoid withdrawing care. The normative (non)equivalence of withholding or withdrawing care in times of scarcity is debated in academic literature.[373 492-494] Furthermore, how this literature relates to 'care' that may be harmful or is uncertain (as in 'no stock, high stakes' situations) is an area that would benefit from research.

As a reminder, Kamran (IDI-796, iNGO, Head Office, health), like most policy-focussed participants, tended to prioritise quality. He perceived that he would be responsible for causing any harm that resulted from the administration of poor-quality medical products, if he had permitted QA requirements to be circumvented. Moreover, he expressed surety that sourcing medical products of uncertain quality would (or would be highly likely to) result in the administration of an injurious compound. It is likely that Kamran's positionality in relation to the patient (or, rather, his concept of the patient) augmented these beliefs.[335-337 462] Consider, the recipient of the medical product could be perceived as 'doubly' vulnerable, being both a patient (or caregiver) *and* a 'beneficiary' of humanitarian aid – designations that are oft described as requiring protection.[202] Furthermore, as both a medical doctor *and* a humanitarian, he may have experienced an enhanced sense of moral duty to protect the patient.[28] For Kamran, risking the health of the patient by knowingly administering potentially harmful compounds was a prima facie unconscionable act and a breach of trust. Thus, he avoided this perceived act of harm and felt morally obligated to safeguard medical product quality standards.

Some studies have noted that those positioned at a greater moral distance from the subject are more likely to apply moral rules more strictly – and judge moral agents more harshly – than those who are witness to the event.[336 340 495] The deontological philosophy that upholding moral rules is of greater import than the consequences of a decision may be relevant to examining policy-focussed

perspectives, like Kamran's. In my study I found that some participants were willing to apply rules regardless of their feasibility or outcome, which supports previous work on how moral distance impacts moral judgement.[339 340] However, many ethicists question the appropriateness of strictly applying rules (like QA policies) in non-ideal settings when their feasibility and relevance may be undermined by (and complicate) the exigencies of the context.[43 45 290 321 485]

These sensibilities were possibly reinforced by a relationship to, and conceptualisation of, the patient. As explained in the previous section, Kamran (IDI-796, iNGO, Head Office, health) felt connected to his vision of *a* patient in an idealised sense. This theoretical group were de facto recipients of care and his iNGO's rules offered clarity and comfort when tending to them in an uncertain context. Conversely, Kamran was not in close proximity to *the* patient in an actual or humanised sense. He did not feel connected to the people and families who were affected by his decision, who would no longer become patients from his perspective, because his iNGO was no longer able to treat them. His distance made him less sensitive to their concerns and plight and he did not articulate feeling responsible for their care.

8.2.3 c) How perceptions of standards differed according to proximity to the patient.

Data from my study suggests that policy-focussed participants tended to appeal to the need for universal standards, whilst patient-focussed ones often argued that standards should be contextual. (For example, 4.3.3 and 5.3.3). One argument for universal standards is based on a Rawlsian concern for equality, and discontent with disparate quality standards.[290 291] However, a problem with applying this moral argument to 'no stock, high stakes' situations is that it depends on an *ideal* setting, in which the 'project' of equality is viewed as feasible.[44 54 354] In a non-ideal setting, Faden and Powers argue that the objective is not necessarily global distributive justice – it is determining "*which inequality matters most*".[290] This changes the moral equation from comparing the standard that is perceived to be best against the standard of the host country (as may be the case for the routine

procurement of humanitarian health supplies) to comparing the standard that is available against no treatment at all. Here, either outcome is unjust.[290 360]

The patient-focussed perspective aimed to deliver flexibility in non-ideal settings, to overcome operational constraints. Those arguing in favour of sourcing legitimate medical products of uncertain quality in urgent stock-outs did so from a position of relative pluralism, which rejected the imperialistic nature of imposed standards and accepted the 'truth' of the Host Government's National Drug Regulatory Authority (HG-NDRA) regarding what is quality.[255 257 322 329] However, it risked taking excessive or unwarranted compromises on behalf of the patient. I contend that this is of particular concern when an iNGO's interests conflict with those of the patient, such as if compromising quality can save costs or facilitate participation in a humanitarian response (which benefits prestige and funding.)[48 49 266] Also of concern were the probability models that several patient-focussed participants used to justify their decision to source medical products of an uncertain quality standard (which compared the possibility of help with the certainty of harm). (For example, 7.2.3). These were simplistic; they made false claims of a choice dichotomy, comparing predicted mortalities of either option and overlooking the ethics of causing morbidity and disability.[204 329 496 497]

Regardless of their perspective on standards, few participants questioned whether the iNGO was the appropriate body to reach a decision. Normative research is necessary to consider whether QA standards should be adapted to accommodate urgent needs in non-ideal settings and, if so, when, to what extent, how, and on whose authority. This research should not purely focus on a comparison between best and current practice, but also consider the case for sufficiency.[498] This work might be informed by studies into the ethics of extending medical product expiry dates during medicine shortages and empirical research of the ethical challenges facing humanitarian health providers.[120-122] However, the consideration of which standards to apply may be academic if there is no consensus – or data – on *how* to evaluate the standards of different QA knowledge producers and how this relates to the quality of the actual medical product.

8.3 Vulnerability and proximity: how institutional-level power dynamics shape the 'no stock, high stakes' problem and entrench systemic inequality.

In my empirical chapters, I detailed how the competing priorities of quality and availability mirrored tensions between the perceived expectations of donor and patient, respectively. This reflected how these two stakeholders (and their primary interests) were characterised by participants: the donor was described as inflexible in their quality requirements, whilst patients were depicted as vulnerable to stock-outs. Thus, when participants debated how they should respond to a 'no stock, high stakes' problem, their concerns for medical product quality and availability were entangled with their commitments to the donor and the patient.[48 266 335 483] Therefore, the conceptual spectrum that emerged had patient concerns at one end and policy concerns at the other.

In this section, I consider what this paradigm can tell us about the sociopolitical context of 'no stock, high stakes' problems. Although organisations do not make decisions, per se, they limit and influence the decisions that are made by people, via the structure and culture of the workplace.[335 478 483 499] Intangible meso-level norms and values of the dominant power can directly influence the micro-level norms and priorities of those who operate within the system. [257 346 233 500] For 'no stock, high stakes' problems, the neoliberal values of donors were reified via policy and profoundly shaped decision-making and patient care.

8.3.1 The multi-stakeholder matrix of interdependency for sourcing medical products for humanitarian health projects.

My study largely sampled participants who had worked with large Northern hemisphere iNGOs that were subject to the Quality Assurance restrictions of Northern hemisphere, multinational donors when sourcing medical products for humanitarian health projects. Analysis revealed that these iNGOs were subject to *critical* interdependencies with four key stakeholders during 'no stock, high stakes' problems.[48 267 303 501] Although I found several theories of value in reflecting on my findings,

none of them were entirely satisfactory for explaining the decision-making context and how it influenced the choice behaviour of participants. Therefore, rather than drawing upon a single theory at the expense of understanding the phenomenon, I have developed a conceptual model to help illustrate and communicate my analysis.

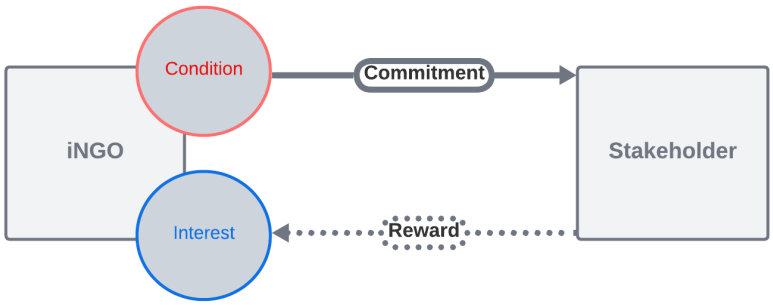


Figure 12: Explainer and key for the iNGO interdependencies illustrated in figure 13.

Figure 12 presents a simple key, which I will explain before presenting the full-scale model. Boxes represent actors: either the iNGO or one of its stakeholders. The arrows between them indicate an exchange: stakeholders offer the iNGO a ‘reward’ (a term that I will use to describe a material or conceptual ‘thing’) in return for a ‘commitment’ (a term that I will use to describe a service or payment). Rewards were conditional. I will use the term ‘condition’ to describe stakeholder requirements and expectations for what the iNGO should (or should not) do whilst engaged in the commitment. Thus, rewards were contingent on fulfilment of the commitment in a manner that complied with stakeholder conditions. Each reward contributed to a specific ‘interest’ (a term that I will use to describe material resources or conceptual permissions that were essential to the humanitarian healthcare enterprise).

As interests were critical to operations – and as rewards contributed to interests – iNGOs were dependent on rewards. As I will present, the degree of dependency appeared proportional to the overall significance of the stakeholder’s contribution to the iNGO’s interests, as well as the exclusivity of the relationship. In other words, iNGOs who had a diversified pool of stakeholders,

and a limited reliance on their contributions, may be less likely to exhibit dependency. Dependency unavoidably manifests vulnerability.[84 345 347] An iNGO's interests were vulnerable to the discontinuation of a corresponding reward. The extent of this vulnerability corresponded to the magnitude of the dependency and the ability of a stakeholder to enforce its conditions. However, iNGO's could mitigate their vulnerabilities by exerting power via various methods. Thus, though the model depicts interdependencies as static and symmetrical, in reality they were fluctuating, contested, and unequally distributed. Moreover, although rewards were *critical* for the iNGO, they were not necessarily *equal* to one another, nor were their stakeholders valued equally.

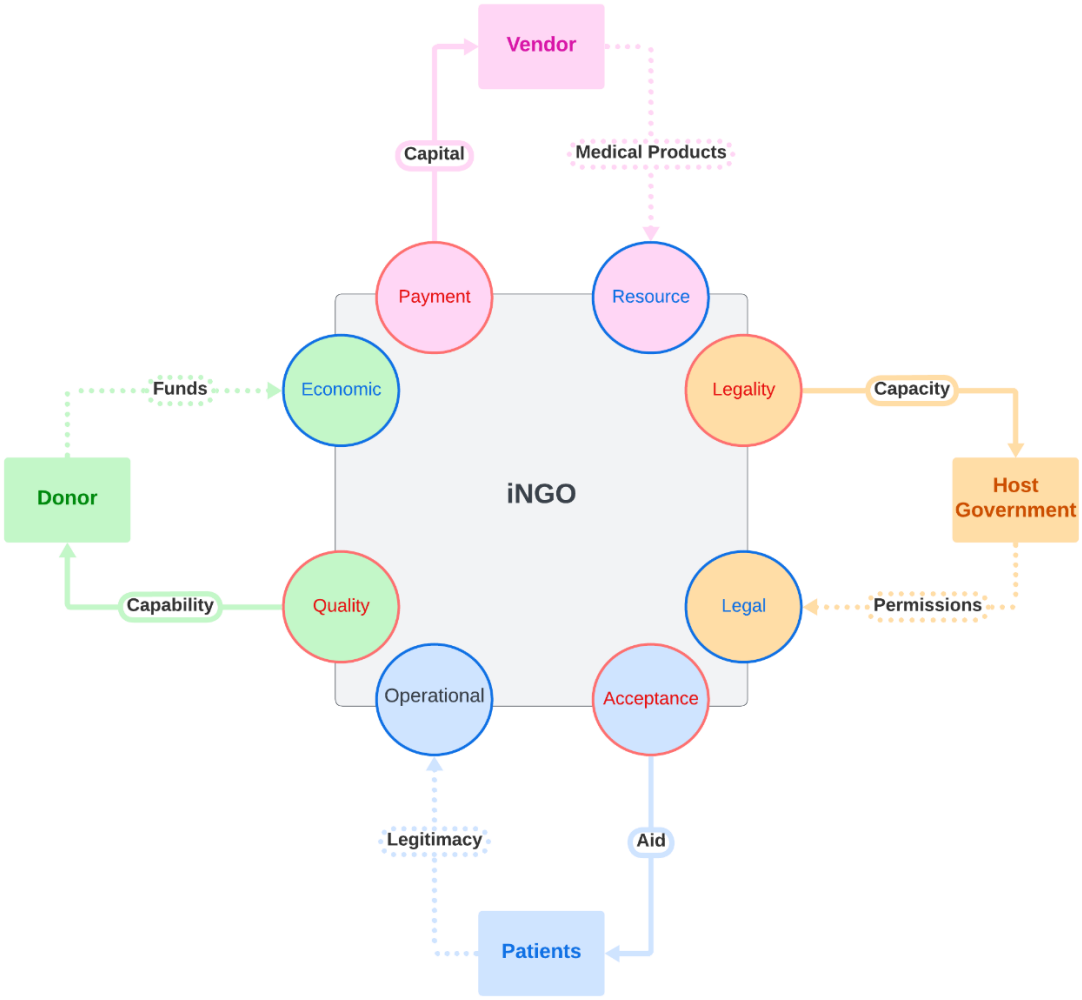


Figure 13: An illustration of the interdependent institutional relationships that shape the 'no stock, high stakes' problem.

Figure 13 applies these concepts to the multi-stakeholder 'no stock, high stakes' problem. On the left, in green, is the donor of the iNGO's humanitarian health project (all of whom, in this study sample, had Quality Assurance (QA) conditions). Although they have Global Health priorities, they often lack a mandate for project delivery.[253] They grant the iNGO with monetary funds (the reward) in exchange for their humanitarian health capability (the commitment)[53]. The funds received from the donor contribute to the iNGO's economic interests, but (as extensively detailed in this thesis) have conditions regarding proof of medical product quality. At the top, in pink, is the vendor. The vendor contributes to an iNGO's resource interests by shipping them medical products (the reward) in return for money (the commitment). Typically, they require customers to comply with specific conditions of payment (which detail where and when funds should be deposited, for example).[16]

On the right, in yellow, is the body that rules and administers the location of the humanitarian health project which, in this thesis, I have termed the Host Government[54]. A *humanitarian* problem is one that overwhelms the capacity of some or all of the national system.[201] The iNGO assists in addressing this shortfall (the commitment) and the Host Government give them the legal permission to do so (the reward). Registrations as a legal entity and a legally recognised healthcare provider, for example, contribute to the iNGO's legal interests, but are bestowed on the condition that the iNGO will uphold national laws and systems. At the bottom, depicted in blue, are patients. Without the existence of a patient population, as an aggregated mass, the iNGO lacks legitimate purpose (the reward).[267] The unmet needs of patients contribute to the operational interests of an iNGO, who strive to offer humanitarian aid to alleviate it (the commitment). However, not all aid is welcome, or

[53] For example, a donor may advertise that they wish to support a specific region in rolling out childhood vaccinations for a specified duration. They would then consider the proposals and suitability of various bidders and select their preferred option. The iNGO would utilise its capabilities in project delivery to attempt to meet the donor's targets, in exchange for the money to do so.

[54] Sometimes a location may be subject to the rule of more than one actor, or control of a location or its population may be contested. This would complicate the situation and could be depicted by adding additional governing bodies to the illustration. Although this may be likely in man-made humanitarian crises, I will present a basic description in which there is a single Host Government entity, for the sake of clarity.

appropriate.[53 203 212 259] Patients expect iNGOs to comply with the explicit and implicit norms of their society (the condition), if their aid is to be 'accepted'.

Thus, iNGOs were dependent on the rewards of these four stakeholders, who were dependent on the commitments of the iNGO. However, these dependencies were unequal – both in terms of reciprocity in the iNGO-stakeholder relationship and comparatively between the different stakeholders (despite the symmetry depicted in figure 13). Next, I will describe how dependency is intertwined with vulnerability, how vulnerability is countered with power, and how, in 'no stock, high stakes' problems, iNGOs are incentivised to shield unmitigated vulnerabilities through their proximity to the stakeholder that wields the most significant power.[38 84 263 266 345 347]

8.3.2 How iNGO-stakeholder power dynamics influence proximity and the handling of 'no stock, high stakes' problems.

Vulnerability is an inescapable feature of dependency.[84 344 347] Although theories of vulnerability often relate to individuals (and groups of individuals), I will apply them to the institutional 'body' of an iNGO. This concept of vulnerability is not one in the corporeal sense, relating to the innate fragility of the human condition.[84] Rather, it draws upon relational theories of vulnerability; an ineradicable feature of a relational agreement (regarding an interest) is the susceptibility to harm to that interest.[38 345 347] This frames vulnerability as being situational (as it differs according to the subject), multifaceted (as it pertains to various discrete interests), dichotomized (as it observes the interdependency of an agreement), and as existing on a spectrum (as the subject may be able to reduce the extent to which it is vulnerable, as I will explain shortly).[38 84] It should be noted that this perspective of vulnerability does not characterise it as being inherently undesirable; it merely acknowledges vulnerability as a feature of relational proximity.[84]

8.3.2 a) The iNGO-Donor power dynamic.

