

Improving Violence Risk Assessment and Intervention in First Episode Psychosis

Dr Daniel Whiting

St Catherine's College

University of Oxford

Submitted for the degree of DPhil Psychiatry

Michaelmas Term 2021

Supervisors:

Professor Seena Fazel

Professor Belinda Lennox

Preface

The work described in this thesis was carried out between November 2018 and December 2021 under the supervision of Professor Seena Fazel and Professor Belinda Lennox, with additional methodological advice from Dr Margaret Glogowska (qualitative and mixed methods advisor) and Professor Sue Mallett (statistical advisor). The work in this thesis is my own. I declare that the work presented in this thesis has not been submitted for any other degree, in this or in any other university or institute of learning.

I was funded for this DPhil by a National Institute for Health Research (NIHR) Doctoral Research Fellowship (DRF-2018-11-ST2-069). The views expressed are those of the author and not necessarily those of the National Health Service, the NIHR, or the Department of Health and Social Care.

All references are presented at the end of this thesis in a general bibliography. Appendices are indexed and presented after the bibliography.

Word count (exclusive of preface, appendices and references): 47,622

Acknowledgements

I am extremely grateful to my supervisors for their considerable expertise and all round good-humoured guidance, and my family for their unstinting support whilst I undertook a DPhil in the unusual and challenging wider circumstances of the pandemic.

I would like to thank the many excellent and dedicated clinicians working in Oxford Health NHS Foundation Trust's Early Intervention in Psychosis services, who wholeheartedly engaged with the work despite also operating in those challenging wider circumstances, and to the patients and carers who shared their valuable perspectives on what is a challenging subject. I am also grateful to the patient and public involvement representatives who engaged in discussion of the work.

Finally, I am indebted to many colleagues in the Department of Psychiatry, in the wider University, in Oxford Health NHS Foundation Trust, and in Thames Valley Police who made the different aspects of this work a practical possibility, including those working in clinical systems, and colleagues in information governance who supported navigation of some substantial approval frameworks. Thank you.

Table of Contents

ABSTRACT		1
CHAPTER 1	Introduction: prediction models, stratified medicine, and their potential application to the adverse outcome of violence perpetration in first episode psychosis	
	Prognostic research and stratified medicine	7
	Violence as an adverse outcome in clinical services for first episode psychosis	14
	Violence risk assessment tools	20
	Summary and thesis aims	24
CHAPTER 2	Prediction model to clinical tool: using qualitative and mixed methods to understand the potential use of a violence risk prediction tool (OxMIV) in Early Intervention in Psychosis services	
	Introduction	27
	Structure and aims of work program	28
	Justification for choice of methodology	30
	Qualitative methods (Stage 1 and 2)	33
	Integration of OxMIV tool into electronic health records (Stage 2)	40
	Quantitative methods (Stage 2)	42
	Mixed methods data integration (Stage 2)	43
	Ethical considerations and approval	43
	Patient and public involvement	45
	Summary	45
CHAPTER 3	Assessing risk of violence in Early Intervention in Psychosis services: a qualitative interview study of multidisciplinary clinicians	
	Introduction	46
	Results	48

Discussion 74

Conclusion 79

CHAPTER 4 A mixed methods study of the clinical acceptability, feasibility and role of the OxMIV violence risk prediction tool in Early Intervention in Psychosis services

Introduction 80

Quantitative results 82

Qualitative results: clinician perspectives 89

Qualitative results: patient and carer perspectives 102

Integrated results 107

Discussion 113

Conclusion 119

CHAPTER 5 A clinically operationalised violence risk prediction tool for Early Intervention in Psychosis services: external validation of OxMIV and its comparison to unstructured clinical judgement

Introduction 120

Aims 121

Methods 121

Results 136

Discussion 150

Conclusion 156

CHAPTER 6 Discussion and conclusions: towards a stratified medicine approach to violence risk assessment and intervention in Early Intervention in Psychosis services

Introduction 157

Aim 1: Understanding current practice and clinical needs 158

Aim 2: Clinical utility of OxMIV and how it can be studied 163

Methodological implications and future research directions 177

Thesis limitations 180

Conclusion 181

REFERENCES 183

APPENDICES 194

List of Tables

Table	Title	Page
	Chapter 1	
Table 1	Exemplar reviews of prediction models in different fields and proportion of identified studies which addressed external validation or clinical impact.	13
Table 2	Characteristics of approaches to risk assessment in Early Intervention in Psychosis services across 12 clinical service areas in South of England.	20
Table 3	Violence risk assessment tools validated in individuals with psychosis.	22
	Chapter 3	
Table 1	Summary characteristics of included sample.	48
Table 2	Identified themes and sub-themes.	49
	Chapter 4	
Table 1	Number of unknown predictors in assessments according to whether risk needs were identified pre-OxMIV.	85
Table 2	Association between risk needs identified pre-OxMIV and whether completing OxMIV helpfully assisted the overall assessment of risk and needs, or led to any changes in a careplan.	87
Table 3	Association between discordance between risk needs identified pre-OxMIV and categorical OxMIV rating, and whether completing OxMIV helpfully assisted the overall assessment of risk and needs or led to any changes in a careplan.	88
Table 4	Summary characteristics of included clinician sample.	89
Table 5	Themes developed across clinician interviews with exemplar quotes.	89
Table 6	Patient and carer participant summary characteristics.	102
Table 7	Integrated results matrix combining qualitative and quantitative results examining the same phenomena.	108
	Chapter 5	
Table 1	Predictor definitions pre-specified for extraction from electronic health records.	126
Table 2	Distribution of outcome and predictors in validation cohort and original Swedish development sample.	138
Table 3	Paired misclassification measures for updated model across range of cutoffs in one imputed dataset.	145

Table 4	Paired misclassification measures of OxMIV and the original unstructured clinical judgement.	147
Table 5	Characteristics of individuals misclassified by unstructured clinical judgement.	148
	Chapter 6	
Table 1	Challenges identified in current practice and linked findings of potential benefit and impact of OxMIV.	166

List of Figures

Figure	Title	Page
	Chapter 1	
Figure 1	Positioning of Early Intervention in Psychosis (EIP) services within mental health and related services in England.	17
Figure 2	The 16 predictors in the OxMIV tool.	23
	Chapter 2	
Figure 1	Outline of two stage work program using mixed methods to examine current practice and subsequent clinical feasibility and acceptability of the OxMIV tool.	29
Figure 2	Predictor information and responses required for OxMIV tool in electronic health records.	41
	Chapter 3	
Figure 1	Outline of two stage work program using mixed methods to examine current practice and subsequent clinical feasibility and acceptability of the OxMIV tool.	47
Figure 2	Representative quotes illustrating range of relative concerns regarding violence risk in the two clinical vignettes.	67
	Chapter 4	
Figure 1	Outline of two stage work program using mixed methods to examine current practice and subsequent clinical feasibility and acceptability of the OxMIV tool.	81
Figure 2	OxMIV assessments completed over 12 months.	82
Figure 3	Interval between referral of individual to Early Intervention in Psychosis services and completion of OxMIV assessment (n=141) in weeks.	83
Figure 4	Proportion of 141 OxMIV assessments completed with 0, 1, 2, 3, 4 or 5 total missing predictors.	84
Figure 5	Proportion of "unknown" scores for each predictor in 141 OxMIV assessments.	85
Figure 6	Interval between commencing and entering the OxMIV form in days.	86
	Chapter 5	
Figure 1	Flow chart of study processes.	136
Figure 2	Proportions of missing data for each individual predictor in the validation dataset.	139

Figure 3	Number of missing predictors per case.	140
Figure 4	Margin plots of age distribution for cases in which indicated predictor (education, parent drug or alcohol use, parent violent crime or sibling violent crime) is missing (red) or observed (blue).	141
Figure 5	ROC plot for 20 imputed datasets.	142
Figure 6a	Calibration plot with 10 risk groups for original model in one imputed dataset.	143
Figure 6b	Calibration plot with 10 risk groups for model with updated intercept in one imputed dataset.	144
Figure 6c	Calibration plot with 10 risk groups for model with updated intercept and rescaled coefficients in one imputed dataset.	144
Figure 7a	Relationship between individuals identified as high risk and true positives across range of cutoffs from 0%-50%.	146
Figure 7b	Relationship between individuals identified as low risk and true negatives across range of cutoffs from 0%-50%.	146
Figure 8	Error matrices for unstructured clinical judgement and OxMIV at 10% cutoff.	148
Figure 9	Net benefit across a range of preferences, where Cost:Benefit Ratio represents the acceptable number of individuals identified as high risk in order to identify each true positive.	149
	Chapter 6	
Figure 1	Summary of findings relevant to Aim 1, to understand current approaches to violence risk assessment and associated challenges and needs.	158
Figure 2	Understanding OxMIV as a complex intervention with interacting components at the level of individual predictions and decisions, and wider impact on clinicians and services.	171
Figure 3	Clinical guidance, refined wording of OxMIV tool and linked suggestions, combined as “OxVERSE”.	173

Improving Violence Risk Assessment and Intervention in First Episode Psychosis

Dr Daniel Whiting, St Catherine's College

Submitted for the degree of DPhil Psychiatry, Michaelmas Term 2021

Abstract

Background

Clinical care is often guided by prognosis. Understanding the chances of future outcomes associated with a health condition can inform decisions around support and treatment for individuals, and decisions at a clinical service or policy level. There is wide interest in refining individualised prognostic understanding to personalise care and inform stratified treatment, where interventions are targeted for maximum benefit. Prediction models are a key part of this progress. These models combine information about predictors of an outcome into a statistical model to estimate the risk of that outcome for an individual, and have had a substantial impact on clinical practice in areas such as cardiovascular medicine. However, many models that are developed are never adopted into practice. This can be due to limitations in development study methodology, or neglect of the stepwise process of translating into a usable clinical tool. Ideally, this should involve validating the accuracy of the model in a clinical setting, and considering practical issues such as its acceptability, feasibility and role.

An important adverse outcome in psychiatry that may benefit from a prediction model approach is violence perpetration. Violence can have significant implications for patients and others, and is a target for prevention at a public health level. There is a small but significant

increased risk of violence perpetration associated with many mental disorders, including schizophrenia spectrum disorders. First episode psychosis has been identified as a higher risk phase of illness, and so this outcome is of particular relevance to community mental health teams called Early Intervention in Psychosis (EIP) services who engage individuals presenting at this early stage. These services do not specialise in violence risk assessment and management however. Currently there are no established ways to support this risk assessment, and how it is undertaken in practice is not well understood.

Whilst many tools to assess violence risk exist in other settings such as forensic psychiatric services or justice settings, there are limitations in how they have been developed, and barriers to their application in EIP services such as the resource required to use them. However, a potentially more scalable model, called "OxMIV", was transparently developed using contemporary prediction modelling approaches. This may be more suited to supporting violence risk assessment in EIP services, but whether and how it could be translated into practice is yet to be explored.

Aims

The aims of this thesis are to first understand current clinical approaches to the assessment and management of violence risk in EIP services, and what the difficulties and clinical needs associated with this are. Whether the OxMIV violence risk prediction tool can meet some of these needs will then be examined. Preliminary clinical use will address practical aspects of its feasibility and acceptability, develop its optimal clinical role, and establish the potential impact of its implementation. The predictive performance of the model in this setting will be examined by externally validating it in individuals assessed by EIP services, and updating the model as necessary. Finally, a framework for how the tool could be integrated into a stratified approach to violence risk, and how the impact of this could be tested, will be developed.

Through this work, an overarching aim is to develop methodological approaches that address the gap between the development of a prediction model and its translation into clinical practice.

Methods

Qualitative methodology (Chapter 2) is used to examine current practice and challenges through individual interviews with 18 multidisciplinary clinicians working in EIP services (Chapter 3). Data is analysed thematically, informed by the constant comparative method.

Mixed methods (Chapter 2) are then used to examine the feasibility, acceptability and role of the OxMIV tool when made available to clinicians in the electronic health record (Chapter 4). Individual interviews are conducted with 20 clinicians and 12 patients and carers. Quantitative data on the use of the tool is also collected, in a convergent parallel design. Quantitative and qualitative data is integrated at the level of interpretation and reporting, using a joint display matrix to draw conclusions that incorporate their combined meaning.

A separate external validation study (Chapter 5) uses routine electronic health record data and police data on violent occurrences to examine the performance of OxMIV in a retrospective cohort of 1,145 individuals consecutively assessed by EIP services between 2012 and 2018. Multiple imputation is used to address missing data, and measures of discrimination, calibration and overall performance are reported. A stepwise process of model updating is undertaken. Data from the electronic health record on the unstructured clinical judgement made by the original assessing clinician is used to further consider the potential role and benefit of OxMIV.

Results

Violence is viewed as an important outcome by clinicians working in EIP services, though relevant in a minority of patents (Chapter 3). Currently assessment is a brief screen, with

fuller exploration if the assessing clinician deems it relevant, involving unstructured information-gathering focussed on the content of psychotic symptoms and individual circumstances. Any linked responses are practical and focus on crisis situations rather than modifying risk in the longer term. Challenges include low clinician confidence, perceived subjectivity, limitations of training and knowledge, wariness around stigma, limited collaboration with patients, issues around obtaining forensic history, and difficulties in how to describe and document risk. Clinicians have varied views on the importance of different risk factors, particularly static factors.

In Chapter 4, OxMIV was found to be a practically feasible approach to address some of these difficulties in EIP services. It was used in a considerable proportion of assessments over 12 months, and clinicians found it quick and straightforward. Required information was available, and the output typically aligned with clinical judgement. In most cases it was deemed to helpfully support the overall assessment, particularly if there were already concerns about violence risk. Clinicians did not require OxMIV to alter their judgement to find it helpful and they reported broad impacts on their practice, including confidence, knowledge and consistency. The summary percentage score provided by OxMIV was felt to provide richer clinical information to focus and clarify the clinical view. Patients and carers felt that using a structured tool was an acceptable approach, and encouraged clinicians to be straightforward in their discussion of violence risk. Modifications in careplans were more likely when risks were increased. OxMIV did not affect whether clinicians collaborated with patients and families. Linked treatment planning was identified as the process on which to focus efforts to improve collaboration. Adding therapeutic suggestions to the tool was deemed a palatable way for a future iteration to improve the linking of risk assessment to approaches to reduce risk.

In the external validation study (Chapter 5), violence perpetration occurred in 11% of the cohort. OxMIV's discriminative performance was robust (area under a receiver operating characteristic curve [AUC] of 0.75), demonstrating its transportability. Calibration was adequately corrected by updating the intercept of the model, without changing any of the predictor coefficients. Unstructured clinical assessment identified violence risk with low sensitivity in the external validation cohort, with only 40% of those individuals who perpetrated violence having had any violence risk identified in their clinical risk assessment. Using a 10% cutoff for designating increased risk, sensitivity of OxMIV was 71%, specificity 66%, positive predictive value 22% and negative predictive value 95%. OxMIV showed net benefit over clinical assessment and default clinical strategies.

Conclusions

Violence perpetration is an important but challenging adverse outcome for EIP services to assess and manage within the limits of their remit and resource. OxMIV has been externally validated and updated as a scalable risk prediction tool to support these challenges. Its practical use is feasible within EIP services, and acceptable in a range of domains to clinicians, patients and carers. Its optimal clinical role is as a complement to routine new assessments, to improve the currently low sensitivity with which needs around violence risk are identified and supported. An updated model is presented in Chapter 6 along with a guide for its use and linked therapeutic suggestions. This includes prompts to shift emphasis toward considering risk more longitudinally, improve collaboration with patients and families, and support the seeking of collateral history about past convictions where appropriate. A framework for how this can be integrated and studied in future work is provided.

Through this work, methodological progress has been made in an important gap in the prediction model literature, that of the stepwise translation of a model to a clinical tool. This

includes the use of routine electronic health record data to examine external validity, and novel mixed methods approaches to study the clinical feasibility, acceptability and role of a prediction model. Future work should develop and apply these methods to other prediction models in EIP services, psychiatry and beyond, and seek to examine in comparative clinical trials the impact of prediction models when they are integrated into clinical systems as complex interventions.

Chapter 1

Introduction: prediction models, stratified medicine, and their potential application to the adverse outcome of violence perpetration in first episode psychosis

Prognostic research and stratified medicine

Prognosis is the understanding of future outcomes in individuals with an existing disease or health condition. In medical practice it sits within the core triad of diagnosis, prognosis and treatment, and features in the earliest records of medical care.[1] Prognosis is first characterised in *On Prognostics*, contained within the ancient Greek medical works of the Hippocratic Corpus. In this text[2] it is suggested that physicians who prognosticate make better decisions, and prognosis is defined in broad terms:

> *"…forseeing and foretelling, by the side of the sick, the present, the past, and the future…"*

As science developed however, it brought with it first advances in the understanding of diagnosis, and then effective treatments. Prognosis became the forgotten element, seen more as a feature of the disease itself rather than the individual patient, and it was the diagnostic framework that instead drove practice.[3,4] There is renewed interest in prognosis in the modern era however. As the amount of available information expands, prognostic understanding is increasingly seen as integral to meeting the demands of contemporary healthcare delivery, which include longevity and multi-morbidity.[1] A prognostic framework widens the perspective from a focus on the disease, to more broadly incorporate the individual patient and environmental factors with which a disease interacts to shape the development of future associated outcomes.[5]

Prognostic information can be engaged on several levels. For example, for individual patients and their families it can inform understanding of their outlook so that they can plan accordingly, or act as a framework for considering treatment decisions along with clinicians. At a healthcare system and public health level, prognostic understanding is important for resource and service planning, and ultimately it can drive the translation of interventions into practice and healthcare policy, with the goal of most effectively improving outcomes.[4,6]

With the renewed interest in prognosis, and the proliferation of related studies in the medical literature, there came a need to bring uniformity to the different stages and types of prognostic research. This led to the development of the PROGRESS framework,[6-9] which outlines themes and good practice which form the basis of the work detailed in this thesis. The framework defines 1) overall prognosis research, which considers average future outcomes with current treatment, 2) prognostic factor research, which identifies factors associated with clinical outcomes in individuals with disease, 3) prognostic model research, which incorporates multiple prognostic factors into statistical models to predict an individual's risk of a future outcome, and 4) stratified medicine research, where interventions are targeted at subgroups of individuals with disease who share particular prognostic factor characteristics.[6-9] In the work that will be described over subsequent chapters, I focus on the latter two of these themes of prognostic research – the development, validation and testing of prognostic models, and how this links to stratified approaches to clinical treatment.

A key rationale for linking prognostic information to treatment decisions in this stratified medicine approach is to achieve maximum absolute benefit. The absolute benefit of a treatment (defined broadly as any intervention or support) depends on an individual's risk of developing the target adverse outcome in the absence of treatment.[9] One way to improve the balance between the overall benefits and potential costs or harms of a treatment, such as those related to resource use or broad adverse effects, is to target the treatment to where absolute

risk of the outcome is higher, so that absolute reduction of risk is higher.[10] More targeted, effective treatment can benefit both patients and healthcare providers.[11] Systematic prognostic information such as from prognostic models can help with this targeting of treatment.

Prediction models in medicine and psychiatry

In this context, interest in prognostic or prediction models in medicine has been rapidly expanding.[12] Searching PubMed for prediction or prognostic model articles published in the year 2000 retrieves 8,000 results; this increases to 25,000 in 2010 and 58,000 in 2020. The terms "prognostic model" and "prediction model" are typically used interchangeably. Henceforth in this thesis, I will use the term prediction model to denote any statistical model that combines information about risk factors (henceforth referred to as "predictors") associated with a particular outcome, to arrive at an individual prediction of the chances of that outcome occurring within a specified time period. One reason for the proliferation of these models has been advances in technology, and the development of large digital datasets which lend themselves conveniently to studying associations between predictors and outcomes at scale. As such, prediction models are putatively regarded as likely to be one of the most impactful influences of information technology on healthcare delivery.[13]

As the nature of the data available for such research has evolved, so too have the methods for harnessing this data to develop prediction models. A broad distinction is typically made between more traditional statistical techniques such as logistic regression and the newer, data-driven approaches of machine learning. The latter may offer greater flexibility to incorporate non-linear relationships, and may be suited to handling high-dimensional data or large numbers of predictors.[14] There are however limitations around transparency and clinical interpretability,[15] and whether overall these approaches offer a significant performance benefit is a matter of debate. This was for example not supported by a recent systematic

review,[16] and may particularly be the case in low-dimensional situations.[17] Although this issue is not a focus of this thesis, it is relevant insofar as it relates to issues of clinical translation that will be discussed in later chapters.

In terms of areas of medicine that have employed prediction model approaches, one field in which model development has been prolific is in cardiovascular medicine, particularly for the prediction of cardiovascular disease in the general population.[12] The most prominent and validated[18] models are the Framingham Risk Score[19,20] and QRISK calculator.[21,22] These simple, scalable models combine information about cardiovascular risk factors (from an individual's clinical history, treatment, and simple continuous variables such as blood pressure and body mass index) to for example calculate the risk of that individual having a heart attack or stroke within 10 years. The key to the use of these models as clinical tools is that they inform specific decisions around treatment, such as who is most likely to benefit from treatment with a statin to lower their cardiovascular risk. Indeed, they are included in national clinical practice guidelines around this process.[23] Cancer medicine is another field in which there has been an emphasis on the potential of prediction models.[24] Again, there is a focus on how these can inform treatment decisions. The NHS Predict tools support decisions around post-operative treatments in early invasive breast cancer,[25] and deciding between conservative and radical management regimes in prostate cancer,[26] by giving predictions of survival and harms with different approaches, and presenting these in different visual and text formats to aid clinical discussion.

Although no prediction models in psychiatry have such prominent roles in clinical practice as the above examples, a recent systematic review found that prediction models for psychiatric outcomes and settings are also being widely developed.[27] The review found replicated models for psychosis onset in high risk groups, and the onset of mood and anxiety disorders in primary care.[27,28] Elsewhere, aside from violence which will be discussed separately,

particular outcomes of interest have included predicting relapse or recurrence of major depressive disorder,[29] cardiometabolic risk in young people with psychosis,[30] recovery and relapse outcomes in first episode psychosis,[31-34] maltreatment and future diagnosis in child and adolescent populations,[35] and risk of developing dementia.[36] Prediction models have also been widely developed to predict suicide attempts and death by suicide.[35,37-39] Suicide is a rare event, and the associated low positive predictive value (PPV) of models (which is the proportion of individuals identified as at risk who go on to develop the outcome) is cited by some as a reason to disregard their potential clinical utility.[40] However, as is expanded below, focus solely on PPV is a narrow interpretation of the role of prediction models, and the performance of a model cannot be fully interpreted without knowledge of the specific clinical decision or process which it is informing.[15,41]

Bridging the gap between model development and clinical practice

As has been described, there are some notable examples of prediction models that are firmly embedded into routine clinical practice with a view to improving patient care and outcomes. Overall however, the promise of prediction models to materially move forward the age of stratified medicine is yet to be realised in a broad or consistent manner, particularly when one considers the number of prediction models that are developed compared to the number that are adopted at scale and with clinical impact. The limitations of the prediction model literature that help account for this mismatch are consistent across different medical specialities.

First, there are common areas of methodological weakness in model development studies that make it difficult in many cases for such studies to support the resultant model's clinical use. These problems include insufficient sample sizes, incomplete reporting of predictor information, inappropriate handling of missing data, and narrow presentation of model performance measures.[12,27,29,35,42] The gold-standard methodological frameworks of the

TRIPOD statement[43] (transparent reporting of a multivariable prediction model for individual prognosis or diagnosis), and the PROBAST tool[44] for assessing risk of bias and applicability of prediction model studies, set out to address some of these methodological shortcomings. The explosion of prediction models related to covid-19 has served as a stark reminder of the need for such frameworks as the field moves forward. A living (iteratively updated) systematic review appraised 169 studies of 232 covid-19 related prediction models, and rated all as being at high or unclear risk of bias, mainly due to problems with representative control samples, model overfitting and unclear reporting.[45,46]

The second key area of weakness is the broad neglect of the target clinical setting in studies of prediction models. In all fields, development studies considerably outnumber studies that externally validate a model (Table 1). External validation, as distinct from internal validation, is where a model's performance is tested in patients that are somehow different from the population in which it was developed, ideally in a population that is representative of the clinical setting in which the model is intended to be used. This is important in order to consider the generalisability of the model, and whether its predictions hold true outside of the data in which it was directly developed.[47] Different aspects of model transportability can be tested by external validation.[48] These are of importance for approaching a target clinical setting and include geographical transportability, methodological transportability where the model is tested with data collected using alternative methods, and spectrum transportability which refers to testing in patients with differences in disease.[48,49] Performance in external validation is typically worse than in development and internal validation, and so offers a more realistic estimation of performance in practice.[50]

Table 1 Exemplar reviews of prediction models in different fields and proportion of identified studies which addressed external validation or clinical impact.

Review	**Area/outcome**	**Number of models or studies**	**Proportion externally validated**	**Proportion with clinical implementation or impact**
Steyerberg et al,[9] 2013	Prediction model papers in 4 general medical journals 2006-2009	71 studies	29.6%	2.8%
Tang et al,[36] 2015	Dementia risk	21 studies	19.0%	0%
Damen et al,[12] 2016	Cardiovascular disease in general population	363 models	36.0%	Not reported
Phung et al,[24] 2019	Breast cancer mortality or recurrence	58 models	29.3%	0%
Moriarty et al,[29] 2021	Depression relapse	11 studies	36.4%	0%
de Pablo et al,[27] 2021	Psychiatry	89 studies	4.6%	0.2%

Studies that assess the impact of a prediction model in clinical practice are even rarer,[51] but are an essential area of development for the field of prediction model research.[9] To positively influence clinical behaviour, outcomes or cost effectiveness, a prediction model needs to fulfil a practical purpose in a clinical setting.[52] Considering predictive performance of a prediction model in isolation is an exercise from which only limited conclusions can be drawn about the potential role or impact as a clinical tool. A gold-standard study of impact, such as a pragmatic randomised trial, is a significant undertaking however. This therefore also requires indication that a model is usable before embarking upon, as well as understanding of how the model can be integrated into a clinical system and what the measurable impact of this may be.[53]

To bridge the considerable gap between the development of a model, and its translation into a clinical tool that is usable and positively impacts clinical care, is a stepwise process. Although there are examples of models that have been implemented at scale without going through this process, driven by urgency of clinical need or expert opinion,[9] few would argue that this is the manner in which prognostic approaches can most effectively and safely impact practice. Instead, there needs to be external validation of a model in a population that represents the target setting, and careful consideration of how the model can best interface with that clinical setting. In this thesis, I focus on this stepwise translational methodology.

Violence as an adverse outcome in clinical services for first episode psychosis

A key adverse outcome in psychiatry which might benefit from the recent advances in prognostic research and stratified medicine is that of violence perpetration. The World Health Organisation defines violence as:

> *"the intentional use of physical force or power, threatened or actual, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation"*

Globally, violence is one of the leading causes of premature mortality and morbidity, and in a shift from a law and order paradigm it is now regarded as an important target for public health intervention.[54] The United Nations 2030 Agenda for Sustainable Development[55] highlighted violence prevention as a key component for development and improving quality of life in all parts of the world. It is important to note that fatal violence is only a small fraction of this well-recognised burden. Non-fatal violence has far-reaching implications, including physical and psychological sequelae, lost productivity and increased demand on health services and other public services. For example, the unit cost of a single violent crime

with injury in England is estimated to be over £14,000, of which there are over one million occurrences in 12 months.[56]

Epidemiology of violence in mental illness

Most violent crime is perpetrated by individuals without mental illness, and most individuals with mental illness are never violent. However, the small but significant increased risk of violence perpetration associated with mental illness is well established. In a recently published review of the epidemiological literature, I found that the odds of violence perpetration in individuals with one of a range of mental disorders were increased by around 2-fold to 4-fold compared to individuals without those disorders, after controlling for important confounders.[57] For patients, perpetrating violence can add to the strain already placed on social and family support networks by severe mental illness. Involvement with the criminal justice system is also extremely disruptive. Being arrested, held in custody, charged with an offence, convicted and fined or imprisoned can fragment healthcare provision and disrupt occupational and interpersonal functioning far into the future. Perpetrating violence may also be psychologically traumatic and in itself perpetuate instability of mental state. Violence also continues to be a leading contributor to stigma in mental illness,[58] and better prevention is one way to address this.

Risk of violence perpetration has been particularly widely studied in schizophrenia spectrum disorders.[59] Here, understanding has been enhanced by several recent large population register-based studies.[60-64] I was part of a team that recently updated the epidemiological evidence in this area, and 24 studies were included in a meta-analysis with 50,000 individuals with schizophrenia spectrum disorders (Appendix 1.1). The pooled odds ratio for violence in patients compared to controls was 4.5 in men (95% confidence interval [CI] 3.6-5.6) and 10.2 in women (95% CI 7.1-14.6). Primary investigations included in this review also allowed estimation of the contribution of important confounding factors such as familial factors and

comorbid substance misuse. Both these factors increase risk, but risk relative to general population control groups remains significantly increased when their effect is removed.[60-62] Absolute risk of violence perpetration in included studies was up to 5% in women and 25% in men. This is clearly therefore an adverse outcome that is of routine relevance to clinical services treating psychotic illnesses. The public health relevance of this association has also recently been underlined by estimates of its economic impact - in England and Wales violence in schizophrenia spectrum disorders accounts for around 5% of total societal costs of violence, around £1 billion per year.[65]

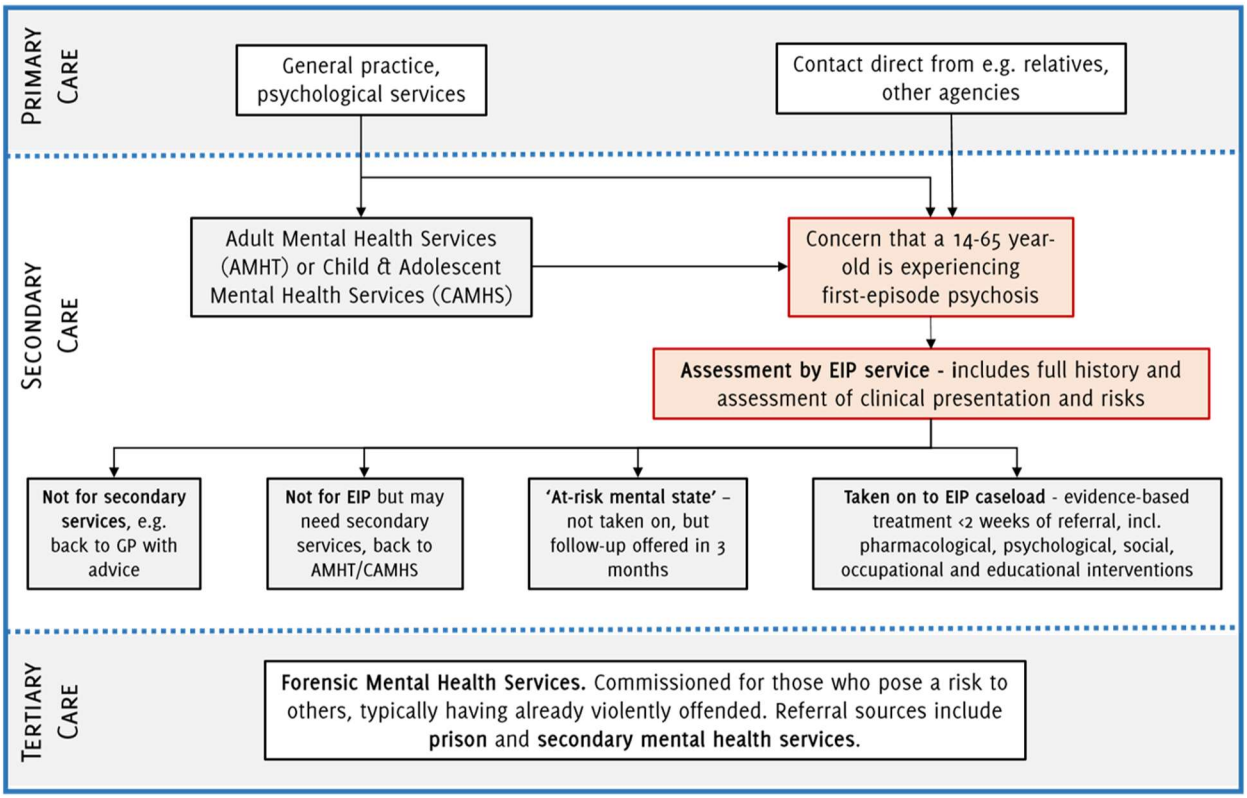
First episode psychosis and Early Intervention in Psychosis services

There is evidence that the peri-diagnostic period in psychotic illness is of particular relevance for violence risk. Among individuals with psychosis who perpetrate homicide, a meta-analysis showed the rate to be substantially higher in first episode psychosis (FEP) than in other phases of illness.[66] In a Danish register study, 12% of men presenting with psychotic illness had a history of violent offending prior to their first contact with services.[67] A study in Israel also showed that among patients with schizophrenia who perpetrated at least one violent offence, the timing of the first offence was most often in the year of their first psychiatric contact.[62] A systematic review of 15 studies of violence in FEP found a pooled prevalence of serious aggression (defined as violent crime or physical violence/assault against another person) of 16% before contact with services and 13% following contact,[68] and a subsequent longitudinal study also showed that 20% of individuals followed up for 10 years from their first episode of psychosis were arrested or incarcerated for violence.[69]

Violence is therefore an adverse outcome of direct relevance to Early Intervention in Psychosis (EIP) services. These are multidisciplinary community mental health teams who engage individuals experiencing, or who have recently experienced, their first episode of psychotic illness. These services represent the gold-standard of care in the UK as well as

Australia, the US and Europe.[70] The positioning within mental health services and referral pathways for a typical EIP service in England is summarised in Figure 1. They offer swift assessment and individually tailored interventions and support to patients and carers, as part of a well-defined and assertive service model. Care coordinators work more intensively with smaller caseloads of patients than in standard community mental health teams.[71] In the UK, to be concordant with the National Institute for Health and Care Excellence (NICE) guidelines, EIP services offer psychological intervention, medication, physical health assessments, family interventions, wellbeing support, education and employment support and carer-focussed education and support.[72] They are busy services, and undertake around 1000 new assessments every month in England (NHS England). The focus is on early intensive treatment, with most services supporting patients for 2 to 3 years, in order to facilitate recovery and improve future outcomes.[71,73]

Figure 1 Positioning of Early Intervention in Psychosis (EIP) services within mental health and related services in England.



Violence perpetration in the specific clinical setting of UK EIP services has also been studied, and its prevalence here is in keeping with the wider epidemiological literature. In a longitudinal cohort study, 14% displayed violent behaviour (self-report of physically harming others) in the 12 months after EIP service entry.[74] I also undertook some previously-published preliminary work locally in EIP services in Oxfordshire and Buckinghamshire, and found that of 177 individuals consecutively assessed by EIP services, around 1 in 7 individuals were arrested or charged for violent offences in the 12 months after assessment.[75] As well as the overarching implications of violence as an adverse outcome, there is indication of its specific importance in this patient group, where a history of violence is associated with poorer prognosis including increased frequency and length of hospital admission, poorer functional status and victimisation.[76-78]

Violence is therefore an important adverse outcome to manage in EIP services, and attention to it is aligned with the prognosis-focussed EIP service model. In many ways, EIP services are a unique time point and setting where more effective approaches to violence risk assessment and intervention could prevent future offending. Indeed, across international clinical guidelines in the UK, USA and Australia and New Zealand, assessing for violence risk in psychosis is considered a routine part of a full initial clinical assessment.[79-81] However, guidance on how to go about this is limited, and expertise in violence risk assessment sits in forensic services (Figure 1) rather than EIP services. The threshold for input from forensic services is high, in that they typically only become involved when a serious violent offence has already occurred. So initial risk assessment responsibility lies with EIP services themselves. This is a challenge in the context of the wide array of assessments and interventions these services provide. Furthermore, the trajectory of violence within FEP before and after service contact suggests that EIP services may need to more directly address

violence risk to positively impact these outcomes.[74] Examining the challenges of this, and improving what is available to support the process, is therefore a clinical priority.

Survey of practice in EIP services

How EIP services currently address violence risk has not been described. To preliminarily test the broad baseline understanding that there is currently no common structured assessment process for violence risk in EIP services, I undertook a brief survey of clinical services across the south of England as part of delivering an online learning event around violence risk assessment. A simple description of how violence risk is assessed and documented within electronic health records (EHRs) was provided by representatives from 12 clinical service areas, covering 27 individual EIP services. Findings confirmed that there is no uniform approach to violence risk (see Table 2 for summary and Appendix 1.2 for breakdown of domains by individual service areas). Most used a free-text box for both assessment and summary, though a few were more complex either by virtue of sub-classifying up to 19 types of violence risk, or requiring some categorical rating. In 4 out of 12 services, some information was given on risk factors in some aligned clinical guidance. One service used a risk matrix with a numerical rating that combined the likelihood of an incident with the severity of the likely incident based upon a descriptor from a 1991 study reference.[82] It is clear therefore from this preliminary exploration that there is no established standardised approach across EIP services.

Table 2 Characteristics of approaches to risk assessment in Early Intervention in Psychosis services across 12 clinical service areas in South of England.

Characteristic of risk assessment form used by service	**Clinical services, n (%)**
Total	12 (100%)
Overall template	
Single tick-box and free-text	4 (33%)
Form with subdivisions	8 (67%)
How violence defined	
Single broad violence category	8 (67%)
Multiple subcategories (range 4-19)	4 (33%)
Divided into timescales of imminence	2 (17%)
Risk summary/formulation	
Free-text only	8 (67%)
Categorical (high/medium/low)	3 (25%)
Numerical risk matrix	1 (8%)

Violence risk assessment tools

There are some established prognostic factors associated with violence perpetration outcomes in mental illness and psychotic illness.[57] Replicated factors include sociodemographic factors such as male sex,[83] criminal history risk factors such as previous violent crime or imprisonment,[84,85] family history factors such as of violent offending,[86] and clinical factors such as substance misuse,[84,85,87] victimisation,[84,87] self-harm,[88] impulsivity,[84] treatment non-adherence[84] and anger from persecutory beliefs.[89] To bring together this prognostic information in a structured manner to support clinical assessment, various tools have been developed for use in psychiatric as well as justice settings.[90] These have varying levels of sophistication in terms of whether factors are formally weighted as part of a prediction model, typically known in the violence risk assessment field as an "actuarial" approach, or

are brought together more qualitatively in a "structured professional judgement" approach. There are some key limitations of existing approaches however, both in general and for their clinical application to EIP services.

First, across the field of violence risk prediction as a whole there is an issue with the transparency and methodology with which tools are developed. This can sometimes be simply guided by expert consensus rather than by integrating epidemiological evidence in a specified manner.[91] The predictive performance of tools is variable,[92] and a study of violent reoffending in released prisoners found that many of the items contained within some of the most widely used tools had no independent predictive validity.[93] There is also evidence of authorship bias, whereby studies directly involving tool developers report more favourable accuracy, often with a lack of appropriate declarations of interest.[94]

Second, for use in an EIP setting, a clear barrier is the very limited validation of such assessment tools in relevant populations and settings.[90] In a previous systematic review only two tools were identified that had been studied in individuals with psychosis[90] (Table 3). Further, for both these tools their resource-intensive nature means they are not routinely feasible for non-forensic clinical settings such as EIP services, where violence risk assessment is not a primary function of the service. The tools typically require many multidisciplinary person hours to complete[95] and incur direct costs for use and training.[96]

Table 3 Violence risk assessment tools validated in individuals with psychosis. AUC, area under the receiver-operator curve; CI, confidence interval. *Denotes number of individuals in validation population for patient group.

Tool	**Items**	**Outcome**	**Population**	**N***	**Median AUC (95% CI)**	**Resource requirement**
HCR-20 (Historical Clinical Risk Management 20)	20	Violent offending	Psychiatric patients with psychosis	696	0.71 (0.67–0.74)	Requires 2-day training course, costs associated with application e.g. manuals, worksheets. Completing assessment takes several hours
VRAG (Violence Risk Appraisal Guide)	12	Violent offending	Violent offenders with schizophrenia	165	0.69 (0.60–0.77)	Suggests 'professional training on the application of the instrument', and requests a psychopathy checklist score (itself consisting of 20 items) as one of its items

The "OxMIV" violence risk prediction tool

More recently, the contemporary prognostic research methods and methodological quality guidelines that have been described were applied to develop a violence risk prediction model that avoids many of the limitations of existing violence risk assessment tools. This therefore may potentially have a role in prediction of violence risk in EIP services.

The "OxMIV" (**OX**ford **M**ental **I**llness and **V**iolence) model[86] was developed with the simple, scalable approaches of tools such as QRISK in mind. Its development with logistic regression (detailed in Chapter 5) used a pre-specified protocol and the methodological quality frameworks described earlier.[97] Candidate predictors were selected based on the epidemiological literature, with the strongest predictors in analysis then being retained in the

final model. Swedish population registers were used to derive and internally validate the model using data from 58,771 individuals with schizophrenia spectrum or bipolar disorders.[86] It was then externally validated in a sample of 16,387 individuals geographically distinct from the derivation sample. The primary outcome was conviction for a violent crime in a 12 month period.

The final model incorporates 16 sociodemographic and clinical predictors. External validation showed good measures of discrimination (c-index, equivalent to area under a curve, of 0.89) and calibration (Brier score 0.0132, with a score of 0 representing perfect calibration). These performance measures are discussed in detail in Chapter 5. Performance was very similar in the derivation and external validation data subsets, suggesting that the model is not over-fitted to the data from which it was derived and is generalisable. The predictors included in the final model are shown in Figure 2, i.e. this is the OxMIV tool. Other than age in years and the personal income decile, all other items require a binary (yes/no) or simple categorical response (for education) for the risk prediction to be calculated.

Figure 2 The 16 predictors in the OxMIV tool.[86]

Predictors for OxMIV model	
Age	Parental drug or alcohol use disorder
Sex	Parental violent crime
Previous violent crime	Sibling violent crime
Previous drug use disorder	Recent antipsychotic treatment
Previous alcohol use disorder	Recent antidepressant treatment
Previous self-harm	Recent dependence treatment
Current episode (inpatient/community)	Personal income
Highest education	Benefit recipient

These predictors are clinical information that might typically be collected in routine clinical practice as part of a full assessment in EIP services, and the information required is in a binary or simple categorical format. The model itself was published in full, as well as being translated into a free online calculator (oxrisk.com) which provides both a percentage risk score and a categorical score (low or increased risk, using a 5% cutoff). This open availability allows validation by independent groups. Indeed, its use has since been studied in a German prison hospital setting.[98] This provided indication of the model's geographical, methodological and spectrum transportability by being shown to retain predicative performance in a different country, with data collected from file review rather than from register data, and in a different population of individuals with schizophrenia spectrum and bipolar disorders incarcerated in a prison setting.[98]

There are therefore reasons to suggest that the OxMIV model may potentially translate to a clinical tool for EIP services. It has been transparently developed in a relevant clinical population, using the most up-to-date prognostic research approaches. It is also simple with no additional resource requirements for use, and there are indications that its performance may generalise well to other settings. This potential however is currently hypothetical, as it has not been validated or had the particulars of the manner or feasibility of its clinical use in this setting examined. OxMIV therefore finds itself at the juncture that, as described earlier in this chapter, is the common stalling point for the prediction model field. The aim of the work described in this thesis is to close this gap toward clinical practice for OxMIV in EIP services, and by doing so advance the methodological approaches in this area.

Summary and thesis aims

In the overview of the fields of prognostic research and violence in mental illness presented in this chapter, I have outlined some key areas of potential, as well as some important

knowledge gaps. There is widespread interest in how advances in the use of data to develop prediction models could facilitate the use of individualised prognostic assessments to target the allocation of treatment and resource. Whilst in some cases this has already led to routine, stratified medicine at a large scale, overall there remains a gap between the development of prediction models and their translation into usable clinical tools. This requires greater emphasis on external validation, and examination of the nature and feasibility of the integration of prediction models into a clinical role. Methodological approaches to these aspects of prognostic research are under-explored compared to those of model development, and the target clinical role is often neglected in discussion of prediction model development and performance.

In psychiatric settings, violence perpetration is an important adverse outcome, particularly in services for FEP. Around 1 in 10 individuals in contact with EIP services perpetrate violence in the first year. Predictors of violence are well established, and adopting a stratified medicine approach to targeting interventions accordingly could be of benefit. However, EIP services do not specialise in violence risk assessment. There are no well-validated or simple prediction tools to support their assessments currently, and no standard assessment structure used across services. How clinicians go about assessing violence risk in the absence of such supports is not well understood. A prediction model called OxMIV could potentially have a role in this gap. It is simple and was developed using robust, transparent methodology. Whether, and with what role, it could be of clinical benefit in EIP services however is unknown.

Therefore, the aims of this thesis are to focus on the clinical translational phases of prediction model research required to develop OxMIV from a prediction model into a clinical tool for EIP services. This will involve developing an understanding of the needs of the target clinical setting, the potential practical role of OxMIV here, and its accuracy in this population. In so doing, an overlooked and underdeveloped aspect of prognostic research will be highlighted

and expanded, with transferrable methodological implications for the study of clinical prediction tools elsewhere in psychiatry and medicine.

In summary, the research questions that this thesis will address are:

1. How is violence risk assessment and management currently approached in clinical services for first episode psychosis, and what challenges and needs are there?
2. Could a violence risk prediction tool (OxMIV) have utility in this clinical setting, and how can this be studied?
    a. Is it clinically feasible and acceptable?
    b. Can its accuracy be externally validated, and performance optimised for clinical use in this setting?
    c. What is the likely impact and benefit of its use?
    d. How can it best be integrated into stratified management for violence risk, and how can this be evaluated?

Chapter 2

Prediction model to clinical tool: using qualitative and mixed methods to understand the potential use of a violence risk prediction tool (OxMIV) in Early Intervention in Psychosis services

Introduction

As detailed in Chapter 1, Early Intervention in Psychosis (EIP) services[99] are clinical settings that may benefit from improved approaches to the assessment and management of violence risk. The association of violence with psychotic illness is well established,[59,60] and it occurs at a clinically relevant rate in EIP services.[68,75] Indeed, some consideration of violence risk is typically a routine part of any comprehensive assessment that would be undertaken by EIP services.[79,80] A challenge however is that relevant expertise and resource, such as the option to use lengthy structured assessment tools,[92] sits not in EIP services but in specialist forensic services. These services only become involved where risk of violence is very high, typically when serious offending has already occurred. Clinical prediction tools are a potentially more accessible way to support routine clinical assessment for adverse outcomes. These are rapidly developing across medicine and psychiatry,[27,100] and as has been described, OxMIV[86] may be a candidate to fulfil this supporting role for violence risk assessment in EIP services.

Central to translating a tool such as OxMIV into improved clinical care and patient outcomes is ascertaining whether, and how, it can be integrated into a specific clinical context. High predictive accuracy is irrelevant if clinicians are unable or choose not to use a tool in practice due to problems with acceptability, perceived validity, feasibility or resource, or even more fundamental issues such as a lack of perceived need or misalignment with the goals of a service. The second question, if a tool is used, is what the most relevant target improvements in clinical care and outcomes are, and how they can be studied.

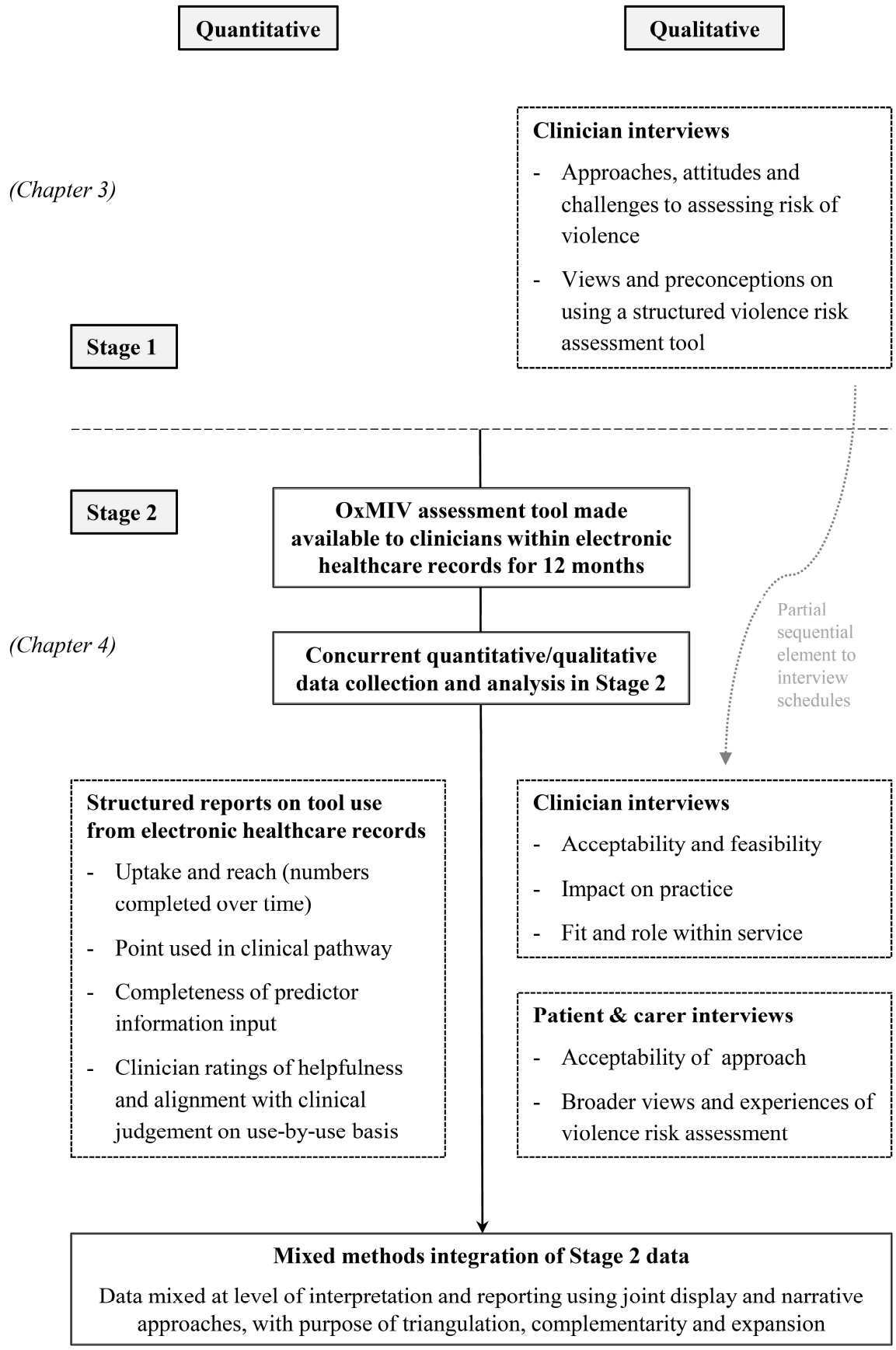
An essential first step in this pathway toward clinical translation and improved care is to understand current practice in depth, including the relevant challenges and areas of need, which of these may be assisted by a tool, and what the barriers to this may be. The manner in which EIP services undertake violence risk assessment in clinical practice has not been previously described in this manner. Studies of risk assessment processes in general psychiatric services typically focus on risk to self[101] rather than of interpersonal violence, which is a discrete outcome in terms of its epidemiology, implications, and relation to wider issues such as stigma. How it is approached clinically is therefore likely to be influenced by a unique range of issues, particularly in EIP services with their specific remit and model. When implementing OxMIV in a clinical setting, these broad contextual issues are likely to be engaged in parallel with the more practical issues of its function, use and role.

In Chapters 3 and 4 I will therefore present findings from a program of work to address these knowledge gaps for the use of OxMIV in the target setting of EIP services. I used qualitative, quantitative and integrated mixed methods to first understand current practice and need in EIP services, and then examine the preliminary clinical use of OxMIV as an assessment support tool with a focus on its feasibility, acceptability and role. Here, in Chapter 2, I will describe the structure and process of this work, and detail the methodologies employed.

Structure and aims of work program

The work was undertaken in two stages (Figure 1). Baseline individual interviews of EIP clinicians were followed by OxMIV being made available within the electronic health record (EHR) for clinicians working in two EIP services in Oxfordshire and Buckinghamshire. In the subsequent 12 months, quantitative data on the use of OxMIV was collected and analysed, and integrated with a second round of qualitative interviews with clinicians, as well as patients and carers.

Figure 1 Outline of two stage work program using mixed methods to examine current practice and subsequent clinical feasibility and acceptability of the OxMIV tool.



Summary and aims: Stage 1

This was a qualitative interview study of multidisciplinary EIP clinicians. The aims were to explore 1) current approaches, attitudes and challenges to the assessment of risk of violence in EIP services, and 2) clinicians' views and preconceptions on using a structured violence risk assessment tool in clinical practice. As described below, interview data was analysed thematically, independent to the Stage 2 work. However, there was a sequential element in that developed themes from these baseline interviews were used to modify the interview schedules for Stage 2, either to examine whether preconceptions had translated to practical experience, or to explore patient and carer perspectives on themes from clinician interviews.

Summary and aims: Stage 2

This followed the integration of OxMIV into the EHR and its use over 12 months by two EIP services. The aims of this stage were to use mixed methods to examine 1) the acceptability and practical feasibility of the tool, 2) the uptake of the tool and any barriers to this, 3) the impact, perceived utility and optimal role of the tool, and 4) broader patient and carer views and experiences of violence risk assessment. As detailed below, having the tool embedded within the EHR allowed quantitative data to be collected to address several of these aims. This data was collected and analysed concurrently with the Stage 2 qualitative interviews. Data mixing (integration of qualitative and quantitative data) occurred primarily at the interpretation and reporting stage. Stage 2 had the dual overarching purpose of informing and refining both the use of the tool, and the methods by which its use and impact can be studied.

Justification for choice of methodology

Identifying and managing risk of violence in mental health services is both complex and potentially sensitive. Understanding practice, and how a prediction tool might integrate with this, therefore required the richness and retention of complexity offered by qualitative

methods.[102] It was also a relatively unexplored area, and so beginning to form understanding using the more inductive approach of qualitative methodology was appropriate.[103] The contextual and explanatory aspects of the work to establish current attitudes and practice benefited from the ability of qualitative methods to describe phenomena, and what lies behind attitudes and behaviours, in fine detail and in the terms of the participants.[104] The evaluative aspects of understanding the tool's integration required the flexibility of qualitative methodology to identify the many factors that can shape this. Qualitative methods also offered a clear manner in which to incorporate different voices into the understanding, including clinicians of different disciplines, and crucially patients and carers.[105]

In the field of prediction models, the value of qualitative methodology for studying the complexities of deploying tools in clinical settings is becoming appreciated. It has been used to explore the contextual issues affecting clinical use of prediction tools in diverse scenarios such as identifying children at risk of maltreatment presenting with head injuries[106] or burns,[107] facilitating end of life discussions with elderly patients in general practice,[108] and increasing uptake for colorectal cancer screening.[109] Whilst there will be some overlapping themes around practicalities, qualitative methods allow the flexibility to identify newly arising, context-specific issues in such different settings.

Qualitative methods alone however could not address all the goals of the work to examine OxMIV in a clinical setting. There are more concrete issues, such as the uptake of the tool in terms of numbers completed, or the pattern of completeness of information input into the tool, that are helpfully examined with quantitative information. This is particularly relevant to the parallel goal of planning future studies. For example, numerical estimation of the proportion of assessments in which clinicians might complete the tool is needed to inform consideration of the size of any future trials. Even for these aspects that could be addressed quantitatively however, this quantitative data alone might give only superficial information,

and not provide helpful insight into the reasons for a particular pattern or how it might be addressed. Here therefore lies the rationale for integrating quantitative data with qualitative data in this work, such that they become mutually illuminating.

Mixed methods research involves the purposeful mixing or integration of quantitative and qualitative data to provide deeper insights than either modality can provide independently.[110-112] It draws on the strengths of both methods to study complex healthcare systems.[113] A key aspect is the integration, where the qualitative and quantitative aspects interact to give added value, rather than simply being presented consecutively.[114] The importance of this genuine mixing has been highlighted due to its initially variable presence in the literature.[115,116] In Stage 2, the purpose of mixing data[117] was for 1) triangulation, where both methods addressed aspects of the same phenomena, for example the availability of the required clinical information, 2) complementarity, where one method elaborated results from the other, for example quantitative analysis of where in the clinical pathway the tool was most frequently completed, elaborated by qualitative views of the tool's optimal role or positioning, and 3) expansion, broadening the scope to different aspects of the phenomena, such as by considering uptake in the context of the wider system, or including patients and carers to add different perspective to clinicians' views on acceptability.

Use of mixed methods in the prediction model field is relatively nascent, but has shown potential to address the complex issues around clinical implementation. For example, a mixed methods studying following a cluster randomised controlled trial of a prediction model for post-operative nausea and vomiting used a sequential approach, by undertaking individual interviews with participating clinicians to guide a subsequent quantitative survey.[118] This illuminated complex issues around the incorporation of the model into decision-making, and suggested that a more actionable output from the tool may improve uptake. Vice versa, a mixed methods study of how family physicians perceive and use clinical prediction models

began with an online survey and then recruited participating clinicians to subsequent focus groups.[119] This allowed fuller exploration of views identified in the survey, and revealed ways in which prediction models were used and factors that influenced this that were previously unreported. Other studies have used a combination of quantitative surveys and qualitative interviews or focus groups to examine oncologists' views on the use of clinical prediction models[120] and issues of clinical usability in diverse clinical scenarios such as vascular surgery[121] and musculoskeletal pain.[122]

In terms of the philosophical underpinnings and assumptions of the work, the paradigm I have adopted in this highly applied research is that of pragmatism.[104] Pragmatism is flexible, adopting the most appropriate methods for a particular research problem (in this case both quantitative and qualitative), and I am focussed on what can be learnt rather than the being tightly bound to a particular philosophical stance.[123,124]

Qualitative methods (Stage 1 and 2)

In preparation for the design and conduct of the work outlined below, I undertook methodological training by attending two in-person taught courses on conducting and analysing qualitative interviews provided by The University of Oxford's Medical Sociology and Health Experiences Research Group. At key points in the design and analysis of the study I also received specialist methodological advice from a senior researcher (MG) in the Department of Primary Care Health Sciences. Individual interviews were chosen as the method of data collection, in preference to focus groups, primarily due to the sensitive nature of the topic and the complications that may arise from this in a group interaction.[125] There would likely have been some tailoring of views for social acceptability in a group, especially where there were differences in professional background or seniority within a clinician group. The simpler practicalities of individual interviews also posed fewer barriers to participation.

Sampling and recruitment: clinicians

Clinicians were recruited from two clinical sites, which were EIP services from a single NHS Trust which serve different counties (Oxfordshire and Buckinghamshire). Purposive sampling was used to identify relevant groups of clinicians.[104,126] This was appropriate to achieve diversity of participants from the multidisciplinary clinical team. Eligible clinicians were clinically qualified staff, all of whom with some role in clinical violence risk assessment and management. Minimum target quotas were set according to two key selection criteria that may plausibly affect perspectives, which were 1) clinical background (medical, nursing, occupational therapy, social work and psychology), and 2) number of years of clinical experience.

I introduced the study at team meetings, followed by sending electronic communication inviting clinicians to express interest and request a written participant information leaflet (PIL, Appendix 2.1). For clinicians wishing to participate, an interview was then arranged at their convenience. In practice, due to the covid-19 pandemic, all interviews took place remotely. All participants provided informed consent, including for audio-recording and the use of written anonymised quotations. As interviews were remote, I took verbal informed consent using standardised recorded wording from the informed consent form (ICF, Appendix 2.1). I completed the ICF and emailed a copy to the participant for their records.

For the Stage 2 interviews, where possible I interviewed those clinicians who had already enrolled in Stage 1. Clinicians who had not participated in Stage 1 were eligible to be included for the Stage 2 interviews provided they had been part of the clinical service for at least 2 months, and a small number were recruited in this manner to replace any clinicians who were no longer available for Stage 2 (e.g. having left the clinical service).

Sampling and recruitment: patients and carers

Patients and carers were recruited from the same two EIP services. For patients, a more iterative theoretical sampling approach was initially adopted.[104] Data was analysed from initial interviews from an open sample, but as categories developed sampling became more purposive. This was suitable due to the relatively exploratory nature of the work. Including individuals with a history of contact with the justice system was a key characteristic sought during the more purposive phase of sampling, however in practice it proved difficult to recruit patients with such histories. This limitation is discussed in Chapter 4. Carers' views were sought in this study not just to support the patient perspective, but due to their importance in their own right. When adverse incidents related to violence occur, it is often retrospectively noted that families were not as involved in the assessment of risk as they had wished to be. One potential benefit of a tool is to help facilitate more transparent conversations with patients and their families about risk, and so understanding carer views on this was important.

Eligible patients and carers were male or female, aged 14-65 years, who were willing and able to given informed consent for participation (or parental consent if aged 14-15 years). They needed to have been deemed suitable to take part by their usual clinician, and to have been involved in reviews, assessments or discussions of risk with EIP services after OxMIV became available. They did not necessarily need to have been directly involved in completing an OxMIV assessment. This was an amendment in response to findings from clinician interviews, in which it was clear that risk assessment and its documentation was rarely done in direct collaboration with patients, and so including only those with such direct experience would have provided an overly restricted sample. Patients were excluded if they entered an acute phase of illness prior to the interview such that participation was unfeasible or posed a risk of further deterioration of mental state, or if they were unable to take part in an interview conducted in English.

Initial contact occurred via the usual treating clinician (i.e. care coordinator or responsible clinician). Clinicians passed on simple invitation letters to patients and carers (Appendix 2.2), who returned their consent to contact via their clinician. On receipt of this consent I then contacted potential participants directly via the preferred method. I explained verbally or over email the purpose of the study, including the format of the interview, options for timing and that it would be audio-recorded, and provided either via email or as paper copy the written PIL (Appendix 2.2). I gave opportunity to ask questions, request further information, and decline further contact. If the participant wished to proceed, interview was arranged at their convenience. Again, in the context of the pandemic, these all occurred remotely. At interview, I ensured that participants had read and have understood the PIL, and if appropriate took verbal informed consent using standardised recorded wording from the ICF (Appendix 2.2), a copy of which I posted or emailed to the participant. For patients aged 14-15, parental consent would have be required, but in the event no participants of this age were recruited. To compensate for their time, patient and carer participants received a £10 voucher.

Data collection

For both clinician and patient and carer groups I conducted semi-structured interviews using topic guides (Appendix 2.3). Interview length was capped at 60 minutes. I developed the topic guides based on the study aims, through discussion with the supervisory team, and through discussion with a public and patient advisory group (see section below). The topic guides were not piloted to maximise the data available for analysis. However, they were iteratively adapted as new topics arose from early interviews so that these ideas were explored with subsequent participants. Recruitment continued until sufficient information power was achieved.[127] This took into account the focussed nature of the study aims and the specificity of the sample achieved by purposive sampling. Data collection finished when new

themes were no longer arising, and enough data had been collected to explain both the issues included in the aims of the study and the new topics that arose.

For clinician participants only, two fictional clinical vignettes were presented in the Stage 1 interviews (Panel 1). I developed these to be representative of clinical scenarios that may typically present to EIP services and prompt consideration of violence risk. The vignettes were used as probes to aid exploration of clinicians' approaches to assessing violence risk. For clinician interviews, the high quality of dialogue obtained from clinician participants who all had professional experience with the topic was also relevant to the information power.

Panel 1 Fictional clinical vignettes presented to clinician participants during interview.

Vignette 1

Patient P is a 21-year old man who has just moved back home with his parents after deferring his university degree due to unusually struggling to keep up with work. He has become withdrawn and self-neglecting. He has auditory hallucinations and florid persecutory ideas, including that his parents are feeding information about him to the government. His mother describes him as irritable and verbally hostile and he is angry about being referred to mental health services.

Vignette 2

Patient M is 25. He is unemployed and currently sofa-surfing. He had a difficult upbringing due to his father being in prison, and was involved in the youth justice system for several years including convictions for assault. He has a long history of self-harm, but now presents with new symptoms of auditory hallucinations in the context of escalating substance use. He has good insight and is keen for support from services.

Transcription

Interviews were recorded using an encrypted digital voice recorder and transcribed verbatim independently by a professional service. Recordings and transcripts were transferred using the Egress Secure Workspace. A formal service agreement including data protection

arrangements was in place prior to transcription. I checked the transcripts against the audio recordings and removed any potentially identifying information. Audio recordings were destroyed after this transcription process and no identifiable information was retained with the transcripts.

Data Analysis

Transcripts were imported into NVivo 12[128] to assist the organisation and retrieval of data, which supported a systematic approach to data management and analysis. Data was analysed thematically,[104] informed by the constant comparative method[129] whereby collected data iteratively informed ongoing data collection. Thematic analysis is a method for identifying, analysing and reporting patterns within data[130,131] that emerged as a pragmatic approach from grounded theory,[132] with a key advantage of its flexibility and not being bound to any one theoretical framework.[130] Themes are the patterns of meaning that relate to the research question, and are actively developed during the course of the analysis.

In practice, during familiarisation with the first set of interview transcripts I gained an overview of the content and generated an initial coding framework which was discussed with other members of the research team. The coding of this first set of interviews identified new issues that were carried forward into the subsequent interviews. Items added to the topic guide for clinician interviews during this process included language used to describe risk, defensive practice, and the therapeutic relationship. Data collection and analysis continued simultaneously as recruitment progressed. This approach ensured that any new themes developed were grounded in the data, and allowed the checking of concepts derived from earlier parts of the data. I developed the coding framework as data collection and analysis proceeded. Initial idea-by-idea open coding was built into wider categories which were refined as data were added, and developed into overall themes. I checked these themes against the component interviews to ensure that raw material had been appropriately captured

in the analysis. The data within themes was described by mapping the range of views, linkages and concepts behind ideas raised.

Trustworthiness

Best practice criteria in qualitative research were considered throughout the design and reporting of the work.[133-135] Central was the concept of trustworthiness, considered across the domains of credibility, transferability, dependability and confirmability.[136] Trustworthiness was addressed by ensuring that analysis was systematic, transparent and comprehensive, with complete and accurate recording of the data and justification for decisions made in the process of analysis. I used memos and notes during the initial stages of analysis to document an "audit trail" of decisions as coding progressed through to interpretation. Findings are therefore confirmable and demonstrably based upon the data. Clear reporting of the sampling strategy, participants and setting allows judgements around transferability to be made. Triangulation (both between cases and sources of data) adds further to the credibility, and there was "fair-dealing", whereby the design of the studies specifically incorporated a wide range of perspectives.[137] Finally, at key points I discussed the developing codes and categories with the supervisory team.

Reflexivity

Reflexivity is the awareness in qualitative research of a researcher's background, perspectives and motives, and a sensitivity to how this may shape the data collection and analysis.[134,137] I conducted this work with an explicit awareness that, as would be expected given my background in forensic psychiatry, I regard prevention of violent outcomes as important for mental health services, and further that simple structured tools might have some potential role in improving this. It would be difficult to imagine undertaking this body of work without holding such views. Nevertheless, this needed to be considered in terms of how it may affect some sections of data collection and analysis. My view was broad, and did not include

preconceptions about whether this particular tool would work in this particular service, or the specific role for such a tool here. The robust and transparent process described above was designed to mitigate the risk of these baseline views impacting study results. In terms of data collection, clinicians being aware of my background did not inhibit the sharing of views to the contrary in terms of the relative importance of violence risk or merits of the tool.

Integration of OxMIV tool into electronic health records (Stage 2)

I worked in close contact with the local clinical services to plan the manner in which to make the OxMIV tool available to clinicians. Initial stakeholder work consisted of meeting with clinical services in best practice and leadership meetings, and in the multidisciplinary team meetings for the two involved services. An important piece of early feedback from these discussions was that, although OxMIV is freely available online, to realistically make any use of it clinicians felt that it needed to be available directly within the EHR. Further, it was clearly evident that one of the predictors (the personal income decile) was clinically unpalatable due to practicalities of estimating it, and so this was truncated into a simpler categorical option that used the average of the coefficients for the higher deciles.

I then worked with the EHR team and clinical directors to develop the assessment form to sit within the EHR system. It was built into the risk assessment tab of the EHR (on a drop-down menu that also includes, for example, the forensic HCR-20 tool). I worded the questions for the predictor information so that the definitions for the information sought were clear and understandable for clinicians (Figure 2). From the clinical directors' perspective, a key aspect was that the adjunctive nature of OxMIV was clear (i.e. that it was not directing care, rather complementing the overall assessment), and that the functionality of the tool within the EHR made it available to use only for the two EIP services as part of this discrete project.

Figure 2 The OxMIV tool as presented in electronic health records.

Sex Code as sex at birth.

Male / Female

Age

Years

Previous violent crime Previous conviction for a violent offence (lifetime). Violent offence defined as homicide, assault, robbery, arson, any sexual offense (rape, sexual coercion, child molestation, indecent exposure, or sexual harassment), illegal threats, or intimidation.

Yes / No

Previous drug misuse Previous diagnosis of drug use disorder (lifetime). Past evidence of drug use disorder – either from documented diagnosis, past contact with drug rehabilitation/treatment services, or detailed history.

Yes / No

Previous alcohol misuse Previous diagnosis of alcohol use disorder (lifetime). Past evidence of alcohol use disorder – either from documented diagnosis, past contact with alcohol rehabilitation/treatment services, or detailed history.

Yes / No

Previous self-harm Previous episode of self-harm (lifetime).

Yes / No

Highest education Formal schooling: secondary (to age 16), upper secondary (to age 18), post-secondary (past 18).

Secondary / Upper secondary / Post secondary / Unknown

Parental drug or alcohol use Parental diagnosis of drug or alcohol use disorder (lifetime). Past evidence of drug or alcohol use disorder – either from documented diagnosis, past contact with rehabilitation/treatment services, or detailed history.

Yes / No / Unknown

Parental violent crime Parental conviction for a violent offence (lifetime). Violent offence defined as homicide, assault, robbery, arson, any sexual offense (rape, sexual coercion, child molestation, indecent exposure, or sexual harassment), illegal threats, or intimidation.

Yes / No / Unknown

Sibling violent crime Sibling conviction for a violent offence (lifetime). Violent offence defined as homicide, assault, robbery, arson, any sexual offense (rape, sexual coercion, child molestation, indecent exposure, or sexual harassment), illegal threats, or intimidation.

Yes / No / Unknown

Current episode

Inpatient / Outpatient

Recent antipsychotic treatment Within the last 6 months.

Yes / No

Personal income Select 'low' if unemployed and/or inadequate financial situation with difficulty meeting basic daily living needs (food, accommodation etc.). Otherwise, select 'stable'.

Low / Stable / Unknown

Recent antidepressant treatment Within the last 6 months.

Yes / No

Benefit recipient Currently receiving benefits.

Yes / No / Unknown

Recent dependence treatment Within the last 6 months. Pharmacological treatment for substance use disorders (e.g. opioids, alcohol).

Yes / No

The simplicity of the model itself made for ease of transfer to the EHR. There was a process of testing the form's functionality within an offline version of the EHR system before it became available in the live EHR from the beginning of July 2020. I introduced this by speaking in team meetings for the two services, communicating electronically with them, and making a short instructional video to complement the simple clinician user guide (Appendix 2.4). I held an honorary clinical role with the larger of the two services, and so remained visible and available for any queries. There was also regular space in monthly business meetings for any issues around the use to be raised.

Quantitative methods (Stage 2)

Embedding of the tool within the EHR as above allowed simple performance reports on its use to be obtained, including using UK-CRIS (Clinical Record Interactive Search). This information was used to examine the uptake of the tool (indicated by the frequency with which assessments were completed over time), the position in the clinical pathway that OxMIV was completed (indicated by the interval between the referral date and the date of OxMIV completion), and the availability of information (indicated by the frequency with which each predictor was scored as "unknown", and the interval between when each OxMIV assessment was commenced and completed).

Embedding of the form in the EHR also gave opportunity to obtain structured feedback on the use of the tool, its helpfulness and impact on an assessment-by-assessment basis. Prior to completing the tool itself, clinicians noted whether or not they had already identified any needs around violence risk for that individual, and whether they thought these were above what was typical in their setting. Subsequent to completing OxMIV itself, they rated in a binary manner whether or not it had helpfully informed their overall assessment, and whether or not there were any modifications to the careplan as a result of their overall clinical

assessment of risk. This allowed quantification of the proportion of cases in which OxMIV was helpful or supported an overall clinical assessment that led to changes in a careplan. I examined whether this feedback varied according to whether clinicians had already identified needs around violence risk prior to completing OxMIV, or according to whether there was discordance between the prior identification of needs and the categorical risk rating of OxMIV. Fisher's exact test[138] was used to test the significance of these associations between categorical ratings, with the null hypothesis that they were independent. Finally, I examined whether the mean number of unknown variables per assessment varied according to whether there were pre-identified needs around violence risk, using Welch's two sample t-test[139] with the null hypothesis that the two group means were identical. All quantitative analyses were undertaken with R version 4.1,[140] and visualisations using the package ggplot2.[141]

Mixed methods data integration (Stage 2)

Stage 2 used a convergent parallel design.[142] Qualitative and quantitative data from Stage 2 were collected and analysed separately, before being integrated at the level of interpretation and reporting to reflect on their interrelation and combined meaning, and make conclusions that incorporated this added value.[116,143] I primarily used joint display to achieve this integration. This is a technique whereby quantitative and related qualitative results are displayed together in a figure or table to form an integrated results matrix, which supports the generation of meta-inferences.[117,144] I also used elements of a narrative integration approach, where qualitative and quantitative findings weave back and forth around the theme being discussed.[116]

Ethical considerations and approval

The OxMIV qualitative acceptability study of clinicians, patients and carers was approved prospectively by the West Midlands – Solihull Research Ethics Committee (reference

20/WM/0011). This was nested within a local project to improve violence risk assessment and documentation by making OxMIV available within the EHR, approved by Oxford Health NHS Foundation Trust's Quality and Audit team. Quantitative data from performance reports related to patterns of use of the form rather than any individual's clinical information. Information on clinician rating of risk and OxMIV's output was obtained anonymously using the UK Clinical Record Interactive Search (UK-CRIS) system in Oxford Health NHS Foundation Trust, approved by the local independent CRIS Oversight Group. In designing the qualitative interviews, core principles as outlined by the Economic and Social Research Council were considered. This included ensuring appropriate participant experiences of the interviews, such as that they felt able to choose not to answer particular questions or divulge more than they wished, and had the opportunity to express their views.

The study involved vulnerable individuals, as it recruited patients accessing mental health services. Any risk of harm associated with this was minimised by using the usual care team to identify only suitably stable patients. I explained to patient participants that I may contact the usual care team if I had acute concerns about a deterioration in mental state that needed appropriate follow-up, whether or not this be directly related to their participation in the study. As a medic (specifically a forensic psychiatrist) by background, I had appropriate clinical experience to respond to any such situations. The main risk associated with the study was that of distress arising from discussion within the interviews, perhaps touching upon a sensitive topic or difficult past experience. The risk was mitigated by making information in the consent process clear. Participants were aware of the likely subject matter beforehand and could consider whether this was likely to be difficult, whether they wished to participate, and if so if there were certain subjects that they wished not to discuss. As part of the introduction to interviews I made it clear that all were free to not answer particular questions, or to say that they do not want to discuss a particular topic further. Finally, individuals under the age of

18 were within the inclusion criteria, as it was important that young people, if deemed suitable by their care team, were not excluded on the basis of their age given that EIP services cover the age range of 14-65. To mitigate any additional risks of harm associated with this, a parent/guardian would have needed to be present for an interview with a 16-18 year old, and for individuals aged 14-15 consent from a parent/guardian was required. In practice however no such individuals were put forward for recruitment.