As I described in Chapter 5, donor sourcing conditions incentivised the prioritisation of medical product quality over availability. Interviewees from donors perceived that this position was financially motivated, to minimise risk to reputation and status (and thus public support), rather than being primarily concerned with the best interests of the patient. In other words, it was perceived that the reputation of the donor would be tarnished *more* by deaths from substandard and falsified medical products of which they had funded the procurement, than from deaths caused by a lack of access to healthcare due to funding that they withheld. Charities are dependent on external funding; their economic interests are vulnerable to the actions of donors.[235 263 473 502] I found that grant-reliant iNGOs often replicated donor requirements within their own policies, creating a satellite that extended the reach and influence of donor priorities.[212]

The pivotal importance of funding, rather than patients, was evident in participant language and descriptions of 'no stock, high stakes' problems. For example, the significance of a stock-out was often quantified in monetary terms and graded by financial magnitude of spend, rather being described qualitatively according to human impact.[329 496] Emerging evidence suggested that donors would be afforded greater power in the relationship according to the economic threat that they posed. (See section 5.3.2, for example). Thus, donors who contributed a significant proportion to the iNGO's income, and were capable of stopping those funds, were powerful. This appeared to be exacerbated if the donor was able to rescind historic rewards through audit.[483 503] Power was evident through the donor's ability to exert control over 'no stock, high stakes' decision-making, as well as by shaping the design of the recipient's organisation and governance (for example, by dictating its sourcing policies, spending priorities, and staffing requirements). Conversely, participants from iNGOs that had a more diversified funding base (such as greater public giving, unrestricted funds, or more numerous donors), exhibited more autonomy in their 'no stock, high stakes' decision-making. (See Ursula's comments in section 6.4.2, for example). They also appeared less preoccupied by the 'gaze' and affirmation of donors, whom they referenced less frequently.[269 463 504]

That the iNGO lacked equivalent power was, perhaps, related to exclusivity within the relationship. Participants from donor organisations appeared untroubled that a project might fail, explaining that they would re-establish the grant with a different iNGO. (See section 5.4.2). According to my model of interdependencies and vulnerabilities, one would predict that project failure would be more significant to the donor if they had a less diversified portfolio of projects, or if there were no other eligible iNGOs (due to being highly specialised, for example). Thus, the replaceability of an iNGO weakened its power. Conversely, data conflicted regarding the exclusivity of the donor. Some donor participants suggested that iNGOs could seek additional funding in 'no stock, high stakes' circumstances (like Liam in section 6.4.2). However, it seems unlikely that another donor would be interested (or capable) of divesting funds for the national procurement of medical products, within the scope of another donor's project, and within a short timeframe.[234 235 254 473 501]

Therefore, the (donor participant) proposal that alternative funding was a viable option appeared to be misleading. Perhaps this was an attempt to dispute the relational proximity arising from an iNGO-donor agreement. This could benefit donors twofold. First, it creates a narrative that the iNGO is not *wholly* dependent on the donor to alleviate economic vulnerability, thus enabling the donor to distance itself from responsibility for the economic vulnerability that it has caused.[84 260 462 498] Second, it shielded the vulnerability of the donor's reputational interests (by avoiding association with negative 'no stock, high stakes' sequalae), upon which their own financial support was conditional.[303 334] The donor's responses to vulnerability (i.e. avoidance of shared responsibility and thus privatisation of vulnerability to the iNGO) were typical of a system that idealised *in*vulnerability.[38] Indeed, iNGOs whose health supply chain and QA system were perceived to be more capable – and less vulnerable – were those that were held in high esteem by donors (as evident in sections 6.2.1 and 6.4.1).

Scholars such as Gilson contend that the valorisation of invulnerability will disincentivise a subject from voicing its needs, or its inability to protect its vulnerabilities.[38] This, perhaps, explains why some iNGOs appeared willing to accept donor QA requirements when they seemed to lack the

competence and capability to fulfil them. (See sections 6.3.1 and 7.2.2). Indeed, QA policies were widely accepted, despite broad knowledge that they were wholly unsuited to responding to 'no stock, high stakes' problems. Data suggests that donor QA conditions were reflective of a neoliberal approach to protecting economic interests and achieving control via a panopticon of audit that enforces self-regulation.[255 263 269 334 483 503] It also offers insights into why external facing iNGO policies do not endorse the sourcing of medical products of uncertain quality in 'no stock, high stakes' problems, as doing so would not align with the dominant economic frame.

8.3.2 b) The iNGO-Vendor power dynamic.

International NGOs were highly dependent on international vendors due to concerns for the quality of nationally available medical products, policies that discounted national vendors, and an approach to import medical products by default.[16 21 505] This vulnerability of resource interests was exacerbated by donors who named and approved a handful of sources. This untransparent method of selection afforded a great privilege to a small pool of humanitarian vendors, unfairly disadvantaged eligible national vendors from trade, and raised questions regarding the moral responsibility of donors for addressing medical product stock-outs.[232-234] With a constrained pool of acceptable vendors, power shifted towards the vendor. Conversely, the pool of humanitarian *procurers* was ample; vendor power was only contested if the customer was a significant contributor to the vendor's economic interests (which appeared out-of-reach for the modest budgets of non-UN agencies). Evidence of vendor dominance was observed through their ability to control aspects of the trade and their ability to refuse certain iNGO demands.

The system of pre-approving vendors was designed to safeguard quality (as outlined in sections 2.3.3 and 5.3.1). However, this short-list of vendors was based on one-off audits and repute; policies indicated that donors rejected responsibility for overseeing them, or liability for incidents of poor-quality.[277 280 281 288] Furthermore, as the pre-approved vendors were generally export-only, they were not a priority for the National Drug Regulatory Authority (NDRA) of the country in which they are

based.[50] Moreover, I found that many iNGOs sought to undermine the Host Government's procedures for conducting medical product quality checks through seeking importation exemptions (as detailed in section 5.4.1). My study did not delve too deeply into the iNGO-vendor relationship; however, many iNGO procurers seemed ill-situated to regulate their international vendor. Not only did many of them lack the capability to do so, but power asymmetry within the relationship also meant that they were unable to exert this (presumably unwelcome) condition.

The result was a QA system that largely relied on vendors to self-regulate. This was profoundly different to the self-discipline created by donors via disallowances; iNGOs were unable to exert pressure on their international vendors, comprehensive batch testing was unviable, and pharmacovigilance systems were unreliable.[179 189 217 506 507] Furthermore, if poor-quality was identified, finding and tracing the cause was challenging.[7] Finally, the iNGO was not the dominant power in the relationship – raising complaints would be a high-risk move. Perhaps international humanitarian wholesalers effectively self-regulated and did so with integrity. However, my research suggests that the donor-contrived system that sought to circumvent poor-quality medical products, ironically, increases susceptibility to exploitation and weaker regulation.[49 274]

8.3.2 c) The iNGO-Host Government power dynamic.

The Host Government was the sole provider of legal permissions; they were of extreme importance to the iNGO because, if rescinded, the iNGO no longer existed as a legal entity within the State. The significance of the reward and the exclusivity of the arrangement made iNGOs completely dependent on the Host Government; indeed, participants aired quasi-existential concerns that related to the vulnerability of the iNGO's legal interests. (See Lynn's views in 5.4.3 a), for example). Similar to the iNGO-donor relationship, there were a multitude of humanitarian actors for the Host Government to choose from. Thus, the power of an iNGO – as a single entity – was relatively minor (unless, theoretically, it possessed a unique and desirable capability). Therefore, one might expect the iNGO-Host Government power asymmetry to mirror that of the iNGO-donor relationship. However, this

system of interdependencies was situated within a neoliberal context so that, as I will explain, when stakeholder expectations were in contention, it was the will of the dominant *economic* power that prevailed.[62 212 269 334]

During 'no stock, high stakes' problems, iNGOs were unable to deliver their commitments to patients within the boundaries of the conditions that have been stipulated by other stakeholders. Specifically, my study identified that *donor* medical product quality requirements were immiscible with *Host Government* importation regulations and the uninterrupted provision of healthcare services required to meet *patient* needs. According to my model of interdependencies, this posed a significant threat to the iNGO's legitimacy, as well as their legal and economic interests. In practice, participants conceptualised these vulnerabilities as discrete risks (such as the risk of losing registration or of a disallowance), which is a common method for operationalising uncertain threats into a paradigm that can be estimated and managed.[251 289 301] Participant reports for how iNGOs negotiated this impasse offered an interesting insight into how power can influence proximity and prejudice. I will examine iNGO negotiations with the Host Government and donor (according to participant reports) and then comment on the iNGO's (lack of) communication with patient populations during 'no stock, high stakes' problems.

Participants spoke of negotiations with both donors and Host Governments to attempt to adjust the conditions of their commitment to something more feasible (such as a short-term reprieve from quality requirements or importation regulations, for example). Data indicated that donors and Host Governments were similarly unwilling to offer flexibilities in their conditions. (For example, sections 5.3.2 and 5.4.1). Unable to satisfy both stakeholders, and with less power than either, grant-reliant iNGOs were thus forced to choose who to appease and with whom to risk reprisal. While Country Office and roving participants were generally accepting of Host Government power, it provoked suspicion, aggression, and malcontent amongst many Head Office interviewees. (Like in section 5.4.3 a). Data analysis indicated that these sentiments may be couched in subverted expectations of

supremacy, due to the personalised and emotive timbre of claims that related to national beliefs and relied on a shared and implicit assumption of superiority.[212 261 265 328 334 508]

Participants spoke of leveraging the economic power of their donor to pressurise the Host Government into acquiescing to donor quality requirements. (As presented in section 5.4.1, for example). In effect, the iNGO removed themselves as a filter; they confronted the Host Government with the reality that *any* iNGO fulfilling a commitment to that donor would be bound by the same QA conditions. Thus, if the Host Government rejected the iNGO on these grounds, it would also raise the spectre of rejecting the donor and, along with it, all the humanitarian assistance that they might bring. These actions, of the iNGO and its donor, conspired to (re)assert the dominance of Global North ideals and to protect legal and economic interests by coercing the Host Government to repeal their conditions by using human suffering (or the anticipation of it) as leverage.[198 215 329 334] Thus, the 'no stock, high stakes' problem was not only situated in a neoliberal paradigm, but it also existed in a neocolonial one.[153 257 261] The Host Government was rendered distal to the iNGO in comparison to the proximity courted with the donor, due to a context that awarded economic power and a culture that favoured centrist cooperation.[14 48 49 212 263 266 483]

8.3.2 d) The iNGO-Patient power dynamic.

Patients are the foundation of this network of interdependencies; without them, the iNGO (and their donor) would be redundant. Yet, my study found that patients are not necessarily the organising concept around which 'no stock, high stakes' problems are determined.[335 478] They are subject to the life altering choices made by iNGOs, but they lack representation, opportunity, and knowledge of decision-making.[62 263 346] In the iNGO-patient relationship, power resides with the iNGO. This is because, although iNGOs are dependent on patients for their legitimacy, this is not a discrete, observable, or spontaneous 'reward'. Patients cannot control it, because iNGO legitimacy is judged by a third party and patients lack autonomy in selecting the iNGO with which to establish a relationship. Moreover, if unsatisfied with the standard or scope of aid, patients require collective

action and advocacy to effect change; they lack the unity and platform that benefits an institution, from which to coherently broadcast their concerns. Boycotts could undermine an iNGO's objectives and, subsequently, their perceived legitimacy. However, this may not be feasible (healthcare options may not exist) and, even so, it would not help the *current* patient, for it would not initiate an immediate effect.

Conversely, a patient's dependence on an iNGO was profound and inextricable from their being; it was an unavoidable ontological vulnerability exacerbated by the humanitarian context.[84] It is widely argued that vulnerability places a moral responsibility upon those with the ability to alleviate it, except where the sacrifice to do so is disproportionate.[38 84 341 347] As I have explained, the patient was dependent on the iNGO and vice versa; however, the act of caring also engendered socially constructed dependencies (and vulnerabilities) upon the iNGO.[345 348 509] In my study, participants frequently expressed moral uncertainty about what they ought to do, and this was mirrored and complicated by a practical dilemma of what, and how much, to risk. (Like Elliot in section 4.3.2). The moral responsibilities of the iNGO in a 'no stock, high stakes' problem are an important and complex vein of future research that should recognise the normative implications of the iNGO's nested vulnerability to facilitate the application of findings to a real-world context.

No interviewee in my study stated that their iNGO would discuss the problem with patients or their communities. There were obvious barriers to this; for example, remoteness, language differences, security threats, practical difficulties with identifying suitable representatives, and ethical concerns of provoking anxiety and hesitancy amongst patients. Yet, the complete absence of communication channels, the profound disinterest in the preferences of the patient population, and the failure to investigate the outcomes of 'no stock, high stakes' problems, suggests that these difficulties lay upon a bed of prejudice, "strategic ignorance", and inequity.[263 298 316 487] Within a neoliberal context, not only do patients lack power, but they also lack value.[319 334] It appeared that the bureaucratic dehumanisation and obfuscation of patients undermined a decision-maker's ability to empathise, and instead encouraged rational choices that prioritised personal and organisational risk.[335 340 510]

Within the paradigm that I have presented (of dependencies with privatised vulnerability and potentially severe ramifications in a neocolonial system with a dominant neoliberal ideology), the iNGO is incentivised to neglect the patient, because they are incentivised to preference risks that minimise economic vulnerabilities in their short-term response to a 'no stock, high stakes' problem, whilst securing longer-term success through shaping and aligning themselves around the dominant stakeholder, the donor.[263 269 334 503] Research into this area is important and should also contend with whether moral responsibilities are incumbent on the wider circle of stakeholders for alleviating iNGO vulnerabilities (and their subsequent ability to serve the patient population) and to what extent.[38 84 323 344 348] For example: should iNGO's be treated as exceptional to importation regulations and, if so, under what circumstances? To what extent should donors create flexibilities in their medical product sourcing requirements, or offer emergency funds for urgent procurement? Should vendors be required to prioritise iNGOs according to urgency, and at what cost? Such initiatives, and agreements to prevent exploitation, would shift the system of interdependencies towards a model of shared vulnerability that centres patient care.[84 347]

8.4 The injustices and inequities of 'no stock, high stakes' problems and decision-making.

8.4.1 Inequitable power and the injustice of prejudice.

Several participants from donors and iNGO Head Office roles made a distinction between the *legal* and *moral* responsibilities for assuring the quality of medical products that were used in iNGO facilities (and others did so with more blurry boundaries, by using *legal* terms like "*due diligence*" to convey *moral* obligations). (Section 5.4, for example). The assumption that one *ought* (in a moral sense) to verify the safety and efficacy of a medical product prior to its use, if quality is doubted, seems to make intuitive sense (to me, according to my own moral reasoning). This is because, to me, this appears to be an implicit requirement of fulfilling the Golden Rule; to treat another as I would wish to be treated, I must first understand what I am treating them with.[349 511] However, the

assertion that the iNGO procurer is *morally* responsible – *and* that they are *not* legally responsible – for medical product quality is founded on several tacit assumptions. In the following few paragraphs, I will make some of these assumptions explicit, consider the narratives that may have informed them, and highlight areas that would benefit from clarification and future research.

8.4.1 a) The assumption that iNGOs are not legally or morally responsible for the AVAILABILITY of medical products in their humanitarian health projects.

A hidden assumption in the responses of policy-focussed participants was that they were not legally or morally responsible for ensuring the availability of medical products that were an essential component of healthcare services. (See sections 5.4.2 and 7.3 for examples). Some inferred that it was acceptable to interrupt agreed healthcare services due to the background level of desperation in the context, and that any contribution was helpful. (For example, section 7.2.2). This view seems to be couched in a "they should be grateful" sentiment to which some participants referred, but which fails to assume accountability for pledges and commitments.[48 62 266] Perhaps iNGOs are inadmissible for health supply chain failures due to the challenges of the humanitarian context.[19 54] However, what if the stock-out is caused by a reliance on importation, the permission for which was obtained through coercion or political pressure?[155 234 512] Moreover, what if the stock-out is a unilateral *choice* by the iNGO that disregards NDRA data that could have resolved it?[22 303 315] Normative and legal guidance is required to adequately answer these questions, but they also raise practical questions. For example, should decisions regarding 'no stock, high stakes' problems be transparent? Should financial contributions be public? Should efforts be made to track the outcome of decisions to inform future practice?

8.4.1 b) The assumption that the iNGO bears no legal responsibility for the QUALITY of medical products sourced from national markets for humanitarian health projects.

To my knowledge, there is no legal precedent that establishes liability in a case where a nationally sourced medical product used for patient care in an iNGO clinic is found to be of poor-quality. Evidence gathered in my study suggested that participants were uncertain about (their) liability for patient harm resulting from substandard and falsified medical products and that this uncertainty contributed to a lack of transparency and communication by the iNGO regarding adverse events. (Section 5.2, for example). In practice, it may be difficult to establish blame in the event of suspected poor-quality medical products.[7 513] There may be ambiguity regarding cause due to an inability to discount antimicrobial resistance, hypersensitivity, or disease progression, for example.[183] It seems reasonable to assume that one would need to establish the point at which the quality problem arose, to establish who was responsible for it. For example, was this during manufacturing, during storage, or was it falsified?[100] However, establishing the precise cause of the problem can be challenging (due to capacity, resources, time, and cost) and may not be sufficient for pinpointing *when* the issue arose.[5 6] Moreover, even if these difficulties are overcome, and the problem is identified, the governing body may lack the judicial powers to hold those responsible accountable to avoid repeated incidents and to seek justice for those affected.[7 175]

Many participants asserted that an iNGO had no legal responsibility for the quality of medical products that were administered in one of their health projects, if those medical products were legally and legitimately sourced from the national market. (Section 5.4.2, for example). This seems to be because NDRAs are delegated with the legal authority to regulate and control medical products in most States, and that this function is recognised by many global institutions.[159 275-277 281] However, should we assume that the iNGO bears *no* legal responsibility for the quality of medical products in non-ideal contexts? As a healthcare provider, the iNGO presumably has legal responsibilities pertaining to the health of its patients.[203 260] Several participants in my study shared a willingness to trade and import medical products in a manner that was perceived to be illegal (e.g. iNGO 'trading')

or illegitimate (e.g. using power to avoid importation regulations) to avoid the "*local market*"; actions that were motivated by a will to protect patients from the perceived risk of substandard and falsified medical products. (See section 6.2.1). If staff questioned the State's ability to safeguard the quality of medical products to this extent, should the iNGO bear or share any legal responsibility for the impact of poor-quality medical products for their patients?[498]

8.4.1 c) The assumptions that iNGOs can estimate medical product quality in 'no stock, high stakes' decision-making, that they are superior to HG-NDRAs in this regard, and that HG-NDRAs are incapable of effective medical product Quality Assurance.

Participant assertions about *responsibility* for medical product QA are not necessarily statements of *capability*. However, in the context of other findings of my study (such as opinions of HG-NDRAs, peer iNGOs, and QUAMED), we can discern that they are imbued with inference about the comparative capabilities of iNGOs and HG-NDRAs. (See section 5.2.2 and 6.4, for example). Namely, there was an assumption that ("peer") iNGOs and their auditors were not only capable, but that they were superior to HG-NDRAs in the matter of medical product QA. However, comparing iNGOs with HG-NDRAs is a false equivalency; it contrasts the greatest weaknesses of an entire national system (upon which the maturity level is determined) with the ideal version of iNGO resources and QA procedures.[497] It overlooks that HG-NDRA *decisions* may not reflect HG-NDRA *competence*; for example, these auditors may gather data that is equivalent to their Stringent Regulatory Authority (SRA) counterparts, but they may need to take greater risks with quality in the interest of lowering costs.[40 228 514] It assumes that the knowledge-producer is always more significant than their method of data collection; most participants treated *any* investigation by QUAMED (even rapid, one-off, half-day investigations by a foreign auditor who may be unable to read procedures written in the national language) as preferable to HG-NDRA data.[39 226 228] And it fails to scrutinise the procedures used by iNGOs during 'no stock, high stakes' problems (rather than routine procurement) and their outcomes.[515]

My study found a general assumption amongst most participants based in the Global North that the data and judgements of iNGOs, rather than HG-NDRAs, should be used in 'no stock, high stakes' problems. (See sections 5.2.2 and 6.4). This was regardless of the HG-NDRA, the medical product, and the source. It is true that the capability of QA knowledge producers – NDRAs and iNGOs alike – is heterogenous.[158 161] There is ample evidence and broad agreement that different NDRAs are of varying abilities and that, frequently, the NDRAs of High-Income Countries that fund or headquarter iNGO projects are of a greater maturity to the NDRAs of countries that are recipients of humanitarian assistance.[3 158 161 162] (This argument was used by some iNGO and donor participants in my study to underpin a justification for importing medical products against the wishes of the Host Government e.g. section 5.4.1.) Indeed, at present, some UN Agencies may be better able to audit the quality of specific medical products than some HG-NDRAs.[137 516]

However, behaviour that mistrusts or overlooks HG-NDRA data and judgements *by default* is problematic because it is over-generalised, dominating, prejudiced, and disregards progress.[265 321 329 467] It is an example of negative bias. Moreover, an iNGO is not a regulatory body. The position that an iNGO is more capable that an HG-NDRA appears to rely on a geographical association with SRAs and an assumption of Northern Hemisphere supremacy, rather than evidence.[265 321 329] (See sections 5.4.3 and 7.4.2). Behaviour that blindly supplants HG-NDRA judgements with those of an iNGO (whose QA procedures are unregulated, unaccredited, and only partially transparent) is an example of positive bias.[17 235 262 515] It is also suggestive of an evasive and morally unjustified phenomenon of "*duty dumping*".[260] I will explore the epistemic injustice associated with these opinions, practices, and consequences in greater depth in section 8.4.2.

8.4.1 d) The assumption that iNGO Head Office staff possessed a superior moral capability to national staff and, therefore, that they should control 'no stock, high stakes' decision-making.

International staff tended to assume that the centre (i.e. donors and iNGO Head Office) possessed superior moral capability compared with those who were peripheral (i.e. Host Governments and iNGO national staff)[55] in the Global Health system and its organisational infrastructures. (See sections 5.2.2 and 7.4.2). The data that I collected showcased that perceptions of (in)capability, (in)competence, and (im)morality were conflated and confused together into a hodgepodge of generalised mistrust for that which was perceived to be 'foreign' by those who identified with the centre, and the perceived superiority of the centre.[87 257 265 345 462 467 510 517] These remote respondents tended to profoundly mistrust the moral intuition of national staff and Host Governments, and the reasonableness of patient communities. (Sections 5.2.2 and 7.4, for example). Instead, they articulated a need to gather information from national staff who were proximal to the problem, so that the centre 'experts' could perform analysis and make judgements.

These attitudes were reinforced by the characterisation of (peripheral) national staff as inherently 'wild', with respect to decision-making. (See section 7.4.2/3) This 'wildness' related to a willingness to compromise medical product quality requirements; delays in the name of data-gathering were associated with prudence.[479 508] National staff who had accepted centre policies and procedures (and had demonstrated the capacity and willingness to mimic the judgements of the centre) were 'good' and 'professional'.[246 268 504] Examples of educating (or 'capacity building' in humanitarian parlance) were sometimes offered as evidence of collaboration and devolution.[153 261 467] However, although tasks or responsibilities may have been delegated to isolated persons, the locus of power and authority remained unshifted. Moreover, it is important to remember that these priorities did not

[55] The terms central and peripheral are intended in a Galtungian sense. See reference 258. Galtung J. A Structural Theory of Imperialism. *Journal of Peace Research* 1971;8(2):81-117.

refer to established ethical principles (as normative research into the 'no stock, high stakes' problem is lacking). These claims related to norms established by the dominant power.[266 269] As yet, no stakeholder has the moral authority to claim to know the ethically right thing to do – or to claim that another stakeholder does not.

8.4.2 Epistemic injustice and the hegemony of Quality Assurance in humanitarian contexts.

For medical products, quality is not a physical and observable 'thing' that can be inspected or quantified.[6] Indeed, arguably the rubric of determining medical product quality is actually the science of estimating the risk of *poor*-quality.[6 100] NDRAs review a plethora of proxy indicators that might confirm the presence, absence, or fulfilment of a thing or procedure.[99 518] For example, site inspections of manufacturers might investigate the performance of the site's air filtration system, the accuracy of pressure in the tabletting machine, and the currency of staff training; audits of distributors could look at temperature logs and procedures for managing vermin; tests of batches might assay specific chemicals or contaminants, like the active pharmaceutical ingredient or its degradation products; dossier reviews could appraise stability studies or regulatory approvals.[6 99] Deviation from one of these parameters does not necessarily indicate poor-quality, just as compliance with all of them does not guarantee quality. Rather, collectively, these proxy indicators provide the auditor with a measure of confidence in the safety and efficacy of the medical product.[478 483] Thus, for an NDRA, 'quality' denotes a reasonable confidence that a medical product is not substandard or falsified, according to their analysis of proxy data (or reliance on a partner's analysis), and their level of risk tolerance.[6 99 147]

In my study, participants viewed QA data as an important part of the decision-making process (as outlined in section 6.4.1). However, SRA-endorsed medical products were inaccessible during 'no stock, high stakes' problems and participants consistently shared the unfeasibility of conducting their own QA investigations due to time, resource, and access constraints. (See section 6.3.1). This demand and scarcity of QA data led it to be treated like a commodity; it held value, it could be

traded, and it offered the owner status. (Section 6.4.1 a) offers examples of this). And, just like other commodities, decision-makers favoured renowned brands and were cautious of unfamiliar ones. Thus, for iNGO and donor participants during ‘no stock, high stakes’ problems, ‘quality’ was a proxy (their confidence in the auditor) of proxies (the auditor’s measurements of poor-quality indicators). Essentially, a participant’s perception of medical product quality was enmeshed with the extent to which they trusted the opinion of the auditor who had assessed the vendor or manufacturer.[39 40 226 241 249]

The ‘system’ of gathering and analysing data to respond to ‘no stock, high stake’ problems, as described by participants, was observed to be influenced by implicit beliefs, unconscious bias, and inequitable mental models of global hierarchies.[298 474 515] (For example, see section 6.2). Many participants from the Global North made statements that furthered a neocolonial narrative, characterising countries, continents, or regions (and their people) as inherently superior or inferior (regarding their comprehension, moral intuition, or corruptibility, for example). (See sections 5.2.2, 5.4.3, and 7.4.2 for examples). These participants (mis)trusted data based on their perception of the knowledge producer, regardless of the method or rigor of data collection.[265 459 462 467 496] Information that challenged these views (i.e. the WHO global benchmarking assessments) was largely disregarded. (See section 6.4.2). Conversely, these views were often justified with extreme – and thus skewed – anecdotal vignettes that were generalised to *all* sourcing decisions in all humanitarian contexts. (Examples of this are in section 5.2.2). This view split the world into two: SRA and not-SRA, knowledgeable and contemptible, trusted and suspicious, included and excluded, us and other.[255 257 258 327 345]

This prejudice was both reflected and reinforced by the donor’s hegemonic approach to medical product quality, which utilised pre-approved lists of vendors and knowledge producers.[280 288] The selection and characteristics of these auditors is described in Chapter 2. Inclusion in this list signified that the iNGO or donor had such confidence in that auditor’s capability that they were willing to trust the decision and would automatically approve the same vendor. (An, “if it’s good enough for

them, it's good enough for me" outlook).[141 144] However, if a medical product lacked these credentials, some participants would view it as being of unknown quality, whilst others would perceive it to be of poor quality. In either case, medical products that lacked the endorsement of a trusted auditor were perceived to be 'guilty until proven innocent' by participants; they were assumed to be of spurious quality until evaluated by a trusted auditor. It was noted that medical products from trusted knowledge producers were the reverse of this; they were treated as 'innocent until proven guilty', with the assumption that they were acceptable quality unless tests or events proved otherwise. (These contrasting views are presented in section 6.2).

So, in 'no stock, high stakes' problems, trust did not seem to arise from a fair, transparent, and current appraisal of information about the knowledge producer, or from an appraisal of *how* they had determined medical product quality for *this* batch or *this* vendor. (Indeed, I do not believe that such data is available from an open source). Trust was based on social relationships and cultural ideologies, which are highly liable to prejudice.[39 40 230 249 459 483] In Chapter 6, I presented data that showed how some Head Office participants trusted 'peer' iNGO data whilst disregarding information from HG-NDRAs, and how some Country Office participants trusted vendors based on personal experience rather than regulatory credentials. (I also offered the insight that this subjectivity was reduced if the participant had a greater understanding of medical product QA, which mostly applied to pharmacists). These findings highlight the role of relationships in decision-making where there is data scarcity (or incomprehension) and broadly aligns with research into the significance of trust in making procurement decisions in uncertain contexts.[39 40 226 241 249]

One of the reasons that these findings are significant is because they indicate that this *method* of QA has changed the *definition* of QA amongst some humanitarian procurers.[87 329 467] Although iNGO decision-makers were unable to apply donor restrictions to 'no stock, high stakes' problems, they were observed to apply the same frames of reference and indicators of trust to these situations. When participants spoke to me about "good" and "poor" quality medical products, (which related to "high" and "low" trust in their QA knowledge of that vendor), they were implicitly communicating

whether they were "policy-compliant" or "not policy compliant" as they usually perceived this to be analogous. This practice creates an inequitable system that is highly problematic for several stakeholders, as I will describe next.

First, it is a libertarian approach to medical product quality that undermines the regulatory authority of the Host Government and, in a display of neocolonial power, controls who has the expertise to declare the knowledge and truth of medical product quality.[329 333 464 519] These findings align with a philosophical and sociological scholarship that examines dynamics between the self and the other in a context of power asymmetry.[212 345 348 484 503] For example, several scholars have observed that 'peripheral' views may be discredited, overlooked, or silenced by knowledge gatekeeping and the hegemonic domination of truth and decision-making by the political elite.[255 257 265 321 329] Second, as highlighted in section 8.3.2, inequitable barriers disadvantaged national vendors, undermining opportunities for financial mobility and perpetuating their powerlessness to compete. Finally, disregarding sources of data and medical products that may be appropriate for 'no stock, high stakes' problems create a gap between what *is* a quality medical product and what is accepted as such. This places additional constraints on medical product availability, thus causing or extending 'no stock, high stakes' problems in frequency, duration, and the number of patients who are unable to access essential healthcare services.

8.4.3 Inequitable standards and health injustice.

In and of itself, the 'no stock, high stakes' problem signposts a terrible inequity and a health injustice.[214 238 290 357 359] Numerous legal articles assert "*the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*", or similar, thus establishing it as an inalienable human right.[360 362 520] Other articles recognise that timely access to safe and effective medical products is a key component of achieving this and, therefore, fair and equitable access is also a human rights issue.[361 521 522] The situation that I have detailed in this thesis places this right in jeopardy, as a patient's opportunity to attain and maintain their health is undermined by poor-quality

medical products, or their unavailability. However, this situation is not merely and solely the result of global inequities and wicked problems that impoverish States and frustrate their ability to realise comprehensive health services for their citizens.[356 523] If so, the deprivation of 'no stock, high stake' problems could be viewed as an unfortunate, circumstantial reality. Rather, my study has revealed that humanitarian health iNGOs and their donors may amplify, create, and complicate health injustices by undermining State systems, dominating priority setting, unfairly discriminating between patients, and excluding patient advocates.

When responding to 'no stock, high stakes' problems, many participants reported that their iNGO would expedite a shipment of medical products from their preferred international supplier. (Section 6.1 and 6.2). However, they also shared that this solution was not immediate, with estimates varying from less than a month to over a year, depending on national importation restrictions and iNGO supply chain infrastructure. (Section 7.2.2). Interim solutions involved tolerating the stock-out or sourcing medical products from a peer or vendor (as explained in sections 7.2.2 and 6.2.1, respectively). No decision-making was guided by established ethical principles, as none yet exist for this problem; therefore, participants could not justify that their decisions were ethical. However, many participants spoke of following – or seeking – the morally 'right' course of action. (For example, sections 4.3.2 and 7.1.1). What was deemed ethical was inconsistent because decisions were arbitrary, informed by diverging perspectives and beliefs.[294 320 481] This inconsistency signifies inequitable treatment and, therefore, a health injustice for those unfairly treated.[170 290 524]

First, let us consider the choice to source medical products of uncertain quality. Doing so raises numerous moral concerns. For example, to what extent is it reasonable for the iNGO to risk poor-quality medical products on behalf of the patient?[22 44 61 525] Also, should this information be shared with the clinical staff who are using and administering the medical products? It seems reasonable to expect that this information is shared, as it may have implications for the care of the patient. However, what moral responsibilities does the clinician then have with regards to administering or withholding medical products of uncertain quality?[59 60 84] Moreover, should the clinician (or iNGO

representative) communicate with the patient and their carers regarding the uncertain quality of the medical product and its potential risks, and to what extent should this be modulated by potential hesitancy (and risks to public health), acceptance (and the risk of unsafe alternative therapies), or security threats?[53 252 322 526] To what extent should patients or their representatives be involved in the decision to use medical products of uncertain quality, and should additional consent ever be required?[62 309 322]

Some participants were not, or not entirely, influenced by what they perceived to be the ethically "good" decision for the affected patient population.[83 296 315 338] For example, in section 7.2 I described how some medical products were associated with an organisation's brand and, consequently, were subject to greater quality requirements. In this regard, the needs of the patient were obscured by the interests of the organisation; describing this in terms of the model that I presented in section 8.3, patient vulnerability was privatised by the more powerful donor or iNGO, which acted to minimise its economic vulnerabilities by protecting its repute.[49 84 255 303 348] Normative research may conclude that prioritising quality to this extent is the morally 'right' thing to do. However, if so, this has ramifications for the *non*-brand medical products that were not subject to the same quality standards. Moreover, those of a non-consequentialist philosophy would likely argue that motives matter; that regardless of (dis)agreement on what should be done, decision-makers should agree that the acts should be made in the perceived best interests of the patient, if this could be reasonably achieved.[37 49 84 329]

My study identified that the resolution of 'no stock, high stakes' problems, and thus the treatment that patients receive, may vary according to the donor of the health project. (For example, see section 5.3.2). As just explained, different donors placed different quality requirements on certain medical products, meaning that patients may receive different quality of medical products according to the donor of the project.[223 233 235 244] I also found that an iNGO may reach differing conclusions regarding the outcome of a 'no stock, high stakes' problem depending on their dependency on the donor (and the size of perceived financial risk). (See section 5.3.2). I also found that a Global South

iNGO did not restrict access to medical products according to quality, like the other Global North iNGOs in my study did. (See Rohan's comments in section 4.3.3). These examples raise the question as to whether the practice of categorising patients or a population according to their health provider's donor – and treating them differently according to the preferences and requirements of that donor – is discriminatory.[323 324 527 528]

Next, let us turn to the choice of abstaining from sourcing medical products of uncertain quality in a 'no stock, high stakes' situation. As described, participants who lacked proximity to the patient were generally willing to tolerate the risk of a medical product stock-out to a greater extent than those in close proximity. (See chapter 7). These interviewees were also more likely to have responsibility for making the 'no stock, high stakes' decision because of organisational norms (such as, neocolonial factors that shaped regard for the inherent capabilities of national staff, neoliberal factors that prioritised economic interests, and corporate factors that shaped organisational governance frameworks and centralised risk-management). (See sections 7.4, 5.3, and 7.3, for example). However, the moral intuition of most patient-focussed participants was to source medical products of uncertain quality for an urgent stock-out of medical products. Furthermore, it could be reasonable to assume that the Host Government would expect the iNGO to source registered medical products from legally certified national vendors (whose quality and legitimacy have been authorised by the HG-NDRA) during 'no stock, high stakes' problems.[137 529] (See also section 5.4.1). This raises the question, on what grounds is it acceptable for an iNGO to suspend healthcare services when superseding an HG-NDRA verdict?[153 255 262 331] Is it feasible to 'prove' poor-quality, given the previously described constraints and limitations of testing?[9 142 178 179 242] In these circumstances, if the iNGO and its donor are not responsible for the provision of healthcare to the affected population, who is?[263 266 267] Furthermore, if health is a human right, is it a violation of human rights to impede access to medical products for reasons *other* than concern for patient wellbeing?[357 359 521]

Regardless of choice, my study found evidence that iNGOs did not routinely gather data regarding the outcome of decisions. This would mean that they were poorly positioned to address (or flag) any

harmful sequalae of their choices and would fail to collect data that could help to inform future decision-making.[204 203 204 289 474 496] This means that patients could be vulnerable to unmitigated harms and repeated, avoidable injustices. Furthermore, a lack of feedback from decisions could serve to further disconnect decision-makers – and their choices – from the subject of their choice, the patient.[329 500] Arguably, the decision to not follow-up on the outcome of 'no stock, high stakes' choices serves to compound a decision-maker's lack of proximity and connectedness to the patient, by further dehumanising, obscuring, and silencing the *actual* patient and insulating the decision-maker from the real-world impact of their choice.[297 298 335 346 474 500] Some research suggests that this lack of feedback could encourage, or fail to dissuade, high risk behaviours.[300 301 486]

This issue is potentially further complicated if there is poor communication and integration with national systems.[137 217] No participant articulated that they would confer with national stakeholders when deliberating a 'no stock, high stakes' problem. If a Host Government is not informed that an iNGO is incapable of maintaining health services or standards, their ability to act in response to the problem is undermined, and their capacity to oversee public health is impeded.[331] This may disadvantage the iNGO's patients and place an unanticipated burden on surrounding healthcare providers. Furthermore, the unilateral manner in which 'no stock, high stakes' problems were reportedly resolved raises questions regarding why patients, caregivers, communities, health advocacy groups, and national health representatives are not involved with decision-making.[62 263 267 346] If an iNGO chooses to suspend some health services, or deviate from their stated medical product quality standards, what authority do they have to make these determinations and to what extent are they accountable to stakeholders for the outcomes?