Patient and public involvement

A public and patient advisory group was formed. This consisted of five individuals with experience, either personally or as a carer, of contact with relevant clinical services. I chaired an in-person initial meeting of the group during the preparation of the protocol, prior to ethical approval, to inform the design of the study. This included discussing topics that should be probed within interview schedules, which directly aided the development of these. Participants highlighted the importance of exploring views in interview on whether there were concerns about risk assessments leading to unhelpful interventions, as well as the theme of transparency, and how interview participants viewed their overall involvement in risk assessment processes. The use of language was also discussed, such as use of the word "violence", and this was also included in the interview schedules. The balance between patient and carer participants was also discussed. Subsequently group members reviewed the participant-facing documentation (PILs and ICFs) for clarity and appropriateness, which I then edited in line with the comments before submitting for approval.

Summary

In this chapter I have detailed how and why I used qualitative and mixed methods to examine current practice in EIP services, and the potential use and role of OxMIV in this setting. In Chapters 3 and 4 I will now detail the results of this two stage work program.

Chapter 3

Assessing risk of violence in Early Intervention in Psychosis services: a qualitative interview study of multidisciplinary clinicians

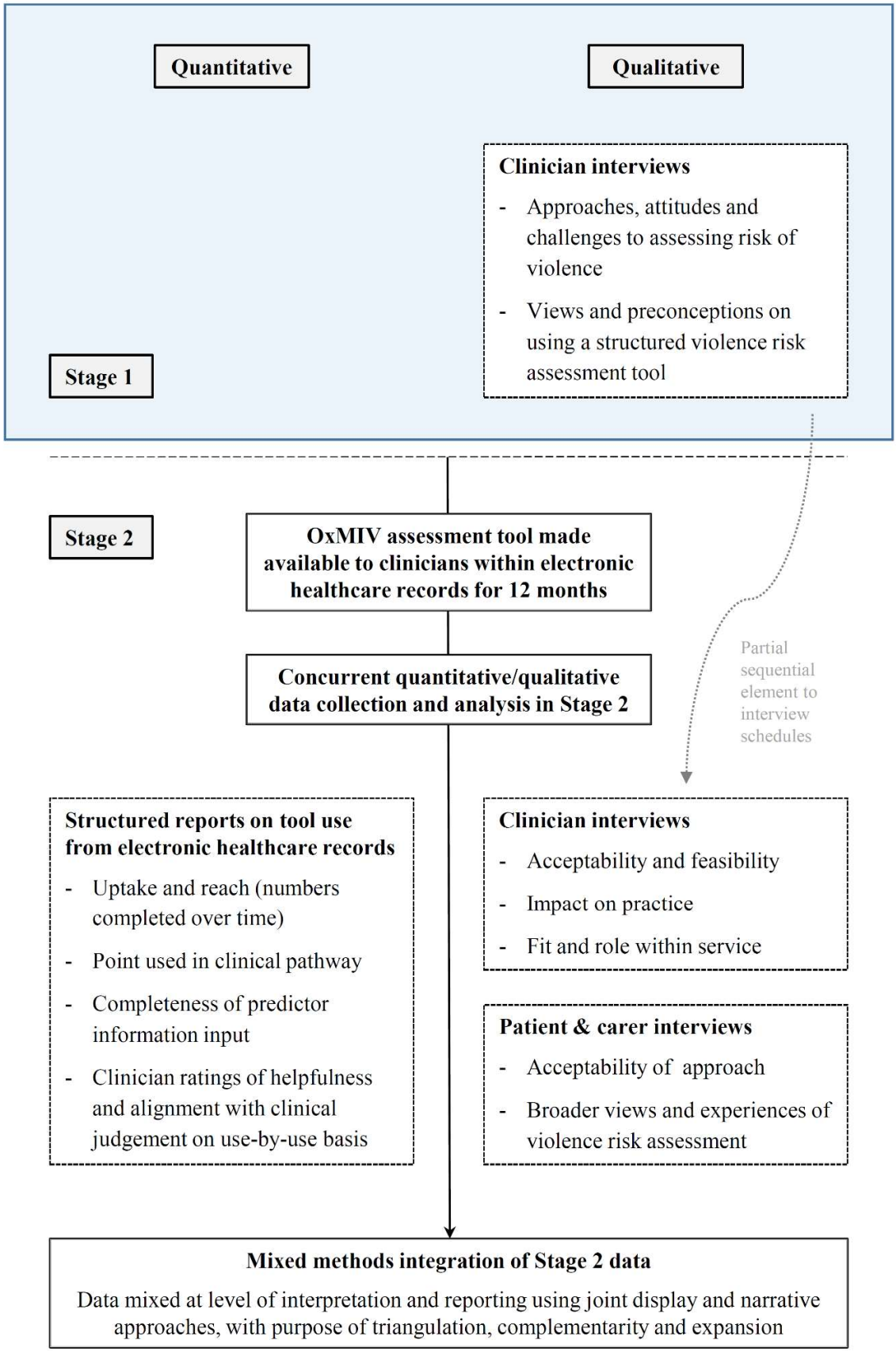
Introduction

To consider the potential benefit and role of any prediction tool in a clinical setting, a detailed understanding of current practice in that setting is first needed. In Chapter 2, I detailed the methodology I employed to address this for the assessment of violence risk in Early Intervention in Psychosis (EIP) services.

In this Chapter, I will present and discuss the findings from the first stage of this work, which involved qualitative interviews of clinicians working in EIP services (Figure 1, blue shaded area). The aims of this study were to explore 1) current approaches, attitudes and challenges to the assessment of risk of violence in EIP services, and 2) clinicians' preconceptions on using a structured violence risk assessment tool in clinical practice.

The results presented are from thematic analysis of qualitative interviews rather than quantitative survey findings, however I have throughout used language to give approximate indication of the prevalence of different viewpoints in the data. For clarity, reference to "most" indicates over half of the participants, "many" indicates up to half (7-9 of 18 participants), "several" indicates 5-6 participants, and "some" or "a few" 3-4 participants.

Figure 1 Outline of two stage work program using mixed methods to examine current practice and subsequent clinical feasibility and acceptability of the OxMIV tool. Current chapter presents qualitative findings from Stage 1 (blue shaded area).



Results

Eighteen clinicians were interviewed, from the full range of professional backgrounds within EIP services (Table 1). A summary of the sample is presented in Table 1 rather than characteristics of each interviewee to protect the anonymity of participants. Ten hours of interview dialogue was transcribed and analysed (average individual interview length 32 minutes). Data was analysed across four main identified themes (Table 2), with themes 1-3 mapping to the first aim of the study, and theme 4 to the second aim.

Table 1 Summary characteristics of included sample.

Participant characteristics		**N**
Sex	Male	8
	Female	10
Age	21-30	2
	31-40	7
	41-50	3
	>50	6
Professional background	Medic	4
	Occupational Therapist	2
	Social Worker	4
	Community Psychiatric Nurse	5
	Psychologist	2
	Other	1
Years working in mental health	0-5	3
	6-10	3
	11-20	6
	>20	6

Table 2 Identified themes and sub-themes.

Themes	**Sub-Themes**
1. General attitudes to violence risk	**a)** Clinical importance **b)** Violence as an "other" risk **c)** Remit of mental health services **d)** Variations in confidence and experience **e)** Individual clinician culpability and the clinical team
2. Current practice and focus of violence risk assessment and management	**a)** Screening and unstructured baseline assessment **b)** Symptom content, context and individuals at risk **c)** Static and other clinical risk factors **d)** Documenting and describing risk **e)** Response to violence risk concerns
3. Challenges and barriers to assessing violence risk	**a)** Lack of established patterns **b)** Stigma, sensitivity and engagement **c)** Non-disclosure and access to conviction history **d)** Subjectivity of clinical judgement **e)** Handover and inter-agency communication **f)** Time pressure
4. Views and preconceptions of structured risk assessment tools	**a)** Experience, openness and potential role **b)** Palatability of actuarial scores and need for anchoring **c)** Alignment with routine clinical practice **d)** Outcome from an assessment tool

1) General attitudes to violence risk

a) Clinical importance

There was consensus that violence is a clinically relevant issue and that its assessment is a routine part of working in Early Intervention in Psychosis (EIP) services. Several clinicians endorsed the importance of violence risk in EIP services in strong terms:

> *…it's really quite important to be addressing it* [violence] *and ensuring that that risk is assessed and managed. I'd say that's probably the main thing after suicide that I…worry about as a clinician...* (P12, Community Psychiatric Nurse)

For several clinicians, relevance was based on an understanding that first episode psychosis is a higher risk group for violence compared with other clinical settings and patient groups. Many described specific psychotic symptoms that make violence risk a consideration, most frequently paranoia and commanding auditory hallucinations (see also *Symptom content, context and individuals at risk*):

> *It's important* [violence risk] *because in psychosis… you can lose insight…and believe you were in a situation where…you're threatened and you need to protect yourself. It's quite common for people to use weapons when they're feeling persecuted. Or to hold weapons…like a knife under the pillow or they go around with. That's not uncommon at all.* (P01, Psychiatrist)

Others noted that aggression can be an indication itself of illness, and that EIP services typically engage lots of young men who on average have more risk of impulsive behaviour and violence. Some cited the medico-legal implications of needing to prevent violent incidents, as part of a wider duty to society as well as to individual patients. The prevalence of comorbidity was also highlighted, including alcohol and substance misuse.

A few clinicians agreed that violence risk is important, but highlighted that this is only for a minority of their patients, typically when there are other factors present, and that violent incidents are not something they encounter frequently.

b) Violence as an "other" risk

Several described violence as one of a range of risks routinely assessed, rather than a primary concern. Clinicians commonly compared the prominence of violence risk with that of self-harm or suicide. Risk to self was considered higher and is more typically the main focus. This emphasis is also reflected in clinical training. Few clinicians reported having received training specific to violence risk. Any training in violence risk is typically as part of general risk assessment training, and violence tends to be a minor feature in this compared to self-harm risk:

> *I think violence seems, at least in my training anyway it never really came up….* [there was a] *lot of emphasis on self-harm and suicide but I do not feel there is anything I can lean on in the same way for risk of violence.* (P02, Community Psychiatric Nurse)

> *To be completely honest with you, we have had nothing on violence. I think historically, certainly within mental health, it has always been about the risk of suicide that we…tend to…look for primarily…we had a full day training in identifying risk factor for suicides… but…very, very little in terms of violence to others…* (P14, Other Allied MH professional)

c) Remit of mental health services

There was some reflection on the emphasis that should be placed on violence risk within the clinical service. One perspective was that it is within the core remit of the service to manage risk due to for example the implications for long term trajectories within mental health services should violence occur (such as entry into forensic psychiatric services). The balance to this however is that the primary goals of the service are more recovery-focussed:

> *You need to assess it* [violence risk]*...accurately…But you don't want to focus*

> *on it too much… we're here to try and help somebody get better from an illness or a condition…and our main…priority is to…get people back on their feet and improve their quality of life…doing that in a safe way and keeping the person safe or keeping other people safe is…essential but…our main focus is not risk management.* (P15, Psychiatrist)

Integral to this balance, and the views of clinicians on whether managing violence risk is within their remit, is whether any identified risk is directly linked to symptoms of mental illness, or rather for example to pre-existing personality factors. One clinician highlighted that violence should not be over-attributed to mental illness. Others felt that, if violence is not directly related to the psychotic illness, then it is more an issue for police than for mental health services to manage. This can sometimes be a difficult issue to navigate:

> *I think with violence…it depends on what diagnosis you are looking at as to sometimes what people's views are. So it could be…they'll have to go down the criminal route if things are acted out or we need to minimise and protect them because they are currently quite unwell, and haven't got the capacity to make decisions around…minimising the risks themselves…* (P18, Social Worker)

> *…just because somebody has mental health issues does not mean that they can't be aggressive and violent, which I can't do anything about in the sense that that's a police matter… who does what and taking responsibility sometimes can be difficult…* (P14, Other Allied MH Professional)

Several clinicians did however describe how, even if risk is not related directly to the presenting mental illness, aggression can still be a separate treatment goal, for example by targeting areas such as substance misuse or anger management. A further issue raised around the responsibility of different services for managing risk was that both police and forensic

mental health services typically respond after an incident has already occurred. General mental health services can however be in the unique and challenging position of trying to predict and manage risk that has not yet escalated to an offence.

d) Variations in confidence and experience

Most clinicians identified the assessment of violence risk as an area of relative clinical weakness, and said that their confidence could be improved. Many felt that they lacked expertise by virtue of working in a general rather than a forensic clinical service, and others linked their low confidence to the limited specific training they had received. They therefore felt they had limited specialist background knowledge, and did not encounter violence frequently enough for this to improve:

> *Not at all* [comfortable with assessing violence risk]. *I feel a little bit like it is alchemy…I am looking at all the available information I have and then I am not necessarily sure I am systematically thinking about the relevant risk factors, because I do not know the literature and I do not work in forensics for example.* (P05, Psychiatrist)

> *…I know there's bound to be things like…age groups…demographics and things…that make the risk of violence greater, aren't there?...So maybe if I did know…static risk factors, if I did know that information then maybe my confidence would increase.* (P10, Community Psychiatric Nurse)

Clinicians were more comfortable with monitoring changes in risk over time with the same patient, and if risks are more clearly related to treatable symptoms. Personal clinical experience also impacted confidence. Two clinicians reported having been previously assaulted, which they felt was relevant to how they now judge risk. The few clinicians who did feel more comfortable with violence risk typically had more direct experience from other

clinical roles including working out-of-hours undertaking emergency assessments, and in forensic or prison services.

Many clinicians stated that there was considerable individual variation in general threshold of concern for violence risk. Some inter-clinician variation was simply put down to the subjective nature of clinical practice and less tangible personal variations between clinicians. Others described how duration of clinical experience was relevant and that risk could become normalised over time.

e) Individual clinician culpability and the clinical team

Several clinicians identified violence risk as a source of anxiety in their clinical practice due to a sense of accountability should there be a serious untoward incident. Some clinicians balanced this by highlighting that it was important not to be too preoccupied with this, rather to just ensure that one has done what could reasonably have been expected. Several highlighted the importance of the wider clinical team for reducing this feeling of personal culpability. Discussions with colleagues led to a sense of taking shared responsibility:

> *…we're quite tightly webbed in a team where risk is shared and where worries about risk are discussed a lot. And so, I'm not so worried about culpability.* (P06, Social Worker)

> *…there's always that dreaded thing of if something goes wrong…is what you've done legally defensible…that's sort of one of the reasons why…I might run things past…other colleagues…* (P08, Social Worker)

2) Current practice and focus of violence risk assessment and management

a) Screening and unstructured baseline assessment

The depth of assessment of violence risk was consistently described as a spectrum. Whether it is touched upon at all, screened for, or considered in more depth depends on the point in the clinical pathway, the context of the clinical contact, and whether there is any indication that violence is relevant. During initial referral triage, safety concerns that might inform the practical arrangements for the first assessment (which may be a home visit) are routinely considered. This relies on the information passed on by referrers or initial telephone contact with the individual.

All clinicians described violence risk as subsequently being a required part of the full general assessment. Most stated that this is however usually a relatively minor part, and framed it more as screening. Any more in-depth assessment is typically targeted by 'flags' indicative of its relevance, such as a known forensic history, that some part of the symptoms, presentation or demeanour indicates risk, or that concern has been raised by another party.

Where a fuller violence risk assessment is undertaken, none considered their approach to be structured or done in a standardised manner. Typically, it is an informal and variable process with an emphasis on information gathering:

> *…I don't* [have a uniform approach]. *I just have a conversation…considering what's in the previous notes, or the GP referral, and a bit of discussion with them…I don't have any sort of set form or set questions I ask really.* (P08, Social Worker)

There was consensus that any fuller consideration of violence risk is typically as part of the new, baseline assessment by the service. It was described as routine to refer back to that initial risk assessment at points of for example medical review, and the assessment of risk made at that first point of contact therefore has an important role in ongoing care. Unless

violence is highlighted in that first assessment, it is not usually reviewed in depth. Exceptions to this are if there is an emergency assessment or acute deterioration, a new incident, or if the individual had been too acutely unwell to provide relevant information at the initial assessment. If there are specific aspects of violence risk identified in the baseline assessment however, these do then form part of ongoing routine reviews:

> *…if somebody's known to be someone who carries a knife…I would always…check…those things with them…It's ongoing for people where it seems to need to be ongoing.* (P15, Psychiatrist)

b) Symptom content, context and individuals at risk

Many clinicians focussed on the content of psychotic symptoms when assessing violence risk. One clinician noted that this may be part of a natural exploration of symptoms, rather than undertaken consciously as a violence risk assessment. In the clinical vignettes presented to clinicians, the most common area of emphasis in the first scenario was the potential risk to parents in the context of apparent delusional beliefs. This was discussed by the majority of clinicians (11/18), including how the content of beliefs might lead to violence:

> *…he's thinking that the parents are feeding information to the government and that makes me feel* [there is a] *risk that he might try to take measures to stop them.* (P13, Psychologist)

A common view was that fear associated with paranoia is a potential trigger for violence. This led to some specific concerns about the potential for associated defensive behaviours, and several detailed how they would screen for whether the individual was procuring access to weapons in the first vignette:

> *…I'd be wondering…what the degree was and to what extent he's feeling, for example, like, he might have to defend himself. Whether he's needing to have…a*

> *knife by his bed or how safe he feels with his parents and whether he's an ongoing risk to his parents.* (P06, Social Worker)

Similarly, several clinicians also wanted to explore the content of the auditory hallucinations that were reported in both vignettes, and whether these included commands. In line with the perceived potential risk towards parents in Vignette 1, several wanted to speak with the parents themselves, both to gather more information about the context, triggers and nature of any hostility, and also to consider safety plans. There was also an emphasis on context and environment in response to Vignette 2. The description of instability of accommodation was commonly identified as relevant, with a focus on the nature of situations that the individual may encounter due to these circumstances.

c) Static and other clinical risk factors

Many clinicians spoke about a distinction in how they considered current risk compared with risk related to factors such as age, gender, or violent incidents that had happened historically. Clinicians had mixed views about the importance of these static factors, and several observed that there is generally less emphasis on these:

> *…the thing that I'm aware of with…violence risk assessment…is that actually…we don't pay enough attention to static risk factors. We pay more attention to dynamic risk factors and so some of the static ones can get missed…like being a young male with a previous criminal record.* (P01, Psychiatrist)

Such observations were supported by the responses to the clinical vignettes, in which only a few clinicians mentioned that the cases being young males was relevant to violence risk. In terms of historical violent incidents, several clinicians stated that their relevance depended on the context in which they occurred, and whether that context was currently active.

In discussion of Vignette 1, which did not refer to there being a violence history, half of clinicians spoke about wanting to know this information. In Vignette 2, the scenario stated that the individual had a history of violent conviction, and nearly all clinicians factored this into their initial consideration of risk. Most felt this indicated increased risk to some degree. However, several spoke about wanting further information about the nature of past offences, and for some the current relevance depended on that contextual information:

> *….he had violent offences…when he was in the youth offending team…that is now nine years ago. So things may have…been completely fine. You don't know, do you? I'd probably go on asking him sort of has he been in trouble with the police since…I suppose I wouldn't necessarily draw myself straight to the fact that he's had a number of sentences without maybe considering the context of those a bit more.* (P08, Social Worker)

> *…I'd like to like learn from him about what the context was of the assaults in the past, but I wouldn't…dig into them if it seemed quite irrelevant to the current situation. But if it was…the same triggers that he's still dealing with now, then I would think he maybe would want some support in how to avoid things turning violent.* (P12, Community Psychiatric Nurse)

Substance misuse comorbidity was highlighted as a broad reason for considering violence risk in patients accessing EIP services, however it was only commented on to a variable degree in response to the individual clinical scenarios, and less so than some other clinical factors such as the content of psychotic symptoms. A few discussed in more depth how the type of substance was important, or whether there were direct links between the substance use and risk. Familial background and early environment was also a common area of focus in Vignette 2, which alluded to a difficult childhood with a parent in prison. Many thought that

this was significant in terms of having been exposed to violence and it becoming normalised or a learned behaviour.

d) Documenting and describing risk

Recording of violence risk is a mandatory part of the risk assessment document within the electronic health record. Most clinicians' experience of this was with a general risk assessment form or template that includes a tick box to designate whether risk of violence or aggression is present, followed by a free-text box for relevant information. There is an additional risk summary box at the end of the form (of all risks, i.e. including self-harm etc.) that is free-text. Views on the merits of this standard template were mixed. Several clinicians felt it sufficient for EIP services. Positive aspects were that all the information about risk is documented in one location, and that free-text space allows for clinical narrative to be included. Many however reflected on some limitations. Several observed that the primary function is a place in which past violent incidents are listed. Although most agreed that it was important to have a record of those, many felt that this could become unhelpful over time if the list becomes long or disorganised. Some also pointed out that the template does not in itself assist or lead to a clear overall summary or understanding of risk:

> *…often I do not find…risk assessment tabs actually to be an assessment of risk. They are more a historical record of risk events which actually is not terrible, because, at least then I can read it and I can use that to inform my thinking about what I know. So, that is not a terrible model but I think to call it a risk assessment is probably…overstating it a little bit. It is actually a record of risk events.* (P05, Psychiatrist)

In line with the varied views around the relevance of past violent incidents, some clinicians had reservations around retaining very historical incidents on this record, particularly if the

contextual information is not detailed.

A few clinicians described how risk assessment documents can seem part of the overall administrative burden, rather than necessarily a meaningful clinical process in all cases. One clinician felt the move towards having a comprehensive risk assessment document for every single patient meant it had become more of a tick box exercise. Others noted an emphasis on the risk assessment only at points of crisis, and that a certain weight was placed on such a document being up to date should an adverse event occur.

There was a consensus that there is no set way that risk to others is written about in these risk assessment documents or communicated verbally in terms of language and framing. Most commonly, clinicians try to name the risk in as specific a manner as possible. Others described distinguishing between past and current risk. A few clinicians described making a rating of high or low risk, or mapping this on to a 'RAG' (Red/Amber/Green) rating of current concern about an individual. However, more commonly clinicians said they had moved away from rating risk in this categorical manner, most commonly due to subjectivity and lack of common definition:

> *Oh, it is difficult…with the low/medium/high…What on earth do you mean by that? Everybody has got different ideas what those words mean. So…there's no point using them really.* (P10, Community Psychiatric Nurse)

Further, some clinicians felt that rating risk, which was never completely absent, as 'low' may minimise it and provide false reassurance. Others also felt that categorising the level of risk into a discrete box was falsely definitive. A few however did describe how, despite sharing these views about the limitations of categorical ratings, this terminology does still feature in some part in their practice:

> *…I think if I'm worried about someone and I think their risk…is high…I might use…'high'. I might…go back to that terminology. I'm not worried about…saying that someone's high risk if I think that's the case.* (P15, Psychiatrist)

Examples were also given of other words or phrases that are used to communicate the presence of risk. Whilst avoiding straightforward categorisation, these typically do still convey something about the level of perceived risk, such as "significant", "prominent" or "concerning". A few clinicians identified personal characteristics in themselves, like a tendency to be cautious, or a style of communicating using quite laid-back language, that affected their practice around discussing and documenting violence risk.

e) Response to violence risk concerns

Most commonly, clinicians described how if violence risk is present they consider practical steps to maintain the safety of clinicians and families or carers. Many described considering the need for clinicians to only visit in pairs, or implications for the sex of the primary worker or the setting in which contacts take place. Such considerations may be recorded in a risk alert or banner that is visible every time a clinician opens the health record. These decisions are not part of a standardised process.

Similarly, many clinicians said that they identify whether there are people in the individual's life who are specifically at risk, due to for example explicit threats, thoughts, or as previously described the content of psychotic symptoms. If so, making them aware of risks is prioritised. This is often in the form of creating a crisis plan, which typically consists of contacting the team out of hours, or emergency services at points of acute concern. To maintain safety, some clinicians described how on occasion this sharing of information may need to be done without patient consent:

> *You know, you might have service users who don't want you to disclose anything to family members, but I think…risk trumps everything, really…if you can't get them on board, then you would have to make that decision whether you breach confidentiality, but if it's about minimising the risk I think you…have to do that.* (P18, Social Worker)

A few clinicians identified an imminent threat of violence as a distinct situation that would typically elicit a more rapid dissemination of information within the team and involvement of senior staff. A direct threat or acute risk, such that some immediate action to mitigate risk is indicated, was felt by several clinicians to be a scenario in which there is more likely to be a direct dialogue with the patient themselves, although a few also worried that this could make an acute situation worse.

3) Challenges and barriers to assessing violence risk

a) Lack of established patterns

In EIP services, individuals are often presenting for the first time to mental health services. Detailed information on past patterns of behaviours in the context of mental disorder is therefore usually absent. This is particularly the case at very first contact, where clinicians said risk assessment may be based more on an immediate appraisal of behaviour or presentation, rather than knowledge of an individual's background history. Clinicians highlighted how a first episode is often an evolving, dynamic presentation, and that risks can be quite unknown to both patients and their support networks, as well as clinicians:

> *…we haven't got this huge backlog of information…and so we haven't got a real picture of someone's pattern of behaviour, whether that's…when they're well and just their lifestyle and how they interact with people or in the context of when they're unwell…* (P16, Occupational Therapist)

b) Stigma, sensitivity and engagement

Aspiring to collaborate with patients by involving them openly in the process of violence risk assessment was deemed important by many clinicians. A few highlighted how this is necessary to demonstrate that the process is intended to support individuals, rather than cause repercussions. However, there was consensus that the actual level of patient involvement varies considerably:

> *I think…we have talked an awful lot in mental health about collaborative risk assessment, but I actually think it's something that clinicians…find quite difficult sometimes, to talk about risks in a very…pragmatic and involving way.* (P17, Community Psychiatric Nurse).

Stigma was raised as a barrier to broaching the subject of violence. Several clinicians spoke of hesitating to discuss violence risk with patients due to wanting to avoid labelling or reinforcing negative stereotypes around the relationship between mental illness and violence:

> *I feel a kind of hesitation to ask about it* [violence risk]*...unless there's an obvious flag, in case it…offends somebody…And I'm…inferring that perhaps, because they've got psychosis, they must be violent… I'm really…wary of reinforcing or indicating that I believe the stereotype that's in the media that people with psychosis are dangerous… We see young people…and it feels relevant to keep things low key and not to make them feel labelled early on.* (P09, Psychologist)

Further, for individuals who do have some history of violence, several clinicians described how asking about these previous incidents can be upsetting or bring up feelings of shame. These issues of sensitivity were highlighted in the context of establishing engagement and a therapeutic relationship in the early period of contact. There was a general view that

collaborative risk assessment was more feasible if there was a good working relationship and the individual was stable in mental state. Many clinicians spoke about the necessity of having first established a rapport to be able to gain relevant risk information from individuals:

> *... you can very easily imagine a situation where the patient is reluctantly seeing you in clinic, has no interest in engaging with you and there is no way of realistically just broaching it saying, "Well, your parents said that you have been violent towards them, what is going on?"...it is very hard to do that.* (P05, Psychiatrist)

Several clinicians described this conflicting demand between needing to obtain information to fully assess risk, and establishing a therapeutic relationship. A few reported this meant that directly pursuing detailed information about violence risk might be avoided initially in favour of establishing engagement. The importance of engagement was further highlighted by the responses to the clinical vignettes. One difference in the two scenarios was the description in Vignette 2 of the individual being insightful and keen to engage. Many clinicians described this as an important positive factor in that it made it more likely that they would be able to obtain a clearer understanding of risk, and to collaboratively mitigate any violence risk.

Clinicians described different approaches to facilitate open dialogue on risk. Several spoke about making the patient comfortable by using clear language, or emphasising that it is a routine enquiry. Others spoke about how they try to get alongside the patient to make it a shared treatment goal. In terms of documentation, it is typically the careplan that is produced collaboratively with patients, rather than the risk assessment itself which might be written in less palatable medical language. Some clinicians also said that patients might simply disagree with a risk assessment, and one explained how a previous complaint along these lines meant that they no longer share full risk assessments with patients.

c) Non-disclosure and access to conviction history

There were some reservations about the robustness of information provided by individuals themselves about past offending behaviour or violence. In some cases this may simply be because the acute nature of symptoms impacts the information individuals are able to provide. However, several clinicians also described how individuals and their families may be hesitant to disclose risk history due to concerns around relevance or repercussions:

> *… people are worried about the consequences, like does this mean that I'm gonna suddenly be rushed into hospital? Are you gonna just suddenly phone the police? And you're trying to explain that often we gather information, just to gather a picture and how to best support them, but I think there's some…reluctance like…do you need to know everything about me? And maybe then not seeing the relevance, why do you need to know I'm on probation?* (P16, Occupational Therapist)

Many also highlighted challenges to obtaining an individual's official conviction history. A few gave notable examples where they learned that a patient under their care had a significant forensic history or was actively involved with offender supervision only after they had already been supporting them for some time. Some described how this left them feeling frustrated, and that although information sharing was not a straightforward issue there were shared goals around providing support and managing risk:

> *…one thing that I have found frustrating in the past is when you are told that there are problems relating to actual forensic history. But you are not privileged to look at the actual police records. And I know that is a tricky issue but just purely selfishly from my perspective it is frustrating that I know there is risk that you are not party to that we effectively manage.* (P05, Psychiatrist)

Several clinicians expressed uncertainty over the threshold to justify seeking out an individual's formal forensic history, and how to go about obtaining that if it was deemed necessary:

> *I wonder if there should be a clearer process for getting information, and if it should be more consistent, like how much information is appropriate to share between the agencies…from my experience it doesn't seem to be something that's particularly consistent.* (P12, Community Psychiatric Nurse)

d) Subjectivity of clinical judgement

Clinicians generally found gauging risk difficult as it felt subjective, uncertain and lacking a formal basis. A common description was how a judgement of risk was reliant upon the pattern-recognition of the individual clinician, and a vague clinical sense or instinct which might be anchored in prior experience:

> *…you're sort of just guessing it and running it past other people on your instincts and beliefs and bits of knowledge…* (P02, Community Psychiatric Nurse)

One area of difficulty highlighted by some was knowing how to respond to concerning statements made by patients such as around violent thoughts or the content of auditory hallucinations, where there was no actual history of violence or acting on these.

These observations around the subjective nature of judging risk were reflected in the responses to the clinical vignettes (Figure 2). Overall, there was no consistent view on which scenario provided more cause for concern. Around half did not feel able to make an overall judgement of the basis of the details provided. Of the remaining half who did form an overall view, these were roughly evenly split among the two scenarios. Among clinicians who felt that Vignette 1 was more concerning, this was mainly determined by the weight placed on the resistance to

Figure 2 Representative quotes illustrating range of relative concerns regarding violence risk in the two clinical vignettes.

...I think possibly [Vignette 1] *might have a greater risk...because...he clearly isn't wanting help and support...he could get quite scared...and you just don't know...if he is already being verbally hostile to his parents, what that could raise, whereas* [Vignette 2], *he's got the insight, he is keen for support... I think that goes a long way.* (P03, Occupational Therapist)

I would probably feel a bit more worried about [Vignette 1], *only because he's living with the family and he's being verbally aggressive and hostile, and quite angry, whereas* [Vignette 2] *doesn't sound as though he's acting in such a way and is willing to engage with services...* (P18, Social Worker)

...the first one believes his mum and dad are [doing] *something to him...they could be very high risk, mum and dad, from this guy...so, on the face of it, scenario two looks more like a risky chap just because* [of] *his history, but...I wouldn't rule out scenario one, you just need to find out more.* (P02, Community Psychiatric Nurse)

...I think the second person probably would score higher [for violence risk]. *But at the same time...I suppose...with the first person there's more unknowns. And there's more ambiguity...so...would make me feel a bit more unsettled...in a clinical setting.* (P11, Psychiatrist)

I think [Vignette 2] *would be more likely to hurt somebody...I feel like the history is such a huge thing...so we can be terrified of our lives being in danger but...unless we've actually had some exposure to causing pain and causing harm to somebody...I think it can be very hard to actually hurt somebody.* (P06, Social Worker)

Who would worry me more? Probably [Vignette 2], *even though he sounds a bit better now I just think that...because he has assaulted people in the past I think that's more indicative...* (P13, Psychologist)



input from mental health services, and the presenting context. Of those who felt Vignette 2 was of more concern, this was typically due to placing more weight on the history of violence. Many felt that both descriptions were of some concern. Several compared the static risk factors in Vignette 2 to the risk more directly associated with symptoms in Vignette 1, which several clinicians found concerning due to their more unknown nature.

e) Handover and inter-agency communication

Many clinicians underlined that there are several points where information on risk might be handed over between professionals, and that this can pose a challenge. Within mental health services handover occurs within teams, such as between an assessing clinician and a clinician who will be providing the ongoing care. It also occurs between separate mental health teams, such as when a patient is referred for more intensive support in periods of crisis. There was consensus that appropriate communication of risk is an essential part of this handover. A few clinicians described how communication within their own team is more straightforward. Challenges more typically arise when trying to ensure risk is adequately communicated to clinicians outside of the usual care team:

> *Clearly…when we're working with people and for example if they become unstable…we might need to look at additional care…you'd have to be quite clear about the risk to a team that hadn't had any involvement with them. So, where…violence or aggression…is a potential, you need to be able to… relay that…* (P07, Social Worker)

One clinician also highlighted how it was important to ensure that risks are well understood by other agencies providing care, such as in supported accommodation, and that this can be another area of difficulty as agencies tend to work in silos with risk assessment. A specific point of communication with an outside agency is the interface with police. Several clinicians

spoke about the different challenges of this discussion in acute situations. The main issue raised was that there can be a different threshold of concern about risk, and that police response might vary depending on how this is communicated.

f) Time pressure

Despite the consensus around the importance of violence in EIP settings, many clinicians described challenges to being able to dedicate sufficient resource to assess risk meaningfully. Most commonly clinicians described time pressure as an important factor:

> *I'll hold my hands up, the…times that I haven't updated the risk assessment when probably I should have done, but…it's the time factor…that quite often gets in the way.* (P03, Occupational Therapist)

Another clinician described the time-pressure at a more service-level, such as the need for a patient to be discharged from an inpatient admission as soon as possible placing pressure on the gathering of information about violence risk.

4) Attitudes to structured risk assessment tools

a) Experience, openness and potential role

Other than the 'risk to others' category in the general risk assessment pro-forma, no clinicians were currently using a structured tool to guide their assessment of violence risk. Some had previously encountered tools such as HCR-20 in forensic settings, but very few had ever used any such approach in EIP services, other than iterations of a generic health record template which several commented had changed frequently over the years. A few had previously used a table or matrix in which a simple ordinal score was applied to different risk domains leading to an overall rating of risk, which was deemed broadly helpful.

Despite this limited experience, many clinicians felt a more structured approach to violence

risk assessment would be an improvement. In general terms several spoke about it being a challenging part of practice that would benefit from any extra support and information. Others focussed on how a tool might improve understanding of the relative importance of different individual risk factors:

> *I think it would be helpful to just have a clear sense in your mind of…what combination of background and current factors add up to an increased likelihood of risk.* (P13, Psychologist)

Several clinicians highlighted that a tool might serve as a prompt or memory aid to ensure that factors are considered consistently. This in itself was considered valuable, as for various reasons information might be overlooked in a given clinical encounter. Several clinicians felt that this more consistent appraisal of factors would increase the objectivity of assessments, and so improve confidence by adding weight or rationale to clinical judgement:

> *I think in order to make sure that you've asked everything that is relevant, because it's not always obvious, and it's not always easy to remember... There is a certain confidence that you get from having used something that's well validated, that you can feel you probably have the back up of managers if you've used something, if something were to happen.* (P09, Psychologist)

Other clinicians highlighted how a structured tool could be most helpful in cases where there is uncertainty about risks, and could help efficiency and team discussions by ensuring that relevant information had been collated before taking it to colleagues or supervisors.

There were some aspects of using a structured tool about which clinicians were more cautious. Most commonly discussed was that the wider individual context and dynamic nature of risk are less readily captured with a discrete risk assessment tool:

> *…tools can be great, but sometimes they can be a bit rigid. And I think with risk… it's a very fluid sort of situation…I'd be a little bit concerned…that it could be a bit too rigid…you just don't know the…circumstances…the environment they were in…* (P03, Occupational Therapist)

Another issue raised was the need to not become over-reliant on a tool, such as by being overly restrictive in response to it, falsely reassured by it, or being discouraged from using one's own intuition and clinical judgement. In line with this, there was consensus that any structured tool should offer flexibility in terms of how it supports, and is combined with, an overall clinical judgement, rather than overriding it:

> *…I do like the idea that you can…do a number of ratings and come to a sort of recommended idea, and you don't have to agree to it, but it…gives you…a little bit to think about*. (P08, Social Worker)

Likewise, retaining the wider context was felt important to allay a concern held by a few clinicians that attribution of a discrete risk score might be inadvertently labelling.

b) Palatability of actuarial scores and the need for anchoring

None of the clinicians had used percentage scores when assessing violence risk. However, several drew parallels with other types of assessment in which this is more familiar, such as for physical health needs (e.g. QRISK). Most therefore said that they would not be averse to such an approach for violence risk assessment. One pointed out that a percentage score would be attractive as paradoxically it better communicates the chances that an incident will not happen. The most commonly discussed advantage was the clarity that an actuarial score may offer over categorical descriptors:

> *…we've had the discussion in the team many times…how…some people's lows are equivalent of some people's mediums, and some people's highs…it is very subjective… Having a percentage kind of…takes it away…* (P08, Social Worker)

However, many pointed out that in isolation a percentage score can be arbitrary and subject to the same difficulties with communication as categorical ratings. Therefore, to aid interpretation any percentage score needs to be carefully explained in terms of what it is predicting. Demonstrating this point, when asked to indicate what percentage score for violence risk would typically be of concern, clinicians gave a wide range of responses. Most indicated that around 50% is a clear marker of concern. However, several gave much lower scores of around 3-5% if referring to serious violence. Several indicated that it depends on the specific nature of the event being predicted:

> *It…slightly depends on…the level of the offence…I mean, 10% would be really high. That would be very worrying. Five… You know, if you think about a serious violent offence even a 5%...is pretty high…if we're talking about a serious violent offence then anything above 3 or 4% would be…worrying to some extent…* (P15, Psychiatrist)

Many clinicians thought being able to make some comparison would be an important part of interpreting a percentage score. For example, anchoring where a score sat in relation to a baseline, or an average or higher-risk individual in their service. Several clinicians described how this anchoring would occur as they use a tool and develop an understanding of how scores are spread among individuals under their care:

> *I think if you were to use* [an actuarial score] *I would…tend to gauge things…benchmarking against existing patients. So if I had patient X*

> *who…came up as 30, and then…if I thought that that patient was quite a risk then I think I would benchmark my risk…* (P14, Other Allied MH Professional)

The main reservations about adopting percentage risk scores again related to the issue of context, and the ability of a precise score to map to a much less precise clinical scenario.

c) Alignment with routine clinical practice

To be of clinical use, most clinicians highlighted that any tool needs to be practicable. Many pointed out that, although being quick is important, moreover it needs to align with routine practice by focusing on relevant clinical scenarios, and only using information that could reasonably be collated during a routine clinical assessment:

> *…it is not about brevity, it is not about simplicity… It is much more about whether or not that tool can marry with the usual clinical practice of assessment. So, if I was to do a robust assessment of…a one-hour clinic appointment with a patient and then came away and I was sat in front of the tool…what would frustrate me is if it said, right, did you ask this…well, no, of course I did not ask that. So, it contains lots of obscure or really detailed things that you would not necessarily expect to cover in a routine assessment.* (P05, Psychiatrist)

The manner in which this information is input was also highlighted in terms of questions being simple and specific, and not requiring the clinician to exercise judgement for each individual item such that it becomes unwieldy. Others felt that the organisation of information in the health record is important, and that any tool would ideally be fully integrated. In terms of routine clinical use, some clinicians also spoke about the importance of the language in the tool, with a view to it being something that assists in gathering information from the patient:

> *Sometimes risk assessments can be a bit nebulous in terms of what they want to find out… So, you'd want it to be specific, meaningful and…user friendly from both practitioner and the service user's point of view…I think the questions have to be carefully composed and be meaningful to the recipient but also easy…for the practitioner to implement in terms of conversation, because it has to be in the form of a conversation or dialogue.* (P07, Social Worker)

d) Outcome from an assessment tool

A commonly held view was that to add value to the overall assessment, a structured tool needs to lead to some kind of clear output or summation of risk, rather than simply being a record of information that reverts entirely to the clinician's judgement:

> *I suppose you want something that gives you quite a clear… I want to say answer, I do not know if that is the right word, but… the outcome of it is quite clear at the end.* (P04, Community Psychiatric Nurse)

Further, several clinicians reflected on the importance of linking the output of a structured tool in some way to an action. One clinician framed this as being important from a service-management perspective, in terms of there being a medico-legal imperative to do something to help reduce risk if a tool indicates that it is increased. Others felt it would be broadly helpful if a tool gave some suggestion of which patients should be offered support to reduce risk, and for example which modifiable factors were relevant.

Discussion

This study contributes a new, rich understanding of how violence risk is approached in EIP services, and the challenges associated with assessing and managing this risk in a non-forensic psychiatric setting.

Clinicians viewed violence as an important adverse outcome. This was however with the caveats that it occurs relatively infrequently, and that risk management is not the primary focus of the service. In most cases therefore, whilst assessment of violence risk is mandatory and routine, this typically consists of a brief screen with fuller exploration reserved for cases where this seems indicated by some aspect of the referring information or presentation. Any fuller risk assessment typically occurs at first assessment, and takes the form of unstructured information gathering reliant on the experience and clinical judgement of the individual clinician.

There were some common areas of focus and confidence among the multidisciplinary clinicians when assessing risk. The content of psychotic symptoms is explored in depth to elicit potential associated risks and understand who may be at risk, with a strong appreciation of the fear associated with paranoia and how this may lead to risk behaviours. Emphasis is on understanding an individual's environment and context to develop a holistic view of risk, and monitoring how this fluctuates over time. Where there are concerns, interventions mainly focus on the acute safety of clinicians, family and carers such as through crisis plans and practical arrangements for clinical contacts. Discussion within the multidisciplinary team is a core part of this assessment and management process, and serves to disperse anxiety related to individual clinician accountability.

There were also clear areas of difficulty highlighted, and aspects of practice around which there was less consensus. Confidence was generally low, in part due to violence being overshadowed by risk to self in both day to day clinical focus and training. Training needs in risk assessment have previously been identified in surveys of mental health nurses,[145,146] and this was shown here in strong terms and across disciplines.

There were mixed views on the remit of mental health services for addressing violence if risk is not obviously stemming from the presenting mental illness, and inconsistency in how clinicians appraise static risk factors including previous violence. Accessing any forensic history is itself problematic. Clinicians are wary that such information may be withheld, but lack a clear threshold or process for seeking collateral information from police. Clinicians also described feeling hesitant to broach the subject of violence for fear of reinforcing stigma, particularly whilst establishing engagement, such that the notion of collaborative risk assessment remains aspirational rather than a current clinical reality. There is no set way to communicate risk between professionals, other than a move toward avoidance of unhelpful arbitrary categories. Handover can be challenging when this involves other teams or agencies, and documentation tends to consist of incident lists rather than summary formulations. The subjectivity that this overall lack of standardised approach is vulnerable to was highlighted by clinicians themselves, as well as by their varied responses to clinical vignettes.

Structured risk assessment tools may address some of these challenges, and the findings suggest there is clear scope to explore their use in this clinical setting. Such approaches are more typically used in forensic services, and indeed none of the clinicians interviewed had used risk prediction tools in EIP services. However, there was openness to this approach. Clinicians thought a tool could improve their understanding of risk factors including overlooked static factors, and potentially prompt more consistent, efficient assessments and aid confidence. The main reservation about such approaches was their ability to capture the wider context and dynamic nature of risk, which is a strength of current practice. It was clear therefore that any tool needs to complement rather than replace clinical judgement. However, clinicians were keen that a tool should provide an overall summary of risk, and were not averse to this being in the form of a percentage score. Clinicians were familiar with similar

methods for cardiovascular risk, and felt that if properly defined this offered some advantages over arbitrary risk categories.

Clinicians emphasised that any more structured approach needs to not only be simple, quick, and ideally integrated into existing record systems, but to also align with current routine practice in terms of the information it incorporates and the outcomes that it considers. Work to examine clinical feasibility and acceptability clearly needs to include exploration of how patients can best be involved in risk assessment, as this study showed that currently clinicians find this a difficult topic to discuss openly, particularly during the early phase of contact which is where the majority of risk assessment occurs.

Actions in response to risk were also highlighted. Currently, these are focussed on ensuring risk is clearly documented, discussed with the wider team, and that practical considerations for clinician visits or crisis plans for families are in place. This mirrors clinical guidelines which mainly address acute situations rather than more longitudinal risk.[57] A few clinicians discussed interventions such as anger management or substance misuse treatment, but there was less consensus around approaching these modifiable factors, particularly where links between psychotic symptoms and risk are not direct. Previous work on the trajectories of violence risk in EIP services does suggest that to reduce risk, interventions will need to go beyond symptom control alone.[74] The clinician perspectives identified in this study around the remit and accountability of services have implications for how any additional violence-focussed interventions can be integrated. There was consensus that any structured approach should be ideally linked to some positive action, and so one role of a tool could be to help provide a clearer framework for considering modifiable factors in addition to core psychotic symptoms.

Aside from the implications for further examination of the potential of OxMIV in this setting, there are two key practical areas of need for clinical services highlighted by this study. First, clinicians feel they often lack information about forensic history. Local operational policies in mental health services should therefore make the process for seeking proportionate, relevant forensic history from police clear and well known. Clinicians would also benefit from a supporting framework for the justification needed to seek such history.

Second, clinicians from all professional backgrounds commonly felt that they do not have a strong baseline knowledge of risk factors for violence, or receive the level of training that they do for risk of self-harm and suicide. Structured tools offer one way to translate this knowledge to clinical practice, but consideration should also be given to the emphasis of clinical training in risk assessment. Previous work that sought to quantitatively examine psychiatrists' completeness of violence risk factor consideration found this to have some positive association with prior training.[147]

Strengths and limitations

By including a full range of multidisciplinary clinicians across clinical services in two counties, with different background experience and associated perspectives, this study has provided broad, rich data and novel insights into the topic. Using individual interviews also contributed to this, allowing clinicians to talk freely. Although only two clinical services were included, EIP services engage a clearly defined patient group with a clear model of care. Identified themes and difficulties are likely to therefore be in common with other EIP services. Further, by describing in full the sample and methods and adopting a transparent, systematic approach to analysis, the findings are demonstrably anchored in the data, and can be judged for their transferability to other settings.

It is possible that those who put themselves forward for participation held stronger views on the topic than those who did not participate, and so some of the views expressed may not reflect the wider views in the service. I also worked within one of the included clinical teams, allowing development of a professional relationship with some participants. It is possible that this may have resulted in some censoring of views, but it is more likely that the rapport facilitated open discussion.

Conclusion

Violence is an important adverse outcome in EIP services. Clinicians are conscious of proportionately addressing this without making it their primary focus or jeopardising early engagement by raising this sensitive topic. Current practice focuses on exploring symptoms and environment, leading to practical safety plans guided by team discussion, but lacks a standardised approach to assessment, communication or management. Clinicians lack confidence in their expertise in violence risk, which receives relatively little focus in training. This is compounded by other challenges such as the availability of background information, and the potential for individual variation in clinical judgements.

This study has therefore clearly identified a clinical need in this service to improve approaches to violence risk assessment and intervention. Further, there was openness among clinicians to the potential of a structured tool to address some of these difficulties. This would need to align with routine practice, and complement the wider context provided by the overall clinical assessment. Whether the candidate tool OxMIV meets these requirements will be explored through its preliminary clinical use in the next chapter. An important theme identified here that will also be carried forward for further exploration in the next chapter is that of stigma, by considering whether OxMIV has any implications for this in practice, and exploring patients' and carers' perspectives on this.

Chapter 4

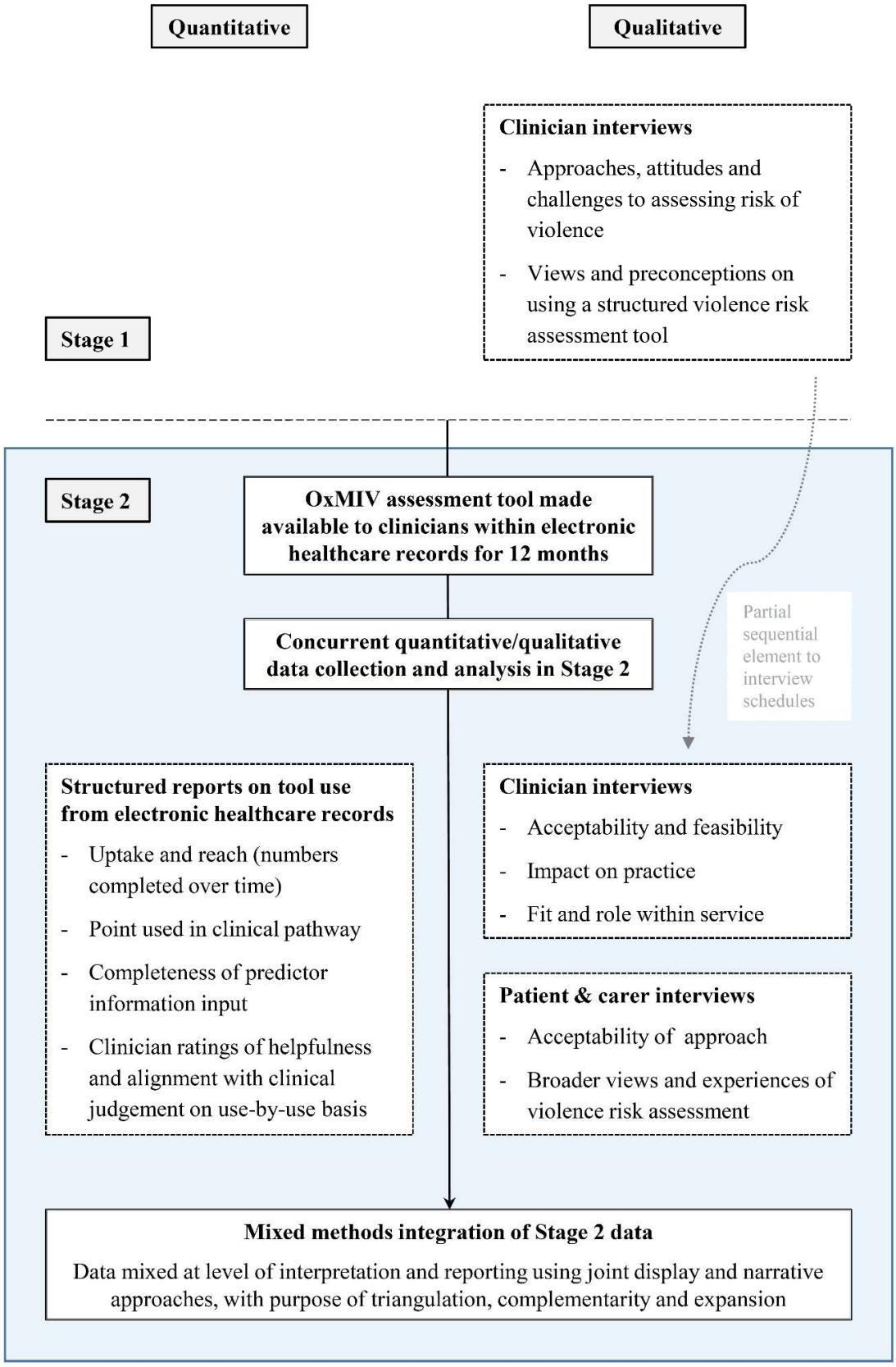
A mixed methods study of the clinical acceptability, feasibility and role of the OxMIV violence risk prediction tool in Early Intervention in Psychosis services

Introduction

In Chapter 3 I established the current practice in violence risk assessment in Early Intervention in Psychosis (EIP) services, the challenges to this, and the preconceptions around using a more structured approach. This demonstrated a clinical need to improve routine approaches to this clinically important adverse outcome, and an openness to the potential of a simple structured approach to assist with this.

In this chapter, I will present findings from the second stage of this work (Figure 1, area shaded blue), the methodology and structure of which was detailed in Chapter 2. Stage 2 followed the integration of OxMIV into the electronic health record (EHR) and its use over 12 months by two EIP services. The aims of this stage were to use mixed quantitative and qualitative methods to examine the acceptability and practical feasibility of the tool, as well as its uptake, impact, perceived utility and optimal role. I also interviewed patients and carers, to understand their views on the acceptability of the OxMIV approach, and their broader perspectives of violence risk assessment. As per Chapter 3, I have again used language within the qualitative results to approximate the prevalence of viewpoints in the data (defined on page 46), with the modification that for the lower number of patient/carer participants (12), “many” indicates 5-6 participants, “several” 4 participants, and “some” 2-3 participants.

Figure 1 Outline of two stage work program using mixed methods to examine current practice and subsequent clinical feasibility and acceptability of the OxMIV tool. Current chapter presents findings from Stage 2 (blue shaded area).



Results

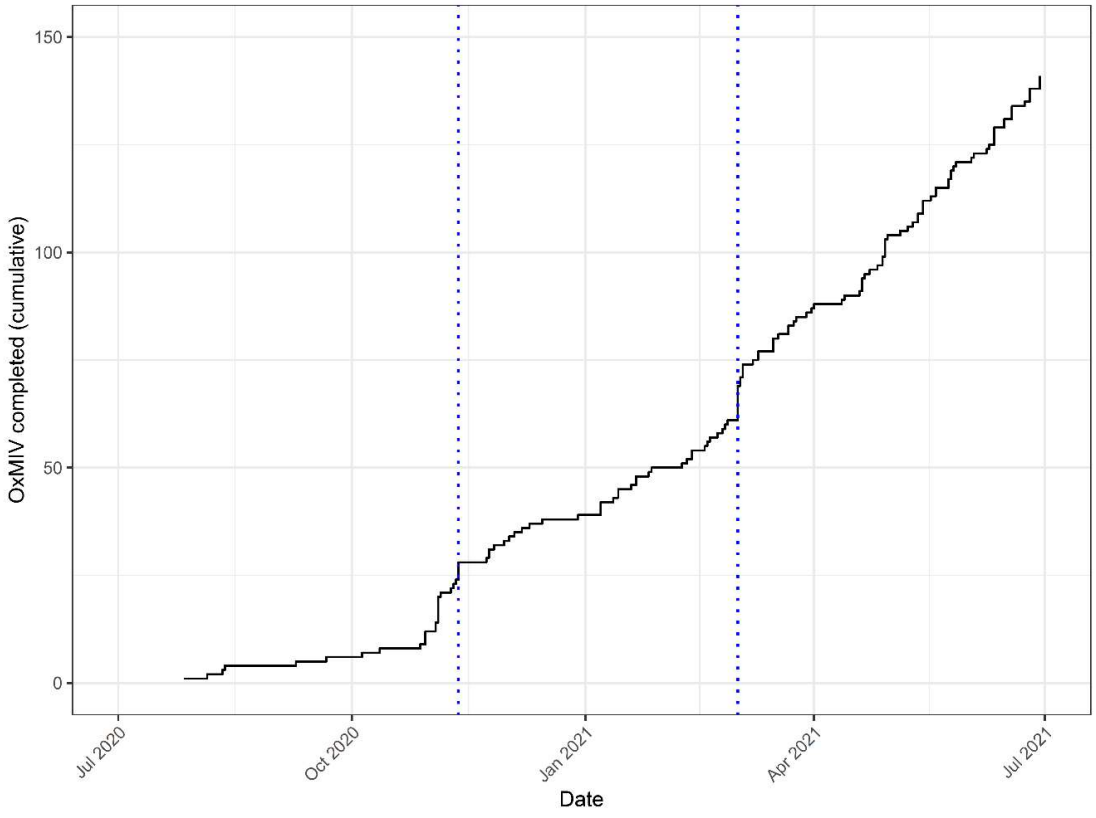
OxMIV was made available to clinicians in the two EIP services from July 2020, and all findings relate to examination of its use over the subsequent 12 months, to end of June 2021.

Quantitative results

Uptake

In total, 141 OxMIV assessments were completed. There was a lag in uptake, with only 8 assessments undertaken in the first 16 weeks (6% of eventual total) before the rate sharply increased (Figure 2). This increase was temporally related to both clinical teams choosing to refine their approach to using OxMIV by focusing on new assessments from November 2020, and supported by renewed promotion of the project in team meetings (timing indicated on Figure 2 with blue lines).

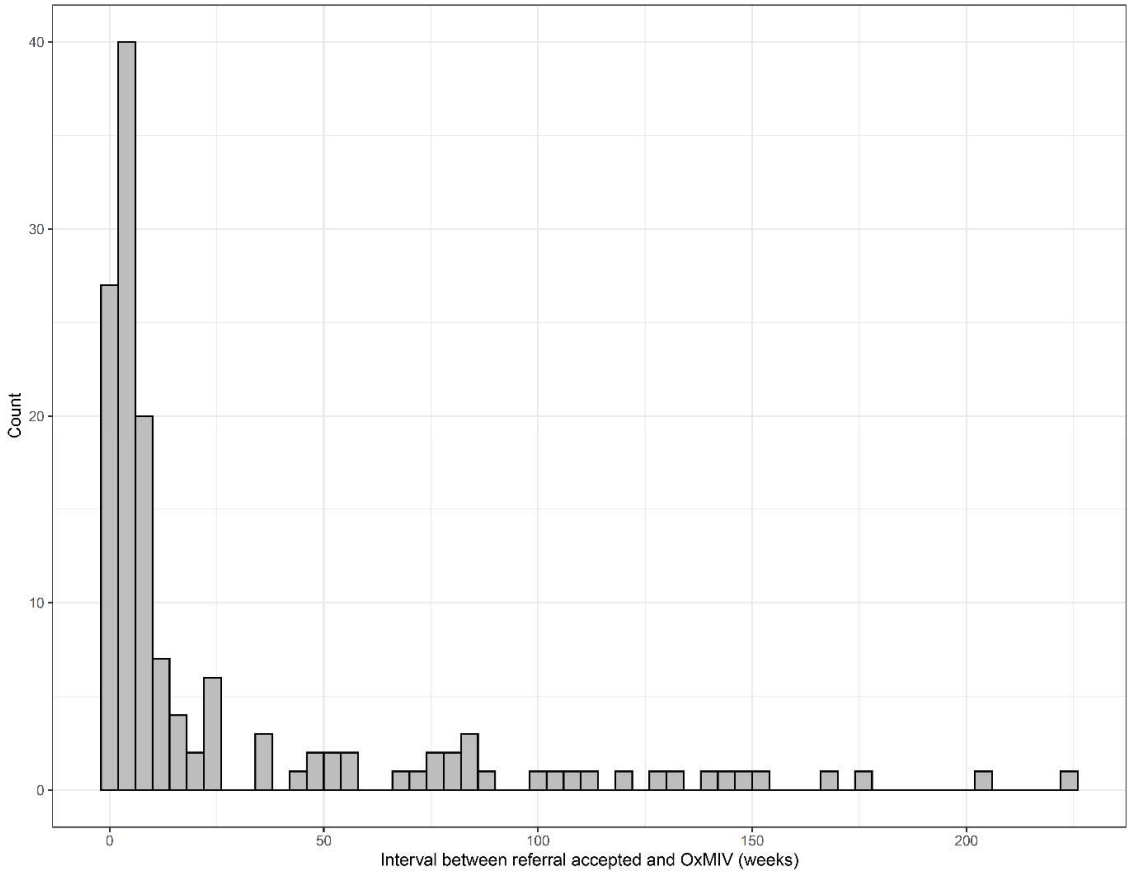
Figure 2 OxMIV assessments completed over 12 months. Blue lines indicate timing of repeat promotion of project in team meetings.



Timing, reach and targeting of assessment

The completion of OxMIV was weighted towards individuals in the early period of contact with EIP services (Figure 3). The majority of assessments completed (n=92, 65%) were undertaken within 12 weeks of the initial referral to EIP services. The combined caseload of the two services is around 380,[32] with around 140 new patients taken on per year. The total of 141 assessments over a year therefore represents around 40% of the caseload, and 92 assessments within 3 months of referral would equate to around 65% of new patients. Prior to completing OxMIV, in n=51 (36%) of all assessments, the clinician identified (by responding to a yes/no option) that there were "any needs" around violence risk prior to OxMIV being competed, and in n=27 (19%) these needs were deemed "higher than average" for individuals in contact with the clinical service.

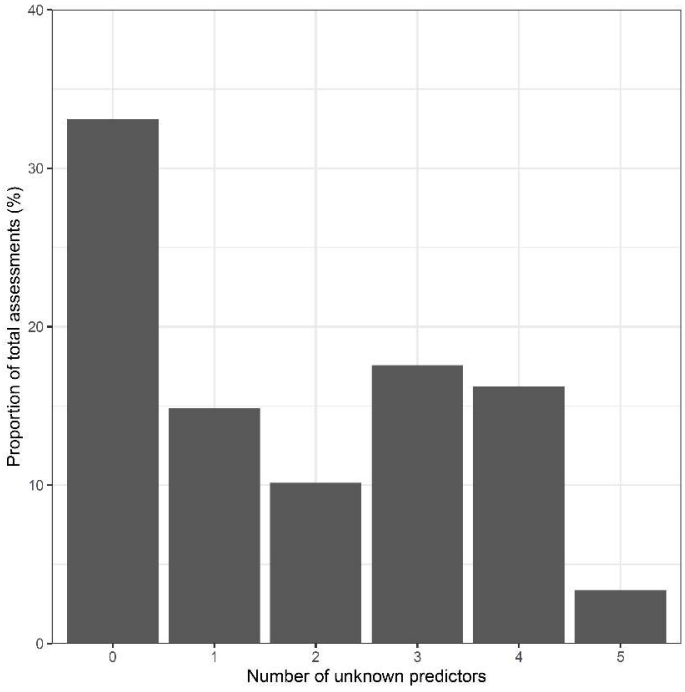
Figure 3 Interval between referral of individual to Early Intervention in Psychosis services and completion of OxMIV assessment (n=141) in weeks. Bin width 4 weeks.



Completeness of clinical information

A maximum of 6 items could be scored unknown in the tool. The maximum number of unknown items per completed assessment was 5, which occurred in n=5 of 141 assessments (3%). In n=49 assessments (33%) no items were scored unknown (Figure 4). Overall there was a mean of 1.8 missing predictors per OxMIV assessment, and this did not significantly vary according to whether risk needs had been identified before completing OxMIV (Table 1, page 85).

Figure 4 Proportion of 141 OxMIV assessments completed with 0, 1, 2, 3, 4 or 5 total missing predictors.



In terms of individual predictors, the three family history items were scored as unknown in just under half (45-47%) of completed assessments. Receipt of benefits, highest education and income category were scored unknown in 16%, 14% and 3% respectively (Figure 5).

Figure 5 Proportion of "unknown" scores for each predictor in 141 OxMIV assessments.

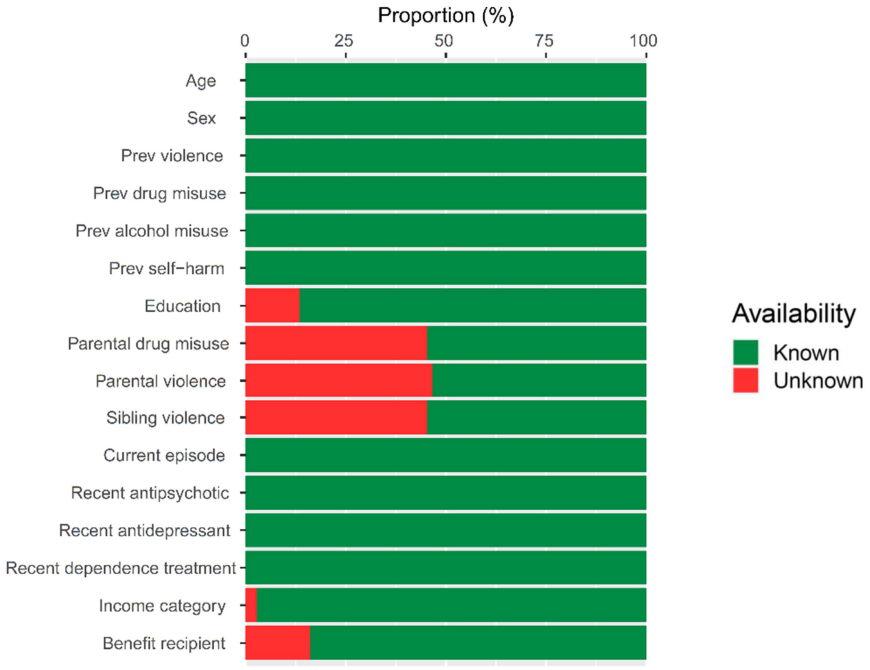


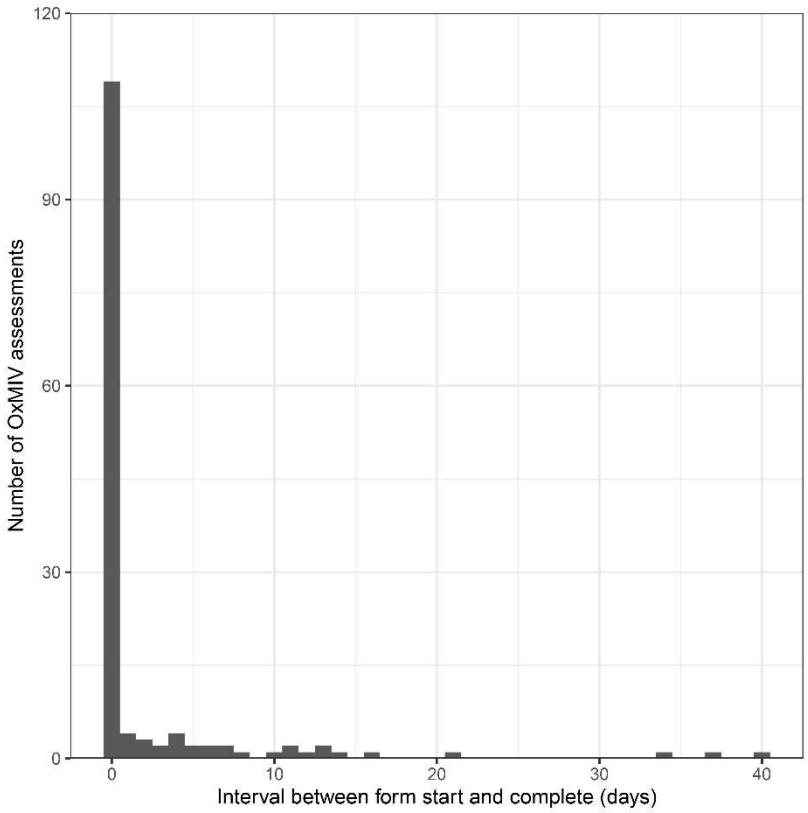
Table 1 Number of unknown predictors in assessments according to whether risk needs were identified pre-OxMIV.

	Mean number unknown predictors per assessment	**Welch's two sample t-test statistic**	**p-value**
OxMIV assessments where no risk needs identified pre-OxMIV (n=90)	1.88	Ref	Ref
OxMIV assessments where any violence risk needs identified pre-OxMIV (n=51)	1.61	0.96	0.34
OxMIV assessments where higher than average risk needs identified pre-OxMIV (n=27)	1.44	1.34	0.19

Time taken to complete

In n=109 of 141 assessments (77%), the OxMIV form was entered on the same day that it was commenced (Figure 6), indicating that it was likely completed as part of a single clinical contact episode.

Figure 6 Interval between commencing and entering the OxMIV form in days.



Perceived utility and promoting additional support

Overall, n=87 (62%) of OxMIV assessments completed were rated by the assessing clinician to have assisted in the overall assessment of risk and needs. Clinicians were significantly more likely ($p<0.05$) to rate an assessment as having assisted if they had already identified needs around violence risk (helpful in 75%) or above average needs around violence risk (helpful in 82%) prior to completing OxMIV (Table 2). Despite the majority of all

assessments being rated as helpful, changes to the careplan (indicated by clinicians responding to a yes/no option to feedback whether this had occurred in each case) were only prompted in a minority of cases - in 5% of all assessments, 12% of assessments where needs had already been identified, and 19% of assessments where needs higher than average had already been identified. Changes to the careplan were significantly more likely where needs around risk had already been identified before using OxMIV (Table 2).

Table 2 Association between risk needs identified pre-OxMIV and whether completing OxMIV helpfully assisted the overall assessment of risk and needs, or led to any changes in a careplan.

	Assisted in overall assessment			**Supported changes in careplan**		
	N (%)	**Odds ratio (95% CI)**	**Fisher's exact test p-value**	**N (%)**	**Odds ratio (95% CI)**	**Fisher's exact test p-value**
All OxMIV assessments (n=141)	87 (61.7)	-	-	7 (5.0)	-	-
OxMIV assessments where no risk needs identified pre-OxMIV (n=90)	49 (54.4)	Ref	Ref	1 (1.1)	Ref	Ref
OxMIV assessments where any violence risk needs identified pre-OxMIV (n=51)	38 (74.5)	2.42 (1.15-5.31)	**0.02***	6 (11.8)	10.49 (1.66-277.47)	**0.01***
OxMIV assessments where higher than average risk needs identified pre-OxMIV (n=27)	22 (81.5)	3.57 (1.31-11.66)	**0.01***	5 (18.5)	17.70 (2.55-485.21)	**<0.01****

Concordance with pre-assessment clinical view

Data was available on how the categorical output of OxMIV aligned with the view of risk needs prior to assessment for n=138 assessments. There was 87% concordance between clinician ratings of higher than average risk needs prior to assessment and the "increased risk" category score on OxMIV (Cohen's kappa 0.68, representing substantial agreement). No significant association was found between discordance in the OxMIV and clinician ratings of risk and whether OxMIV was perceived as helpful in the overall assessment, or supported changes in careplans (Table 3).

Table 3 Association between discordance between risk needs identified pre-OxMIV and categorical OxMIV rating, and whether completing OxMIV helpfully assisted the overall assessment of risk and needs, or led to any changes in a careplan.

	Assisted in overall assessment			**Supported changes in careplan**		
	N (%)	**Odds ratio (95% CI)**	**Fisher's exact test p-value**	**N (%)**	**Odds ratio (95% CI)**	**Fisher's exact test p-value**
All OxMIV assessments with complete concordance data (n=138)	87 (63.0)	-	-	7 (5.1)	-	-
OxMIV assessments where OxMIV category agreed with prior clinician rating as to whether risk was higher than average (n=120)	26 (60.1)	Ref	Ref	1 (2.8)	Ref	Ref
OxMIV assessments where category discordant with risk needs identified pre-OxMIV (n=18)	14 (77.8)	2.24 (0.65-9.92)	0.20	2 (11.1)	2.84 (0.25-19.26)	0.23

Qualitative results: clinician perspectives

Twenty clinicians were interviewed (Table 4), of whom 17 had previously participated in the Stage 1 interviews. Six hours of interview dialogue was transcribed and analysed (average individual interview length 19 minutes). Data was analysed across 10 themes (Table 5).

Table 4 Summary characteristics of included clinician sample.

Clinician characteristics		**N**
Sex	Male	8
	Female	12
Age	21-30	3
	31-40	8
	41-50	3
	>50	6
Professional background	Medic	5
	Occupational Therapist	3
	Social Worker	4
	Community Psychiatric Nurse	6
	Psychologist	1
	Other	1
Years working in mental health	0-5	6
	6-10	3
	11-20	5
	>20	6

Table 5 Themes developed across clinician interviews with exemplar quotes.

Themes	**Exemplar quotes**
1. Clinical utility and impact on practice	*I've done quite a lot on risk factors for…offending…so I've got the knowledge there but it just kind of wasn't there. So what it's done* [OxMIV] *is it's brought it to my fingertips a bit more. And made it…more accessible…more there in the room, I guess… I'm more aware of it, rather than it being…an abstract concept of what risk might be.* (P01, Psychiatrist)
2. Acceptability of the required clinical information	*I quite liked the way the setup intuitively made sense…and…the questions I was being asked…in my head…I could deduce why those questions would be …related to the overall risks. So that…was nice, I enjoyed using it.* (P14, Other MH Professional) *It's not part of our routine screening* [family history of violent crime]*... I could certainly add in those questions... I suppose I would have to put a bit of thought into how I can organically bring that into the assessment… You have to get in the flow, don't you, of how you bring in certain more difficult questions?* (P16, Occupational Therapist)

3. Practical usability and functionality within the Electronic Health Record	*It was trivially easy. The order that the questions are presented is logical and…it almost feels like a decision flow-chart that you're going through. So…it's presented in a very logical order whereby it asks you one question and naturally leads to the next.* (P05, Psychiatrist)
4. Interpretation of output	*…low or moderate…is just one jump, whereas to look at a number…compared to somebody else you might've done the day before, it does show the big difference in the risk I think when…you're not just jumping from one category to another. You're looking at the difference in score completely…* (P19, Occupational Therapist)
5. Alignment and integration with clinical judgement	*…it's got a good benefit to…time cost ratio…it's not an hour long thing…it's something you can do really quickly and a snapshot that…may not actually change your overall opinion…it might reassure your opinion you already had, or it might open up the discussion that will help your opinion…so on the back of it, even if it just leads to a discussion about that's a bit concerning, maybe we'll discuss this in the team, it kind of makes sense.* (P08, Social Worker)
6. Positioning within the team and clinical pathway	*I think…it's definitely quite good to have it as part of the assessment process, because ...we have quite a few tick boxes anyway, for different tabs. So…it's quite easy to remember…to do it at that stage, so I think it's quite good having it integrated into that process.* (P14, Psychiatrist)
7. Barriers to integration and adoption	*…we haven't had this previously and…implementing that change of mindset for me* [was a challenge] *and maybe just the title, the fact that it's got violence in the title. I wonder whether that could make people think well that's not applicable to me because my client isn't violent.* (P03, Occupational Therapist)
8. Stigma and labelling	*…if you're doing a risk assessment then you're already starting to…classify levels of risk and whether you…do it in the OxMIV way…with some numbers or you don't…I don't, personally…think it makes that much difference and… what we're trying to do is…to be…as aware as possible of levels of risk so that we can help manage them…that's potentially very much in the patient's benefit if we can help them…manage their risks and not end up in trouble…then that's gonna help them as well as others.* (P15, Psychiatrist)
9. Discussion and collaboration with patients	*…I don't think I'd feel all that comfortable doing it* [in conjunction with patient], *but…that's just me and the way I engage with people… I find that the form is…too much of a tick box to go through with someone, so…I'd rather…address the issues that I can and come back and complete it separately.* (P12, Community Psychiatric Nurse) *…what it* [OxMIV] *has helped…is to have the discussion…about what they consider might be the triggers. And that I think that has been helpful…in as much as they've been able to associate the acts of violence that they were involved with and that… substances…were a major contributory factor. So I think it's opened up the opportunity to look at that in the round and say these are things that…are having a very negative effect on your behaviour if you continue to use these substances or in the way that you have. So I think it's helpful to be able to have that conversation...* (P07, Social Worker)

10. Attitudes towards linked interventions	*…when we…risk assess for suicide risk, that always leads quite directly into…safety planning... Whereas risk of violence tends to be more…in our minds whether we need to think about MHA* [Mental Health Act Assessment], *or you know, something more restrictive…rather than…thinking more collaboratively. So…to have* [suggestions for management] *would be quite helpful.* (P20, Psychiatrist)

1) Clinical utility and impact on practice

Most clinicians were positive about their experiences with OxMIV, with the majority indicating an inclination to continue using it in the future. None had encountered any difficulties arising from its use. Several discussed how a key component of its utility was its simple and clearly circumscribed focus, and some highlighted that it felt clinically purposeful:

> *I can see it being quite useful…the thing I enjoyed with it…there's a purpose behind adding it. A lot of the…paperwork we tend to do, it seems pointless and I often wonder is anybody ever even going to look at this? But…getting feedback back* [from the OxMIV output]*…that's quite helpful, that's quite novel.* (P02, Community Psychiatric Nurse)

Many spoke about how the tool improved their confidence. Three main aspects of this described were 1) that it ensured that there were no important omissions in assessments, 2) that its broad alignment with overall clinical view provided reassurance, and 3) that the perception of the overall assessment being more robust improved clinicians' confidence in their subsequent clinical reasoning, and for example their rationale for approaching seniors for support:

> *…it can be difficult to…remove any subjectivity from any risk so I think having* [OxMIV] *as well…helps perhaps do that. And so hopefully if the two marry up* [OxMIV and clinical judgement], *you can feel a bit more confident…about your*

> *risk assessment. And…then it kind of gives you…more confidence in using that as a rationale to…take it further. Because if for example you…wanted to take it to an MDT* [team meeting] *or a complex case or just to one of the consultants…you can…take it with…that as an added extra…to…support your…general risk assessment…* (P04, Community Psychiatric Nurse)

As well as serving as a prompt to consistently explore risk factors already known to clinicians, many also stated that OxMIV had an educational element and had improved their knowledge of risk factors. This was felt to improve clinical practice more widely than just when directly using the tool as a prompt, as these risk factors became more widely embedded in their practice. In general its use was felt to improve the focus of assessments and awareness among the team.