8.5 Limitations of this study and opportunities for further research.

This study has identified, and contributed to addressing, a research gap that is important to the lives and livelihoods of many patients of humanitarian health projects, and to the staff who work to deliver and support such services. However, my study is 'just' a single doctoral research project that has

revealed and explored a large and complex topic; inevitably, my study is limited by its scope and focus and does not offer a comprehensive examination of situations that I have termed 'no stock, high stakes' problems. Moreover, the issues, agendas, and priorities that prevailed during data collection may have influenced my data (due to participant availability or common discussion topics, for example).[66 72] In this section I will summarise factors that may have impacted my research.

8.5.1 The types of iNGOs from which participants were recruited.

As described in Chapter 3, my sampling strategy focussed on recruiting individuals who were likely to have experienced intense and complex medical product stock-outs. While this helped me to gather a rich description of the problem and the moral worlds of some participants who had encountered it, it is unlikely to be representative of *all* aid workers. Table 6 (in section 3.5.1) described the preferred attributes of the iNGOs for which a participant had worked. These were: international, very large, multi-sector, with a medical product QA policy, working in a humanitarian context, and delivering responsive and complex health services. Participants working for iNGOs that had a different set of characteristics may experience medical product stock-outs in a different way and, therefore, offer different findings.

For example, *national* NGOs may face different pressures and expectations due to different relationships with Host Governments and donors. Small iNGOs may not have the choice afforded to charities with greater resources and, therefore, their staff may relate to the ethics of the problem differently. The culture and systems of health-focussed iNGOs, or iNGOs that lack policies relating to the procurement of medical products, may give rise to different norms, priorities, or ways of working – all of which could affect a participant's perspective on how they 'should' respond to a stock-out.[46 47] Similarly, individuals who are involved with emergency response or development assistance may engage with the problem in an entirely different way (to each other, as well as to the participants recruited for my study) because of their different mandates, procedures, life experiences,

and perceived risks. Moreover, perhaps risk perception and proximity to the patient is quite different amongst individuals that work for iNGOs that focus on a certain condition, service, or patient group.

There are also organisations that support and offer health services in humanitarian contexts that are not non-governmental. For example, several agencies of the UN work closely with Host Governments to deliver humanitarian aid. As enormous and political institutions with significant logistics and QA capabilities, participants from the UN may offer different perspectives on the problem and its ethics. Also, participants working for faith-based charities could lend a different and interesting view on how various beliefs can influence proximity to the patient and moral reasoning about how to respond to ‘no stock, high stakes’ problems. These examples of heterogeneity are not exhaustive; rather, they serve to highlight that my study has gained insight into a small but significant part of this world, and that the topic would benefit from further research.

8.5.2 The attributes of participants sampled for this study.

Based on the analysis that I have presented, one would expect that participants with different responsibilities and meso-level relationships might view the ethics of ‘no stock, high stakes’ problems differently. In this study I focussed on recruiting individuals with specific experience, from specific types of iNGOs, who had worked in specific roles, and were from certain locations (section 3.5 refers). These choices necessarily resulted in ‘gaps’ in the perspectives that were gathered; future research that focusses on these gaps would be of value in broadening our understanding of ‘no stock, high stakes’ problems. Notably, the views of patients and ‘communities’ are absent from my study due to the ethical concerns explained in section 3.3.3. In addition, the term ‘Country Office’ can encompass a wealth of heterogeneity in terms of country, economic status, culture, urbanisation, work site, and so on. While I sampled from a range of regions, certain groups were inaccessible due to COVID-19 travel restrictions. Those with the greatest physical proximity to the patient (such as those in austere settings and health clinics who may lack reliable internet connection) were out of reach.

8.5.3 Potential changes to workplace relationships, responsibilities, and policies.

Data collection commenced during the height of the COVID-19 pandemic, whilst travel restrictions and social distancing requirements were in place. The pandemic wrought unprecedented global supply chain challenges, high-profile incidents of falsified medical devices, the phenomenon of vaccine nationalism, and exacerbated the inequitable distribution of medical products. Media coverage of these issues, which are pertinent to the research topic, may have raised participant awareness of them and elicited greater discussion during interviews. Within organisations, new ways of working were established to enable effective, remote communication between staff and teams. For multi-national aid agencies, this may have led to different responsibilities and relationships for engagement, training, government liaison, advocacy, and so on.

Additionally, conflict was rife during the study: the Russia-Ukraine war, the Gaza-Israel conflict, the Sudanese civil war, and the cessation of a NATO peacekeeping presence in Afghanistan occurred (or were inflamed) during this period. These events led to man-made humanitarian crises with complex issues of access (for medical products, for example) and strained geopolitical tensions along religious, racial, and national lines. Some participants that I spoke with were personally and professionally impacted by these events, and the prejudice that they ignited. Furthermore, decolonisation discourse in multinational aid institutions was active during the study and the years immediately preceding it. Several participants spoke of it as a 'current' topic, sometimes referencing new workplace initiatives or offering personal reflections on the subject. Findings relating to epistemological inequity may have been more prominent in my data due to the currency of discussions about decolonisation and the backdrop of conflict.

Both COVID and decolonisation may have led to organisational change and, whether these changes were temporary or permanent, their lasting impact will not have been captured by my study. For example, perhaps relationships and data sharing with external stakeholders (e.g. donors and other iNGOs) will have shifted because of novel procedures, changes to the economic climate, and fewer

face-to-face meetings. Internal roles, responsibilities, and dynamics may have altered, due to increased delegation to national staff. Interactions with Host Governments may also have changed due to, for example, the overwhelming needs of the pandemic and the violent injustice of COVID vaccine inequity. Therefore, data collected during the study may relate to policies, roles, or relationships that have evolved in response to the COVID pandemic and decolonisation discourse, but which have had a profound impact on the phenomenon of interest and its context.

It is also noteworthy that my study took place at a time of regulatory transition. For example, the African Medicines Agency was launched during my study, in 2021, to much acclaim and anticipation. This new regulatory body heralds the opportunity for increased harmonisation, advocacy, and global partnerships, which will surely impact the capacity of its members and their relationships with industry.[15 137 144 154] Furthermore, my study straddled a period of ebb and flow in the categorisation of NDRAs; the concept of SRAs was considered outdated, but the World Health Organization enterprise of benchmarking NDRA maturity levels was not yet fully functional. With time, these changes will impact the language and policies of Global Health organisations and, therefore, perhaps also their beliefs regarding QA expertise (cf Chapter 5). At the time of my study, some participants anticipated these changes but freely admitted that they were unclear what they would be, or what it would mean for medical product QA.

8.5.4 Data collection techniques.

The data that I gathered through interviews and FGDs tended to relate to memorable events that were distressing or difficult. Unfortunately, COVID-19 social distancing requirements meant that I was unable to use participant-independent methods to gather data. Techniques like participant observation (PO) may reveal situations that are less memorable and therefore, perhaps, have different characteristics.[66 387] Also, I used vignettes to help participants discuss the perceived risks and ethical tensions of a 'no stock, high stakes' problem in a grounded and shared scenario (section 3.6 refers). This data possibly represented an idealised version of how each participant believed one

should handle the situation. It would be well-complemented with PO-derived data. For example, ethically relevant factors, or morally questionable behaviours, that were undisclosed because they were considered inconsequential or sensitive.

8.6 Recommendations.

My recommendations are not long-term resolutions that seek to 'fix' 'no stock, high stakes' problems, for two main reasons. First, in this study I examined a sample that had experienced the issue and gathered data on what *is* – I cannot claim what *ought to be*.[470] Although perspectives on the ethical problem that I have described are a valuable foundation for future normative work, they cannot inform us about the morally right path to take. Second, the ethically fraught decision that I have uncovered in this thesis is spawned from the far greater wicked problem of inequitable access to health and substandard and falsified medical products (and their disproportionate prevalence in humanitarian contexts).[13 185 240 356 530] Only by addressing these inequities will we eradicate 'no stock, high stakes' problems and ensure that all people have access to safe and effective medical products that enable them to achieve and maintain their highest attainable standard of health.

While I strongly recommend that all relevant stakeholders work together to create a future in which quality medical products are accessible to all who need them, the recommendations that I list in this section will focus on how to learn to contend with their absence, within the specific situation that I have described. These points represent some initial steps, largely to better understand the scope, impact, and ethics of 'no stock, high stakes' problems and the identities, responsibilities, and rights of its stakeholders. Once this work has been done, more specific recommendations can be drafted that translates such research into practice.

1. Broaden scope of understanding of ‘no stock, high stakes’ problems.

My study focussed on iNGO decision-makers and there are many groups that I did not interview (or even identify). Therefore, it would be a mistake to assume that this thesis is authoritative and to design normative studies on this basis. In particular, qualitative research that is inclusive of invisible and ignored populations is recommended to better understand these perspectives and to adopt approaches that are sensitive to these views and preferences.[491] Notable groups for inclusion are NDRAs and patients and their communities.

Furthermore, understanding how different contexts lend nuance to ‘no stock, high stakes’ problems would be of value. The feasibility of a comprehensive understanding may be frustrated by the vast potential heterogeneity of the situation. However, centring patient care (by focussing on factors that cause significant changes to the quality and availability of medical products that are used by and administered to patients) will help with study design. For example, donor policies in emergency and development contexts tend to have quite different medical product quality requirements, as do national NGOs and small iNGOs that, as an aggregate, have enormous reach.

2. Identify the moral values at stake and how these might vary with context.

Our ability to develop practical guidance for reaching ethically sound decisions hinges on normative research that identifies the moral principles at stake, the contextual factors that have ethical significance, and that advises how to weigh the former according to the latter. The potential for variation in ‘no stock, high stakes’ problems suggest that principles for ethical decision-making, rather than a substantive process, would be more practical. Therefore, this work should dovetail with other research, such as who should have moral authority for the decision, how should competence be assessed, and what are the likely legal ramifications. I will touch upon these areas next.

3. Clarify and agree stakeholder responsibilities.

I found that ambiguity and assumption surrounded responsibility in 'no stock, high stakes' decision-making. I envisage that research to clarify this could involve three strands (normative, legal, and technical), two tiers (meso and micro), and attention regarding how these results might interfere with one another. It is important that such studies offer a *balanced* account of responsibilities: they must not focus on medical product quality and neglect the matter of availability.

Normative research would establish the moral duties of stakeholders to one another, and to the patient. It should recommend adaptations for situations in which capability is in doubt. Jurisprudence of the problem should propose legal responsibilities for the quality and continued availability of medical products by all stakeholders to patients, in cases where iNGOs deliver humanitarian health projects. It would define boundaries of authority and permissions required for certain actions, clarifying hierarchies where stakeholders and their regulations come into conflict. Proposing grounds for jurisdictional contraventions would also be helpful. Research into technical matters would offer clarity on whom should do what, how, and according to which standard. It seems that this should centre around the question of knowledge (or, indeed, ignorance), given the uncertainty of the problem. For example, what constitutes data, is there a minimum dataset required, who should interpret the results, and how should this be applied to problem?

I found that normative, legal, and technical responsibilities were uncertain at both meso (i.e. organisational) and micro (i.e. individual) levels. For example, earlier I highlighted that work is needed to clarify a donor's moral, legal, and technical responsibilities to a patient population (and wider stakeholders, including iNGOs and Host Governments) to ensure an ethically judicious response to a 'no stock, high stakes' problem. However, we also need to understand how determinations of meso-level obligations might translate into real-world settings. For example, how do the responsibilities of a patient-facing prescriber differ, conflict and impact those of a Head Office policymaker or donor budget holder when determining the quality and availability of medical products?

4. Clarify transparency and monitoring requirements.

It seems reasonable to assume that clinicians should be informed of changes to the quality and quantity of medical products that they use in their practice; this seems pertinent to prescribing decisions that they may need to adapt to treatment risk-benefit estimates or resource constraints, for example. Moreover, as medical product quality is projected rather than known, this information is needed to allow clinicians to interpret and adapt patient therapy to response. Similarly, it seems important for clinicians to communicate unexpected and undesirable effects of medical products to those who select vendors or make procurement decisions. However, I found evidence that communication of ‘no stock, high stakes’ problems – and their decisions and outcomes – was not consistently shared with many internal or external stakeholders. Work is needed to clarify how the problem, its determination, and its consequences should be communicated, to whom, how, within what timeline, and under what protective measures.[204 480]

It is noted that this work could have normative implications (and impact research into responsibilities, that I raised earlier). For example, how are a clinician’s responsibilities to the patient impacted by their knowledge that a medical product may be of poor-quality – and what does this mean for the locus of decision-making? Also, what information should be communicated to the patient (or caregiver), how does this impact consent for treatment, and how should this be weighed against the potential public health risks of hesitancy or seeking traditional healers?[61] The work also has practical implications. For example, an understanding of who the stakeholders are is a prerequisite, and one that will shift according to context. This should be sensitive to invisible groups, as well as the roles of prominent ‘non-participating’ stakeholders (e.g. the WHO). Moreover, it requires clarification of data collection. For example, how should screening and testing technologies be used to inform decision-making, and how should the outcomes of decisions be monitored and communicated? The latter could give rise to legal implications; for example, whether reparations are needed in cases of harm and from whom.

5. Clarify the competence and capacity needed for capabilities related to 'no stock, high stakes' problems.

Once normative research establishes the ideal responsibilities of stakeholders in 'no stock, high stakes' problems, then work will be needed to understand the skills, competencies, and capabilities needed to shoulder them. Moreover, a fair method of evaluating these attributes is needed, as well as guidance for who should intervene in cases of temporary or permanent incapacity. There appears to be two key capabilities that relate to 'no stock, high stakes' decision-making. The first is estimating the quality of medical products. My study found that oversight of iNGOs and some wholesalers (who were assumed to be capable in conducting QA) was neglected, and that the capability of non-SRA NDRAs was contentious. The second is the overall decision: deciding the risks to take, to what extent, and with what mitigations. Many participants made claims of (un)suitability, but the experience, knowledge, and competencies required to handle the decision are, as yet, unmapped.

6. Review policies, rules, regulations, and contracts.

Once the aforementioned strands of research and work has yielded results, it will need to be reflected in the documentation that influences 'no stock, high stakes' problems. This will require a review of existing policies, rules, regulations, contracts, agreements etc, as well considering what amendments, additions, and omissions are recommended. Moreover, how such requirements shape and constrain decision-makers and decision-making should be examined. Even while research is ongoing, stakeholders could review documentation in light of the findings of my study. This could make improvements in the care of humanitarian patients, as well as offering valuable findings that could inform research.

9

Conclusion.

This study investigated perspectives on how to handle urgent medical product stock-outs for health projects delivered by grant-reliant international Non-Governmental Organisations (iNGOs) that have Quality Assurance (QA) policies, in contexts in which the quality of medical products is uncertain. Using qualitative methodologies to speak with those who have encountered the problem, I found that this situation places medical product quality in tension with medical product availability and is experienced as a moral issue. Should decision-makers source medical products that are immediately available on the national pharmaceutical market they might address availability concerns, but they risk administering substandard or falsified medical products to their patients. If they wait for the importation of quality assured medical products from approved international suppliers, they prioritise the safety of medical products at the expense of their ability to treat and prevent the health conditions of a vulnerable, humanitarian population. I termed this predicament a ‘no stock, high stakes’ problem.

Despite its theoretical dichotomy of choice, I learnt that participants facing ‘no stock, high stakes’ problems in real-world settings sought to establish a balance between competing priorities and risks. This led them to question the extent to which they should risk compromising medical product quality or availability, for how long, with what mitigation measures, and on what authority. I found that opinion on how to resolve the problem was contentious and reports of professional conflict, strained relationships, and moral distress were common. Opinions were rooted in fundamentally differing perspectives on ethically poignant concepts, like scope of responsibility, how to define quality, and what harms were permissible to who and by whom. When devoid of external pressures, I noted that participants were wholly concerned with making a choice that was perceived to be in

the best interests of affected patients. However, I discovered that the priorities and choices of participants might change when factoring-in the competing pressures and threats of the real-world context.

A pattern emerged amongst interviewees. The primary concern of those involved with the delivery of clinical care or operations tended to be guided by their perception of the risks that threatened the affected patient population. Although those with responsibilities for developing and implementing QA policies were concerned with patient well-being, their primary focus tended to be the perceived risks arising from non-compliance with policy requirements that might threaten themselves, the organisation, and, therefore, wider populations who were recipients of their aid. I termed the former "patient-focussed" and the latter "policy-focussed" and noted that, rather than static binary positions, participants moved between these poles along a spectrum. I found that a participant's preferential position along the conceptual spectrum correlated with their proximity to the patient. Participants that were witness to the patient, or capable of emotionally or morally connecting with their situation, were often patient-focussed and more sensitive to compromising medical product availability. Factors that decreased a participant's physical, emotional, or moral proximity to the patient (for example, with prominent responsibilities and risks that competed with patient associated risks) were more common amongst policy-focussed participants and usually led to a greater tolerance for medical product stock-outs.

Participant statements and my analysis of data found that the sociopolitical context may manifest and complicate this situation through a web of meso-level iNGO interdependencies that created a swathe of critical vulnerabilities. The contested and competing hierarchy of stakeholders led to a dysfunctional system of polycentric governance in which the iNGO was forced to "choose sides" during 'no stock, high stakes' problems to avoid existential threats. Chiefly, the heavy financial penalties of donors were pitted against the legal permissions and controls of the Host Government; medical products at the centre of the exchange became a contested object of power and a physical representation of dominance. Findings indicated that 'no stock, high stake' problems are shaped by

macro-level power asymmetries, arguably serving as a case study that illustrates the power, control, and priorities of the wider humanitarian enterprise and controversy that surrounds aid. A neoliberal system was found to dominate the priorities, policies, language, and choices of iNGOs facing ‘no stock, high stakes’ problems, privatising their vulnerability and disincentivising the centring of patient need.

This economic dominance was enmeshed with a culture of neocolonialism that influenced (mis)trust for those perceived as ‘other’. Participants that lacked proximity to the Host Government tended to be the most suspicious of them. Presiding QA policies adopted a Eurocentric, hegemonic approach to medical product approvals were found to shift the ‘truth’ of ‘what is quality?’ and create an unfeasible frame of reference for navigating ‘no stock, high stakes’ problems. These procedures reinforced a disregard for ‘distal’ expertise and contributed to a culture of epistemological inequity. Moreover, a neocolonial informed culture was evident in iNGO decision-making, which resisted ceding control to national staff. Given findings that those in the centre were likely to be less sensitive to patient concerns, and that a lack of guidance resulted in arbitrary, inconsistent, and unethical decision-making, this locus of control has troubling ramifications for patient-centred care.

At present, ‘no stock, high stakes’ problems are determined without transparency, accountability, or a follow-up of outcomes. This secrecy neglects patients, hinders learning, undermines justice, perpetuates repeated harms, and stifles progress towards an ethical framework for handling the decision. It is imperative that stakeholders with the capacity to influence medical product quality and availability (such as those loosely mapped in appendix B) acknowledge the tension between them, consider how policies for one may counter the feasibility of the other, and accommodate for non-ideal contexts in which tough choices must be made. Failure to do so only serves self-interests; it neglects those who grapple with the tragedy of ‘no stock, high stakes’ problems and contributes to a grave health injustice to the “forgotten” stakeholder: patients.

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Appendix A

Literature and policy search.

Overview.

In Chapter 2 I explained the approach and methods used to gather articles of interest for my literature and policy review. The supplemental information here details the search terms that were used, how they were organised, and how I combined them into searches.

Key terms.

Key words (table 11 refers) were cultivated from the research question's core concepts and synonyms and were refined using preliminary searches and heavily cited articles of interest. This was guided by a PICo (Population, Phenomena of Interest, and Context) process, which is suited to literature searches for qualitative studies (rather clinical interventions). I complemented this with "S" for "study type", to assist with targeting suitable literature. To further organise the large number of search terms generated and to clarify purpose, I created three subcategories for each: macro-level, meso-level, and micro-level.

Population				
Populations	**Macro level**	**Meso level**	**Micro level**	**NOT**
NGOs	organi?ation* administration institution* third-party "third party" "international cooperation" [MeSH]	*NGO "Non-governmental organisation" Non-profit Not-for-profit Humanitarian "humanitarian organisation" "humanitarian operations" "relief operation" Aid "international aid" "international development" Agency Charity Relief Emergenc* Disaster Development Assistance ODA "overseas development assistance"	<names of iNGOs> MSF "Medicin Sans Frontier*" "Save the Children" "International Rescue Committee" IRC IMC "International Medical Corps" BRAC "Malaria Consortium" UN "United Nations" WHO "World Health Organization" UNICEF UNFPA UNDP	
"Beneficiaries"	Beneficiar* Recipient "Service user"	Refugee		Patient Sick Community victim
Donor	funder donor grant	Philanthrop* "Public giving" multilateral bilateral "source of funds"	<names of donors> "World Bank" GFATM "global fund" "Gates foundation" DfID FCO USAID UKAID	

Regulators	Regulat* (regulation, regulator, regulate) Auditor State government International agencies [MeSH]	"Regulatory Affairs" "Regulatory Authority" "Stringent Regulatory authority" SRA "national drug regulatory authority" NDRA "competent authority" "professional bod*"	<name of NDRA> interpol	custodian judicia* "border force"
Vendors	Vendor Seller Procurer	"Procurement Agent" Wholesaler Distributor Peddler Hawker Counterfeiter Falsifier	IMRES IDA MEG CHMP MEDS	Pharma "Pharmaceutical industry" Manufacturer "Drug compan*"
Phenomenon of Interest				
Phenomenon	**Macro level**	**Meso level**	**Micro level**	**NOT**
Decision point	decision "decision mak*" decision-mak* choice "choice behavio?r" "decision making" [MeSH] "Choice Behavior" [MeSH]			strategy behavio?r authoris* deliberat* impact Option Alternative Opportunity conclusion
Risk	Risk "high risk" Uncertain* Risk [MeSH] Prevalence [MeSH]	Crisis Concern Problem Threat Danger Hazard Emergenc* Jeopard*		Clinical risk

		Weak* stress vulnerab*		
Ethical dimensions	Ethic* bioethics practical	problem challenge barrier "wicked problem" "ethical dilemma" moral "moral problem" "moral dilemma" dilemma difficult* norm* principle* (principles, principled) value* "moral intensity" "tragic choice"	"resource allocation" non-maleficence beneficence paternalism autonomy "informed consent" sovereignty "social justice" "health justice" "human rights" "global health justice" inequality inequity postcolonial* post-colonial* decoloni* injustice "immoral entrenchment" "strategic ignorance" avoidance responsib* accountab* integrity transparency	issue situation opinion
Context (Disciplines)				
Contexts	**Macro level**	**Meso level**	**Micro level**	**NOT**
LMIC	LMIC Low-Income "Low Income" Middle-Income "Middle Income"	"Low resource" "fail* state" Fragile "Resource Poor" "Resource constrained" poor	Sub-saharan subsaharan Africa Asia Latin America "africa south of the sahara"	Socioeconomic Conflict

		"Developing countr*" Marginali?ed Developing "third world"		
Health	Health Medicine	"Global Health" "Global Public Health" "International health" "Tropical Medicine" Neglected NTD "Neglected tropical disease" "public health" "health system"	"Access to Medicine" "Essential Medicine" "medical product" Medicin* (Medicine, Medicines, Medicinal) Pharmaceutical "pharmaceutical preparation" Drug "Dosage form" "Medical device" "Assistive technology" "laboratory reagent" chemotherapeutic "healthcare commodit*"	Food veterinary cosmetic nutrition* herbal medicines alternative medicines homeopathic medicines Class I / illegal drugs specific products: Antimalarial ACT "Artemisinin combination therapy" "rapid diagnostic test" RDT "Family planning" Contracept* (contraceptive, contraception) OCP "oral contraceptive pill" Condom Barrier Implant "Intrauterine device" "Long-acting reversible contraception" vaccin* PPE "personal protective

				equipment" mask ventilator
Supply Chain	"Supply Chain" "Value Chain" logistics SCM "Organization and Administration" [MeSH]	Procur* Purchas* Sourc* Buy* "category management" Import* Gift* (gifted, gifting) Donat* (donation, donated, donate) GIK "gift in kind" gift-in-kind		Aqui*
Policy	Bureaucra* Governance Administration regulation* rule law Policy [MeSH]	Policy Procedure Algorithm Waiver Derogation Guideline Protocol	<name of policy> "procurement policy" "Quality Assurance policy"	
Access	"Access to medicines" barrier	Availability access Fail*	Shortage Stockout stock-out "stock out"	
Quality	Quality	"Quality Assur*" "Quality Control*" Pharmcovigilance	Falsified Substandard Spurious Fake Counterfeit Fraud* (Fraud, fraudulent) Contamina* (contaminant, contamination) "Poor quality"	

			Pseudo Adulterated Inauthentic genuine "substandard drugs" [MeSH] "drug counterfeiting" [MeSH]	
Power	System relations* "interpersonal relations" [MeSH]	Power Influence* Trust proximity reliance confidence Pseudo Performance masking Perspective "power dynamic"		
Study				
Study	**Macro level**	**Meso level**	**Micro level**	**NOT**
Methods	qualitative empirical IDI "in-depth interview" FGD "focus group discussion" vignette			

Table 11: Literature & policy review search terms and their organisation.

Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion criteria
Considers substandard or falsified medical products, or medical product quality	Is unavailable
Concerns humanitarian health projects	Is not in English
Concerns LMICs, or Global Health	Does not concern allopathic healthcare
	Does not relate to medical products (e.g. cosmetic products or food)
	Relates to a nutritional product (even if 'therapeutic')
	Is clinically focussed (including trials)
	Concerns medication use, error, or safety
	Focusses on pharmacoeconomic aspects (such as health insurance, financing, or trade agreements)
	Is a book review
	Is an RSS feed
	Concerns development aid
	Concerns national NGOs
	Concerns food
	Is veterinary (or not related to humans)
	Is focussed on cosmetic
	Pertains to nutrition*
	Focussed on herbal medicines
	Focussed on alternative medicines
	Focussed on homeopathic medicines
	Focussed on Class 1 or illegal drugs

Table 12: Inclusion and exclusion criteria for literature and policy review.

Appendix B

Stakeholder analysis.

A stakeholder analysis was conducted at the beginning of the project to assist with selecting the focus of my research. It was informed by experience, informal conversations, a policy review, and a literature review, and sought to identify who (in an individual or institutional sense) could influence the quality and availability of a medical product that is administered to, or used by, a patient in a humanitarian health project. Stakeholders were then collated into categories (figure 14 refers). It was noted that some categories of stakeholders would impact others; they were loosely organised into an order that reflected this sphere of effect. For example, a manufacturer's impact on medical product quality and availability will be influenced by those upstream of it (such as the policy makers, standard setters, and researchers) but not those downstream (such as vendors, prescribers, and patients). (This is a loose and general observation to assist with mapping stakeholders in a two-dimensional format; in reality, feedback and circular influences exist.) This resulted in a linear diagram of nested stakeholder categories.

I noted that there was a fundamental difference between stakeholder categories that were up- or down- stream of the red diamond. This is the point at which the medical product of interest shifted from conceptual to actual; it changed from being *a* theoretical medical product to which policies were applied (for example), to *the* physical medical product that possessed a batch number and expiry date. I hypothesized that this decision would be highly significant in the patient experience, as it is a potential filter against poor-quality medical products reaching them. Therefore, I chose to centre my project around the procurement of medical products in humanitarian settings. Of the stakeholders that I had identified, iNGOs were the preferable option because they possess fewer resources than UN agencies (and are therefore less able to mitigate challenging circumstances) and had a more accessible pool of interviewees.

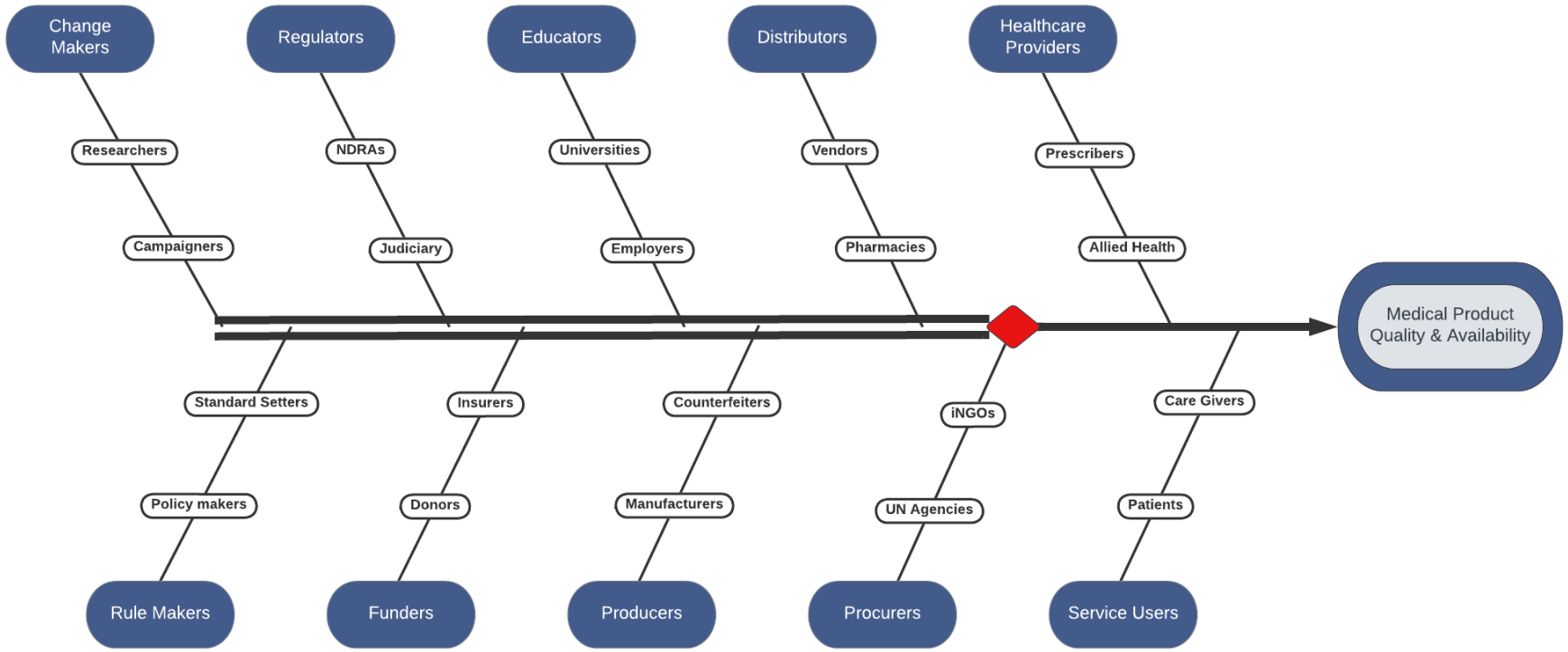


Figure 14: Theoretical map of stakeholders with the potential to influence the quality or availability of medical products administered to a patient in a humanitarian health project.

Appendix C

Topic guides.

Overview.

This document presents the topic guides that were developed in support of semi-structured in-depth interviews (IDIs) and focus group discussions (FGDs).

Topic guide for semi-structured in-depth interviews.

Presentation and organisation of IDI topic guide.

The IDI topic guide was iterated during the study in response to findings, as well as being adapted 'in the moment' to the responses and experiences of the participant. The topic guide presented below is the fifth and final version. It is arranged as follows:

Key Word. The topic guide is separated into five sections, denoted by a key word subheading. Key words provided a prompt to rapidly keep track of planned discussion topics during the interview.
Aim: Under each key word is the aim of that section. These were for personal use; they were not spoken aloud to the interviewee. These aims were useful when running out of time, or when posing unscripted questions, to maintain the focus and direction of the interview.
Preamble: The preamble preceded a 'grand tour' question. Words and hesitations were carefully scripted in a manner that sought to avoid unintentional bias and create rapport, before being committed to memory. However, the script was not read or recited during the interview – it was adapted to each interviewee to reflect their language and style.

Grand Tour Question: a main line of inquiry that is written in a contrasting colour to aid speed of reference.

Probing Question: anticipated follow-up questions listed by bullet points.

3.1.1 Topic guide used for In-Depth Interviews.

1. Opener.

Aim: To build the participant's confidence and comfort in being interviewed. To generate insights into the career background of the participant and experiences that were formative for the individual.

Preamble: OK, so, I've just been talking about how we're going to be exploring this research topic through your eyes, so I'd like to start off with learning more about you. And, specifically, I'd like to begin by exploring the impact that you have – personally – in this space.

Question: So, to start, could I invite you to reflect on how you feel that **you** have influenced access to medical products?

2. Influences.

Aim: Learn of the structural, procedural and relational factors that influence the individual's prioritisation and decision-making.

Structural influences preamble: OK, thank you – that's so interesting. Um, as you speak about your influence, I find myself wondering about what – in turn – influences you. So in your role, in your team, in your organisation, even in Global Health – I'm wondering about what influences the choices and decisions that you make.

Question: If there are more things on your to do list than time available, how do you decide what to prioritise and what to … compromise?

Procedural influences preamble: Lots of people that I've spoken with have given me a window into the, um, bureaucratic side of "saving the world". I've heard about policies… and technical guidelines… and national procedures… and professional standards… and donor regulations… and so

on, and so on. If it's OK with you, from now on I'm just going to refer to all of those "things" as "documents". Does that work? OK, so I'll just be using the word "document" as a really broad term for anything that you might use as a reference or source of information, I guess.

I am really interested in hearing about any "documents" that are meaningful for you – specifically when it comes to medical procurement. And by 'meaningful', I mean both the good and the bad. Those that you refer to for help, but also those that seem to take up all of your time. Those that you recommend to people, and those that don't exist, but you wish that they did. Does that make sense? Great – so, thinking purely in terms of medical procurement now…

Question: what 'documents' are meaningful for you?

Probing questions:

- Why?
- In what circumstances?
- I notice that you haven't mentioned any < donor / finance / quality assurance > documents…
- Are there any that you've found irrelevant or unworkable?

Relational influences preamble: Gosh, that's so informative. And so valuable for this research, so thank you. So, although we've just been focussing on role of "documents", one of the things that has actually come up fairly regularly is that documents don't necessarily reflect real life.

Question: I've heard that, in some organisations or in some circumstances, relationships might be more important than procedures. Is that something that you've found?

3. Transition.

Aim: Openness and forewarning to create safety and predictability for the respondent.

Preamble: OK, next I'd like to move on to try and understand more about how difficult decisions are made in humanitarian contexts. And the way that I'd like to do that is through a scenario, so that we can, kind of, immerse ourselves in the situation.

C-4 | 'No stock, high stakes' problems

So, I'm going to outline a scenario, which is a medical supply problem, and I'd like for you to think about it 'out loud'. You'll probably find that you want to know more about the situation – in which case we'll talk about what you want to know, why you feel like it's important, where you may go for that information, that kind of thing. Hopefully that makes sense, but I'll give you an example from a different walk of life, to show you what I mean and also to explain why we're doing it.

OK. Let's say the scenario is "I don't know what to get for my niece's birthday". If I ask that question to one person, the first thing they may wonder is, "well is it a boy or is it a girl?" So that tells me that gender is seen as significant to that person. But if I asked a different person, they may say, "well, what kind of books do they like?" In that person's world, it may be taken for granted that you give books to children for their birthday.

Neither of those answers are right or wrong. They just give me a window into what is perceived to be the norm, or important, or a concern for that person. And by asking the same scenario of lots of different people, I will hopefully find some patterns – where some groups of people tend to look at things a similar way. Does that make sense and does it all sound OK?

4. Scenario.

Aim: To observe prioritisation, decision-making, and reflection in a live setting.

Preamble: So, the scenario is that you work for a large iNGO. You receive news from a Country Office that one of their medical warehouses has burnt down. All of the stock has been destroyed and they are seeking approval to purchase it on the local market.

Before we jump in, I just want to check…

Question: does that sound like a feasible scenario to you?

[Adaptation and co-construction if necessary.]

Individual decision-making:

Question: Could you tell me about what you're thinking?

Probing questions:

- Why is that significant?
- Who or what would you confer with for guidance?

Perceived institutional decision-making:

Question: How do you think this situation would be resolved in practice?

Probing questions:

- What would a "good" decision look like?
- One person I spoke with said that 'quality assurance is just about deciding where to buy from'. Would you agree with that?

5. Quality.

Aim: to uncover implicit beliefs regarding trust and threat.

Preamble: OK, I want to use this scenario to dig a little bit deeper into the idea of quality. In particular, I'm interested in what happens when there's a difference of opinion between, say, a national auditor and an international one. So, I'd like to augment our scenario with Quality Assurance information that you've gathered from different sources.