A few clinicians found that, although using OxMIV had not highlighted any additional needs for their own caseloads, this demonstration of low risk was itself helpful. One clinician described themselves as "ultra-cautious" and said that it had reduced overall anxiety about the level of risk associated with their work. Another clinician highlighted how, even when risks were low, this could get lost among the multiple different versions of risk assessments present on care records, and that in this scenario it was helpful to summarise risk with an OxMIV score. One clinician also highlighted how it could make risk in the early period of contact feel more manageable:

> *I think it is helpful* [OxMIV] *because you often feel like you're working with a lot of unknown risk…it's often people with no contact with mental health services at all. And …it feels very risky because you've got maybe…a couple of weeks' worth of notes, maybe not much information from them and a little bit of the back story to the family… it feels quite complicated and loaded. I think if*

> *you're putting in what you know* [to OxMIV], *and if you have got an answer for a lot of those things, then I think that can be quite reassuring that it feels that the risk is manageable.* (P04, Community Psychiatric Nurse)

2) *Acceptability of the required clinical information*

There was consensus that overall the information input into OxMIV married well with what was clinically available, albeit this could vary depending on how forthcoming an individual was with background information. The items also held face validity for clinicians in terms of seeming relevant in the consideration of violence risk.

Whilst no clinicians deemed any factors to be obscure or irrelevant, many agreed that the family history items, and to a lesser extent educational history, were less routinely enquired about in assessment. Some felt that these were more odd or awkward topics to ask about in an assessment unless they had come up naturally as relevant to an individual's background circumstances. Most felt that this meant some thought was required as to how such questions were integrated into assessments.

Several clinicians made the point that they took it as a given that the items included in the tool had all been demonstrated as relevant in empirical research. A few were more reflective about the direct relevance of certain items in each individual case however:

> *...I was intrigued about having...your highest education and also...parental violent crime and sibling violent crime... I hadn't...thought in my head, I mean obviously the environment that somebody's growing up in is...very...influential, but...it might be that yes their parents have done a violent crime but they...have no contact with them anymore or it might be...their siblings who they haven't seen in 20 years... So although yes they...obviously...can be informative, they might not actually have a direct impact.* (P03, Occupational Therapist)

Finally, one clinician was concerned that the inclusion of a question about an individual's benefit status might go against efforts to "de-stigmatise" this, and that the overall framing was therefore important.

3) Practical usability and functionality within the Electronic Health Record

There was a consistent view that OxMIV was quick to complete, particularly if the patient was known, with the majority of clinicians estimating that it took them no longer than five to ten minutes. There was consensus that this did not therefore add excessively to the overall time and administration burden associated with assessments. Many also felt the questions themselves were simple to complete as they were straightforward, there was no equivocation, they required broadly known information, and used drop-down boxes rather than requiring free-text to be input:

> *…it takes so little time compared to…a generic risk assessment…and I've got to do one of those anyway, and…I feel like doing it…helps inform the risk assessment side of things anyway and…my understanding of it. So it…just fits nicely and…it's not overly laboursome to do really from an admin point of view.* (P08, Social Worker)

The main practical issue, raised by several clinicians, related to the descriptions used for the coding of some of the diagnostic predictors (e.g. whether an individual had a history of a drug use disorder). Although these were described within the tool, there was still some lack of clarity around the threshold for coding these items as positive. The ability to put "unknown" for several items was noted by a few to be helpful in this regard.

Of high importance to clinicians was how OxMIV was embedded within the electronic record. All agreed this was fundamental to the adoption and sustainable use of any such approach. Most felt that it was helpful that OxMIV was available at least in the same tab as

the general risk assessment. Many however wanted it to be embedded within the standard risk assessment itself, to both increase its visibility and minimise any duplication of effort or time spent navigating the EHR:

> *…as soon as you have to click another box, and I know it doesn't seem like much but… there is so much stuff… There is so much stuff and we're asking people to do more things all the time… And then you'll have a push because, you know somebody somewhere in data analysis have realised we're not* [recording X] *status and so then you get an email round "Right a big push on* [X] *status." You know so everyone's got to click on again and… click, click, click.* (P13, Psychologist)

Others mentioned advantages to any information (such as age or sex) that could be auto-populated. Several spoke more broadly about some of the difficulties with the organisation of the EHR as a whole, and that including OxMIV in some kind of front sheet would also increase its visibility and act as a prompt for completion.

4) Interpretation of output

Most clinicians used the categorical and probabilistic output of the tool in combination. Having a percentage score was a novel aspect that most clinicians had not used previously. However, most found this easy to interpret, and several described how they found this continuous score more richly clinically informative than a category alone. An aspect of this mentioned by several clinicians was its ability to demonstrate more clearly the range of risks, and emphasise the magnitude of difference that there may be:

> *I'm surprised about the real jump in some people. So, lots of people are very low risk. And then suddenly you just have some young guys who just have very high risk. And I guess that's the case, isn't it…that's what's it like in the general*

> *population. Most people do have very…low risk. If you're a young male using drugs and alcohol and… you're a bit paranoid, then actually you are* [higher risk]. (P01, Psychiatrist)

5) *Alignment and integration with clinical judgement*

All clinicians found that OxMIV typically broadly aligned with their own overall view of risk. A frequent description was that it focussed and clarified the clinical view, rather than disagreeing with or altering it. Several made the point that its utility was not reliant on substantively changing the clinical view, rather on how it was integrated into the overall assessment process. A few examples were given where clinicians felt that risk was potentially higher than was indicated by OxMIV. This was typically due to lower-level aggressive behaviours or other incidents during periods of illness that clinicians worried were risky, but which for whatever reason had not led to any previous convictions and so were not captured by the tool.

6) *Positioning within the team and clinical pathway*

There was consensus that OxMIV sat most naturally and helpfully as part of the initial assessment phase of an individual's contact with services, more so than being routinely useful for those who are stable on the caseload. This was due to the new assessment being regarded as the clinically obvious time-point at which risk is fully considered. One clinician found that it was difficult to integrate OxMIV with the many other considerations at the point of assessment, however several others felt that its practical integration was also best here, as the questions may be more readily asked as part of a full screening, and it fitted well with the range of other baseline tasks and documentation.

Several clinicians pointed out that main difficulty with having it as part of the new assessment was that the full information might not be available if there was acute illness or

difficulties with initial engagement. Several therefore described how it could straddle the period of first assessment and handover from the assessment clinician to early contact with the care coordinator for ongoing care – either to complete if it required further information, or to highlight as part of the handover that there were needs around violence risk:

> *…it felt right to do it after about three months when I'd gotten to know them a little bit more and get…more of a sense of their risk history. I would struggle to do it…very early on. If the risk assessment was fairly complete from before, then it…would be fine, but…the kind of thing that's hard to ask about when you're early in engagement. If they've ever had… convictions for example… I wouldn't necessarily feel confident that I had all of the relevant information until I'd known them…for a couple of months.* (P12, Community Psychiatric Nurse)

In terms of its use for people already on the caseload, this tended to be for those who were clinically regarded as higher risk. It was mainly assessing clinicians and care coordinators, rather than psychiatrists (unless undertaking the new assessment) that completed the tool in practice, as care coordinators would be more readily familiar with the requisite history for that individual. One psychiatrist described how this worked best as a collaborative discussion with the care coordinator. Finally, a specific clinical scenario in which one clinician found OxMIV to be a less natural fit was when an individual was accepted under the care of EIP services as part of an inpatient hospital admission. This was due to the initial contact with EIP services having a different emphasis in this case; the assessment including risk assessment is predominantly undertaken by the inpatient team, and the role of initial contact with the care coordinator is more around building a relationship in preparation for post-discharge follow-up.

7) Barriers to integration and adoption

A common appraisal of the reach achieved by the tool was that it was well understood among clinicians working within the assessment function, but less so among care coordinators who were not involved with assessments or taking on new patients. A few clinicians said that they were initially unsure whether it was applicable to individuals in whom they did not have active concerns about violence. Several spoke about the importance of an ongoing process to prompt use such as in meetings and through supervision to embed the tool into practice. Some clinicians highlighted how this was particularly important as there was quite high turnover of staff. Several reflected on the extent of use and discussion of OxMIV in terms of the remit and culture of the service. It is not primarily a risk management service, and so the balance of attention given to risk management is important, and discussion of outputs of more formal risk assessments is not commonplace:

> *I think…we've got these competing demands and I think we've really got to be careful that we do not hold risk management over and above…compassionate care. And…so we've got to…hold risk as a really important conversation. Something we need to respond to and be very aware of. But should not take precedence necessarily… I mean it's a complex relationship…So obviously you want to be caring and risk is care for others as well, isn't it?* (P01, Psychiatrist)

Among the few clinicians interviewed who had not themselves used the tool on more than a couple of occasions, the main reason given was that violence risk was perceived as low in the patients they had contact with, and formalising this assessment was not high on their clinical agenda. Although as previously discussed there was consensus that the amount of time that OxMIV added to assessment processes was minimal, when clinicians deemed violence risk to be a very low priority, OxMIV was still regarded as an additional administrative burden:

> *I suppose things that would prevent me* [using OxMIV in the future] *are it's*

> *another form to fill in. We obviously have several forms already…and… it's a bit of an add-on…or at least for me it didn't feel like it would be pertinent for everyone…to have this tool…filled in. So, I can see how in a forensic setting…it would feel much more part of your bread and butter…rather than an add-on. So, I suppose…where it fits in the service and the patient population will vary.* (P11, Psychiatrist)

8) Stigma and labelling

None of the clinicians' experiences of using the tool led them to a view that inadvertent stigmatisation or labelling was a concern. Many felt that whether risk was assessed formally with a tool or in the standard unstructured manner made no difference to such issues. Others highlighted how the purpose was quite the opposite and, particularly in EIP services, the process was viewed as leading to positive input rather than having any negative connotations. An alternative view offered by one clinician was that having a separate tool focussed solely on violence risk brought this to the forefront when this might not always be appropriate, and that its integration within general risk assessment processes could help reduce this perception. Another clinician also highlighted that how any more historical risk is communicated between different teams was also an important consideration, but again this applied as much to standard risk assessments and alerts as to OxMIV.

9) Discussion and collaboration with patients

Most clinicians did not find that use of OxMIV altered the default tendency to complete a risk assessment subsequent to an assessment, rather than as an explicitly discussed part of it. As per the standard general risk assessment, OxMIV was typically seen as part of the post-assessment paperwork, and clinicians integrated any additional questions organically into their assessment rather than completing the tool in conjunction with a patient. Some felt that

doing it directly with a patient might add time to the assessment, or might seem too rigid. A few clinicians did have experience of OxMIV prompting a subsequent discussion, with two clinicians giving similar examples of how having a more formal assessment of risk had supported a frank and collaborative discussion about the impact of substance misuse on risks of repeat offending behaviour. Others agreed that it is more around the discussion of reducing risk, rather than undertaking the assessment itself, that a more collaborative approach could be pursued with OxMIV. A few thought it could be used to quantitatively demonstrate the effect of modifiable factors like substance misuse, and others thought it could assist in framing any plans to support and address risk:

> *It's quite a gentle tool isn't it? ...I think if I had somebody come out…higher risk I'd have been able to go through the tool with them and say look we've looked at this and this indicates the possibility and now what we're going to do is look at how we can reduce this for you. How we can make it manageable… Doesn't mean to say it's going to happen, but we've got to…formulate something. If somebody's risk is higher it would encourage you, it would drive your interventions wouldn't it, it would be something that you would use to...reduce the risk.* (P02, Community Psychiatric Nurse)

A few did also think that it could be completed with patients, which would have the advantage of likely obtaining more complete information. As with other aspects of assessment however this would vary patient to patient, and require a tactful overall approach.

10) Attitudes toward linked interventions

There was consensus that OxMIV did not typically lead to direct changes in careplans, largely as risks were low for most people, and also that the output of the tool tended to align with clinical judgement. As has been described above, the perceived helpfulness of OxMIV

was not dependent upon it changing the plan or clinical view. Indeed, many indicated that it was important for its acceptability that assessments with OxMIV were not frequently discordant with the clinical judgement. Nevertheless, many clinicians agreed that ideally risk assessment should be more embedded within subsequent management plans, and that this required more of a culture shift. Most clinicians were positive about the idea of a future iteration of the tool providing some suggestions or options for support and management that could help reduce risk. One clinician suggested that this might help clinicians to think about violence risk more longitudinally, rather than focussing solely on acute restrictive responses:

> *...I mean ultimately the aim is about managing risk, isn't it, I think? And…the first bit is assessing and then the second bit is, "Well, what can we do?" And…in some ways it feels like the second bit is harder, to…come up with a plan or figure out what would be good thing to do. So…that could be a very helpful thing to have some suggestions. But then…it would need to be viewed as suggestions rather than, you know, "You must do this or that." But…at least there'd be things for consideration, wouldn't there…? So yeah… I'd…view that as a…helpful direction…* (P15, Psychiatrist)

The importance of such an approach being suggestive rather than directive was echoed by several clinicians. Two of the psychiatrists highlighted this in the context of a wariness that such an approach could be too protocolised. Further, one offered the view that the suggestions would perhaps be too obvious to add significant value. Others noted that the feasibility of implementing any linked suggestions would depend on whether the individual being assessed was being taken on by EIP services or not, with both primary care and general psychiatric services less able to work in such a manner. A few clinicians also felt that there would be a ceiling to how specific the suggestions could be, given the nature of the tool.

Qualitative results: patient and carer perspectives

Twelve patients and carers were interviewed (Table 6). Four hours of interview dialogue was transcribed and analysed (mean individual interview length 18 minutes). Data was analysed across four themes.

Table 6 Patient and carer participant summary characteristics.

Participant ID	Role	Sex	Age bracket
P1	Patient	Female	51-60
P2	Carer (parent)	Female	51-60
P3	Carer (parent)	Female	61-70
P4	Patient	Male	21-30
P5	Patient	Male	51-60
P6	Patient	Female	31-40
P7	Patient	Female	21-30
P8	Patient	Male	21-30
P9	Carer (spouse)	Female	51-60
P10	Patient	Female	21-30
P11	Patient	Male	21-30
P12	Patient	Male	41-50

1) Acceptability of broaching topic of violence risk

There was consensus among patients and carers that consideration of violence risk is a legitimate, expected and understandable component of being assessed by mental health services. Some framed this in terms of its relevance to treatment planning and the practical safety of healthcare staff. A few did agree, when asked, that stigma could be an issue when thinking about the risk of violence in mental illness. However, those who felt this was an issue spoke about it in terms of how mental illness is portrayed in the media, and it was not felt that this was something that should prevent health professionals assessing risk:

> *…I think for the safety of people and the staff, they should definitely check* [about violence]. *There's no stereotypes about it, you know, if you go into a mental hospital…some staff will have past experience of violence…like I say you can*

> *never tell with people, so…I think you should always…be sure who you're dealing with.* (P8, Patient)

Many of the patients interviewed did not recall discussion of violence risk as seeming a prominent aspect of their assessment with services. Of those that did remember this more specifically, a key aspect of its acceptability was that it occurred as part of an interaction that felt professional and supportive:

> *They definitely asked about have I been in trouble with the police…I do remember them talking about that in the interview when I first went to* [the assessment]*, and then it was brought up…just as they were trying to establish everything that had happened and home stuff…I was…forthcoming with my answers to all of them, because I just needed help basically…I knew that I was being supported...* (P12, Patient)

2) *Language and framing of violence risk assessment*

The use of the word "violence" in assessments was discussed. Whilst many agreed that it was a strong word, and one carer said it felt quite uncomfortable, there was consensus that on balance it best captured the intended meaning and there was no suitable alternative. One patient explained that the manner in which the issue was approached was more important than words themselves. Many highlighted the importance of being straightforward, and emphasised that it was helpful to make any questions about violence feel like a routine component of gathering information at an assessment. One patient suggested that using OxMIV could help with this aspect by making it seem less personal:

> *I think…just being…open and there is nothing wrong with a question that's…to the point, really. I think it's better to be crystal clear and ask the question rather than faff around and not really ask the question clearly…and then making it*

> *clear that they do this with everybody, rather than it's, you know, "We picked on you because we think you're a risk"...* (P5, Patient)

One patient recalled feeling slightly surprised at being asked about criminality in assessment, as this came out-of-the-blue in the context of the health-focussed questions. Others agreed that a simple precursor or explanation of that part of the assessment would help avoid this:

> *It was surprising* [to be asked about violence history] *because I was expecting to get asked about my medical...my health history and then all of a sudden I was asked about…crimes…if you just explain it…why they're asking us…I think that should be enough.* (P4, Patient)

3) Seeking collateral history for risk assessment

One aspect of the assessment process that clinicians highlighted they lacked confidence in pursuing was seeking collateral information from police (see Chapter 3). Patients and carers however generally thought this was a reasonable thing to do where indicated:

> *…they're…just…checking to see if you've got any…criminal past…because they* [patient] *might have been violent to somebody, and…they* [clinicians] *just wanna check…what's happened…it's all in one thing because the health authority, the police…they've got to know what's been happening in a person's past to…understand what's been going on.* (P1, Patient)

Some patients thought that individuals with a history of violence might be reluctant to disclose the full details. One described how they might have avoided this themselves whilst in hospital, as they perceived this would have been linked to more restrictions being place on them on the ward. A few specifically raised the issue of domestic violence, and that it was important to facilitate families to be able to privately share any such concerns, which they might find it difficult to communicate in front of the patient:

> *You may not feel able to disclose it in front of the person, but if* [clinicians] *can find that information out some other way it's got to be helpful for managing the risk to the family…in cases of domestic violence it is often very difficult…to disclose everything in front of the person. There may be details that haven't been shared and to get that information is really helpful.* (P9, Carer)

Carers felt strongly that the information that they may be able to provide as the people who know the patient the best should be integrated into any assessment of risk and the individual context of that:

> *…if you're living very closely with someone…we're not experienced professionals in terms of their symptoms or their problems, but…we know them generally speaking as carers…we know them better than…whoever is treating them does. So, whilst we might not understand the problems, I don't think that a full picture can necessarily be gained without more input from close family members…* (P2, Carer)

Similarly to patients, carers agreed that an unambiguous approach to asking for information was preferable, and that this information might not always be provided unless asked directly.

4) Acceptability of OxMIV approach

There was broad positivity about the idea of clinicians using OxMIV to improve their risk assessments. Patients and carers thought it could make it more open, and none would have objected to being involved in completing it during their assessment with services. One patient had spent some time exploring the online version of the tool themselves:

> [OxMIV] *looked pretty good…it's easy to use, it was straightforward, the questions weren't too invasive…they were put nicely.* (P8, Patient)

> *If you are feeling hesitant, a structure is always a useful way forward, isn't it? And it also kind of opens up…other situations where there might be aggressive behaviour like…drugs or alcohol…So I think it's good. It's good to get it out in the open and it will cover more specific detail than somebody might disclose at the time…* (P9, Carer)

A limitation raised by two participants was the ability to apply the output of the tool to changes in an individual's situation and presentation, and how the static assessment was communicated and regarded by clinicians going forwards was therefore important. One carer gave an example of a specific risk behaviour their family member displayed when unwell, but which was not relevant when more stable in mental state. One patient described in detail why they thought the tool should provide a baseline for more clinical judgement:

> *I'm like* [X]*%* [on OxMIV]*...But even I was getting wound up* [on the ward]*, you could see it on my face…I think the best thing to do is use* [OxMIV] *at first and get the idea of how violent they could be. And I think after that, they* [staff] *should just go completely on eye…the body language…just watching how…you react with staff after that.* (P8, Patient)

Important to several of the participants was that the assessment led to something helpful. For patients, this was the aspect that they most wanted to be directly involved in, and carers highlighted that they also needed to be incorporated into this:

> *I think…all of this is about assessing the individual who has got a mental health issue, but I suppose…I wonder what support would be on offer to families where there is violence…so the follow-up support. If you discover the person has been violent…I would want something else to follow on from that, not just for the patient but for the family.* (P9, Carer)

One carer described how worrying about potential violence, despite there having been no history of this, was one of the stressful unknowns around the onset of illness, and that OxMIV could have a role in communicating the often low magnitude of risk to families:

> *Definitely, definitely* [would find communication of low risk from tool helpful]… *it's not ever a problem we've had, but it hasn't stopped worrying about things that potentially could happen so you know when you're lying there in bed at night and your imagination starts to run wild…* (P2, Carer)

This was in the context of all the carers having had some past experience of feeling sub-optimally informed in their family member's care, including risk issues, due to rigid boundaries around confidentiality. One carer recounted a more positive experience of interacting openly with services, where a frank discussion risk of violence risk was helpful in supporting the family during an acute crisis that led to hospital admission:

> *…we discussed how* [family member] *might behave when the ambulance came… And all of that was discussed very openly… As it happened* [family member] *wasn't violent, but, you know, that was really helpful and supportive, just thinking about the family as a whole. But it was just explained… "This sometimes happens and …"... I think all of that would be helpful. I mean it's scary enough…but actually to feel that people are supporting you as an entire family unit by asking those questions is helpful, I think.* (P9, Carer)

Integrated results

Where quantitative and qualitative findings examined the same phenomena, these results were considered together and presented in an integrated results matrix across the areas of uptake, reach and role, acceptability and availability of information, and utility and impact (Table 7).

Table 7 Integrated results matrix combining qualitative and quantitative results examining the same phenomena.

Quantitative results	**Qualitative results**	**Analytical integration**	**Implications for practice and research**
Uptake, reach and role			
Lag in initial uptake, with only 6% of eventual total of assessments completed over 12 months undertaken in first 16 weeks.	*Clinician theme 7* Some clinicians initially unsure of the role of tool i.e. that it could be used for all, rather than only in those with significant forensic history. Not primarily a risk management service, therefore use/discussion of formal tools not previously commonplace. Several highlighted that difficult to access all staff to provide the necessary information, especially with high staff turnover. *Clinician theme 3* Position in EHR fundamental - is on risk tab, but can be forgotten as not linked directly into general risk form.	Convergence across qualitative and quantitative findings that integration is a shift in approach that requires prompting and time to adopt. Subtotal understanding of purpose of tool amongst teams likely accounted for initial slow uptake. Prominence of tool on EHR also relevant to uptake and level of awareness in team.	Requires time and repeated contact with clinical team during initial integration period. Basic purpose and process around use of tool needs to be clearly communicated. Embedding of tool in EHR important for future implementation.

OxMIV used in approximately 40% of caseload or 65% of newly taken-on patients over 12 months. In 77% of assessments the form was completed the same day it was commenced. 65% of all OxMIV assessments were completed within 12 weeks of initial referral to services.	*Clinician theme 3* Agreement that OxMIV quick and easy to complete, did not add excessively to administrative burden. *Clinician theme 7* Some clinicians regarded violence risk as a low clinical priority for their caseload and so were less likely to use. *Clinician theme 6* Most naturally integrated as part of assessment phase, where risk is most fully assessed. Fitted well with range of other paperwork completed at first assessment. If full information not available at first assessment or other barriers, may helpfully straddle the initial period of handover from assessing clinician to care coordinator.	Convergent findings that OxMIV was efficient enough to have been used for a considerable proportion of the risk assessments undertaken by the clinical services. Natural clinical role indicated by both sets of findings was as routine part of new assessment process (either first assessment or early phase of care coordinator contact), and used more selectively with patients already known to the team (i.e. only if concerns about risk).	Tool is feasible to use in EIP services. Future implementation should focus on routine role in new assessments.

Acceptability and availability of information			
Mean of 1.8 predictors scored as unknown per OxMIV completed, which did not significantly vary according to whether there were concerns about risk pre-OxMIV. The three family history items were scored as unknown in 45%-47% of assessments. Benefits, highest education and income category scored unknown in 16%, 14% and 3% respectively.	*Clinician theme 2* Consensus that overall information required for OxMIV married with what was clinically available and felt relevant. *Clinician theme 3* Questions themselves straightforward with no equivocation, understood what was being asked. *Clinician theme 2* Family history items, and to a lesser extent education, were less routinely enquired about. May be awkward to bring up unless relevant in history. Some queried relevance as risk factor in every case. *Clinician theme 9* OxMIV did not change tendency to complete risk assessment as part of paperwork post-assessment, rather than directly during assessment. Some felt OxMIV could be completed with a patient, which would improve completeness of information, others would rather integrate questions organically. *Patients and carers theme 1* Consensus that routine enquiry around violence risk is acceptable as long as integrated in a professional and supportive manner. *Patients and carers theme 2* Approach of using structured tool deemed acceptable as can make risk assessment feel more routine.	Convergent findings that most information is routinely available and acceptable. Family history of violence and substance misuse less routinely explored in current practice. Quantitatively, information used to complete OxMIV was not more complete when there were risk concerns, i.e. does not seem to be prompting gathering of extra information. Potentially explained by finding that some clinicians regard family history items as awkward to enquire about, and no clinicians typically completed assessment directly with patients. Also some mixed views about direct relevance of these predictors in every case. Clinicians' perceptions of sensitivity diverged from patients' and carers' views that unlikely to cause offence if framed appropriately, and that tool may support making it feel routine.	To improve information completeness tool may need to specifically suggest seeking additional information, highlight items' relevance as predictors, and reassure clinicians as to the acceptability to patients/carers.

Utility and impact			
OxMIV rated as helpful in 62% of assessments overall, and more likely to be deemed helpful if risk needs identified pre-OxMIV (helpful in 75%, p=0.02), or higher than average risk needs identified pre-OxMIV (helpful in 82%, p=0.01).	*Clinician theme 1* Overall positive view of OxMIV- felt purposeful, improved consistency, knowledge of risk factors, provided reassurance, and helped confidence such as in taking a case for further discussion. A few highlighted value of demonstrating low risk with OxMIV, for reassurance or summarising messy risk assessment documentation. *Patients and carers theme 4* View from carers that a low risk rating from OxMIV could be reassuring for families, as can worry about this even if no history of violence, and can often feel sub-optimally informed by services due to confidentiality issues.	Convergent findings in that clinicians typically found OxMIV a helpful addition. Case-by- case utility expanded by qualitative descriptions of wider benefits such as in consistency and knowledge. Some divergence in qualitative findings, with some clinicians and carers highlighting the merits of OxMIV when risk is low, whereas quantitative findings showed clear signal that case-by-case OxMIV was regarded as more helpful when there were concerns about risk.	Findings support clinical use of OxMIV based on perceived utility, with low resource implications. Evaluation of impact needs to take account of the range of perceived benefits.
OxMIV categorical rating and pre-OxMIV view of whether needs around violence risk were above average aligned with 87% concordance. Discordance was not significantly related to perceived utility (p=0.20) or likelihood of changes in careplans (p=0.23).	*Clinician theme 5* OxMIV typically aligned with clinical view, good benefit/time ratio, quick enough that focussing and clarifying the clinical view was enough to be helpful rather than needing to alter judgement. *Clinician theme 1* Alignment of OxMIV with clinical judgement provided reassurance and helped support confidence.	Convergent finding that changing the clinical view was not necessary in order for tool to be perceived as helpful. Whilst it did not directly alter the clinical views, its simplicity meant that it offered a net benefit.	Implementation of tool should highlight clinical role as a complement to clinical assessment that will more typically support and refine this clinical view rather than contradict it.

OxMIV only supported changes in careplan in 5% of assessments overall, more likely if risk needs identified pre-OxMIV (12%, p=0.01), or higher than average risk needs identified pre-OxMIV (19%, p<0.01).	*Clinician theme 10* Consensus that OxMIV did not typically lead to changes in careplan, as risks were most often low, and typically aligned with clinical view. Many agreed that need to embed risk assessment more into management plans, and were open to a tool offering suggestions for this, albeit would need to be general and suggestive rather than directive to avoid becoming overly protocolised. *Patients and carers theme 4* Several raised importance of assessment leading to some helpful support, and it is this aspect that patients and carers particularly want to be involved in.	Agreement between qualitative and quantitative findings that impact and benefit was in ways other than directing a practical addition to a careplan, though this occurred in 1/5 of those with the highest perceived risks. The idea of adding therapeutic suggestions to the tool was both broadly palatable to clinicians, and important to patients/carers who wanted to be involved in this aspect.	Tool would need to link to suggestions for management to have a more direct impact on this. A prompt to more directly involve patents/carers in the treatment planning aspect may be helpful.

Discussion

This mixed methods study examined the preliminary use of OxMIV to support clinical assessments of violence risk over 12 months in two EIP services. Quantitative data on the utility and patterns of use of the assessment tool within the EHR was triangulated, complemented and expanded by qualitative interviews of 20 clinicians with experience of using the tool. The acceptability of the approach and broader issues around broaching violence risk was further examined through qualitative interviews with 12 patients and carers. This methodology yielded a detailed understanding of the practical issues around the clinical use and role of OxMIV, its feasibility and acceptability, and wider themes around how clinicians approach violence risk and gather information for the purposes of risk assessment. The understanding gained has implications for the optimal role and future clinical integration of OxMIV, and how this can be studied at scale. Further, the novel demonstration of how mixed methods can be used to examine clinical use of a prediction tool can inform clinical translation work with prediction models in psychiatry and elsewhere in medicine.

Acceptability and feasibility of OxMIV

Over 12 months, OxMIV was used on 141 occasions. In the context of a total average caseload of fewer than 400, with fewer than 150 patients newly taken on in 12 months, this represents good reach. That its routine use within an EIP service was feasible was supported by the qualitative feedback from clinicians. There was consensus that it was practically straightforward to complete and quick, taking no longer than five to ten minutes, therefore not adding substantively to the overall time spent on risk assessment documentation. The binary or categorical responses required to the questions were well received. The main cognitive effort clinicians described during assessment was considering whether histories met the pragmatic thresholds for a past history of drug or alcohol use disorders.

In terms of the information required for the tool, there was agreement that this broadly aligned with routine information collected at assessment, with the main exception of the three family history items. This mirrored quantitative results, in which these were the only items scored as "unknown" to any substantial degree. Whilst some clinicians felt incorporation of these additional risk factors into their assessments was a helpful impact of the tool, a few felt these factors were more difficult to ask about or may not be directly relevant. Quantitatively, information was no more complete when there were concerns about risk, and so it does not appear that OxMIV prompted gathering of additional information in these cases if it was not already known. Patients and carers provided an alternative perspective on this perceived sensitivity of information gathering around violence risk. There was consensus that routinely broaching the topic of violence risk was understandable and acceptable, and they typically endorsed a straightforward approach to asking questions. Patients particularly highlighted that a feeling of routineness helped avoid any personal sensitivity, and that a structured tool might support this.

Uptake and barriers to use

The resource and process required to integrate even a simple clinical adjunct was well illustrated by this work. There was a lag of three to four months between the tool becoming available to clinicians, and its use being adopted to any meaningful degree. Clinicians highlighted how this was a relatively novel addition for a non-forensic service. Another issue was variable awareness of it being applicable as a simple screen for all, rather than only for considering risk in individuals with significant forensic history. Achieving penetration of this information across the team required repeated communication in different forms, with staff turnover proving an additional challenge. Also, whilst the tool's interface within the EHR was acceptable, many felt that it needed to be more directly integrated within the general risk assessment form to avoid being forgotten. Among clinicians who did not use OxMIV

extensively however, the main reason for this was that violence risk was a low clinical priority for their individual cohort of patients, in which case even the short amount of time required was a barrier to using OxMIV.

One theme that arose previously in baseline interviews (Chapter 3), but which in practice was not felt to be a barrier to the use of OxMIV, was stigma. Clinicians were wary of broaching the topic of violence risk for fear of inadvertently reinforcing stigma, however there was consensus in this study that this was no more a concern with OxMIV than with any other method of assessing risk. Patients and carers were also not of the view that concerns about stigma should preclude clinicians routinely assessing risk, and that this was not a particular issue in the context of professional interactions. An overarching factor that was noted by clinicians as relevant to the uptake of the tool however was the proportionality of emphasis that could be placed on this within the team, given that violence risk management is important but not the primary function of the service.

Utility and impact on practice

Clinicians deemed OxMIV to have helpfully supported the majority of assessments. A significantly higher proportion were rated as helpful when risk was already considered to be increased. However, a few clinicians and carers highlighted how the reassurance provided by reinforcing a low risk assessment was also helpful. A clear finding was that the perceived benefit of the tool was not linked to it diverging from the clinical view of risk, and indeed many commented that they would have questioned its validity had it frequently done so. Clinicians described more how it clarified and focussed the overall assessment, particularly with the percentage score which many felt provided helpfully richer clinical information about the magnitude of difference in risks. It was more in this manner that clinicians described the impact of OxMIV, as well as improving confidence, objectivity, consistency, and knowledge. There was much more limited impact in terms of actual changes in careplans,

although this was more common in those at highest risk, of whom around 1 in 5 had some extra support incorporated following assessment.

Optimal clinical role and toward linked interventions

The initial assessment period emerged as the preferred position for OxMIV within the clinical pathway, as part of the information gathering at first assessment and/or during the early period of contact with a care coordinator. Its routine use as a screen during a full assessment was acceptable here to both clinicians and patients, and it was generally felt to integrate with the already extensive documentation associated with such assessments. A secondary role was for refining risk assessments for those already known to the service for whom there were some concerns about violence risk. Clinicians saw less value in completing OxMIV at reviews for those already known to them for whom risks were deemed low, aside from providing a summary in cases where risk assessment documents had become long and unclear over time.

In line with their approach to risk assessments in general, clinicians saw the role of OxMIV as part of the paperwork and in assisting formulation following an assessment, rather than a tool to actively complete with patients during the assessment itself. Some thought that in theory it could be used more directly, and patients and carers did not think that this would be unpalatable. However a more typical view was that any role in improving collaboration could more helpfully be at the stage of developing a support plan in response to the outcome of the assessment. Clinicians agreed that risk assessments needed to be incorporated into management plans more directly, and were open to the idea of a future iteration of the tool providing suggestions for this. Patients and carers placed value on the assessment leading to something helpful, and also highlighted this as the aspect they most wanted to be directly involved in. Clinicians, more so psychiatrists than other members of the multidisciplinary

team, had some reservations around this becoming too protocolised, and felt that any interventions should be broad suggestions rather than directive in nature.

A strong theme from interviews with carers was the sense that they can feel "in the dark" around care due to confidentiality issues, and carer participants were supportive of a tool as a framing for them to feel more included in conversations around risk, either providing information for it or to facilitate more inclusive discussions around risk. Rather than exclusively in cases where risk is present, there was an identified role to reassure families where risks are low, as this can often be a source of anxiety in the new situation of an emergent serious mental illness.

Implications for future research

For future work with OxMIV, several key elements are identified by this study. For example, a considerable run-in period is required for adoption. Clear identification of its role would need to be established by a sustainable process, and once established within a team, use with 70% of all new assessments would be a reasonable target based on this work. Measuring impact on a service would most helpfully capture provision of additional support to reduce risk, for which linked interventions would likely be needed. I will discuss these issues around the framework for future trials in Chapter 6.

For the prediction model field, where greater emphasis on studying clinical translation is clearly needed, this study demonstrates the value of mixed methods, and again I will return to the wider implications of this work in Chapter 6. A novel aspect developed here was combining the use-by-use structured feedback on utility, and data on the patterns of use, with qualitative interviews. Integrating these sources of data provided clear added value and facilitated a more detailed understanding than any of these approaches would have provided in isolation. This approach can be directly applied to other tools and settings.

Strengths and limitations

As above, the use of a mixed methods approach allowed incorporation of a wide range of perspectives and data sources. The trustworthiness of the findings is increased by this level of triangulation. A novel aspect of the quantitative data, and the manner in which it was obtained, was that it was collected on an assessment-by-assessment basis. This offers therefore a genuinely different and complementary insight to either qualitative methods, or surveys, as whilst the latter allow for quantitative analysis, they can be prone to recall bias.

One key limitation was that it proved difficult to recruit patients to the interview study who had a significant forensic history. It is plausible that such individuals would have a different perspective on the issues explored. This difficulty seemed to mirror the wider perception by clinicians of violence being a sensitive topic to broach, and they were therefore perhaps more hesitant to invite those to the study for whom they thought it may be more personally sensitive. The clear consensus from participants that the topic should simply be broached in a straightforward, routine manner should therefore be interpreted with this caveat in mind. In terms of the perspectives gained from clinicians, as I discussed in detail Chapter 2 it is also important to reflect on my background and the potential for this to affect the views that clinicians felt comfortable presenting to me. As well as the systematic and transparent analysis process, I also took care to mitigate this risk further in clinician interviews by highlighting at the start that my research would not be adversely affected by any negative views of the tool they might have, and I encouraged them to share these.

An overarching limitation is that the work took place during the covid-19 pandemic. This had two main implications. First, all interviews were undertaken remotely rather than in person. However, whilst it is perhaps more difficult to build rapport over the telephone than in person, it may also be that patients in particular felt more able to discuss challenging topics over the telephone. It also proved convenient in terms of practicalities, and so may in practice

have facilitated involvement of clinicians as well as patients and carers. Second, and more pertinently, was that the service as a whole was clearly operating in a different fashion to usual. One obvious practical issue was that all team meetings occurred online, and the team office base was populated on a rota basis, rather than all clinicians being in the office together. The main impact of this was the visibility of the OxMIV work. Opportunities for me to have ad-hoc contact with the team, to prompt and advise, were much reduced. More widely, the teams were also under new pressures due to the complex effects on their way of working. One would expect a future integration, such as in a trial, to be more efficient.

Conclusion

The OxMIV tool proved to be feasible to use in EIP services, with an optimal primary role for new assessments. It was rated positively by clinicians, who felt it improved their confidence, consistency and knowledge. It aligned well with clinical views but refined these such as with the richer information provided by a percentage score. Required information married well with that routinely collected, aside from the family history items which were more novel and around which clinicians had mixed views on relevance or ease of obtaining. The approach was considered acceptable by patients and carers, who felt that it was reasonable to routinely assess violence risk, and encouraged a direct approach. Impact on provision of support was limited, and future development should focus on linking to suggestions for management. Findings from this study suggest that communication and planning around reducing risk is the juncture at which the tool may have a role in facilitating more open collaboration with patients and their families, rather than the assessment itself.

Having established the practical acceptability of OxMIV in this setting, in Chapter 5 I will assess its predictive performance here, and compare this with that of unstructured clinical judgement to further understand its potential benefit and role.

Chapter 5
A clinically operationalised violence risk prediction tool for Early Intervention in Psychosis services: external validation of OxMIV and its comparison to unstructured clinical judgement

Introduction

In previous chapters, I have demonstrated the importance of violence perpetration as an adverse outcome in Early Intervention in Psychosis (EIP) services in terms of its prevalance,[68,75] association with poorer overall prognosis,[76] and repercussions for patients, their families, health and emergency services and society.[65] Assessment to identify whether violence risk is relevant for an individual patient is an integral part of any full assessment undertaken by EIP services. Currently this relies on the clinical judgement of assessing clinicians, and I examined this process and the associated challenges in depth in Chapter 3.

One way to meet some of these challenges is with the support of a simple prediction tool. OxMIV[86] is a candidate for this role in EIP services. It was developed and validated using logistic regression in a related diagnostic population of individuals with schizophrenia spectrum and bipolar disorders in Sweden. In Chapter 1, I highlighted two important but often overlooked phases of research to translate a prediction model into a clinical tool. One is to understand the practicalities of its use in a clinical setting. For OxMIV I addressed this in Chapter 4, where I examined its feasibility and acceptability in EIP services, and established its likely impact and role. A second key undertaking is to ascertain its predictive accuracy in this population through external validation. This step is often neglected[148] but is essential for understanding the likely accuracy of prediction in a clinical setting, and therefore the type of management decisions it can safely inform. This includes ensuring adequate calibration,[149]

and if necessary updating the average prediction made by the model to match the baseline event rate in a new setting.

This study therefore sought to externally validate OxMIV for predicting violence in an EIP population using a retrospective cohort design. As has been the case throughout this thesis, emphasis was placed on direct clinical applicability. In this study this was by using routine clinical data from the electronic health record (EHR), pragmatic inclusion criteria and predictor definitions, and a clinically meaningful outcome measure. To allow fuller interpretation of the potential clinical role and net benefit of OxMIV, a measure of the unstructured risk judgement made by clinicians at the time of assessment was also obtained.

Aims

The aims of this study were to 1) examine the performance of the OxMIV model for predicting violence in a clinical population of individuals presenting to EIP services, 2) update and recalibrate the model as necessary, and 3) compare the accuracy of OxMIV with that of unstructured clinical risk ratings, and consider its potential clinical role and benefit.

Methods

Study design and data sources

The study used electronic health record (EHR) data from a retrospective cohort of individuals consecutively assessed by EIP services in two English counties between 2012 and 2018, combined with data on violent occurrences held by local police. A protocol was followed and the guidance set out in the TRIPOD statement[97,150] applied throughout (Appendix 5.1).

The included population was all individuals aged 14-65 years who received a full in-person assessment with EIP services from Oxford Health NHS Foundation Trust. Two separate EIP teams cover the Oxfordshire and Buckinghamshire areas, serving a population of 1.2 million

with a combined average annual caseload of around 380.[32] The decision to include all individuals assessed by these services, rather than restricting to only those meeting full criteria for first episode psychosis (FEP), was driven by the aim to validate the model in a clinically meaningful manner. There is often diagnostic uncertainty at this juncture, and so the clinically relevant question is how a tool performs in this context. Further, the service has responsibility to assess and communicate risk, and direct toward appropriate support, even for those not meeting the symptom criteria for EIP services. Indeed, if not taken on by the service, many of the individuals assessed will be referred on to other secondary mental health services[75] and the presence of risk may influence this decision. Prior to a full in-person assessment, referral information is triaged, possibly supplemented by a preliminary telephone assessment with the patient or discussion with families and referrers, to ascertain whether there is sufficient possibility of FEP to warrant full assessment. Individuals whose referrals were triaged in this manner, but who did not go on to have a full in-person assessment, were not included in the cohort.

I extracted data to populate the OxMIV model manually from routine assessment documentation within the EHR in assessment forms, clinical summaries, risk assessments, clinical progress notes and letters. Whether or not an individual was identified as being at increased risk of violence in this original clinical assessment was also recorded, along with any significant violent incident in the 12 months following assessment (see below). Using the free-text search functionality of the EHR to scan clinical notes for relevant incidents was previously shown to be an effective strategy.[75] For each included individual, I then manually extracted police-recorded violent occurrences from Thames Valley Police's Niche record system. By collecting data retrospectively and entirely offline from the clinical setting, the study avoided impacting on clinical practice or decision-making.

Definition of violent outcomes

For model validation, violence was recorded as a binary outcome in the 12 months following assessment by EIP services, defined as a police occurrence for a violent offence, or an incident documented in the EHR of interpersonal violence involving a weapon or resulting in physical injury (i.e. regardless of whether this resulted in police contact). Outcome data collection was blinded in that an OxMIV score had not been calculated at the point of recording the outcome.

Officially registered violent outcomes such as arrest or conviction offer a clear advantage over measures that rely on ongoing contact with mental health services, as this engagement may be disrupted as a direct consequence of developing the outcome (e.g. incarceration after a violent offence). Official outcomes also avoid limitations of self-report scales such as interrater variability and recall bias. Conviction is the most robust measure, however there are practical limitations in a psychiatric population as there may be delays or diversions from the justice pathway. I therefore used police-recorded occurrences of an individual having been arrested, charged and/or a suspect for a violent offence. This objectively captures a significant incident that is stressful, disruptive and stigmatising, and also consumes both police resource and healthcare resource for potential future care. It is therefore an important adverse outcome to be targeting. Relevant offence codes were pre-specified (Appendix 5.2) and included assault, robbery, arson, sexual offences and illegal threats or intimidation. Codes for offences pertaining to possession alone of a weapon (i.e. without any associated threats or assaultive behaviour as defined above) were not included, as these can occur secondary to proactive policing measures. To be included, the date of the incident (rather than the date of arrest or charge) must have been within 12 months of the EIP assessment.

Despite the advantages of using a police-recorded outcome, it is also clinically well recognised that significant violent incidents may occur which do not lead to police contact. Typically these can occur during acute-phase illness, such as during an inpatient hospital admission, where normal criminal proceedings may not be pursued. Although clinical policies typically still encourage the reporting of such incidents to police, in practice this is not universally the case for a variety of reasons including that clinicians may feel conflicted as to its appropriateness.[151] Nevertheless, such incidents are of clinical importance[152] and in stakeholder work with local clinical services (which consisted of presenting study plans at a clinical best practice meeting and multidisciplinary team meetings [Chapter 2]) it was deemed relevant for the clinician-perceived validity of the model that these were included. To avoid missing such outcomes therefore, police data was supplemented by a focussed review of the 12 month period in question in the EHR to identify any relevant documented incidents. The threshold of severity for this was pre-specified as involving a weapon or documented physical injury, so as to only include objectively clinically significant incidents. Finally, a free-text search of the EHR was also applied to seek documentation of any violent arrests, to capture any that may have occurred outside of Thames Valley Police's geographical jurisdiction and so not be recorded in local police records.

Definition of predictors

Information was collected from EHRs for all predictors included in the OxMIV model (Table 1, page 126). In model development, predictors were defined by their coding in Swedish registers.[86] Operationalised definitions were required for the current external validation to allow extraction from EHRs (Table 1), and also to validate predictor definitions that are directly clinically applicable (the acceptability of which in practice was discussed in Chapter 4). For example, a diagnosis of a lifetime substance use disorder is inconsistently recorded as an extractable structured diagnostic code on EHRs. This was therefore coded according to

whether details of substance use history documented in the assessment were likely in keeping with diagnostic criteria for a substance use disorder.

For personal income, the development study used a decile classification.[86] Stakeholder work with clinicians indicated that this was clinically unpalatable, and a potential proxy of estimating decile using postcode was also deemed unlikely to be clinically feasible. Therefore for this validation the predictor information for income was truncated into two simple categories rather than deciles (Table 1), with 'low' income as baseline as per the lowest decile in the development study, and the 'stable' category adopting the pooled coefficients from deciles 2-10. This approach retains the predictive information from the previous study, but validates this in a clinically operationalised form.

If relevant sections of an individual's EHR did not contain sufficient information to code a predictor, this was recorded as "NA". For a random sample of 20 individuals, predictor data extraction was also blindly independently extracted from the EHR by a second researcher. Concordance was 90%-100% for all but three predictors, which were highest education, sibling violent crime (both 85%) and parental violent crime (75%). Discordance was around the threshold of confidence required to assign a value to the predictor based on available information rather than recording as "NA", and this was resolvable through discussion.

Table 1 Predictor definitions pre-specified for extraction from electronic health records.

Predictor ***(code)***	**Definition**	**Data recorded**
Age *(Age)*	Age at time of assessment.	Age in years
Sex *(Sex)*	Sex at birth.	Male / female
Previous violent crime *(PrevViol)*	Any lifetime conviction for violence (assault with or without injury, homicide, robbery, arson, any sexual offence, illegal threats or intimidation). If not explicitly stated, but risk assessment identifies no history of risk towards others, recorded as 'No'.	Yes / No
Previous drug misuse *(PrevDrug)*	Lifetime diagnosis drug use disorder, from documented diagnosis, or indicated by past contact with drug rehabilitation/treatment services or detailed history.	Yes / No
Previous alcohol misuse *(PrevAlc)*	Lifetime diagnosis alcohol use disorder, from documented diagnosis, or indicated by past contact with alcohol rehabilitation/treatment services or detailed history.	Yes / No
Previous self-harm *(DSH)*	Lifetime episode of self-harm (any form, e.g. deliberate self-poisoning, cutting).	Yes / No
Highest education *(Education)*	Formal schooling: secondary (to age 16), upper secondary (to age 18), post-secondary (past 18).	Secondary / Upper secondary / Post-secondary
Parental drug or alcohol misuse *(ParentDrug)*	Parental lifetime diagnosis of drug or alcohol use disorder (definitions as above for personal history).	Yes / No
Parental violent crime *(ParentViol)*	Parental lifetime conviction for a violent offence (defined as above for personal history). History of incarceration taken as a proxy of violent offending.	Yes / No
Sibling violent crime *(SibViol)*	Sibling lifetime conviction for a violent offence (defined as above). History of incarceration taken as a proxy of violent offending.	Yes / No
Current episode *(Episode)*	Inpatient hospital admission or outpatient community patient at point of assessment.	Inpatient / Outpatient
Recent antipsychotic treatment *(Antipsych)*	Prescribed and taken any antipsychotic drug in 6 months before assessment.	Yes / No
Recent antidepressant treatment *(Antidep)*	Prescribed and taken any antidepressant drug in 6 months before assessment.	Yes / No
Recent dependence treatment *(Dependence)*	Any pharmacological strategy to treat dependence (e.g. replacement therapy such as methadone) prescribed and taken in 6 months before assessment.	Yes / No
Personal income *(Incomecat)*	Low: unemployed and/or inadequate financial situation with difficulty meeting basic daily living needs (food, accommodation etc.). Otherwise, 'stable'.	Low / Stable
Benefit recipient *(Benefit)*	Currently receiving social or disability benefits of any kind.	Yes / No

Clinical judgement comparator

To further interpret the potential of the tool to add value to usual clinical practice, whether violence risk was noted as relevant in the original unstructured clinical assessment was also recorded. This was gathered by examining the relevant risk assessment summary within the risk assessment section of the EHR completed closest to the first assessment, or the assessment letter. This was extracted in a binary manner using clear pre-specified definitions. If the summary did not mention risk to others, or referred to risk as "low" (including synonyms such as "absent", "not identified", "nil significant", "no concern"), this was recorded as "not increased". Alternatively, if 1) there was any documentation that risk to others was "moderate" or "high" (including synonyms "elevated", "escalating", "concerning", "acute", "unsafe"), 2) the categorical option in the risk assessment template was marked "risk identified", or 3) there were features within the management plan specifically addressing violence risk (for example documentation of safety advice given to a relative on how to respond in the event of aggression), then risk was recorded as "increased".

Sample size

The sample size was determined by the principle widely adopted in the field of prognostic research that to externally validate a prediction model, a minimum effective sample size of 100 participants with and 100 without the event of interest is required.[153] A 10% event rate was estimated based on previous literature[74] including preliminary work in the local clinical population.[75] Based on an estimate that around 85% of referrals result in face-to-face assessment (therefore meeting inclusion criteria), 1,300 consecutive referrals were assessed to ensure inclusion of a minimum sample size of 1,000. New statistical approaches to calculating minimum sample sizes for external validation of prediction models for binary outcomes have now been described,[154] which incorporate other factors that influence the

precision of performance measures, such as the variance of the linear predictor in the validation dataset and the anticipated miscalibration. However, the study design predated these methods.

Missing data

Missing data is a common challenge in the validation of clinical prediction models, but its handling is often poorly reported.[148] Improper approaches can lead to inefficient use of data (such as through complete case analysis which can discard a substantial proportion of available information), or produce biased performance estimates and standard errors. Although the predictors required for the OxMIV model would typically be expected to be considered in a full clinical assessment, a level of missingness of some predictors was expected due to variation in the depth of assessments and the nature of the routine clinical documentation used to obtain the data. This was anticipated to likely primarily affect the family history items. However, this is not a barrier to proceeding with external validation, and imputation approaches allow validation even where predictors are systematically missing from a new dataset.[155]

First, the proportion and pattern of missingness in the dataset was examined and considered in the context of knowledge of the clinical processes upon which recording relied. This was to consider the plausibility that data was missing at random (MAR), where missingness is dependent on observed data but not on unobserved data or the missing predictor itself.[156,157] The other possible patterns of missing data are missing completely at random (MCAR), where there is no systematic differences between observed and missing values, or missing not at random (MNAR), where missingness is dependent on the missing predictor itself or some unobserved variable. It is typically assumed that data is at least MAR, but this is an untestable

assumption. MCAR is testable however, and missing data was examined for this along with any obvious indication of MNAR.

Multiple imputation by chained equations[158] was then used to impute missing data to create 20 imputed datasets. The imputation model included all other predictors and the outcome, to model the MAR process.[159] Performance measures were then calculated separately for each imputed dataset in the standard manner, before being pooled according to Rubin's Rules.[160] This method is optimal as it incorporates both the within- and between-imputation uncertainty into the final point estimate and variance. It is preferred to simpler methods such as mean imputation, which does not take into account correlations between predictors or the uncertainty of results, and regression imputation, which does account for correlation between predictors when estimating missing values, but then treats these imputed values as if correct.[156] The number of imputations was set at 20 based on computational feasibility (i.e. that the size of the dataset was not such that precluded a large number of imputations), and that simulation studies have shown that with 50% missing data, greater than 5 imputations only marginally improves variance estimates.[161,162] The plausibility of imputed datasets was checked by visually examining the distribution of predictors in observed and imputed data using stacked bar charts.

Model performance

The performance of the OxMIV model was examined with measures of discrimination, calibration and overall performance.

Discrimination is the ability of a model to separate (i.e. order correctly) any random pair of individuals with and without the outcome, and was quantified with the AUC (area under the receiver operating characteristic [ROC] curve), which for a binary outcome is identical to the concordance or c-statistic.[163] The ROC curve plots the relation between sensitivity and

specificity across the full range of consecutive cut-offs for designating a binary prediction. An AUC of 1 represents perfect discrimination, whereas 0.5 indicates a model that performs no better than chance.

Whilst discrimination is important, for a tool to be clinically usable it must also be adequately calibrated in external validation. Calibration is how well predictions match the observed data, i.e. do X% of individuals with a predicted risk of X% develop the outcome? A model with good discrimination can nevertheless give systematically off-target predictions if it is poorly calibrated, which is not clinically helpful and may even be harmful.[164] Despite this, calibration is poorly reported in validation.[149] Examining calibration in the current study is especially important, as the event rate was expected to differ from that in the development dataset. Calibration was examined with 1) calibration-in-the-large (CITL),[165] which estimates the difference between the mean predicted outcomes and the mean observed outcomes where CITL<0 indicates that predicted probabilities are higher than observed proportions and vice versa, 2) the expected/observed ratio (E/O),[166] related to CITL but more intuitively summarising the ratio of the number predicted to have the outcome to the number observed to have the outcome, where 1 is perfect, 3) the calibration slope,[165] where a calibration model is fitted and the slope coefficient indicates the degree of deviation from a perfect slope of 1 (<1 for an over-fitted model with predictions that are too extreme at low and high probabilities, and >1 for an under-fitted model), and 4) visual inspection of calibration plots, with predicted and observed probabilities plotted in decile risk groups.

For overall model performance (i.e. encompassing both discrimination and calibration), the Brier score was calculated.[163] This is the squared difference between binary outcomes and predictions, where 0 represents a perfect model.

Model updating

The OxMIV model is expressed by the equation:

$$Y = A + B_1*X_1 + B_2*X_2 + \ldots$$

Where Y is the linear predictor which is then converted to a probability scale by the logit link function, A is a constant (representing the Y-axis intercept), B is the regression coefficient for each predictor variable, and X is the predictor variable. All corresponding values for the OxMIV model are published in the derivation study[86] (-3.7273 + 0.8400*Male – 0.0468*Age + 1.6149*Previous violent crime + …).

A stepwise approach to updating the model was pre-specified.[167] First, baseline risk (analogous to the Y-axis intercept of the model) was adjusted by updating the constant of the model, thus bringing predicted and observed outcomes in line (i.e. correcting CITL, without affecting discrimination or any coefficients for individual predictors in the model). Next, the calibration slope was used as a single rescaling factor applied to all model coefficients. This re-calibration still only effects calibration, as the relative effects of predictors on outcomes remains unchanged. The degree of improvement in performance with this second step was examined to decide whether this rescaled model should be adopted in favour of the model with only the updated intercept. Re-estimation of a subset of coefficients using the new data was held in reserve as an additional step, as this would represent moving away from external validation toward development of a substantively different model.

For the updated model, paired measures of misclassification around a decision threshold (sensitivity, specificity, negative predictive value and positive predictive value) were calculated for a range of clinically sensible cutoffs.

Clinical benefit

The intended purpose of OxMIV, as with most clinical prediction models, is to assist clinical assessment, decision-making and patient outcomes. It has been recognised that measures of discrimination or calibration alone give relatively little information on this clinical value.[168,169] This was addressed in the current study by examining net benefit with decision curve analysis.[170-172] This approach has become widely reported, although it has been the subject of some misinterpretation and clarification.[173,174] The benefit of the OxMIV model was plotted as the net increase in proportion of true positive or appropriately "treated" patients (or, with an opt-out approach, the net decrease in proportion of patients treated unnecessarily), compared to baseline strategies of "treating none", "treating all", or the rating made by unstructured clinical judgement.[173] The measure of net benefit incorporates an "exchange rate" – the number of patients it would be acceptable to treat, i.e. classify as higher risk, in order to offer this treatment to one true positive. For consistency and to facilitate interpretation, in the case of the OxMIV model the exchange rate is the same as the cutoff or threshold probability. The exchange rate is a subjective preference that depends on the perceived relative harms of false positives and false negatives, which in turn depend on the nature of the outcome and the intervention. For OxMIV, linked interventions are likely to involve fuller assessment and more time spent devising risk-management and monitoring plans, and non-harmful additions of support such as for substance misuse comorbidity or anger-management. Potential linked interventions are discussed in fuller detail in Chapter 6.

Decision curve analysis reflects this subjectivity by plotting the net benefit across a range of preferences or clinically reasonable cutoffs that may be applied to the model. Net benefit is given by the formula:

$$\textit{Net benefit} = (TP/N)-(FP/N) \times (\textit{threshold probability} / \textit{1-threshold probability})$$

By plotting net benefit across a range, decision curve analysis can be applied directly to a validation dataset rather than requiring information to be input on costs and harms. It gives information on the optimal strategy at a given preference. The ideal for a new model therefore is that it provides net benefit compared to other baseline strategies across a range of clinically reasonable preferences. The net benefit of OxMIV was plotted for threshold probabilities of 0-50%, a range that was based on 1) prior clinician interviews that suggested it unlikely that a clinician would not address risk for an individual at greater than 50% risk of perpetrating violence, and 2) the intended clinical use of OxMIV being centred on non-harmful interventions, that could reasonably be offered even with high false-positive rates (i.e. at low threshold probabilities).

Statistical analysis

Analyses were undertaken with R version 4.1.[140] Missing data was visualised with the packages Hmisc,[175] mice[158] and VIM,[176] and generalised linear models were fitted to examine associations with missingness of a predictor as a binary dependent variable. The mice[158] package was used for multiple imputation and subsequent pooled analyses, specifying logistic regression for imputation of binary data and a multinomial logit model for imputation of education (factor with >2 levels). Analyses of complete datasets were undertaken with the packages pROC,[177] DescTools[178] and caret,[179] with performance measures reported where applicable as pooled point estimates with 95% confidence intervals derived from total variance across individual analyses of complete imputed datasets.

To update the intercept of the model, linear predictors were first calculated with the intercept term removed, and then a logistic model fitted with these new linear predictors as the offset term. To update both intercept and slope, a logistic model was fitted using the linear predictors with the intercept removed as the only predictor. For the selected final model,

paired misclassification measures (sensitivity, specificity, positive predictive value [PPV], negative predictive value [NPV]) around a decision threshold were calculated. Confidence intervals were calculated with the exact, conservative Clopper Pearson method for sensitivity/specificity and asymptomatic logit intervals for predictive values.[180,181] Confidence intervals were also reported for the incidence of violence in the cohort using the Wilson method,[182] as this may inform future work. Decision curve analysis was undertaken using the rmda package.[183]

Ethical approval and information governance

The study was approved by the Health Research Authority following review by the London-Bromley Research Ethics Committee (REC reference 19/LO/0498) and the Confidentiality Advisory Group (CAG reference 19/CAG/0092). Confidentiality Advisory Group (CAG) support was required due to the necessity to access patient identifiable information without individual patient consent. Individual consent was not feasible due to the size of the required retrospective cohort, and that including only those who I was able to contact and consent would substantially skew the included population, disproportionately excluding those who may be uncontactable as a consequence of having developed the outcome of interest. Identifiable information was only required for long enough to link the EHR data with police outcome data. The approved process was that I undertook this manually, using name and data of birth to extract the relevant binary outcome information from police records, and linking this back to the health record data via a linking identifier. All identifiable information was securely deleted at the point that the police and healthcare data was combined, and analyses undertaken with this anonymised dataset. Linkage of this data was undertaken using the University of Oxford's High Compliance system, a secure environment for the manipulation and storage of sensitive data. As part of obtaining CAG support a Data Privacy Impact Assessment was also undertaken, and I worked with relevant information security colleagues

in the University to fulfil the requirements of an NHS Digital Data Security and Protection Toolkit assessment.

The remit of CAG support covered only the use of NHS data for the purposes of this study, and additionally a written data sharing agreement was in place between the University of Oxford and Thames Valley Police which formalised the use of police data in the study. This was under the legal bases of Article 6(1) of the UK General Data Protection Regulation ([e] processing of personal data for performance of a task carried out in the public interest), and additionally Article 9(2) of the UK General Data Protection Regulation and Schedule 1, Part 1 of the Data Protection Act 2018 ([j] processing of special category data and law enforcement data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes).

Public and patient involvement

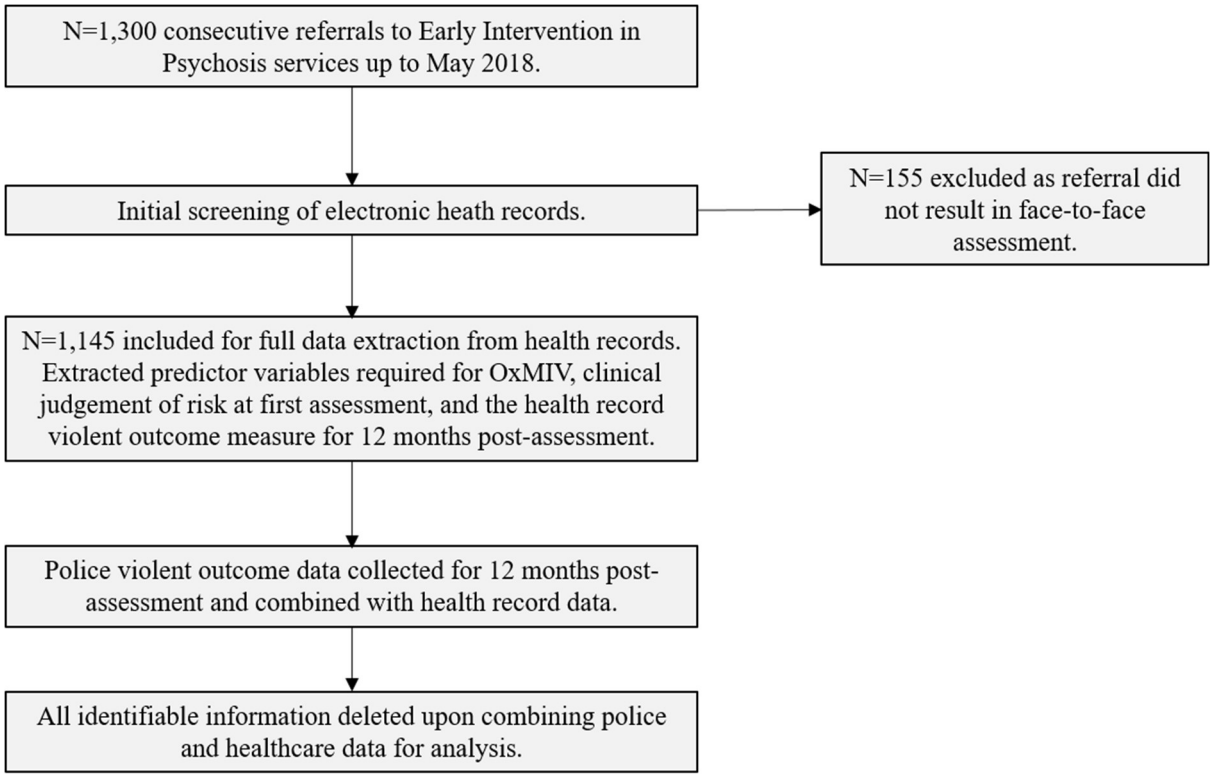
I shared and discussed the methodology of this study with a wide range of public and patient representatives. Given the "offline" nature of the study (using only routine EHR data), the primary focus of this public and patient involvement was to test the acceptability of the methodology, particularly that it did not involve individual patient consent. Input also assisted in producing the patient-facing documentation, which was limited to a poster communicating the study activity and the mechanism for dissent (Appendix 5.3) that was displayed in relevant patient areas. Over the course of the different stages of design and approval, 17 individuals were involved. This included carers and individuals with personal experience of EIP and forensic mental health services. There was positivity around the potential clinical applicability of the work. The importance of the information security safeguards, particularly the interface with police, was highlighted by representatives, who were reassured by the formal frameworks in place around this.

Results

Included population

Of the 1,300 individuals consecutively referred to EIP services from January 2012 to May 2018, 1,145 received an in-person assessment and so were included in the validation sample (see Figure 1 for summary of study processes). Of all those assessed, 131 (11.4%, 95% CI 9.7%-13.4%) perpetrated a violent outcome in the 12 months after first assessment (defined as the date of the first physical contact with the assessing clinician from the EIP service). Of these 131 violent outcomes, 55 were captured in police data only, 43 in both police and EHR data, and 33 in EHR data only. Of all 1,145 individuals assessed, 845 (74%) were offered follow-up under EIP services, of whom 85 (10.1%, 95% CI 8.2%-12.3%) perpetrated a violent outcome. Of those not followed-up by EIP services, 46 (15.3%, 95% CI 11.7%-19.9%) perpetrated a violent outcome.

Figure 1 Flow chart of study processes.



The prevalence of predictors in the validation cohort is presented in Table 2, alongside their prevalence in the Swedish development sample.[86] As expected for a first episode cohort, the validation sample was younger in age (average 25 years vs. 44 years in the development cohort). The largest absolute difference in prevalence of a clinical predictor was that of history of self-harm, present in 43% of those assessed by EIP services but only 20% of the development cohort. This is likely due to a difference in severity threshold captured by the register record of hospital-presenting self-harm in the development sample, in contrast to the reliance on self-report for the recording of this information in the EHRs used for validation. There was also a notably lower prevalence of individuals receiving benefits in the external validation cohort, likely an artefact of mapping the definition across international welfare systems.

Table 2 Distribution of outcome and predictors in validation cohort and original Swedish development sample.

Predictor	**Validation cohort (n=1,145)**	**Development sample[86] (n=58,771)**
12 month violent outcome, n (%)	131(11%)	830 (1%)
Male, n (%)	687 (60%)	29,077 (49%)
Age (years), mean (SD)	25 (10)	44 (13)
Previous violent crime, n (%)	103 (9%)	9,212 (16%)
Missing	12 (1%)	
Previous drug misuse, n (%)	237 (21%)	7,123 (12%)
Missing	3 (0%)	
Previous alcohol misuse, n (%)	83 (7%)	8,897 (15%)
Missing	2 (0%)	
Previous self-harm, n (%)	489 (43%)	11,510 (20%)
Missing	4 (0%)	
Educational level, n (%)		
Lower secondary	348 (30%)	17,814/50,752 (35%)
Upper secondary	312 (27%)	26,449/50,752 (52%)
Postsecondary	324 (28%)	6,489/50,752 (13%)
Missing	161 (14%)	
Parent drug or alcohol misuse, n (%)	134 (12%)	5,214/47,957 (11%)
Missing	137 (12%)	
Parent violent crime, n (%)	34 (3%)	3,203/47,957 (7%)
Missing	489 (43%)	
Sibling violent crime, n (%)	19 (2%)	4,028 (7%)
Missing	522 (46%)	
Current episode inpatient, n (%)	214 (19%)	18,160 (31%)
Missing	0 (0%)	
Recent antipsychotic treatment, n (%)	568 (50%)	18,401/34,039 (54%)
Missing	0 (0%)	
Recent antidepressant treatment, n (%)	378 (33%)	13,255/34,039 (39%)
Missing	0 (0%)	
Recent dependence treatment, n (%)	14 (1%)	1,030/34,039 (3%)
Missing	1 (0%)	
Personal income category, n (%)		
Low	194 (17%)	5,444/57,867 (9%)
Stable	941 (82%)	(first decile)
Missing	10 (1%)	
Benefit recipient, n (%)	155 (14%)	37,210/57,876 (64%)
Missing	59 (5%)	

Missing data

Of the 16 predictors, 11 were present in the external validation dataset with a missingness of 1% or below (Table 2, Figure 2). Three predictors were missing at 5%-14%. These were benefit recipient (5% missing), parental drug or alcohol use (12%), and highest education (14%). Parental and sibling history of violent crime were more substantially missing, in 43% and 46% respectively. In 950 cases (83%), two or fewer of the 16 predictors were missing, and 471 (41%) were complete cases with no missing data (Figure 3). The most complete predictors were as expected in terms of the most core aspects of history and the structure of documentation within the EHR.

Figure 2 Proportions of missing data for each individual predictor in the validation dataset. See Table 1 for predictor codes.

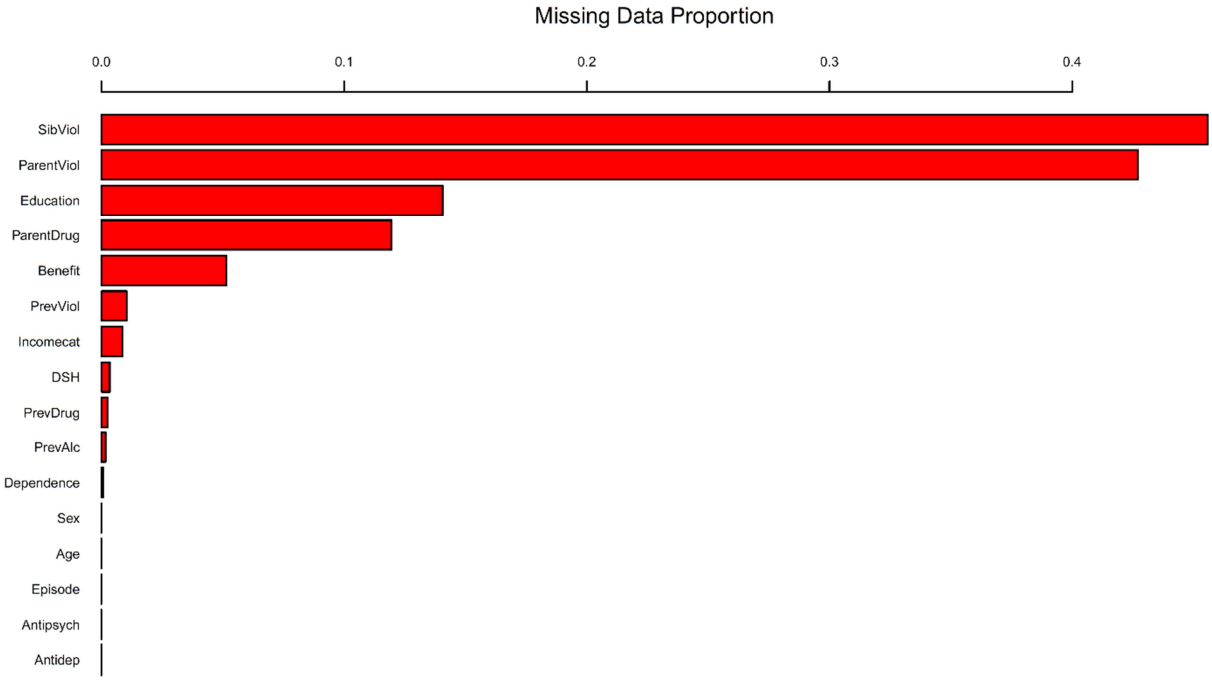
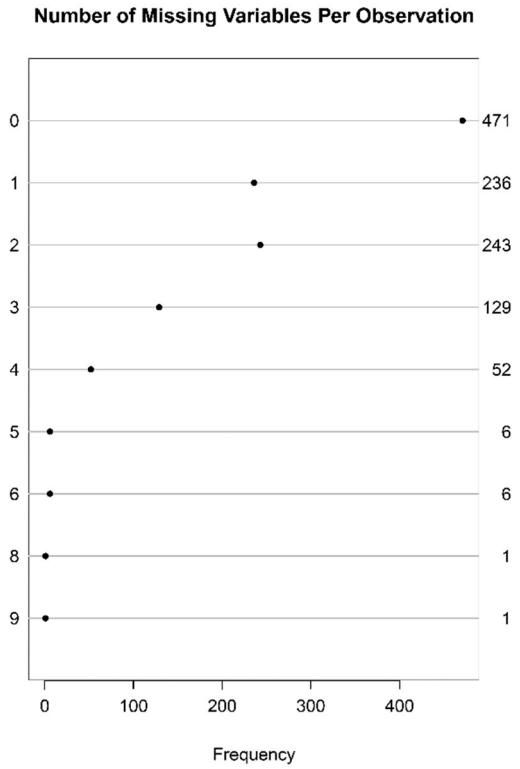


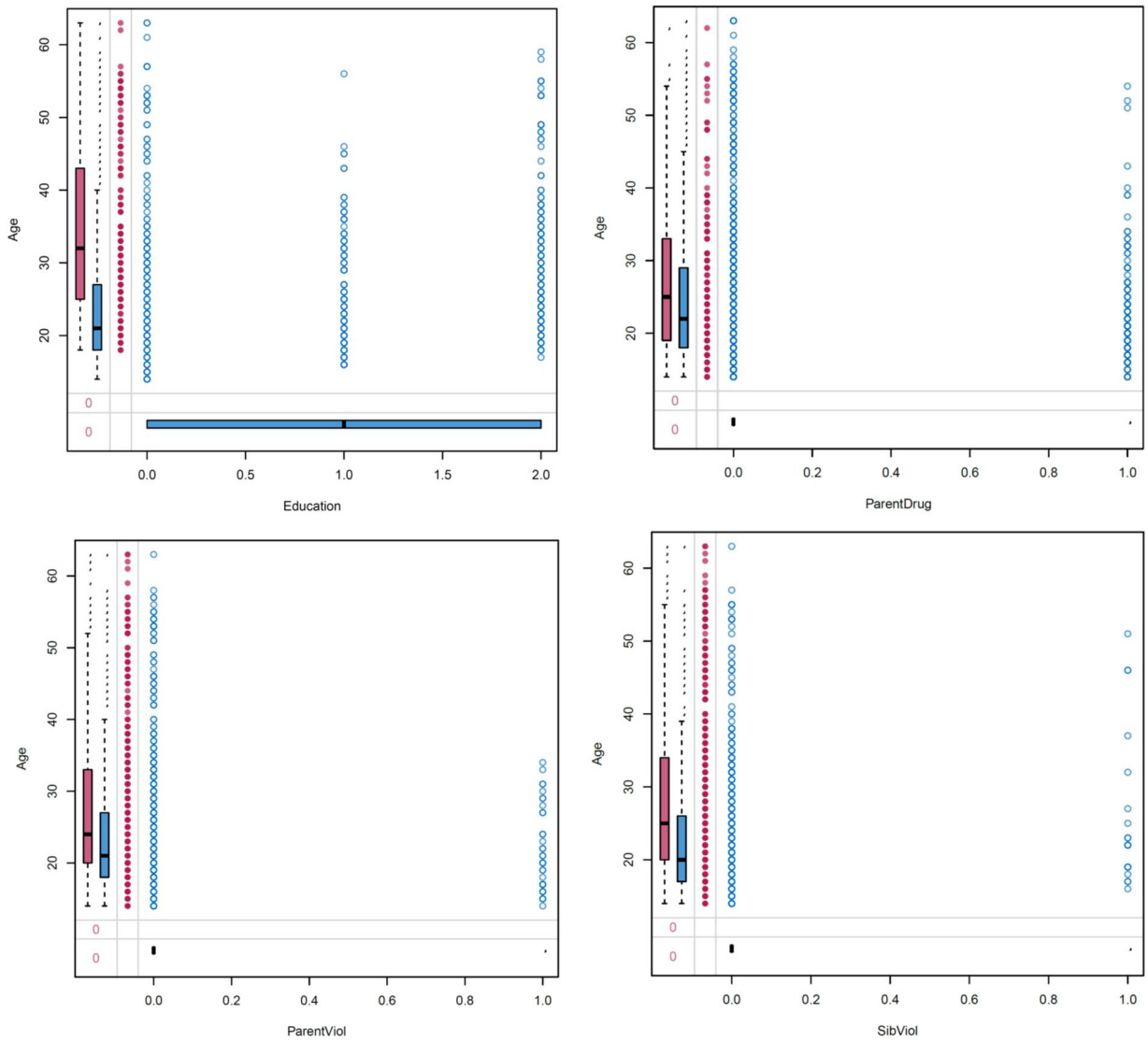
Figure 3 Number of missing predictors per case. Left column indicates number of missing predictors, right column total cases with that number of missing predictors.