Let's say that the Country Office pharmacist has identified five potential suppliers. She has checked the credentials of these vendors with the national regulatory authority. All are of them have been recently inspected and are fully quality assured. However, QUAMED audited these suppliers and failed them. So, we have a difference of opinion here.

Question: Who would you say is right?

6. SF.

Aim: to gain a better understanding of the participant's perception of the risk of poor-quality medical products.

Preamble: Maybe, just before we finish, we could talk about the 'opposite' of quality: substandard and falsified products. So many articles that I've come across state that "1 in 10 medical products in LMICs are SF" – or some variation of that statistic.

Question: What do you think about that statistic?

Probing questions:

- Do you think that you've ever encountered a substandard product or a falsified product?
- How would you identify that a product was SF?

7. Ethics.

Aims: to close the interview in a manner that engenders safety and helps to recover from discomfort and conflict that may have arisen during the interview. To gain insight into the participant's explicit moral world.

Preamble: OK, so we're nearing the end now and I wanted to finish by exploring the idea of "right" and "wrong".

Question: What would you say gives you confidence in whether a decision is "right" or "wrong"?

Probing questions:

- Do you feel as though you've been expected to implement decisions that you feel are wrong, during your career?
- How did you deal with that?

Topic guide for focus group discussions.

Organisation and description of FGD topic guide.

The FGD topic guide was a PowerPoint slide deck, illustrated in figure 15. The section describes the contents of each slide and how it was presented to participants. About a third of the ninety-minute meeting was allocated to slides one to five, whose purpose was to create a sense of safety and build rapport amongst the group.



Slide 1

What's the aim of this meeting?

You have a unique – and valuable – perspective about iNGO medical procurement decisions. I'm hoping to capture that perspective by means of a discussion. It will inform my research on decision-making in iNGOs.

What does the meeting entail?

I have constructed a couple of scenarios (informed by interviews that I've conducted) to spark discussion and debate. We'll use them to get the conversation going. However, like any conversation, we will talk about things that we find interesting.

But what should I say?

Anything! This is not a test. There are no right answers. I want to hear your thoughts and opinions. This is about what you think and feel. And remember that this is a safe space to talk. Anything you say will be anonymised and not attributed to you or your organisation.

Slide 2

GROUND RULES

Be present

Respect confidentiality

Slide 3

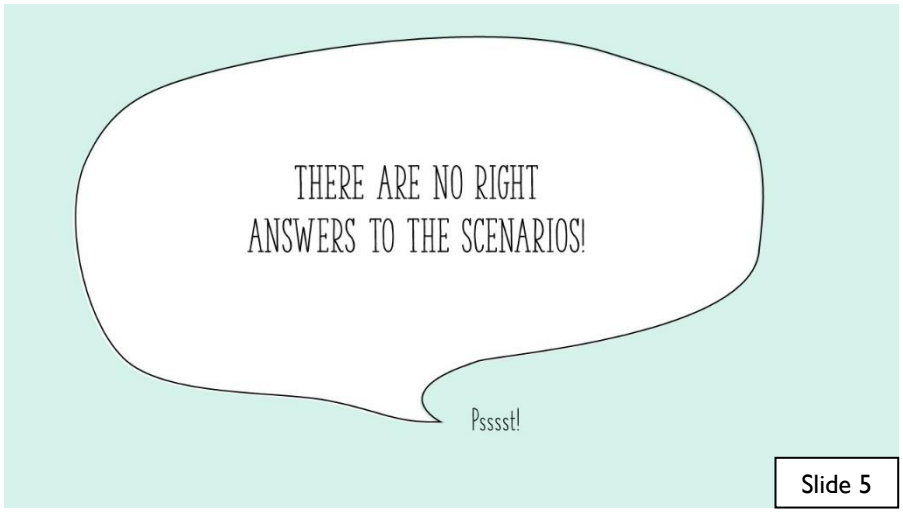


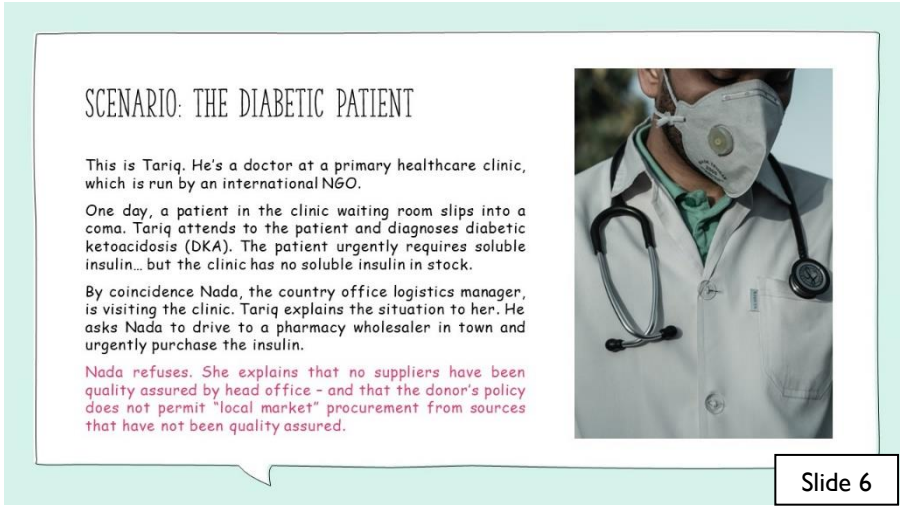
INTRODUCTIONS

Please introduce yourself:

- Your first name
- Guess the fake
- Estimate % of fake medicines in Yemen
  (Don't worry, it's just for fun – nobody knows for sure!)
- Share how you're feeling

Slide 4





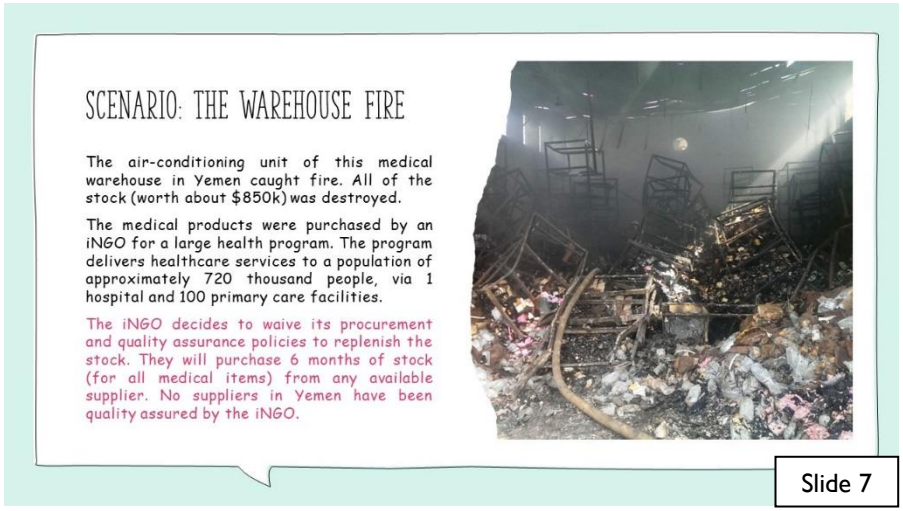




Figure 15: Focus Group Discussion topic guide.

Slide one shows a picture taken by a close friend, who faced an ethical problem when encountering this stock of medical products (antiretrovirals) and being uncertain of their quality. I described the purpose of the research by means of this personal vignette.

Slide two outlined what to expect during the session. I was clear about why participants were there and what I expected of them. They were informed that they had been chosen because of their unique perspectives and that they each had a valuable contribution to make to the research. These statements aimed to clarify and balance the roles of interviewer and participant; to avoid participants feeling as though they were being judged and to highlight that I was there to learn from them. I also sought to shift any notions of expertise from professional knowledge to personal judgement – and thus to encourage confidence and debate.

Slide three articulated two "ground rules" for the session: "be present" and "respect confidentiality". While I was aware that rule-setting would highlight the power differential between myself and participants, I felt that the potential benefits outweighed the negatives. The first rule required participants to avoid using their devices during the discussion (a problem that arisen several times during IDIs). The second rule was an attempt to build a secure space for sharing; it was an implicit statement that participants were protected from external scrutiny within this forum. In this manner, I was exercising my power to offer a sense of security to the members of the group.

Slide four described an 'icebreaker' exercise. The icebreaker required participants to introduce themselves to the group, to guess which medical product was fake (from two near-identical photographs), and to estimate the percentage of fake medicines in Yemen. The purpose of this was for each participant to experience sharing opinions in front of their peers (indeed, ones that may not perfectly align with the rest of the group) in a low risk setting, before doing so with material that may feel more sensitive. It also aimed to situate the discussion within the context of uncertain medical product quality, in a manner that avoided lecturing or imparting my own bias.

Slide five offered a short transition from the icebreaker to the scenarios. I re-emphasized that there were no 'right' answers to the scenarios and re-asserted that my study was seeking to gather opinions. I then stated that we would move into one of the scenarios and offered participants the opportunity to select one, or to propose their own, as I briefly showed them each slide. Both groups stated no preference and neither proposed their own scenario. I spent about thirty minutes on each scenario in turn. For each scenario, I informed participants that I would read the scenario through two times, then ask each FGD member in turn whether they "found the decision, highlighted in pink, to be understandable?", before entering plenary discussion. This occurred for both scenarios and both FGDs.

Slide six was entitled "scenario: the diabetic patient", which was as follows:

> *This is Tariq. He's a doctor at a primary healthcare clinic, which is run by an international NGO. One day, a patient in the clinic waiting room slips into a coma. Tariq attends to the patient and diagnoses diabetic ketoacidosis (DKA). The patient urgently requires soluble insulin… but the clinic has no soluble insulin in stock.*
>
> *By coincidence Nada, the Country Office logistics manager, is visiting the clinic. Tariq explains the situation to her. He asks Nada to drive to a pharmacy wholesaler in town and urgently purchase the insulin.*
>
> *Nada refuses. She explains that no suppliers have been quality assured by Head Office – and that the donor's policy does not permit "local market" procurement from sources that have not been quality assured.*

Slide seven was entitled "scenario: the warehouse fire", which was as follows:

> *The air-conditioning unit of this medical warehouse in Yemen caught fire. All of the stock (worth about $850k) was destroyed.*
>
> *The medical products were purchased by an iNGO for a large health program. The program delivers healthcare services to a population of approximately 720 thousand people, via 1 hospital and 100 primary care facilities.*

The iNGO decides to waive its procurement and quality assurance policies to replenish the stock. They will purchase 6 months of stock (for all medical items) from any available supplier. No suppliers in Yemen have been quality assured by the iNGO.

The **scenarios** were specifically designed to explore how scale influenced decision-making (based on the hypothesis that greater scale would lead to greater moral distance, whilst individual problems would engender proximity). The first scenario related to a single patient and a single medical product. The slide was designed to humanise the situation: the doctor is named, the condition and needs of the patient are articulated, and the image is of a person. The second scenario related to an inconceivable number of patients. The slide is designed to avoid encouraging empathy: the image is of a location (rather than a person), the scenario does not reference names, roles, needs, or potential health impacts, and the description references financial data.

Slide eight offered participants the opportunity to propose or construct a scenario from their own (individual or collective) experience, in case the previous scenarios were deemed unacceptable or irrelevant.

Appendix D

Analytic themes and codes.

	Theme	Codes
See Chapter 4	**SHORT TITLE** **Long name** Theme description	**"Encapsulating quote": code name** Code description *Where the codes are predominantly presented in this thesis*
	PROBLEM **The 'no stock, high stakes' problem: a previously undocumented problem in humanitarian health in which ethical tension exists.**	**"There are no other facilities nearby": descriptions of the context.** Reports about the austerity and uncertainty of the humanitarian context and how this contributes to the incidence and complexity of the problem. *See Chapter 4.2*
		"We are confronted with that all the time": descriptions of prevalence. An indication of the frequency or scale of the problem, according to the participant. *See Chapter 4.1*

	Data that highlight the existence of the problem, offer insight into its boundaries, and detail the nature of its ethical tension.	**"God, that was bonkers": participant experiences and descriptions of the problem.** First-hand stories from participants, illustrating their experience of medical product stockouts in humanitarian health projects. *See Chapter 4.2.2*
		"That's what the 'moral' boils down to": participant perspectives on the risks of harm for patients. How participants were observed to engage with (and interpret) the risk of harming the patient, regardless of their decision. *See Chapter 4.3.2*
		"This is my mission": participant perspectives on their perceived moral obligations to patients. Moral obligations that guided participant decision-making and their inclination to either source or abstain from sourcing medical products of uncertain quality. *See Chapter 4.3.3*
		"If somebody dies, this is your fault": reports of workplace conflict arising between individuals with differing perspectives on how to respond to the problem. Reports of conflict between the two incompatible moral obligations (to conduct QA procedures or to ensure supply chain continuity) and, therefore, whether to prioritise availability or quality. *See Chapter 4.3.3*

		Unknowns and uncertainties: instances in which participants were observed or reported to be ignorant or uncertain of an aspect that related to the 'no stock, high stakes' problem. The unknowns and uncertainties of factors relating to the problem were manifold and had a profound impact on a participant's ability to estimate risk and their behaviour towards the problem. They were organised into the following child codes: • Normative (what should I prioritise?) • Governance (what should my boundaries be?) • Procedural (who should decide and how?) • Pharmaceutical (what standard should I apply?) • Relational (who should I trust?) • Consequences (what will happen?) *Diffused throughout the thesis, but particularly see Chapters 4.3.2 and 6.3.2.*

Table 13: List of codes for the theme "problem".

See Chapter 5	Theme	Codes
	SHORT TITLE **Long name** Theme description	**"Encapsulating quote": code name** Code description *Where the codes are predominantly presented in this thesis*
	POWER THROUGH POLICY	**"It is probably related to access to HIV/AIDS treatment": narratives on the origin and evolution of QA policies.** Data relating to how QA policies and procedures developed in iNGOs and donor organisations. *See Chapter 5.2.1*

	The ways in which policy shaped the truth of 'no stock, high stakes' problems and who had the power to respond, and how. Data that describe the landscape of donor QA requirements for the sourcing of medical products for humanitarian health projects by iNGOs and how donors were perceived to create these requirements to protect their reputation and how they enforced compliance using economic power.	**"I don't care what the National Drug Regulatory Authority says": attitudes towards HG-NDRAs as QA knowledge producers.** Attitudes towards the HG-NDRA as a QA knowledge producer. *See Chapter 5.2.2*
		"I think our hope is that, at some point, it will get better": the perceived explicit purpose of donor QA requirements. Donor participant perspectives on the purpose of donor QA requirements and why they supported them. *See Chapter 5.3.1*
		"It can impact your notorietee": the perceived implicit purpose of donor QA requirements. Insights into the hidden purpose of donor QA requirements and the reason for their levels of stringency. *See Chapter 5.3.1*

		"If you do not comply with the rules, then we get the money back": reports on the enforcement of donor QA requirements and its impact on the problem. The ways in which donors enforced QA requirements and the impact that this was reported to have on the iNGO and on 'no stock, high stakes' decision-making. *See Chapter 5.3.2*
		"We are the government, <u>not</u> you.": an HG-NDRA claim for authority to control and determine medical product QA. Claims that HG-NDRAs are responsible for determining the quality of medical products. *See Chapter 5.4.1*
		"We give responsibility [to iNGOs], you understand?": participant perspectives on donor and iNGO responsibilities regarding the medical product sourcing. The isolation of iNGOs in handling 'no stock, high stakes' problems and how donor requirements challenged the authority of HG-NDRAs. *See Chapter 5.4.2*

		"The amount of power that the government wield in this is […] quite substantial": participant perspectives on legal power of Host Governments. Participant perceptions of the risk of legal or operational recourse by Host Governments and the impact that this had on the handling of 'no stock, high stakes' problems. *See Chapter 5.4.3*
		"We need grant finance": participant perspectives on the economic power of donors. How grant-reliant iNGOs are vulnerable to financial risks and, therefore, the conflict of interest this may create due to the influence of donors at the point of decision-making, and the consequences for 'no stock, high stakes' decision-making. *See Chapter 5.4.3*
		"We're caught between two worlds": the impact of the donor / HG-NDRA poly-governance on iNGO. Insights into the poly-governance of iNGOs who are caught between conflicting HG-NDRA and donor expectations regarding the sourcing of medical products. *See Chapter 5.4.3*

		"The obvious answer is QUAMED is right": perspectives on QUAMED as a QA knowledge producer. QA knowledge producers that were not the HG-NDRA, and participant attitudes towards them. *See Chapter 5.4.3*
		"What do you know, eh?" participant perspectives on who should (not) have the power to make 'no stock, high stakes' decisions. Participant perspectives on the competence, knowledge, and moral authority to determine the outcome of 'no stock, high stakes' problems. *See Chapter 5.4.3.*

Table 14: List of codes for the theme "power through policy".

See Chapter 6	Theme	Codes
	SHORT TITLE **Long name** Theme description	**"Encapsulating quote": code name** Code description *Where the codes are predominantly presented in this thesis*
	PROCUREMENT & PREJUDICE	**"We'll trust those people more because they're an iNGO": participant perspectives on using information or medical products from other iNGOs.**

	Navigating uncertain pharmaceutical markets. Data relating to how participants selected sources of medical products in 'no stock, high stakes' problems, including the proxies that they used for trust and quality in the absence of familiar systems.	Findings that familiarity and perceptions of a shared identity with other iNGOs led to trust for medical products and medical product data. An explanation of how participants differed in who they trusted and viewed as a 'peer'. *See Chapter 6.2.1 (borrowing medical products) and Chapter 6.4.1 (using information)*
		"The local market is horrendous": participant perspectives on the risk of substandard and falsified medical products from national sources. Participant perspectives on the threat and likelihood of substandard and falsified medical products from national sources and different ways in which participants interpreted the phrase "local market". *See Chapter 6.2.2*
		"It's very unlikely": the (un)feasibility of complying with donor QA requirements during the 'no stock, high stakes' problem. Explanations that donor QA requirements were incompatible with the urgent sourcing of medical products in 'no stock, high stakes' situations. *See Chapter 6.3.1*

		"I evaluate [HG-NDRAs] myself in my head": how participants described evaluating non-SRA NDRAs. How participants (arbitrarily) evaluated HG-NDRAs and their views on the novel WHO Global Benchmarking System that grades the 'maturity level' of NDRAs. *See Chapter 6.4*

Table 15: List of codes for the theme "procurement & prejudice".