Examining the patterns of missingness among predictors (Appendix 5.4) showed that the family history items tended to be missing together; the most frequent overlap was for sibling violence and parental violence, which were both missing in 32% of cases. Clinically, it is plausible that the missingness of these two family history items depended on the level of detail of the assessment, rather than the missing value itself (i.e. an MAR pattern). Further, it would be expected that family history items would be less complete in older individuals (an observed variable), and more complete in individuals whose reference episode is a hospital admission (also an observed variable), as this typically means a fuller admission summary is documented with mandatory components. Margin plots (Figure 4) showing the distribution of age when each of four predictors were either observed or missing (sibling violence, parental violence, parental drug and alcohol use and education) were in line with individuals with unobserved predictors tending to be older, in keeping with MAR. Generalised linear models

showed that missingness of education and the three family history items was positively associated with age (i.e. older individuals were more likely to have these predictors missing), violating the MCAR assumption but in keeping with MAR (Appendix 5.5).

Figure 4 Margin plots of age distribution for cases in which indicated predictor (education, parent drug or alcohol use, parent violent crime or sibling violent crime) is missing (red) or observed (blue).



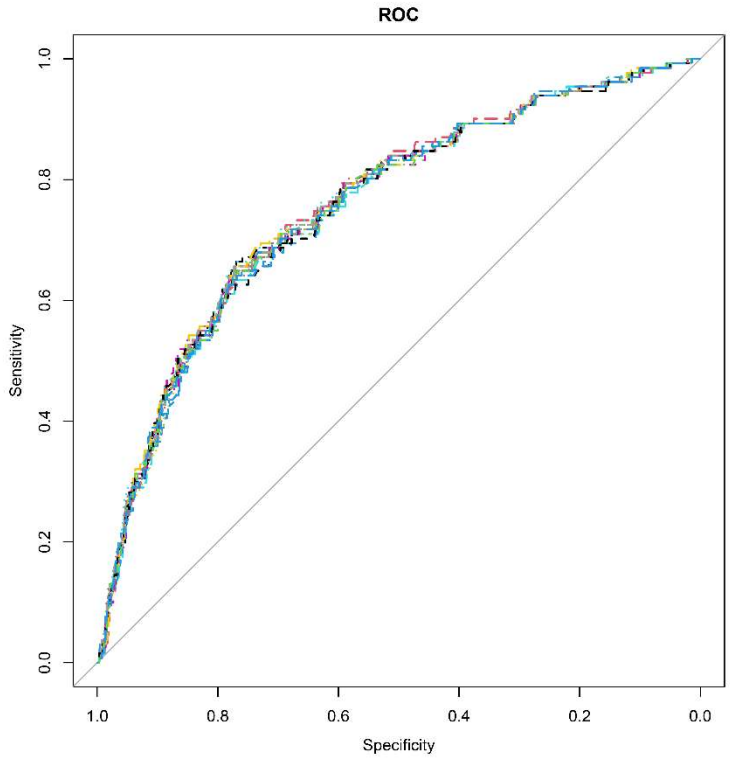
Missing data was imputed using the described methods. Visual inspection of stacked bar charts of the distribution of predictors in observed data and each imputed dataset showed the

imputation model produced sensible proportions for the five predictors for which missingness was 5% or more (Appendix 5.6).

Model performance and updating

When the original OxMIV model was applied to individuals in the external validation dataset, discrimination as measured by pooled AUC was 0.75 (95% CI 0.71-0.80) (Figure 5). The Brier score was 0.11, where Brier score is measuring overall model fit with range from 0 to 1, with better scores being closer to zero.

Figure 5 ROC plot for 20 imputed datasets. Pooled AUC 0.753 (0.708-0.799).



As expected due to the different outcome prevalence, there was miscalibration with the model under-predicting outcomes (Figure 6a). Expected/observed ratio was 0.18, CITL was 2.00 (95% CI 1.80-2.19) and the calibration slope was 0.84 (95% CI 0.66-1.03). Recalibration by updating the intercept corrected the expected/observed ratio to 1.00 and CITL to 0.00 (95% CI -0.20-0.20) (Figure 6b). The Brier score improved to 0.09. Discrimination and CITL were

unchanged. Visual inspection of calibration plots (see Figure 6a-c for calibration plots in one imputed dataset) suggested that residual miscalibration was largely at the upper end of predicted probabilities, which is less clinically important as this would likely be above any decision threshold used for the tool. This was improved by additionally updating the model by using the calibration slope as a rescaling factor. This corrected the calibration slope to 1.00 (95% CI 0.79-1.21). Overall performance as measured by the Brier Score however did not materially change (0.09), as expected as only the calibration slope was changed. As further improvement with rescaling was limited, and the model with only the updated intercept showed adequate calibration around likely decision thresholds, the model with only the updated intercept was selected. See Appendix 5.7 for performance of the original and updated models across each of the 20 individual imputed datasets, and Appendix 5.8 for the model coefficients including the updated intercept.

Figure 6a Calibration plot with 10 risk groups for original model in one imputed dataset. Histogram above legend represents distribution density of predicted risks within dataset.

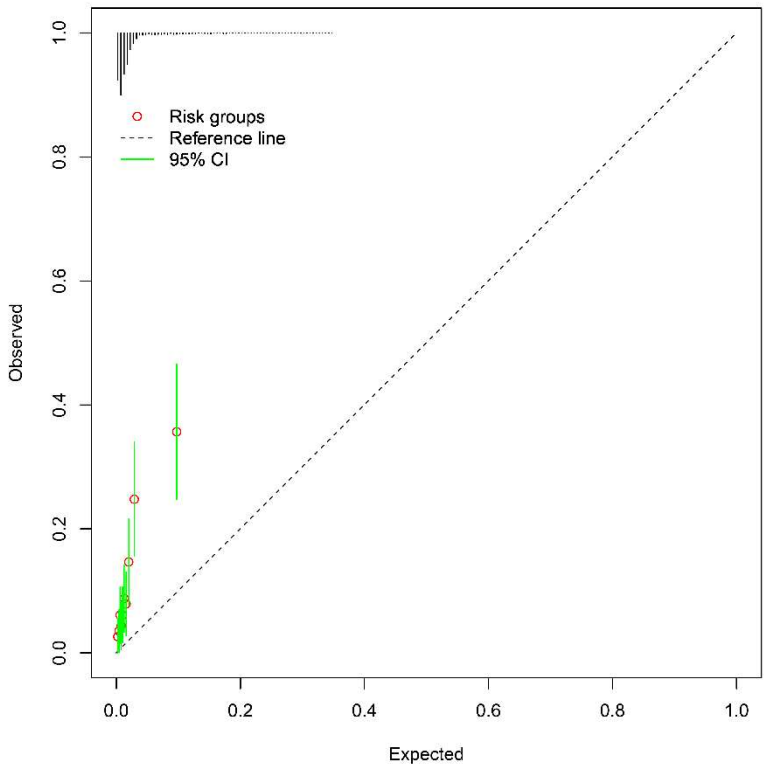


Figure 6b Calibration plot with 10 risk groups for model with updated intercept in one imputed dataset.

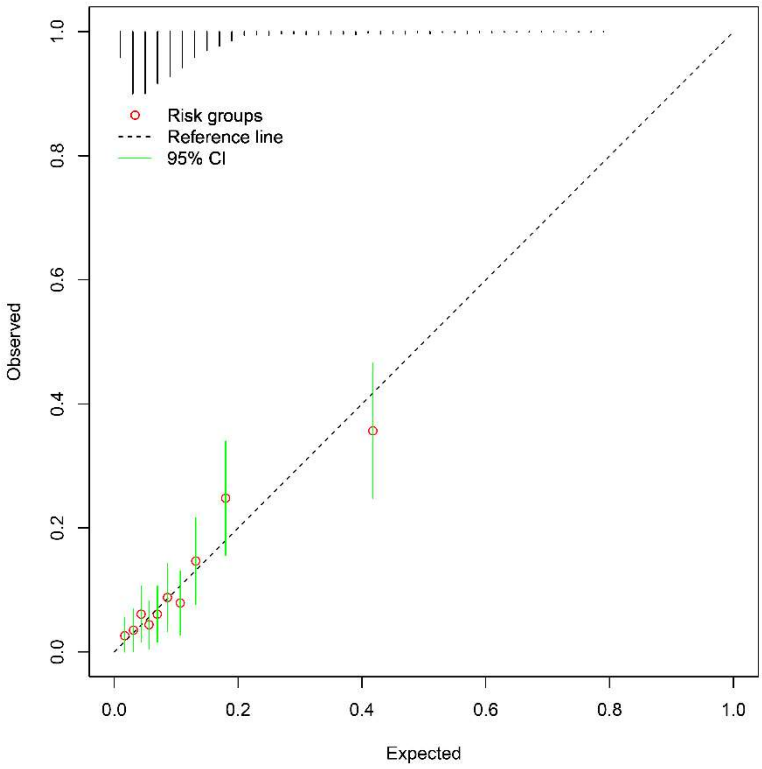
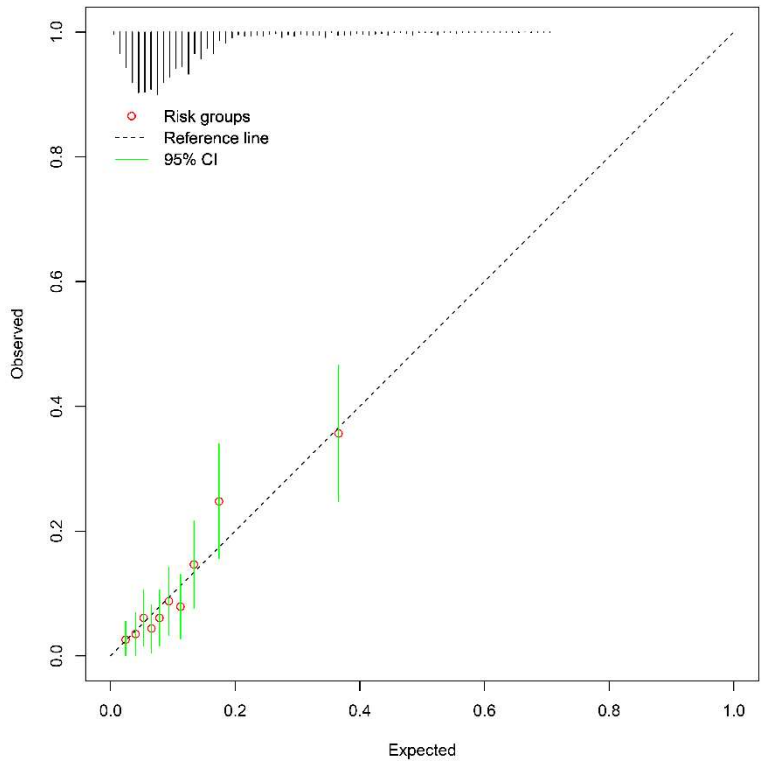


Figure 6c Calibration plot with 10 risk groups for model with updated intercept and rescaled coefficients in one imputed dataset.



Decision threshold, clinical context and net benefit

A range of clinically relevant cutoffs was considered for the updated model in external validation. Table 3 shows the sensitivity, specificity, PPV and NPV across this range.

Table 3 Paired misclassification measures for updated model across range of cutoffs in one imputed dataset.

	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%	20.0%
Sensitivity (95% CI)	0.98 (0.93-1.0)	0.89 (0.83-0.94)	0.83 (0.76-0.89)	0.72 (0.63-0.79)	0.63 (0.54-0.71)	0.51 (0.42-0.60)	0.37 (0.28-0.46)
Specificity (95% CI)	0.11 (0.09-0.13)	0.33 (0.30-0.36)	0.53 (0.50-0.56)	0.66 (0.63-0.69)	0.78 (0.75-0.81)	0.84 (0.82-0.87)	0.91 (0.89-0.93)
PPV (95% CI)	0.12 (0.12-0.13)	0.15 (0.14-0.16)	0.19 (0.17-0.20)	0.22 (0.19-0.24)	0.27 (0.23-0.30)	0.30 (0.25-0.34)	0.35 (0.28-0.42)
NPV (95% CI)	0.97 (0.92-0.99)	0.96 (0.94-0.98)	0.96 (0.94-0.97)	0.95 (0.93-0.96)	0.94 (0.93-0.95)	0.93 (0.92-0.94)	0.92 (0.91-0.93)

The optimal cutoff depends upon the consequences of false negatives (i.e. the harm of the adverse outcome), and the nature of the intervention linked to the tool. With a more resource intense intervention, or one associated with potential adverse consequences, one would prioritise specificity over sensitivity. Vice versa, with a less resource intense and non-harmful intervention, high sensitivity would be more relevant. This balance was also considered by visualising the number of individuals who would be identified as high risk or low risk, and the proportion of those who are true positive or true negative, at different thresholds (Figures 7a and 7b). Cutoffs of around 10% to 12.5% provide most balance between sensitivity and specificity. Further consideration of the optimal cutoff would also involve the views of clinical stakeholders in the context of a more clearly defined linked intervention (discussed further in Chapter 6).

Figure 7a Relationship between individuals identified as high risk and true positives across range of cutoffs from 0%-50%.

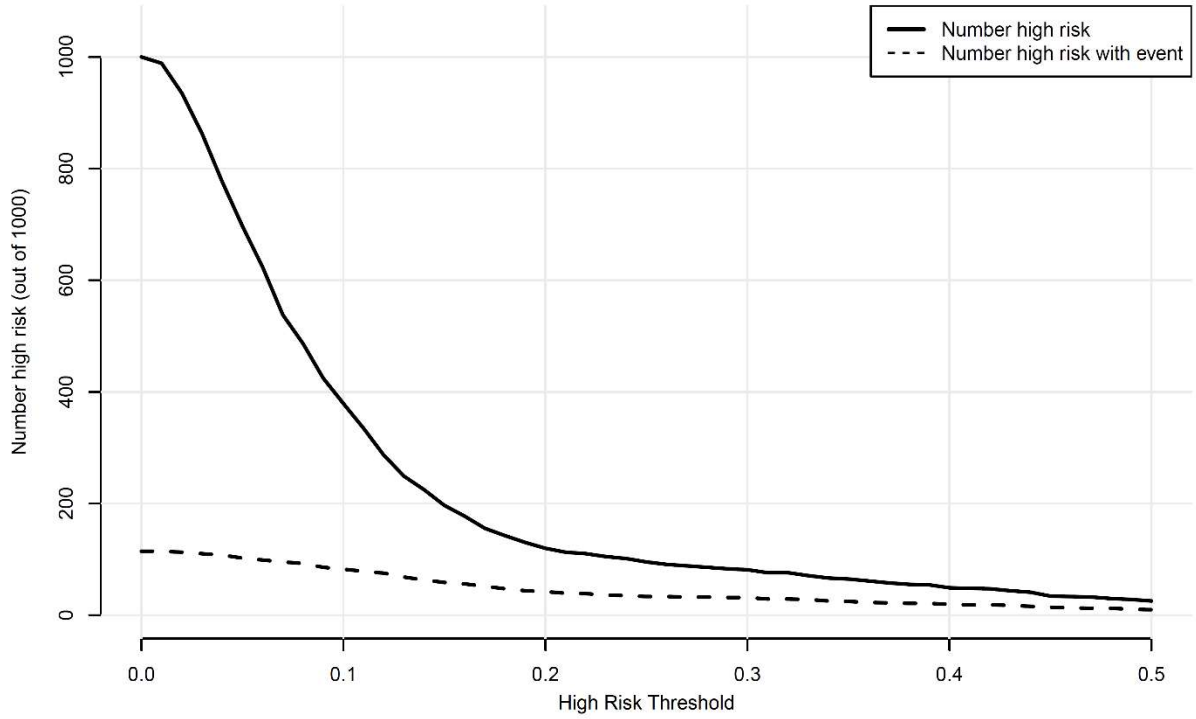
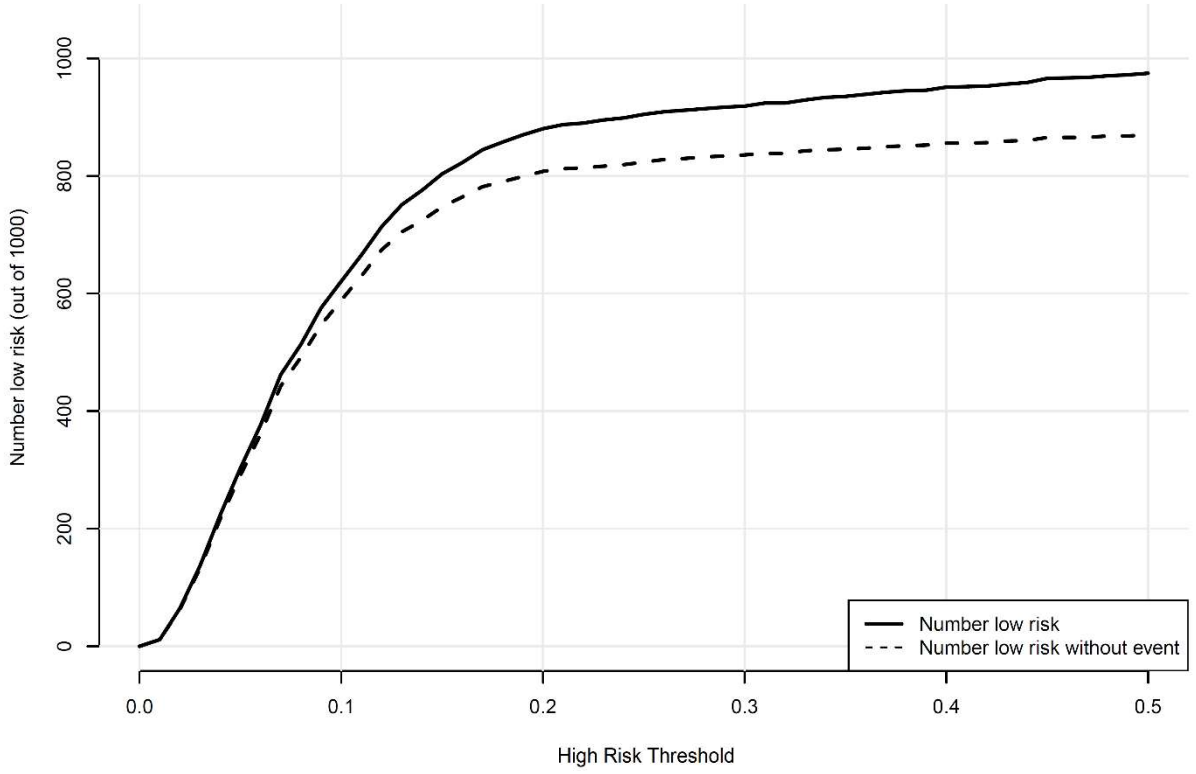


Figure 7b Relationship between individuals identified as low risk and true negatives across range of cutoffs from 0%-50%.



The nature of the unstructured clinical risk ratings from the EHR is also relevant to choosing the appropriate cutoff for OxMIV. Clinicians identified violence risk in a relatively low proportion of individuals they assessed. Violence risk was only noted as potentially relevant in 167 (15%) of all 1,145 individuals assessed, and in only 52% of the 103 individuals who disclosed a previous violent offence. This approach had high specificity but low sensitivity (Table 4). Of the 131 individuals who developed a violent outcome, 52 (40%) had been noted as having any potential needs around this in the clinical assessment.

Table 4 Paired misclassification measures of OxMIV and the original unstructured clinical judgement.

	OxMIV at 10% cut-off	Unstructured clinical judgement
Sensitivity	71%	40%
Specificity	66%	89%
PPV	22%	31%
NPV	95%	92%

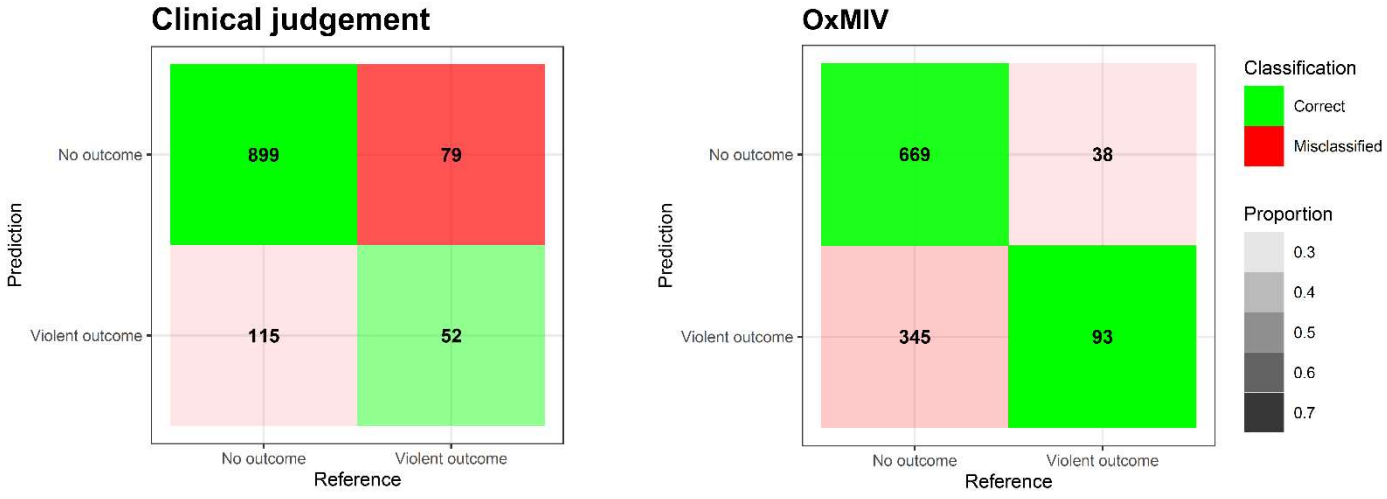
Examining the characteristics of 79 individuals misclassified as false-negative by unstructured clinical judgement (i.e. no needs around violence risk noted in original clinical assessment, but developed a violent outcome in 12 months) showed these were typically males in their early 20s who would have scored on average 18% using OxMIV (Table 5). Patterns of missing data were comparable to those in the overall cohort (data missing in 10% for education, 13% for parental drug misuse, 49% for parental violence, and 44% for sibling violence). Examination of individuals misclassified as false-positive by unstructured clinical judgement (i.e. risk identified by assessing clinician but no violence in 12 months) showed that these on average would have matched with OxMIV ratings (average 20%, Table 5). It is also possible that a treatment effect may partly account for these misclassifications, if identifying the risk led to some management that prevented an outcome. Patterns of missing data were again similar (education 15%, parental drug misuse 15%, parental violence 50%, sibling violence 55%).

Table 5 Characteristics of individuals misclassified by unstructured clinical judgement. OxMIV scores based on one imputed dataset.

	False-negative on unstructured clinical judgement (n=79)	**False-positive on unstructured clinical judgement (n=115)**
Male, n (%)	65 (82%)	93 (81%)
Age (years), mean (SD)	23 (8)	26 (9)
Previous violent conviction, n (%)	13 (16%)	31 (27%)
Mean OxMIV score (95% CI)	17.6% (14.3%-20.9%)	19.8% (16.3%-23.2%)

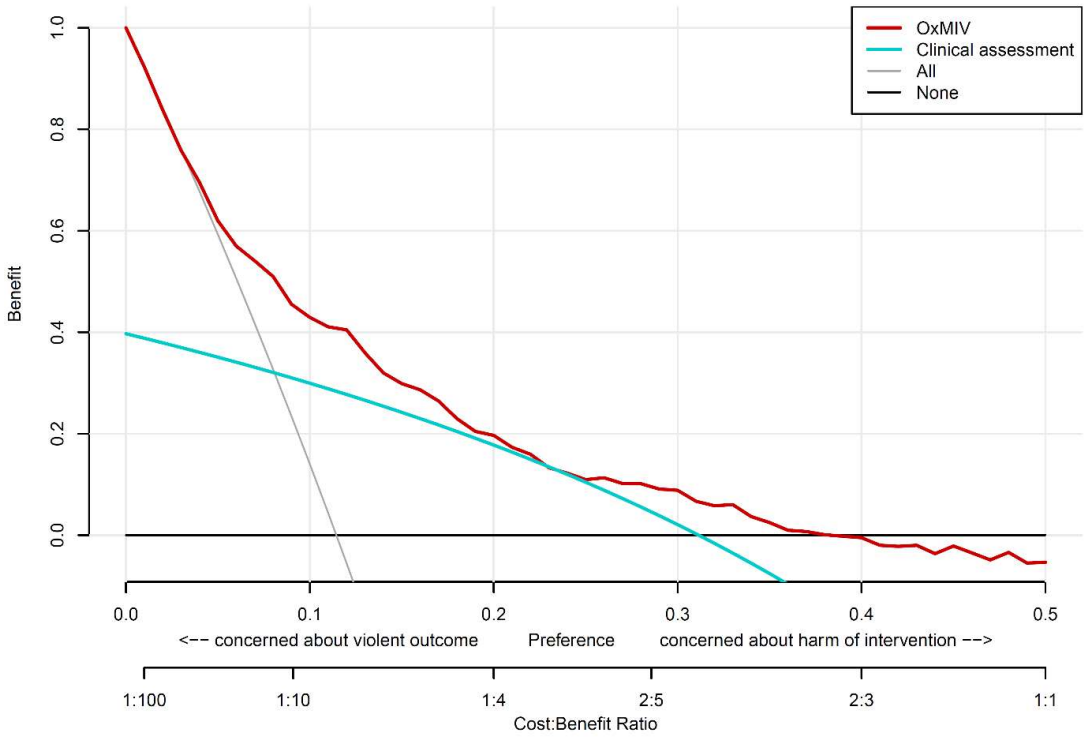
Taken together, these results highlight false-negative clinical judgements, i.e. low sensitivity of clinical assessment, as the key target for improvement. This suggests that OxMIV should most helpfully favour sensitivity, in which case choosing a 10% cutoff provides optimal balance. At this threshold, sensitivity of OxMIV was 71% (95% CI 63%-80%), specificity 66% (95% CI 63%-69%), PPV 22% (95% CI 19%-24%) and NPV 95% (95% CI 93%-96%) (see Appendix 5.9 for performance in individual imputed datasets). Figure 8 shows 2x2 error matrices for unstructured clinical judgement and OxMIV.

Figure 8 Error matrices for unstructured clinical judgement and OxMIV at 10% cutoff. Numbers in squares are for true negative, false negative, false positive and true positive cases. Density of shading of squares is relative to proportion of reference group.



The net benefit of OxMIV was compared to that of unstructured clinical judgement against default strategies of "treating all" and "treating none". OxMIV was the optimal strategy across a range of clinically relevant preferences or cutoffs for OxMIV (Figure 9). Note that the performance of unstructured clinical judgement is as per the data presented, i.e. 40% sensitivity and 89% specificity, and what is varied to produce the clinical judgement curve is the weighting preference for the relative harms of misclassification. For OxMIV at a 10% cutoff (chosen as per the discussion above), net benefit was 4.8%, meaning that an additional 43% of those who go on to perpetrate violence (standardised net benefit) could be offered intervention. For clinical assessment at this preference, net benefit was 3.4%, or an additional 31% of those who perpetrate violence. The relationship was also plotted if used to screen individuals out of an intervention (Appendix 5.10). Figure 9 is for an imputed dataset in which OxMIV performed in the mid-range. See Appendix 5.11 for plots in imputed datasets

Figure 9 Net benefit across a range of preferences, where Cost:Benefit Ratio represents the acceptable number of individuals identified as high risk in order to identify each true positive. Plotted for OxMIV, unstructured clinical judgement, and default strategies of "treat



in which OxMIV was at the lower and upper end of its performance range across the 20 imputed datasets. These do not provide materially different conclusions.

Discussion

This study is the first external validation of a prediction model for violence in UK EIP services. It used routine clinical documentation and pragmatic clinical risk factor definitions to validate OxMIV in a manner that reflects its potential clinical use. In a cohort of 1,145 individuals consecutively assessed by EIP services, 131 (11%) perpetrated a violent outcome in the subsequent 12 months. OxMIV showed robust discrimination for prediction of violence (AUC 0.75, 95% CI 0.71-0.80). Calibration was adequately corrected by updating the intercept to reflect the event rate for this population and outcome definition. Using a risk cut-off of 10%, sensitivity was 71%, specificity 66%, PPV 22% and NPV 95%. Decision curve analysis showed a net benefit of OxMIV over clinical judgement and default strategies of treating all or none across a range of clinically sensible cutoff preferences between 5% and 35%. There are several implications of these findings for the potential clinical role of OxMIV in these services, and for future clinical prediction model research.

In terms of the clinical need for a prediction tool, the relevance of violence as an adverse outcome in this setting was clearly demonstrated. In this large clinical cohort, 9% disclosed a prior violent conviction at the point of assessment, and 11% perpetrated violence in the subsequent year. This is in line with previous studies in these clinical services, and of the peri-diagnostic period in schizophrenia spectrum disorders.[67,68,75] The high prevalence of two of the strongest modifiable risk factors for violence, drug and alcohol misuse comorbidity[57] (present in 21% and 7% respectively), further underlines the importance of identifying clinical needs and offering interventions that can reduce violence risk. The pattern with which violence risk was noted by assessing clinicians however suggests that identifying these needs

with unstructured judgement alone is suboptimal. Clinicians identified risk in only 40% of individuals who went on to perpetrate violence in the next year, among whom on average objective clinical predictors for violence were demonstrably present. A key need is therefore for methods to improve the sensitivity of routine assessments.

The performance of OxMIV in external validation suggests that it could help improve these clinical assessments. Although comparing the discrimination of prediction models for diverse outcomes and clinical contexts gives little indication of clinical utility, the AUC in external validation of 0.75 is broadly comparable to tools adopted into clinical use in other areas of medicine,[148,184,185] and to models developed in early psychosis populations for outcomes such as transition to psychosis[27] and cardiometabolic risk.[30] It also compares favourably with two other violence risk assessment instruments (HCR-20 and VRAG) whose predictive accuracy has been studied in individuals with psychosis.[90,186-188] As detailed in Chapter 1 these tools are lengthy and resource-intensive however (i.e. unfeasible for EIP settings), and were studied in forensic psychiatric populations rather than general psychiatric settings. There are no other simple violence risk assessment tools either used routinely or studied in equivalent settings with which to directly compare OxMIV.

OxMIV retained discriminative performance in external validation despite some differences in the casemix of the validation sample compared to the Swedish population in which the model was first developed and externally validated.[86] The EIP population was younger, with other notable differences in the prevalence of drug and alcohol misuse, history of self-harm, and being in receipt of benefits. This was likely due to a combination of differences in the mix of the populations and the use of operationalised definitions for predictors, in order to pragmatically extract them from routine clinical records rather than population registers. The performance despite these challenges provides evidence for the transportability of the model. Further, by not applying strict diagnostic inclusion criteria, the findings are applicable to

"real-world" clinical practice in this particular setting, where diagnostic uncertainty is common.

Calibration was an important consideration, as the event rate of 11% in the validation sample was substantially higher than the 1% in the development study. This was expected, due to the use of a broader outcome measure for violence than that of conviction alone as was used in development.[86] Applying the original model therefore under-estimated observed outcomes in the EIP sample. This is important if predictions in absolute terms are to be used for clinical decision-making or discussion. Re-estimating the constant of the model (i.e. the intercept) to account for this new baseline event rate adequately corrected this miscalibration, without altering the effect or weighting of any of the predictors. This step is essential to adequately apply a prediction tool in a given target clinical setting, yet is frequently overlooked.[149]

In terms of other transferrable methodological implications, this study has shown the feasibility of externally validating a prediction model using only routine EHR data in a psychiatric setting, even when predictors are not recorded as structured fields. This is provided that included predictors are those that are relevant and used in routine practice. The scale at which such an approach can be applied could be improved using techniques such as natural language processing to extract data from free-text fields in a more automated manner.[189] The level of missing data encountered with this approach was within the range of that which is addressable with imputation techniques to minimise bias and incorporate appropriate uncertainty into the final performance estimates.[156] It was also shown that tightly-defined register-based predictors can be successfully translated into more pragmatic and usable definitions for validation and clinical use.

Clinical role

The clinical role and potential benefit of OxMIV can only be appraised with reference to the clinical decision pathway that it would inform. Incorporating information on the benefits of correctly identifying more "true positive" individuals, and the harms of misclassification, is challenging in a clinical scenario for which the linked intervention is 1) not currently well developed or standardised, and 2) likely to be complex i.e. multi-faceted and individualised. However, decision curve analysis allowed this subjectivity to be incorporated by examining a spectrum of preferences for whether minimising false negatives or minimising false positives is more important. To compare OxMIV with other approaches, net benefit was calculated – a measure of additional true positives weighted for a given preference. This showed OxMIV to provide favourable net benefit compared to unstructured clinical judgement, or offering an intervention to everyone or no one, across a clinically sensible range of relative weighting preferences.

The net benefit gives an indication of the potential clinical value of OxMIV, but it is important to note that OxMIV would complement, rather than replace, the unstructured clinical judgement with which it is compared. The key limitation of unstructured clinical judgement was its low sensitivity of 40%, compared to 71% with OxMIV at a 10% cutoff. Therefore, in simpler terms the core clinical role of OxMIV identified in this study may be that of improving sensitivity. It could support clinicians to identify more clinical needs around violence risk and offer additional support or treatment to a greater number of individuals for whom this might prevent a violent outcome, without simply offering this intervention to an unfeasibly large proportion of individuals, or to those for whom it is clearly not a clinical need. One way to understand how the performance of OxMIV may address this is that, at the 10% cutoff, it would have identified potential violence risk needs in around an additional 271 individuals out of 1,145 assessed, and in so doing offered intervention to

around an additional 41 of the 131 individuals who did develop a violent outcome. The impact of this improvement in prediction on violent outcomes will in turn depend on the effectiveness of linked interventions.

When considering the nature of linked interventions, it is important to consider that the positive predictive value of OxMIV at the 10% cutoff was 22%. This means that around 1 in 5 individuals classified as being at risk with this approach developed the outcome. Therefore, any intervention linked to this decision threshold clearly needs to be non-harmful in nature. There are examples of a 10% decision threshold informing practice elsewhere in medicine, such as whether to offer a statin to reduce the risk of cardiovascular disease.[190] The findings of this study show that OxMIV performs adequately in this target clinical setting to have a role in a stratified intervention pathway for violence risk. The understanding gained of the likely net changes in classification compared to current practice is important to inform any future work to implement and test a stratified intervention pathway for violence risk.

Strengths and limitations

By externally validating OxMIV in a relevant target clinical setting, and doing this in a manner akin to its clinical use, this study represents a stage of clinical prediction model research which is absolutely critical for adoption of prediction tools and yet only found to be undertaken in a minority of prediction tools.[9,27] In addition, this validation study was adequately powered (including over 100 individuals with the event and over 1,000 without the event) and provides information on OxMIV's performance that can be directly applied to develop its clinical role. The richness of this information is enhanced by the data obtained on the unstructured risk judgements made by assessing clinicians. Throughout, high quality methods and reporting were followed,[44,150] including in the examination of calibration and approach to missing data.

A key strength specific to this clinical scenario is the use of a hybrid violent outcome measure that combined EHR and police data. This ensured it was both clinically meaningful (with an objective threshold and inclusive of serious inpatient violence that may not be reported to police), and did not miss outcomes in individuals who have lost contact with health services. This is particularly important as loss of contact may be directly due to having perpetrated violence. Relying solely upon healthcare data risks excluding those individuals whose unmet clinical needs are the primary focus of the study, and indeed for 42% of the 131 individuals who developed the outcome this was indicated by police data only.

The use of routine EHR data was necessary to allow data collection to occur offline from clinical practice. There is a limitation however to the quality and completeness of extracting data that was not specifically recorded for a particular purpose. One important predictor that is likely to have been under-reported is that of a past violent conviction. Although using official conviction data for this predictor would have improved its accuracy, an important argument against this approach is that this information is not routinely available at the time of clinical assessment, and it would therefore not be clinically meaningful to incorporate this additional information in the validation. In any case, the principle of data minimisation in ethical permissions (i.e. obtaining only the information necessary to undertake the study) precluded adopting this approach.

The study incorporated information from two English counties. There is a clear national model for EIP services which would support the transferability of findings to other EIP services, however ideally the validation would have included a more geographically diverse population. A key systemic barrier to the feasibility of undertaking this particular study on a larger scale is the lack of anonymised methods for linking healthcare and police data. The solution in this case was a manual approach which, although robust in terms of data security and the quality of information obtained, has limitations in terms of being able to feasibly

apply this across geographical areas precluding external validation studies at a significantly larger scale.