	Theme	Codes
	SHORT TITLE **Theme name** Theme description	**"Encapsulating quote": code name** Code description *Where the codes are predominantly presented in this thesis*
See Chapter 7	**PROXIMITY** **Factors that influenced the extent to which a participant was willing to risk sourcing medical**	**"It's always a balance of risk": how participant positionality impacted perspectives on risks in 'no stock, high stakes' problems.** Data illustrating how participants differed in the risks they experienced, their estimation of risks, the weight they afforded certain risks, their risk preferences, and the extent to which they were willing to take risks in the interest of ensuring the availability of medical products. *See Chapter 7.1*

	products of uncertain quality – and those that did not. Data relating to 'no stock, high stakes' decision-making and participants' perception of risk.	**Factors that did not (significantly) influence decisions.** Factors that were not significant to the participant, evident through explicit statements, implication, or absence. Organised into the following child codes: • The big picture and System Strengthening. • Communities. • National laws and practices. • HG-NDRA assessments. • Past decisions and their outcomes. *Diffused throughout the thesis, but particularly see Chapter 7 and the discussion.*
		"We probably won't be able to focus on everything": participant perspectives on the risks of a stockout and the importance of medical products. Participants differed in how they conceptualised medical products and stockouts. This code relates to perspectives on the extent to which it was viewed as important to address the stockout and replenish it with a quality assured medical product. *See Chapter 7.2.1*

		"Balance [... of] optimal process versus what is timely": participant perspectives on temporal risks (and the tension between knowledge generation and medical product urgency). Participant perspectives on time during 'no stock, high stakes' problems; the extent to which participants preferred speed (thus risking greater ignorance of the medical product and its source) or knowledge (thus risking greater duration of the stockout). *See Chapter 7.2.2*
		"Buy it […] because it will save the life": the concept of lifesaving medical products. Participant perspectives on urgent *and* important medical products that were described as lifesaving and how this tended to align with moral intuition. *Chapter 7.2.3*

		"The part that will bubble up is that you're having a health expert talking to a logistician": participant perspectives on career risks and how profession intersects with the problem. Observations and reports of how roles and responsibilities influenced the risks, perspectives, and priorities of participants. *See Chapter 7.3*
		"To be unpopular…": participant perspectives on the risk of social disapproval in 'no stock, high stakes' decision-making. Observations and reports of pressurising or ostracizing participants when their views on handling the problem conflicts with the norm of the group or organisation. *See Chapter 7.3*

		"The further we get away from the field [...] the less it feels like we're concerned about the actual patient": participant perspectives on place and how proximity influenced risk perception and preference. Participant perspectives on how physical location, status, and seniority influenced whether an individual was primarily concerned about the needs and risks of the patient or were preoccupied with other concerns (and personal or organisational risks). *See Chapter 7.4.1*
		"We have the expertise": participant perspectives on expertise to handle the problem. Conflicting views between Head Office and Country Office staff regarding where the locus of decision-making should reside based on who was perceived to have the expertise to reach a sound decision. *See Chapter 7.4.2 & 7.4.4*

		"There are some wild ones!": Head Office participant perspectives that ('uninitiated') Country Office staff are unfit to make 'no stock, high stakes' decisions. Participant perspectives that the locus of decision-making should be central, at the iNGO Head Office, and justifications for this opinion. *See Chapter 7.4.2*
		"We needed to protect the local staff": participant perspectives that Country Office staff were unsafe if they made 'no stock, high stakes' decisions. Participant perspectives that being responsible for 'no stock, high stakes' decisions would place national staff in danger and that the solution was to prevent *all* national staff from decision-making, regardless of the context. *See Chapter 7.4.3*
		"We're just instantly assuming that other people are more savage": participant perspectives on security risks. Participant perspectives on the risk of governments, communities, and families harming iNGO staff due to the consequences of 'no stock, high stakes' decisions. *See Chapter 7.4.3*

		"Who has the better understanding of the context?": participant perspectives on the significance of context to 'no stock, high stakes' problems. Participant perspectives on the (un)importance of physical location and contextual knowledge in the handling of the problem. *See Chapter 7.4.4*

Table 16: List of codes for the theme "proximity".

	Theme	Codes
	SHORT TITLE **Theme name** Theme description	**"Encapsulating quote": code name** Code description *Where the codes are predominantly presented in this thesis*
See Chapters 4-7	**LATENT** **Making explicit the implicit.** Ancillary codes that were used in the analysis of data to uncover implicit norms, bias, and motives, through an examination of *how* something was said, rather than what was said.	**Discourse analysis.** A collection of codes that paid particular attention to words, phrases, or styles of speaking, to analyse the use of language to emphasise, hide, or manipulate and to help uncover the true motives and beliefs of the speaker. Organised into the following child codes: • "Beneficiary" (instances of the participant referring to the patient). • "Local market" (instances of the participant using this phrase – see Chapter 7.2.2 in particular) • Diplomacy and business speak (instances in which the participant shifted from their natural style of speaking to become more officious.) • Hyperbole and performative language (instances in which the participant seemed bombastic).

		• Supremacism (instances in which the participant aired opinions of the 'natural' supremacism of a particular group).
		Non-verbal cues. Codes that assisted with identifying and analysing emotions to uncover why those feelings may have arisen. Organised into the following child codes: • Deep thought (instances of long pauses and reflection.) • Emotional discomfort (instances of agitation or distress, visible through behaviour or demeanour).
		Relationship dynamics. Instances in which the speaker related their interpretation of an event, which offered insight into the relationship dynamics of the actors involved. The relevant actors were coded and cross-referenced with the following child codes: • Control. • Reliance. • Disregard. • Suspicion. • Deception. • Collaboration. • Struggle.

		Case classifications.
		
		The following codes were used to categorise cases and cross-reference them with other codes to search for patterns in behaviours, beliefs, and norms.
		
		The child codes were organised as follows:
		
		• Organisations.
		  ○ Donors.
		  ○ Host governments.
		  ○ Other iNGOs.
		  ○ QUAMED.
		  ○ UN agencies.
		  ○ Service users.
		  ○ Vendors.
		• Location.
		  ○ Head Office.
		  ○ Country Office.
		  ○ Roving.
		• Professions.
		  ○ Health.
		  ○ Logistics.
		  ○ Operations.
		  ○ Pharmacy.
		• Professional focus.
		  ○ Policy.
		  ○ Patient.
		  ○ Product.
		• Response type.
		  ○ Emergency.
		  ○ Development.
		  ○ Humanitarian.
		• Advocacy.

		Great quotes. Quotes that were particularly insightful, that resonated with a particular code or theme, and that brilliantly captured a feeling or finding. Used to aid write-up and for distilling a code or theme into a single ‘thought’.

Table 17: List of codes for the theme “latent”.

Appendix E

Summary of participants.

This appendix summarises participants in several different ways. First, individual participant attributes are summarised. Second, the humanitarian institutions for whom participants reported working for (at any point in their career) are listed. Third, an aggregated summary of participant demographics and the form upon which they reported are detailed.

Individual participant summaries.

Pseudonym	Code	Institution	Location in organisation	Speciality	Tendency towards patient- or policy- focussed concerns	Research activity
Skye	101	iNGO	Roving	Pharmacy	Patient	IDI
Jabari	113	iNGO	CO	Health	Patient	FGD
Taylor	121	iNGO	HO	Logistics	Policy	FGD

Yolande	133	Regulator	N/A	Pharmacy	Unclear	IDI
James	137	iNGO	CO	Logistics	Policy	IDI, IC
Arjun	147	iNGO	CO	Logistics	Patient	IDI
Bella	200	iNGO	HO	Logistics	Policy	IC
Omar	209	iNGO	CO	Pharmacy	Patient	FGD
Martin	231	iNGO	HO	Pharmacy	Patient	IDI
Farid	267	iNGO	CO	Logistics	Unclear	IDI
Hugh	269	UN	Roving	Operations	Patient	IDI
John	284	iNGO	Roving	Pharmacy	Patient	IDI
Ikolo	359	iNGO	Roving	Health	Patient	IDI
Lynn	385	iNGO	HO	Health	Patient	FGD
Yazhu	450	iNGO	CO	Pharmacy	Unclear	IC

E-3 | 'No stock, high stakes' problems

Nikolas	458	Donor	N/A	Policy	Policy	IDI
Ursula	460	iNGO	HO	Pharmacy	Policy	Joint IDI
Florence	462	iNGO	HO	Health	Patient	FGD
Ishaan	476	iNGO	CO	Pharmacy	Patient	IDI
Pete	499	iNGO	Roving	Operations	Patient	IDI
Rohan	502	iNGO	CO	Logistics	Patient	IDI
Youssef	554	iNGO	CO	Logistics	Policy	FGD
Noah	586	iNGO	HO	Pharmacy	Unclear	IDI
Viktor	626	Vendor	N/A	Logistics	Policy	IDI
Elliot	668	iNGO	HO	Operations	Patient	IDI
Olga	671	Donor	N/A	Pharmacy	Policy	IDI

Justin	696	iNGO	HO	Logistics	Unclear	IDI
Olivier	751	iNGO	Roving	Logistics	Policy	FGD
Liam	764	Donor	N/A	Pharmacy	Policy	IDI
Guy	775	iNGO	Roving	Operations	Unclear	IDI
Ahmed	790	iNGO	HO	Pharmacy	Unclear	IDI
Kamran	796	iNGO	HO	Health	Policy	IDI
Babiker	814	Regulator	N/A	Pharmacy	Unclear	IDI
Genevieve	881	iNGO	HO	Pharmacy	Policy	Joint IDI
Jan	886	Donor	N/A	Health	Policy	IDI
Claudette	933	Vendor	N/A	Pharmacy	Policy	IDI
Derek	969	iNGO	HO	Logistics	Policy	FGD, IC

Table 18: Summary of participants.

5.1.1 Explainer for summary table.

Pseudonym (column 1)

The pseudonym applied to the participant. It was chosen according to the geographical and cultural origin of their true name and searching for a common alternate name from that region or culture.

Code (column 2)

The participant identification number, to offer anonymity. It was created using a random number generator, which is not chronological in sequence. Participants were not informed of their identifier.

Institution (column 3)

Options:

Donor	iNGO	Regulator	UN	Vendor

The category of institution for whom the participant worked (or most recently worked). The categories of employers are: iNGOs (any international non-governmental organisation); UN (any United Nations Agency); donors (any multilateral, bilateral, or philanthropic organisation); regulators (any national drug regulatory authority or consultants that offer services for medical product quality assurance); and vendors (any procurement agents, brokers, and

wholesalers, but not manufacturers). This data was gathered from communications with the participant. Their stated institution is where they currently worked (or, if they were not currently employed, for whom they had most recently worked). Note that some participants had worked for a variety of institutions. This information is relevant because the type of organisation had an influence on organisational mandate and culture, which had a bearing on the decision-making context.

Location in organisation (column 4)

Options:

HO	CO	Roving	N/A

This indicates the office to which the participant was predominantly affiliated (or was most recently, if not currently employed), according to their line management and location. The categories were: Head Office (HO), Country Office (CO), Roving, or not applicable (N/A). Participants designated as "HO" were predominantly line managed and situated at the iNGO's headquarters. They often had roles that required a strategic overview of numerous health projects and were involved with policy development. Those designated as "CO" were national or expatriate staff who were line managed and situated in the same country as the health project/s that was/were being implemented. (In cases of exceptional security concern, CO staff were sometimes situated in a neighbouring country e.g. for projects in Syria). They were often based in a city (thus remote from the project site) but had responsibilities that related to operational delivery. Some iNGO staff did not fit neatly into these two countries and were designated as "Roving". Broadly, they fell into two categories. First were participants from a Regional Office. These interviewees liaised between the Head Office and Country Office, supporting the policy implementation of the former, the capacity building of the latter, and with an overall focus on project implementation. Second were participants who were

line managed by the Head Office, but who spent most of their time working at health projects sites. Interviewees who were not from an iNGO were listed as "N/A". This data was gathered from participant reports of their job title, role, and geographical location. The information is relevant because it offers an insight into the participant's physical proximity to the patient.

Speciality (column 5)

Options:

Health	Logistics	Operations	Policy	Pharmacy

This indicates the participant's current speciality within their organisation; it reflects their professional experience *and* the current skills for which they are employed. Healthcare professionals other than pharmacists (e.g. medical doctors and nurses), who were in a role that utilised their professional clinical qualifications, were categorised as "Health". Participants working in any supply chain role (e.g. category management, warehousing) were categorised as "Logistics". Interviewees in roles that were associated with the design and execution of humanitarian health projects were assigned the "Operations" category. One individual, who worked in a potentially niche and identifying role for a donor institution, was assigned the category of "policy". This maintained their anonymity and was an accurate representation of his primary responsibilities, in relation to 'no stock, high stakes' problems. Any participant who used pharmacy qualifications as part of their role was categorised as "Pharmacy". Findings emerged that pharmacists had a perspective on 'no stock, high stales problems that were distinct from those in health or logistics, even if their role may closely align with these specialities. Thus, a separate category was created for any participant with a pharmacy qualification (e.g. quality assurance auditors, warehouse managers, advocacy workers.) Categories were

determined according to reported role and qualifications listed on the participant demographics form. The information is relevant because it offers a clue to the participant's epistemology and professional responsibilities.

Tendencies on the patient- or policy- spectrum of concern (column 6)

Options:

Policy	Patient	Unclear

Findings emerged from the data of my study that the predominant concerns of participants existed on a spectrum. One end of the spectrum was the patient and concerns for their welfare. The other end of the spectrum was policy and a concern for compliance with medical product quality assurance requirements. This column summarises my interpretation of their prominent concerns during our conversation. I determined these tendencies by noting which concern they led with, which appeared to cause them the most distress, which they spent more time talking about, and the content of their response. Some tended towards policy, some tended towards patients, but none were absolute in their concerns: it was a spectrum. Some seemed equally troubled by both during a response or at different points during the interview and, therefore, were categorised as "unclear".

Research activity (column 7)

Options: FGD (Focus Group Discussion); IC (Informal Conversation); IDI (In-Depth Interview)

This column details the types of research activity in which the individual participated. Activity descriptions are detailed in Chapter 3.

A summary of participant humanitarian organisations.

Table 19 lists the iNGOs and UN agencies that participants stated that they had worked for (as an employee or consultant) in the participant demographics form. Institutions are listed alphabetically. Note that these institutions did not 'participate' in the study and were not contacted for approval. *Individuals* participated in this study and the following list summarises the institutions at which they gained their humanitarian experiences.

iNGOs and UN Agencies that participants claimed to have significant work experience with.	
Access to Medicines Foundation	Médecins Sans Frontières (MSF)
ACTED	MEMISA
Aga Khan Foundation (AKF)	Mercy Corps
Alight (formerly the American Refugee Committee)	MERLIN
AUSMAT (Australian Medical Assistance Team)	Norwegian Church Aid
BRAC	Norwegian Refugee Council (NRC)
CARE	Oxfam
Catholic Agency for Overseas Development (CAFOD)	Pharmaciens Sans Frontières (PSF)
CONCERN	Project HOPE
Cord	QUAMED

Damien Action	Relief International
Deutsche Welthungerhilfe	Save the Children
GIZ (Deutsche Gesellschaft für Internationale Zusammenarbeit)	Swedish Committee for Afghanistan
GOAL	UK-Med
HelpAge	United Nations Development Programme (UNDP)
Humanity & Inclusion (formerly Handicap International)	United Nations Population Fund (UNFPA)
International Committee of the Red Cross (ICRC)	The UN Refugee Agency (UNHCR)
International Organization for Migration (IOM)	United Nations Children's Fund (UNICEF)
International Rescue Committee (IRC)	Voluntary Service Overseas (VSO)
Marie Stopes	World Health Organization (WHO)
Medair	World Vision
Médecins du Monde (MDM)	

Table 19: Summary of humanitarian agencies at which participants had worked.

An aggregated summary of participant demographics.

A participant demographics form (PDF) was used to collect data pertaining to interviewee attributes. Care was taken to phrase and structure questions neutrally, and for ease of completion. It was emailed to all IDI and FGD participants on *completion* of their involvement in the study to avoid unconscious bias. The form was developed in three stages. First, an initial list of attributes that were potentially relevant to the decision-making context was collated from the literature review and intuition. Second, this initial list was distilled to focus on the preliminary findings of pilot interviews. Topics of interest were responsibility (e.g. to a professional body), and proximity (e.g. to the patient). Finally, questions were formulated that might to contribute to a participant's sense of responsibility and proximity to the patient or donor. An aggregated summary of responses is displayed in table 20.

I would be grateful if you could complete this questionnaire, so that I can understand more about the people who have taken part in this study. I will use this information in my analysis of conversations, and to aid me in identifying patterns in people's opinions and perspectives.

The information that you provide here is anonymous and completely confidential.

The questionnaire will take about 5 minutes to complete.

- Some questions have set options – please highlight or circle the one that you feel is the best fit.
- Some questions have a space to write your answer – a couple of words is fine, but feel free to write as much as you wish.

Many thanks for your time in reading and completing this form, and for your participation in this study.

#	Question	Responses			
Q1	How old are you?	Participants selected a 10-year age range. Purpose: to explore the influence of age and to seek variation in sampling.			
		30-something	10	40-something	15
		50-something	6	60-something	3
Q2	What is your biological sex?	Participants answered in free text. Purpose: to explore the influence of gender and to seek variation in sampling.			
		Male	25	Female	9
Q3	How would you describe your ethnicity?	Participants answered in free text. Information was converted to geographical regions in the interests of anonymity. Purpose: to explore influence on decision-making and to seek variation in sampling.			
		Africa (Central)	1	Asia (Southern)	4
		Africa (Eastern)	2	Asia (Western)	2
		Africa (Northern)	2	Europe	16
		Africa (Southern)	1	Oceania	3
		America (Northern)	3	Did not answer	1
Q4	Would you describe yourself as religious?	Participants wrote free text. They were counted as answering "yes" if they wrote the name of a religion or were affirmative. Purpose: to explore the influence of religion on moral decision-making.			
		Yes	16	No	17
		Did not answer	1		
Q5	Where did you grow up? (name of country)	Q5 & 6: Participants wrote free text. Purpose: to explore whether nationality or Head/Country Office membership influenced proximity to the patient.			
Q6	Where do you live? (name of country)	Q5 & 6: Answers redacted for anonymity.			

About your qualifications

Q7	Do you hold any qualifications? If yes, in which professional disciplines?	Q7 & 8: Participants wrote free text. Purpose: to explore the influence of epistemology and professional accountability on moral decision-making.
Q8	Are you a member of a professional body?	Q7 & 8: Answers redacted.

About your field experience

Q9	Have you ever deployed to the field in support of an emergency response?	Participants wrote free text. Purpose: to explore whether experiencing the first phase of an emergency response would influence proximity to the patient or flexibility in applying policies.			
		Yes	27	No	7
Q10	How much 'field experience' would you say that you have?	Participants self-reported their experience of working at project sites. Purpose: to explore its bearing on proximity to the patient.			
		Extensive	11	Lots	10
		Some	8	None	5
Q11	When was the last time you were at a 'frontline' field site? (E.g. a clinic or warehouse. Not capital offices, conference centres etc.)	Participants wrote free text. Purpose: to explore whether 'field experience' needed to be recent, if it did influence proximity to the patient.			
		Answers redacted.			

About your fundraising experience

Q12	How much fundraising experience would you say that you have? (Please include 'internal' pitches and business cases in your response.)	Participants self-reported their experience. Purpose: to explore whether experience with interacting with donors and seeking funding influenced proximity to the patient.			
		Extensive	2	Lots	4
		Some	10	None	18

About your career history

Q13	Which iNGOs have you worked for? Please write these in the space provided and circle or highlight any that you feel are particularly significant (e.g. you worked there for a long time or were particularly formative for you.)	Responses presented in previous section.			
Q14	What type of programmes have you supported during your career?	Participants indicated the types of projects that they had worked on in their career. Most selected more than one. Purpose: to explore whether project experience influences decision-making.			
		Emergency	27	Humanitarian	29
		Development	24	Advocacy	7

Table 20: Aggregated summary of participant demographics.

Appendix F

Participant Information Sheet.

Invitation

You are being invited to take part in a research study that is exploring how decision-makers can influence access to medical products. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve.

Please take time to read the following information carefully before deciding whether to take part. You can discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this.

About the research

What is the title of the study?

When Quality is Uncertain: International Non-Governmental Organisations Determining the Availability of Medical Products in Global Health

Who will conduct this research?

The research will be conducted by Kate Enright, a doctoral student at the University of Oxford.

Why is the research being conducted?

Development assistance, humanitarian aid and emergency response activities play an important role in the delivery of healthcare services in many low-income and middle- income countries (LMICs). However, the shape and purpose of these interventions can differ greatly from one project to the next. For example, one project may be responsible for the entire provision of primary care services to a large proportion of the country, whilst another may augment existing services in a small region, through offering specialist support on a seasonal or emergency basis.

No matter the type of health intervention, the actors involved can have a profound effect on the quality and availability of medical products that are accessible to a beneficiary. Decisions that relate to things like policy, budgets, procurement, or prescribing, for example, can be pivotal in this regard. However, decisions can be influenced or altered by external pressures and unforeseen barriers. Consequentially, the quality or availability of the medical products that are accessible to the beneficiary may be affected.

Currently, there is little information available regarding who influences the quality and availability of medical products, how, to what extent, and in what circumstances. This research project will explore how intentional actions, unintentional decisions, organisational culture, human behaviour, and other factors may have an impact on medical product quality and availability. This research aims to characterise these influences and influencers, and the impact that they can have, in order to guide future decision-making.

Who is funding the research?

This research is funded by the Wellcome Trust [grant number 209830/Z/17/Z], under the project entitled "Fakes, Fabrications and Falsehoods? Interrogating the social, ethical and political features of pseudo-global health".

Who has reviewed the research project?

This project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee. [Reference number: R75317/RE001].

About your involvement

Why have I been invited to take part?

This study aims to recruit about 45 participants. You have been invited to take part because of your professional experience. This may be experience of international Non-Governmental Organisations, of medical procurement, of healthcare in LMICs, of medicines regulation - or a combination of these experiences. You were identified because you were suggested by another participant, or due to your public profile.

What does the research involve?

This research will involve "focus group discussions" and "in-depth interviews". These terms are explained in the next two paragraphs. Some individuals will be invited to participate in both a focus group discussion *and* an in-depth interview, whilst some individuals will be invited to participate in one or the other. Specific information about what these activities will involve (i.e. what to expect) are provided on the next page.

Focus group discussions are like "workshops" or "roundtable discussions", which you may have encountered in your job. They involve a small group of people talking to one another about a certain topic. I will facilitate these discussions, by helping the conversation to flow and by keeping us focussed on the discussion topic.

In-depth interviews are <u>not</u> like job interviews. They are more like "meetings" or "one-to-ones". They involve having a conversation with me, on your own. During our conversation we will explore several different topics. I will guide the conversation using questions. These questions are to help me understand your perspectives, experiences, opinions, and feelings. They are **not** to test knowledge or to check facts.

What am I being asked to do?

You are being invited to participate in an in-depth interview. This information sheet will help you to consider whether you are happy to take part in the study. If you have any questions, I am very happy to meet with you to answer them, to talk about the study, and to discuss the study's procedures.

If you are happy to participate in the study, I will ask you to give consent via email and arrange a time for us to meet. The interview can either be in-person or online. During the interview, I will ask you questions. Sometimes these will be from a predetermined list, but sometimes I will ask you questions in response to something that you have said, or about the overall thread of our conversation. The interview will take approximately 60 – 90 minutes, but you can pause or stop the interview at any time.

With your consent, I would like to create a temporary recording of each focus group discussion (both the video and audio). I will use these recordings as a reliable and accurate reference of the discussion. The audio will provide me with a record of exactly *what* was said (and in what context). The video will indicate *how* things were said and with what emotion. In addition, I would like to make some handwritten notes while we talk. After this, your involvement in the study is complete.

Do I have to take part?

No. It is up to you whether you take part or not. You can ask questions about the research before deciding whether to take part. If you do decide to take part, you will be given this information sheet to keep. You will also be asked to sign a participant agreement form, and I will ask you for consent at the beginning of any research activity.

If you decide to take part, you are still free to withdraw yourself from the study at any time, without giving a reason and without detriment to yourself. (Please refer the rest of this document, in particular "what happens if I change my mind about taking part?" for further information.) If you choose to withdraw yourself from the study, I will not collect any further information from or about you. If you wish, you can also request to withdraw all or part of the information that you have contributed to the research. If it is possible to do so, I will remove it. Unfortunately, it will not be possible to withdraw information after the publication date. (Please refer to the rest of this document for further details, particularly the section entitled: "about the data".)

If you or any family member have an on-going relationship with the University of Oxford, or with the research team (e.g. as a member of staff, as a student or as another service user) your decision on whether to take part (or continue to take part) will not affect this relationship in any way.

What happens if I change my mind about taking part?

You can stop participating in any of the study activities, at any time, without giving a reason, and without detriment to yourself. If you change your mind, you can inform me by any method that you prefer, for example by email or phone call. My details are provided at the end of this participant information sheet.

Are there any potential risks in taking part?

There is a risk that you will find the research activities distressing. You or someone that you care about may have been deeply affected by issues surrounding the availability and quality of medical products, or perhaps you have had a role in which you have experienced moral distress regarding these issues. Some people find it helpful to talk about these issues, whilst others may find it distressing. You experience distress and wish to withdraw from the study, you are able to do so at any time.

Due to the risk of reputational damage, your participation in the research will be confidential and your data will be pseudonymised. This means that if someone were to access the study data without authorisation, the identity of participants would be unknown. Video and audio recordings of you will be held in a secure and encrypted location and access will be limited to my supervisor (whose details are provided at the end of this leaflet) and me. For further information about how these recordings (and the data) will be managed, please refer to the section entitled "about the data".

Are there any benefits in taking part?

There will be no direct or personal benefit to you from taking part in this research.

Expenses and payments

There will be no payment for taking part in this study. However, reasonable and relevant costs will be reimbursed if you are required to travel in order to participate.

About the data

What personal information will you collect about me?

To participate in this research project, we will need to collect information that could identify you. This is called "personal identifiable information". Specifically, we need to collect:

- Your name
- Your job title and organisation
- A brief career history
- Your qualifications
- Your email address

I am collecting and storing this personal identifiable information in a secure location, in accordance with data protection law, which protects your rights. These state that I must have a legal basis (specific reason) for collecting your data. For this study, the legal basis is that it is a "public interest task" and "a process necessary for research purposes".

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Oxford is the Data Controller for this project. As such, it is responsible for determining how your personal information is used and for keeping it secure, confidential, and used only in the way that you have been told it will be used.

Please also note that individuals from The University of Oxford or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

What are my rights in relation to the information that you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information that we hold about you, including the video recordings.

If you would like to know more about your different rights, please consult the Information Commissioner's Office website.

Will I be recorded, and how will the recorded media be used?

With your consent, temporary video and audio recordings will be made of the interview. The recordings will be used for the purpose of creating a transcription, whereupon they will be deleted. It is estimated that the recordings will exist for about a month. No other use will be made of the video recordings without your written permission, and no one outside the project will be allowed access to the original recordings.

The transcription itself will be pseudonymised (i.e. your name and organisation will be removed from the transcript and a code will be used to refer to you and your organisation). In addition, information that may identify you or your organisation (for example, your role in an event, or terms that are specific to an organisation) will be anonymised. The pseudonymised text may be used in the thesis, conference presentations, lectures, or academic papers.

How will the data be handled?

Your data will be looked after in the following way:

- Your personal information, and any data produced from this study, will be pseudonymised and treated as confidential. Only the immediate research team will have access to it.
- Your personal information will be pseudonymised as soon as possible. The data that connects participants and their identification codes will be held on an encrypted and password-protected external drive.
- Each temporary video and audio recording will be stored on an encrypted device, or as a password protected file on the University of Oxford's GDPR-compliant cloud storage. They will be deleted once a transcription has been made of them (which is estimated to be no more than one month).
- Data (including identifiable participant data) will be stored on the University of Oxford's GDPR-compliant cloud storage. It will not be shared via email.
- Project governance documentation, including signed copies of consent forms and agreements will be securely retained for 3 years after completion of the research, as a record for how the research was conducted and who took part. This is the standard retention period. The only personal identifiable information in this documentation will be your name and signature, which will not be linked to any research results.

How will the data be used?

The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research.

The research will be written up as a student's thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives to facilitate its use in future research. If so, the thesis will be openly accessible. In addition, the research may be published in academic publications, on websites (e.g. as blogs), and discussed in presentations (e.g. at conferences).

You will not be able to be identified in any external reports or publications about the research, without your specific consent.

If I change my mind, what happens to my data?

If you decide to withdraw from the study, I will not collect any further information from or about you.

If you withdraw from active participation in the study, I would like to keep the information that has already been collected from or about you, if it has on-going relevance or value to the study. However, if you wish, you can request to withdraw all or part of the information that you have contributed. If it is possible to do so, I will remove it. Unfortunately, it will not be possible to withdraw information after the publication date.

Your legal rights to access, change, delete or move this information (including your personal identifiable information) are limited, as I need to manage your information in specific ways so that the research is reliable and accurate. However, if you have concerns about how this will affect you personally, you can raise these with me when you withdraw from the study.

Complaints

Who do I contact if I have a concern about the study or if I wish to complain?

If you have a concern about any aspect of this study, please contact me by email at Katherine.Enright@stx.ox.ac.uk. Alternatively, you can contact my supervisor, Dr Patricia Kingori by email at Patricia.Kingori@ethox.ox.ac.uk. I/we will acknowledge your concern within 10 working days and will give you an indication of how it will be dealt with. I/we will do our best to answer your query however, if you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible. Their contact details are below.

Chair, **Medical Sciences Inter-Divisional Research Ethics Committee,** Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

Further information

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Katherine Enright, Ethox Centre & Wellcome Centre for Ethics and Humanities, University of Oxford, Big Data Institute, Li Ka Shing Centre for Health Information and Discovery, Old Road Campus, Headington, Oxford, OX3 7LF - United Kingdom.

Email: Katherine.Enright@stx.ox.ac.uk

Document Control

<table>
<tr><td>Document type</td><td colspan="2">Instrument</td><td>Related Activities</td><td>IDIs</td></tr>
<tr><td rowspan="4">Version history</td><td>V1.0</td><td colspan="3">14 March 2021 – first iteration</td></tr>
<tr><td>V1.1</td><td colspan="3">5 May 2021 – minor amendments based on IDREC feedback:
Complaints: amended chair contact details
Data: greater clarity on ability to withdraw information
Minor grammatical changes</td></tr>
<tr><td>V1.2</td><td colspan="3">3 February 2022 –
minor edits to reflect changes to research question.
WEH and OxPop header</td></tr>
<tr><td>V1.3</td><td colspan="3">8 March 2022 –
Updated title</td></tr>
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Appendix G

Participant consent.

Introduction

This document details aspects of consent for the study. It describes when and how consent was obtained for in-depth interviews (IDIs) and for focus group discussions (FGDs), as well as the rationale for why these two research activities had differing procedures. It also lists all the consent statements requested of potential participants and its accompanying information.

Timing of consent

All participants received consent documentation when they were invited to participate in the study, in addition to a participant information sheet (appendix F refers). When they were requested to complete and return their written consent differed depending on the research activity.

In-depth interviews

For IDI participants, written consent was obtained after the interview had concluded. The intention was to create psychological safety for participants. With complete knowledge of what had been shared during the interview, the participant may have felt a greater sense of power and control in deciding whether to participate and may have felt more at ease during the interview itself. Verbal consent to take audio and video recordings was obtained immediately prior to conducting each interview.

Focus group discussions.

Obtaining written consent after an FGD was deemed problematic due to the number of individuals involved and the effort of organizing the activity. Concerns arose that if one or more participants refused (or failed) to give consent, then the entire dataset may become unworkable. Time was spent considering how to remove an individual's contribution to an FGD. However, an individual can influence the direction and tone of a conversation, as well as being involved in a back-and-forth dialogue. Therefore, it was decided that a full dataset was essential for analysis and that written consent was essential prior to participation.

Method of consent.

Due to the unprecedented circumstances of the COVID-19 pandemic, all consent was obtained via email. For security purposes, rather than completing a form or attachment which can be falsified, participants were asked to send their consent statements in the body of an email, from an account in their name.

Information provided to individuals invited to participate in the study.

The following text is a copy of the information that was provided to potential participants:

Purpose of the study.

Development assistance, humanitarian aid and emergency response activities play an important role in the delivery of healthcare services in many low- and middle- income countries (LMICs). However, the shape and purpose of these interventions can differ greatly from one project to the next. For example, one project may be responsible for the entire provision of primary care services to a large

proportion of the country, whilst another may augment existing services in a small region, through offering specialist support on a seasonal or emergency basis.

No matter the type of health intervention, the actors involved can have a profound effect on the quality and availability of medical products that are accessible to a beneficiary. Decisions relating to policy, budget allocation, procurement, or prescribing, for example, can be pivotal in this regard. Such decisions are not fixed: they can shift when faced with significant pressure or unforeseen barriers. Consequentially, the quality or availability of the medical products that are accessible to the beneficiary may be affected.

Currently, there is little information available regarding who influences the quality and availability of medical products and how, to what extent, and in what circumstances. This research project will explore how intentional actions, unintentional decisions, organisational culture, human behaviour and other factors may have an impact on medical product quality and availability. This research aims to characterise these influences and influencers, in order to guide future decision-making.

Aspects of consent.

Please read the statements below. If you are happy with the statements, please copy and paste them into an email and send this to me at Katherine.Enright@stx.ox.ac.uk. This will constitute your having given consent to participate in the study.

If you have any questions about the research or the statements below, please do not hesitate to contact me.

Statements:

1. I confirm that I have read and understand the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any adverse consequences or penalty.

3. I understand that research data collected during the study may be looked at by authorised people outside the research team. I give permission for these individuals to access my data.

4. I understand that this project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee.

5. I understand who will have access to the personal data that I have provided, how the data will be stored, and what will happen to the data at the end of the project.

6. I understand how this research will be written up and published.

7. I understand how to raise a concern or make a complaint.

8. I consent to audio being recorded.

9. I consent to video being recorded.

10. I understand how video and audio recordings will be used in the research outputs.

11. Please select the most applicable option:

a) I agree to the use of direct quotes, attributed to my name, in research outputs.
b) I agree to the use of pseudonymised quotes in research outputs.
c) I agree to the use of anonymised quotes in research outputs.
d) I do not wish to be directly quoted.

12. I give permission for the researchers to re-contact me to clarify information.

13. I agree for research data collected in this study to be given to researchers, including those working outside of the UK and the EU, to be used in other research studies. I understand that any data that leave the research group will be anonymised so that I cannot be identified.

14. I agree to take part in the study.

Appendix H

Participant Demographics Form.

Introduction

This document describes the participant demographics form (PDF), in terms of its content and how it was developed. The PDF itself is displayed in table 20, in appendix E.

Development of the form

First, attributes that were potentially relevant to the decision-making context were collated. These were based on the literature review and intuition. The list was extensive and, therefore, impractical. Thus, second, the list was distilled to core attributes of interest according to the preliminary findings of the pilot interviews. With a goal of limiting the PDF to two-sides of A4, these encompassed accountability (e.g. to a professional body), proximity (e.g. to the patient), moral values (e.g. religiosity), and general personal attributes (e.g. age). Third, questions were formulated that could, hopefully, parse out experiences and attributes that may explicate a participant's attitude to accountability, proximity, or values. Care was taken to remain neutral through a mindful selection of terms and the structure of questions. (This work was informed by demographics forms from other qualitative studies, research into fundamental principles for quantitative survey development, and feedback from expert advisors). Finally, the questions were organised and formatted for ease and speed of completion.

Timing of the participant demographics form

Version 2.0 of the PDF is displayed on the next two pages. It was sent to all participants on completion of their involvement in the research activities. The rationale for this was twofold. First, similarly to the consent form (appendix G refers), I aimed to build psychological safety. The PDF asked for personal information, which may feel uncomfortable to divulge prior to meeting and building rapport. Second, I aimed to avoid any preconceptions that may unconsciously bias my approach to the interview. The PDF was sent via email to all participants within a day of their involvement in the study, along with a note of thanks.