Conclusion

This study externally validated the OxMIV violence risk prediction model for EIP services using routine data, pragmatic and clinically-operationalised predictor definitions, and an objective and clinically important measure of violent outcomes. The tool showed sufficient discriminative and overall performance, and was adequately calibrated around relevant decision thresholds by updating the intercept in line with the prevalence of the outcome in this setting. Net benefit and measures of misclassification suggest a benefit of OxMIV compared to current practice, with a potential clinical role of primarily improving the low sensitivity of 40% of unstructured clinical assessments. This could support clinicians to appropriately allocate more non-harmful interventions for reducing violence risk to those most likely to gain benefit.

This results of this study complement the findings of Chapters 3 and 4 on the challenges of assessing risk in EIP services, the practical use of OxMIV, and its likely role and impact. In the next, final chapter, I will discuss all these findings together, and develop a framework for a stratified assessment and management pathway that the tool might inform.

Chapter 6
Discussion and conclusions: towards a stratified medicine approach to violence risk assessment and intervention in Early Intervention in Psychosis services

Introduction

In this thesis, I have described different stages of applying prognostic research methods to assist the important but challenging clinical process of assessing and managing violence risk in clinical services for first episode psychosis (known as Early Intervention in Psychosis [EIP] services). I have used qualitative methods, mixed methods, and contemporary statistical approaches to external validation and model updating to examine the performance of a violence risk prediction model (OxMIV) in this setting, and the complex issues around its use as a clinical tool. To return to the thesis aims introduced in Chapter 1, these were:

1. How is violence risk assessment and management currently approached in clinical services for first episode psychosis (FEP), and what challenges and needs are there?
2. Could a violence risk prediction tool (OxMIV) have utility in this clinical setting, and how can this be studied?
    a. Is it clinically feasible and acceptable?
    b. Can its accuracy be externally validated, and performance optimised for clinical use in this setting?
    c. What is the likely impact and benefit of its use?
    d. How can it best be integrated into stratified management for violence risk, and how can this be evaluated?

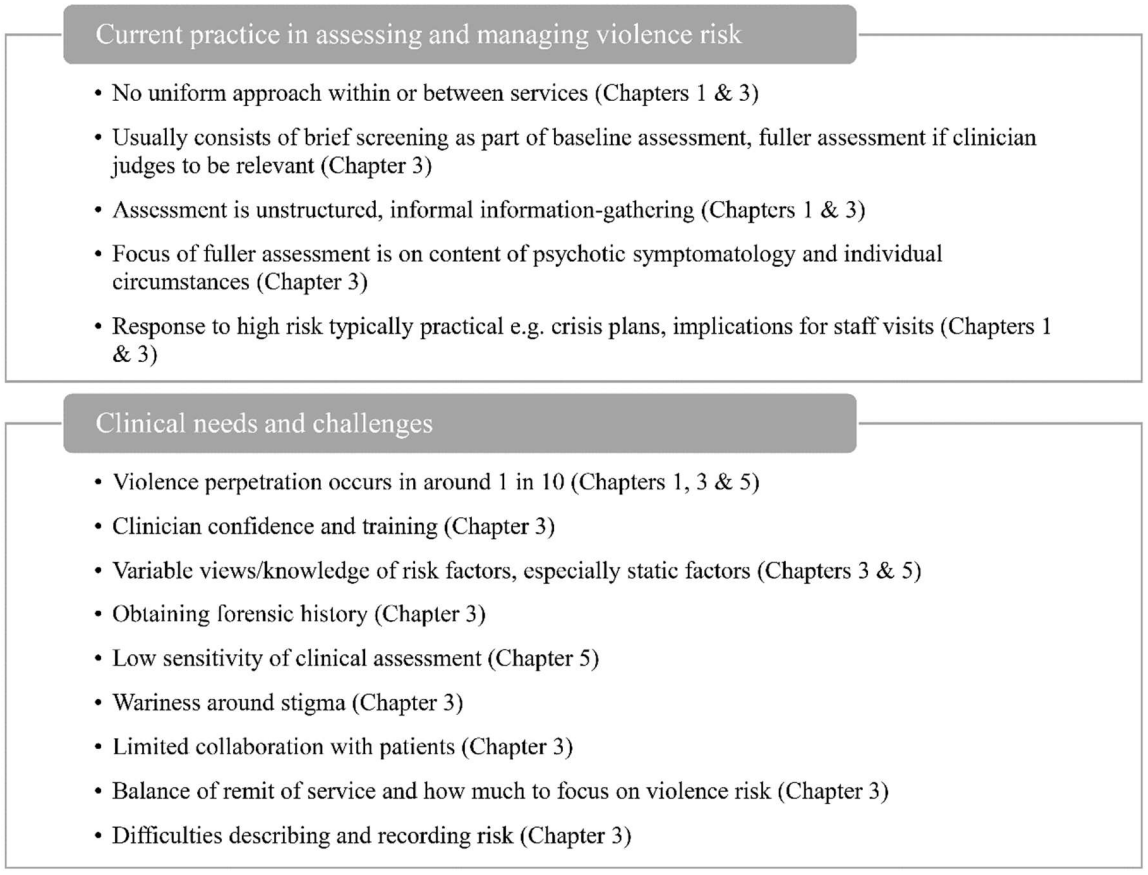
In this final chapter, I will discuss each of these aims in turn by bringing together relevant findings from the results detailed in Chapters 3, 4 and 5, set in the context of the background

detailed in Chapter 1. In doing so, I will outline the development of a framework for how the updated OxMIV prediction tool can be integrated into clinical practice, linked to suggested interventions, and the impact of this further examined. I will also discuss research limitations and the transferrable methodological implications for the field of prognostic research, particularly in the development of mixed methods approaches for the clinical translation of prediction models.

Aim 1: Understanding current practice and clinical needs

In this thesis I have developed an understanding of the relevance of violence perpetration in EIP services, how this risk is currently approached in practice, and the areas of difficulties and need associated with this. Findings relevant to Aim 1 are summarised in Figure 1.

Figure 1 Summary of findings relevant to Aim 1, which was to understand current approaches to violence risk assessment and associated challenges and needs.



Importance of the outcome

In Chapter 1, I detailed the epidemiological literature that demonstrates the importance and increased risk of violence perpetration as an adverse outcome in psychotic illness[60,61] and FEP.[62,66,68] The findings from a cohort of 1,145 individuals consecutively assessed by EIP services (Chapter 5) make an important contribution to this epidemiological literature. Of all individuals assessed, 11% perpetrated a violent outcome in the first 12 months after assessment. As well as the size of the cohort (which is more than two-fold larger than any previous primary study in a previous systematic review of violence in FEP[68]), as discussed in Chapter 5 a strength of this research is the outcome measure used. By incorporating police data, rather than relying on patient interview or file review,[68] and by using an objective threshold to capture only incidents of a clear clinical relevance, it is an improvement on previous studies.

Thus, in terms of the epidemiology, violence perpetration has been clearly demonstrated as clinically relevant for EIP services. Baseline qualitative work with EIP clinicians (Chapter 3) aligned with this. There was consensus that, whilst affecting a minority of patients, violence is a relevant outcome that is routinely considered in clinical practice. A simple but fundamental requirement for a prediction tool to be of use is therefore met – that it is predicting an outcome that is important in the target clinical setting.

Current practice

Findings from clinician interviews (Chapter 3) tallied with the survey of regional EIP services in Chapter 1, suggesting there is no uniform approach to risk assessment and formulation in EIP services. For most patients, risk is briefly screened as one of the numerous other risks that are considered during initial assessment. It is only assessed in more depth should there be some indication of its relevance to the assessing clinician. Fuller assessment relies on the judgement and experience of the individual clinician, and typically focusses

most strongly on whether there are risks directly related to active symptoms of psychosis, or whether there are specific individuals at risk such as families. Should there be concerns around risk, it was reported that the response focuses on documenting this risk, sharing it with the team, considering whether there are implications for staff safety in how they work with the patient, and making a safety plan.

Challenges and limitations of current clinical approaches

Across Chapters 3, 4 and 5, new insight was gained into the complex challenges of identifying and reducing risk of violence in EIP services. This highlighted some key areas of clinical need on which to focus initiatives.

In the baseline interview study (Chapter 3), clinicians described lacking confidence in their expertise in violence risk assessment, particularly those who had no experiences of working in a forensic setting. This partly stemmed from having typically had much less training in violence risk compared to risk of self-harm, and many felt that they lacked foundational knowledge.

Individual variation was particularly apparent in views on static risk factors such as past violent conviction. Epidemiologically, a past violent conviction is a strong, replicated risk factor for future violence, typically the most predictive of the various clinical items that might be considered.[84,86] Clinicians had mixed views about the relevance of a previous violent conviction however, including in response to the clinical vignettes. This was also reflected in the data on the original clinical assessments in the external validation cohort (Chapter 5). There were 103 individuals who clinicians documented had a prior violent conviction at the point of assessment by EIP services, but for only 52% of these individuals were any needs around violence risk documented in the risk summary by the assessing clinician. Individuals in the validation cohort who perpetrated violence but where no risk was

noted in the original clinical assessment (i.e. false negative) on average had objectively increased violence risk factors that could have been identified. Translation of epidemiological knowledge about the factors associated with risk of violence, particularly static factors, into routine clinical practice is therefore a clinical need.

Clinicians described how, as there is currently no standard process to assess violence risk, such assessment can feel subjective and lacking a formal basis. This was also reflected in the range of responses to the clinical vignettes, particularly the different weights that clinicians placed on factors such as past history or current behaviour and engagement to form their view. There is a need therefore to improve the objectivity and consistency with which risk is assessed.

A difficulty that clinicians described in strong terms was the limited access to reliable information about an individual's forensic history, perhaps due to non-disclosure. Given that a prior violent conviction was present in at least 1 in 10 of the individuals assessed by the service (Chapter 5), this is an important issue. There was a lack of clarity about the threshold and justification needed to seek collateral history on this, such as from police. There is a need therefore to support this process of gathering past forensic history, so that clinicians are better facilitated to do so when appropriate. Interviews with patients and carers (Chapter 4) provided reassurance that this is typically viewed as an acceptable exercise, ideally done in a transparent manner.

It was identified in the baseline interview study (Chapter 3) that clinicians are wary of the potential stigma and sensitivity of discussing violence, and this can prove a barrier to raising the topic or seeking relevant information, particularly where engagement is fragile. This provides some further context to the finding that in the external validation cohort (Chapter 5), the original clinical assessment identified risk with high specificity (89%) but low sensitivity

(40%). One interpretation of this is that clinicians have a high threshold for flagging violence risk as relevant. This may be due to the fears of stigma or labelling, which might lead to clinicians placing a high value on avoiding false-positive attributions of risk, as well as the variable appreciation of the relevance of static risk factors that has been described. A linked challenge is that, for similar reasons, risk assessment is not typically in practice a collaborative process. Again, patients and carers did not share clinicians' concerns around stigma, or think that assessing needs around violence risk was necessarily problematic. They instead encouraged a straightforward approach as part of a supportive and professional interaction (Chapter 4).

Also relevant to this high threshold for clinically identifying risk is that response to violence risk is typically focussed on the acute scenario, both in clinical guidelines[57] and in the practical, safety-focussed or crisis interventions described by clinicians (Chapter 3). There is need and scope therefore for some reframing of the overall approach to violence risk, where clinicians are supported to consider it more routinely, and pursue supportive measures to reduce risk by targeting modifiable risk factors more longitudinally over the medium and longer term. This would represent a shift from focusing only on acute scenarios or seeing the identification of clinical needs around violence risk as a potentially harmful action.

An overarching challenge is the balance of risk management within the remit of EIP services, which are more recovery-focussed than focussed on risk. This was reflected by the observation that for most, consideration of violence risk consists of a simple screening (Chapters 1 and 3). A challenge is therefore to improve this, whilst remaining within the resources and remit of the service. Further, clinicians were less clear as to their role in managing risk when this was not directly related to the psychotic symptoms. There were issues around interface with other agencies and whose responsibility risk was in such situations, particularly in the context of some anxiety around professional culpability

(Chapter 3). This is also an area of need that may benefit from more clarity and support, to facilitate clinicians to identify risk and suggest helpful interventions, even when risk is not a direct effect of active psychosis.

In more practical terms, the documentation of risk assessments was noted to be suboptimal, often becoming a repository of lists of risk incidents rather than a document that provides a clear summary of risk. Time availability was a key barrier to the quality of documentation. Further, there is no set way to communicate risk either verbally or in writing (Chapters 1 and 3), and although categorical ratings were widely felt to be arbitrary, poorly defined and generally unhelpful, they continue to be used to some extent (Chapter 1). There is therefore need for greater clarity around how risk is communicated and recorded, particularly with the multiple points of intra- and inter-agency communication that were identified (Chapter 3).

Aim 2: Clinical utility of OxMIV and how it can be studied

In Chapters 4 and 5 I detailed work to examine OxMIV in a manner that was firmly anchored in the routine practice of the clinical setting of EIP services. This helped to determine from a range of perspectives whether, and how, the OxMIV model might function as a clinical tool here.

a) Feasibility and acceptability

As presented in detail in Chapter 4, an integrated mixed methods approach to examining the preliminary use of OxMIV over 12 months indicated the tool to be feasible in EIP services. It achieved good reach across the service in terms of the number of OxMIV assessments undertaken, particularly when considered as the proportion of new assessments in which OxMIV was used during the period. As below, supporting new assessments was the main role to which the tool was naturally placed. Clinicians found it quick and straightforward to complete and it did not add significantly to the overall administrative burden. Clinicians

found the interface within health records easy to use, though thought it could ideally be even more fully integrated into the general risk assessment form. Required information matched well with what was clinically available, with only the three family history items recorded as missing in just under half of cases. The availability of clinical information from the mixed methods study was reinforced by the external validation study (Chapter 5), in which it was possible to extract sufficient information to validate the tool simply from the routine documentation within health records (which had not been recorded with OxMIV in mind).

OxMIV was also broadly acceptable within the context of the service and its remit. In practice, clinicians did not feel that using the tool led to more stigma than other ways of assessing and documenting risk. Whilst a few items, such as the family items, were felt to be more difficult to ask about, none precluded clinicians using the tool, especially with the option to score as unknown. The balance between resource required and benefits (detailed below) was felt to be favourable. There was also broad alignment between the output of the tool and clinical judgement which was noted to be important for acceptability. Patients and carers thought that using a structured approach to improve assessments was acceptable and thought it could help with the openness of this process.

b) External validation

In Chapter 5, I presented a study of the external validation of OxMIV in EIP services. This had adequate power, and used routine clinical documentation, clinically operationalised predictor definitions, and an objective and clinically meaningful violent outcome measure that incorporated both clinical and police data. Discriminative performance was robust (AUC 0.75) and comparable to tools adopted into different clinical settings, as well as to other violence risk assessment tools whilst requiring a fraction of the resource (Chapter 1). Calibration was also assessed, and the model was updated by re-estimating its intercept for the higher prevalence of the outcome in this setting compared to the development study. This

adjustment sufficiently corrected calibration without requiring changes to the predictor coefficients within the model. Using a 10% cutoff, sensitivity was 71%, specificity 66%, PPV 22% and NPV 95%. The implications of these results for OxMIV's clinical role and benefit over current processes is discussed below.

This process provided evidence for OxMIV's geographical, spectrum and methodological transportability (defined in Chapter 1) respectively by demonstrating its accuracy in a UK setting, in patients presenting to EIP services without any strict diagnostic inclusion criteria (akin to its likely flexible use in clinical practice), and using data collected from routine health records rather than population registers. As has been discussed, only a minority of tools developed are externally validated, particularly so directly in a clinical setting. The updated model (including intercept and all coefficients) is presented in Appendix 5.8.

c) Benefit and impact

As I discussed in detail in Chapter 4, the clinical use of OxMIV was positively received. Feedback from clinicians on a case-by-case basis was that OxMIV assisted the overall assessment in the majority of cases, more so when there were already some concerns around violence risk. Some clinicians also found the reassurance of confirming low risk helpful. A clear finding was that the perceived utility and benefit did not depend on OxMIV altering the clinical view of risk. Clinicians spoke more around how the use of OxMIV clarified and focussed their assessment, and that the percentage score provided richer clinical information than categorical ratings by highlighting the potentially large differences in the magnitude of risk. There were broad benefits to areas such as confidence and knowledge, and these findings were relevant to several of the challenges that were identified in the baseline interview study. These relationships are presented in Table 1.

Table 1 Challenges identified in current practice and linked findings of potential benefit and impact of OxMIV.

Challenge or limitation of current practice	**Relevant finding of potential benefit or impact of OxMIV**
Clinicians have low confidence in their expertise in violence risk assessment (Chapter 3).	Clinicians felt more confident that they were not omitting important information, and found the alignment of OxMIV with their overall clinical views reassuring (Chapter 4). Clinicians stated OxMIV clarified and focused their assessments which felt more robust (Chapter 4).
Clinicians feel they lack training and knowledge of risk factors for violence (Chapter 3).	Clinicians described an educational benefit from using OxMIV and considering a broader range of risk factors, which affected their wider practice (Chapter 4).
Clinicians have mixed views about relevance of static risk factors for current risk (Chapter 3). Only half those with a previous violent conviction had violence risk noted as relevant in their clinical risk summary (Chapter 5).	Clinicians commented that having a percentage score highlighted the differences in magnitude in risk, and the higher risks in e.g. young males (Chapter 4).
Clinicians perceive their unstructured judgements as subjective and informal (Chapter 3). Views of risk in response to clinical vignettes varied (Chapter 3).	Clinicians described OxMIV acting as a prompt to ensure they consistently explored the relevant risk factors (Chapter 4).
Clinicians have limited access to forensic history and are unsure of justification needed or processes to seek this (Chapter 3).	With OxMIV clinicians felt their assessment was more robust and were more confident to e.g. take this for discussion with seniors (Chapter 4). An extension of this may be to support seeking more detailed collateral information.
Clinical risk summaries that noted violence risk as relevant predicted violence with low sensitivity (40%) (Chapter 5).	In external validation, using a cutoff of 10%, sensitivity of OxMIV was 71% (Chapter 5).
Interventions focus on crisis plans and practical safety measures (Chapter 3).	Clinicians were broadly open to development of a more directive output to suggest approaches to modifiable factors (Chapter 4).
Risk assessment documents can become disorganised and difficult to gain an overall summary from (Chapter 3).	Provision of an output from the assessment (i.e. risk score) was a novel aspect compared with standard risk assessments and was positively received (Chapter 4). Even where risk was low clinicians found it helpful as a way to summarise multiple prior risk assessment documents if these were unclear (Chapter 4).

No standard manner to document or communicate risk, categories deemed unhelpful but still used to some extent (Chapters 1 and 3).	Clinicians found the categorical and percentage scores easy to interpret and were explained clearly within the tool (Chapter 4).
Clinicians are wary of reinforcing stigma and the sensitivity of discussing violence risk (Chapter 3). Risk assessment is not a collaborative process in practice (Chapter 3).	OxMIV did not impact the practice of risk assessment being an administrative exercise following assessment rather than a collaborative one (Chapter 4). Patients and carers felt discussion of risk could be approached in a straightforward manner, helped by being made to feel routine, which they thought use of a tool might support (Chapter 4). No clinicians felt that OxMIV posed additional issues relating to stigma compared to standard risk assessment processes (Chapter 4).

Another potential benefit of OxMIV was also examined in the external validation study (Chapter 5). A key limitation of current practice identified was its low sensitivity for identifying those who go on to perpetrate violence. An advantage of OxMIV as a decision support may therefore be to increase this sensitivity. Decision curve analysis was also used to examine the net benefit of OxMIV at different preferences for the relative harms of false positives and false negatives. OxMIV compared favourably to other strategies (treat all, treat none or clinical assessment) across a relevant range of thresholds for this preference weighting (Chapter 5).

However, OxMIV helped to inform specific changes to support and careplans in 5% of all assessments in EIP, although this proportion was higher (19%) in cases where there was already higher than average concern about risk. Although this did not detract from clinicians' perceptions of the helpfulness of the tool, it may nevertheless limit the impact of the tool in terms of improving patient outcomes, and this is discussed further below.

d) Developing and examining stratified management for violence risk

i. Clinical role and integration of OxMIV

By anchoring the work in the thesis directly in the setting of EIP services, a clear understanding of the optimal clinical role of OxMIV has been developed.

First, this role is firmly as an adjunct or complement to clinical judgement. This terminology is widely used to describe the clinical role of prediction models, however what this means in practice is not well described and will vary between clinical scenarios. For the use of OxMIV in EIP services, the complementary role was clear – rather than modifying clinical judgements, it adds clarity and focus, summarises the overall risk, and provides richer information through the percentage scores that better illustrate the magnitude of differences in risks. By supporting consistency and improving knowledge it improves clinicians' confidence in their assessments, and in turn can facilitate consideration of more proactive support around risk. The simplicity and tightly-focussed remit of the tool allows clinicians to combine it with their wider contextual assessments, such as the environmental circumstances and nature of psychotic symptoms, which is a strength of current approaches and which clinicians were keen to retain.

The optimal positioning of the tool within the service has also been clarified. Primarily this is as a routine part of the full new assessment process for all patients, either within the first assessment or extending across the early phase of assessment and handover to the care coordinator from the assessing clinician. By integrating here, OxMIV aligned with the information gathering process and the range of assessment documentation that is already completed, and sits well in practical terms as part of this assessment battery. A secondary role is more flexibly as a tool that can be used for those already known to the team. This is more typically where there are concerns around violence risk, and there is less of a role for its

routine use in individuals well known to the team whom clinicians are confident do not have significant needs around violence risk.

In terms of its practical integration, this requires clear framing and communication of its role, particularly to ensure clinicians are aware that it can be used for all rather than only those with a clear forensic history. Sustainable embedding in routine processes is required, such as becoming a standard component of assessment administration. Within the healthcare record, it needs to be accessible and ideally embedded within the general risk assessment form. Where there is scope from a digital perspective, automating elements such as age or sex to reduce further the administrative burden is valuable.

ii) Stratified management

As has been discussed, there are benefits to OxMIV in current form, and the work in this thesis supports its clinical use. However, some of the clinical needs identified remain unmet, and further development of the tool is required to address these more directly. These are to 1) translate the higher sensitivity of OxMIV into offering supportive interventions to a higher proportion of those who would go on to perpetrate violence, with more focus on modifiable factors rather than only acute interventions, 2) improve the gathering of collateral information, particularly from police, and 3) improve collaboration with patients and families, scope for which was indicated to be more around planning treatment support rather than the risk assessment itself.

The relatively low frequency with which using OxMIV led to changes in what care and support clinicians offered (Chapter 4) is in keeping with previous studies of prediction models that suggest to influence outcomes, an assessment tool alone has less impact than when it is presented with linked therapeutic recommendations.[191] For example, a trial of approaches to reduce future suicidal behaviour in individuals presenting to emergency

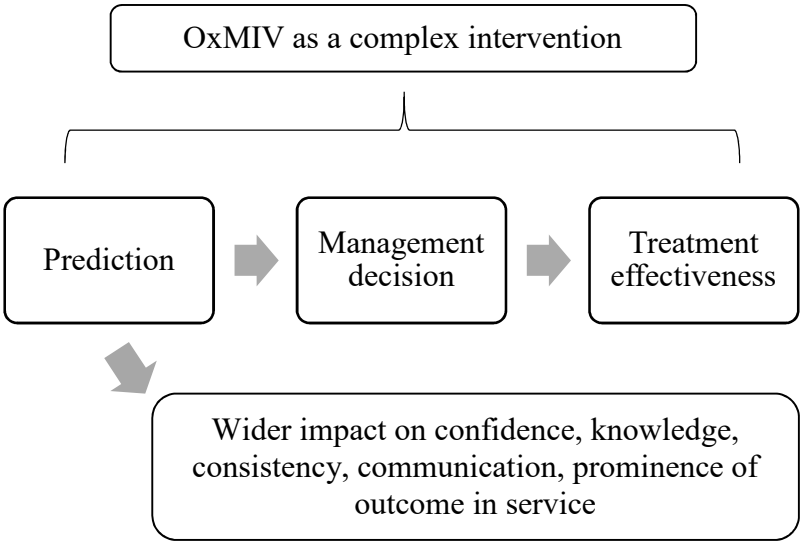
departments with suicidal ideation or attempts compared treatment as usual, universal risk screening, and risk screening plus an intervention.[192] Outcomes were only significantly better than treatment as usual in the intervention group. Similarly, in a cluster randomised controlled trial in forensic psychiatric outpatient settings, risk assessment alone was found not to improve reoffending outcomes.[193] Therefore, to more directly influence positive changes in the support that is provided to reduce risk, OxMIV likely needs to also provide some therapeutic direction. The acceptability of this was discussed in Chapter 4, with clinicians responding positively with the caveats that these were framed as suggestions rather than directions, to avoid care becoming too protocolised.

In moving toward linking therapeutic suggestions to the tool, it becomes increasingly relevant to draw on aspects of the recently updated framework for developing and evaluating complex interventions.[194,195] Even in its current form, i.e. a prediction without any further direction, the work in this thesis has shown the relevance of considering a prediction tool to be a complex intervention in how it interacts with a clinical system.[196,197] This is due to the flexibility with which clinicians may incorporate the tool into their practice, and the range of behaviours that can be impacted at multiple levels - for an individual clinical scenario, for an individual clinician's wider practice, confidence and knowledge, and at the level of the clinical service including the uniformity with which violence risk is considered, documented and communicated. The most downstream goal of a tool that predicts violent outcomes is to reduce those outcomes. However, this thesis has demonstrated that to assess the value of a tool relative to its resource implications (which in OxMIV's case are minimal), a broader view of its impact is required.

Further, any suggested linked interventions will also necessarily be flexible and multi-faceted. The impact of a violence prediction model on violent outcomes is therefore a complex interaction between overarching contextual factors,[198] the accuracy of the prediction

model (i.e. how well it can target interventions to those with the highest absolute risk, as outlined in Chapter 1), the extent to which this impacts clinical decisions for individual patients, and the effectiveness of these linked decisions in reducing risk, as well as the wider effect of implementing a prediction tool on clinicians and the service as a whole (Figure 2).

Figure 2 Understanding OxMIV as a complex intervention with interacting components at the level of individual predictions and decisions, and wider impact on clinicians and services.



With regards to OxMIV as a circumscribed prediction model, the work outlined in this thesis has addressed to a substantial degree the elements of feasibility, acceptability and implementation that are core to the complex interventions framework.[194] The framework is also applicable to considering linked therapeutic suggestions. To develop these I have combined two elements, 1) the actions that clinicians already take in a non-standardised manner in response to concerns about violence risk, as illuminated in the work of Chapters 3 and 4, and 2) the existing evidence for modifiable risk factors for violence, consideration of which as part of a longer-term view of risk management is not a current emphasis of the response to violence risk. Specifying the appropriateness of a fuller assessment, beyond the baseline screening that is the current framing, is another resource-allocation decision. This is

currently decided in an ad-hoc manner, but can be standardised by being linked to the tool. Supporting clinicians to obtain collateral forensic history is another need that has been clearly identified, and likewise may benefit from being addressed in this more standardised manner. Finally, the finding that carers may feel excluded by confidentiality barriers may be also be assisted by a prompt to consider this in the context of concerns about risk.

I have combined these elements with succinct guidance for clinicians on using and interpreting the tool, which integrates findings from Chapters 3 and 4 around the framing and explanation of the tool and its role and benefits. Altogether, I have presented these developments as "OxVERSE for Early Intervention in Psychosis Services" (**Ox**ford **V**iol**E**nce **R**isk **S**cr**E**en and Support) (Figure 3). This embeds the updated OxMIV model within a clear framing for its role and integration, and a simple set of linked suggestions. Each element of this is demonstrably based upon the work in this thesis or the evidence base for modifiable risk factors for violence. The name alteration is in response to the finding that clinicians were initially unclear as to whether OxMIV ("mental illness and violence") can only be used in the context of individuals with a forensic history. The clinical guidance and suggestions target the key unmet needs outlined above, and capture the broad ways in which the tool can support clinical practice evidenced in this thesis.

Figure 3 Clinical guidance, refined wording of OxMIV tool and linked suggestions, combined as "OxVERSE".

OxVERSE for Early Intervention in Psychosis Services

Oxford Viol**E**nce **R**isk Scr**E**en and Support

Purpose

OxVERSE aims to assist clinicians in Early Intervention in Psychosis (EIP) services to consistently identify potential clinical needs related to behaving violently, and accurately offer support for this to those individuals assessed by EIP services who are most likely to benefit. It is not about acute safety, which clinicians already have a uniform response to. It is about considering non-harmful, non-restrictive actions to support individuals and families and reduce risk longer-term. This is less commonly emphasised.

Why is this important?

Risk of violence is not a primary focus of EIP services. However, around 1 in 10 individuals assessed by EIP services perpetrate violence in the next year. This can affect their lives, care, prognosis and family. OxVERSE can help improve the approach to this important adverse outcome, without placing a disproportionate emphasis on it.

What is it?

- a prediction tool or calculator that uses simple clinical information to estimate the risk of an individual perpetrating violence (involving either police contact, physical injury or a weapon) in the next 12 months
- suggestions for what further assessment, support or discussion might be considered

Clinical role

OxVERSE should complement clinical assessment. Clinicians find it typically matches their judgement, but adds clarity such as by summarising risk with a percentage. It can improve confidence, knowledge, communication and objectivity. It takes a few minutes. Its optimal role is as a routine part of all new assessments, where all risks are considered and a range of assessment documentation already completed. The required information is routine.

Most clinicians do not involve patients directly in risk assessments, partly due to wariness about reinforcing stigma by broaching the subject. Patient interviews however suggest that asking straightforward questions about violence is acceptable if made to feel routine and supportive. Using a tool may help this. The linked treatment-planning has been highlighted as the key point at which there is scope to improve collaboration.

Development

The prediction tool was developed and tested in data on >75,000 individuals in Sweden. It was validated and updated in >1,100 individuals assessed by UK EIP services. Diagnosis can be uncertain, so everyone who had a full assessment was included. So OxVERSE can be used for anyone assessed by an EIP service. Linked suggestions are based on evidence for modifiable risk factors, and research on how clinicians respond to risk in EIP services.

OxVERSE for Early Intervention in Psychosis Services

Oxford ViolEnce Risk ScrEen and Support

Sex Code as sex at birth.

Male / Female

Age

Years

Previous drug misuse Previous diagnosis of drug use disorder (lifetime). This can be pragmatically rated based on a detailed history that indicates likely drug use disorder, as well as from documented diagnosis, or past contact with rehabilitation/treatment services

Yes / No

Previous violent crime Previous conviction for a violent offence (lifetime). Violent offence defined as homicide, assault, robbery, arson, any sexual offense (rape, sexual coercion, child molestation, indecent exposure, or sexual harassment), illegal threats, or intimidation.

Yes / No

Previous alcohol misuse Previous diagnosis of alcohol use disorder (lifetime). Can be pragmatically rated as per drug misuse.

Yes / No

Highest education Formal schooling: secondary (to age 16), upper secondary (to age 18), post-secondary (past 18).

Secondary / Upper secondary / Post secondary / Unknown

Previous self-harm Previous episode of self-harm (lifetime). Any form.

Yes / No

Parental violent crime Parental conviction for a violent offence (lifetime). Violent offence defined as for personal history of violent crime. History of imprisonment can also be taken as a proxy of violent offending.

Yes / No / Unknown

Parental drug or alcohol use Parental diagnosis of drug or alcohol use disorder (lifetime). Can be pragmatically rated as per personal history.

Yes / No / Unknown

Sibling violent crime Sibling conviction for a violent offence (lifetime). Violent offence defined as for personal history of violent crime. History of imprisonment can also be taken as a proxy of violent offending.

Yes / No / Unknown

Current episode

Inpatient / Outpatient

Recent antipsychotic treatment Prescribed and taken any antipsychotic drug in 6 months before assessment.

Yes / No

Personal income Select 'low' if unemployed and/or inadequate financial situation with difficulty meeting basic daily living needs (food, accommodation etc.). Otherwise, select 'stable'.

Low / Stable / Unknown

Recent antidepressant treatment Prescribed and taken any antidepressant drug in 6 months before assessment.

Yes / No

Benefit recipient Currently receiving social or disability benefits of any kind.

Yes / No / Unknown

Recent dependence treatment Any pharmacological treatment for dependence (e.g. replacement therapy such as methadone) prescribed and taken in 6 months before assessment.

Yes / No

OxVERSE for Early Intervention in Psychosis Services

Oxford Viol**E**nce **R**isk **S**cr**E**en and Support

What does the score mean?

A percentage score of X% means that if there were 100 people with exactly the same combination of clinical factors, on average X of them would perpetrate violence in the next 12 months. Most clinicians find that this percentage gives the richest information. However, the risk categories below may also help with decisions around resource allocation.

Low risk needs category: This includes everyone with risk less than 10%. In the validation study, out of every 100 individuals in this category, 5 perpetrated violence in the next year.

Increased risk needs category: This includes everyone with risk over 10%. In the validation study, out of every 100 individuals in this category, 22 perpetrated violence in the next year.

Are needs around violence risk low?

Consider discussing this with patients and families. Research with carers has shown that they may worry about this risk even when there is no history of violence, as part of the wider uncertainty around their loved one developing a psychotic illness. Sharing clear information about risk may be reassuring, and gives opportunity for carers to divulge any important collateral information that they may find difficult to share without prompting.

Are needs around violence risk increased?

1. **Further assessment**
    a. **More background history needed?** E.g. forensic history, collateral from family
    b. **Dynamic risks linked to psychotic symptoms?** E.g. anger in context of persecutory beliefs, individual triggers and patterns of behaviour
    c. **Are specific individuals at risk?**

Clinicians can be unsure of the justification needed to seek violent offence information from the police. Interviews with patients suggested this is acceptable, and should ideally be done transparently. Concerns about risk from clinical judgement supported by the tool could prompt seeking this important information via local arrangements.

Carers can find communication difficult due to confidentiality barriers. If there are risk concerns it should be ensured that families have had opportunity to share necessary information or concerns.

A strength of clinical practice is the rich contextual information clinicians gather around symptom content, individual patterns and relationships. If risk is increased this could support the decision to allocate time to undertaking this fuller risk assessment.

OxVERSE for Early Intervention in Psychosis Services

Oxford **V**iol**E**nce **R**isk **S**cr**E**en and Support

2. Actions

- **Collaborate:** Discuss with patient and family if possible. The tool might serve to frame discussion about the need to consider ways to reduce risk.
- **Team:** Discuss within the MDT. Team discussion helps share responsibility and supports decision-making. Clinicians were more confident bringing cases for discussion having assimilated relevant information with the tool.
- **Target modifiable factors:**

  Substance misuse This is a strong risk factor for violence. If risks are increased and substance misuse is relevant then emphasis should be placed on supporting this need as a way to reduce risk.

  Psychotic symptoms The burden of positive symptoms, especially persecutory beliefs, is associated with violence. So too is medication non-adherence. Consider allocating additional resource to achieve fuller symptom control e.g. frequency of medication reviews, proactive side-effect monitoring, pharmacy input for psychoeducation and side-effect optimisation.

  Insight & disengagement Increased risk may be a rationale for prioritising psychological therapy or considering individualised ways to target disengagement, which is a dynamic risk factor for violence.

  Impulsivity Consider local options for psychological therapy targeting this domain or e.g. groups on anger and managing strong emotions.

  Environment Unstable accommodation is associated with perpetrating violence, as is being a victim of violence. Violence risk is an additional rationale to support these vulnerabilities if present.

- **Safety:** Implications for staff visits or crisis plans with carers. These practical responses to risk were highlighted by clinicians, particularly ensuring risks are communicated at transitions in care such as involvement of crisis services.
- **Link with other services:** Are there other agencies to involve or improve communication with? The more complete assessment supported by the tool may assist discussions with local forensic services where clinically indicated. Clinicians highlighted that incidents can happen where services work in silos, so increased risk should encourage close working with agencies who may be involved such as police, probation or MAPPA, substance misuse services, housing providers or social services.

Methodological implications and future research directions

For OxMIV and the new iteration OxVERSE, there are some specific findings in this thesis for guiding the examination of impact at a larger scale. First, as described above, the manner in which the tool is optimally integrated into a clinical service has been established. In the OxVERSE document above I have framed it simply to convey its role to clinicians. There needs to be some lead-in time due to the relative novelty of the approach in this setting and time required for processes to be embedded for its use. This uptake took 3 to 4 months. It is also apparent in terms of resource that a local lead within a clinical service to support and prompt its uptake and ensure dissemination of the information about its role to all members of the team would be necessary. Local integration will require work with the relevant electronic health records team in order to embed as closely as possible within existing risk assessment areas.

In terms of the design for a trial of impact, the findings from Chapter 4 demonstrate the broad effect that the tool has on the team and clinicians' practice, such as the improved knowledge of the relevant risk factors. This highlights the consensus that despite the additional resource requirements, a cluster design is the ideal comparative approach to understand the impact of a model in practice,[52,53] and in this case randomisation at the level of clinical service would be the best approach to avoid contamination.[199] The evidence for the feasibility of the tool in this thesis is a prerequisite before considering such an undertaking. An appropriate target outcome would be the linking of the risk assessment to individually tailored support to explicitly address any identified violence risk. This can also be considered in terms of the proportion of individuals who go on to perpetrate violence who are offered support, with a view to increasing the sensitivity of this assessment and linked provision. As discussed, in its non-directive form, OxMIV prompted changes in support in around 1 in 5 occasions of its use in those with identified risks, and this would be expected to increase with the specific linked

suggestions of OxVERSE.[200,201] The effect on downstream violent outcomes will depend on the ability of the tool to improve these management decisions, and the effectiveness of the linked provision. There are examples of cluster designs to evaluate the impact of such models and interventions,[53,202,203] however as described in Chapter 1 this is a key area for future development in prognostic research.

An area in which this thesis has made progress is in the application of mixed methods approaches to examining the feasibility, acceptability and practical integration of a prediction tool. This has relevance to both the field of mixed methods, and that of prediction model research, where the clinical end of the development spectrum remains underdeveloped. Mixed methods in health research remains in flux in terms of how it is defined and approached.[143] In particular, approaches to how data is integrated continue to be clarified and refined,[117] and so, for example, the manner in which an integrated display matrix was used in Chapter 4 represents a valuable contribution to this ongoing development.[144] A novel aspect here was that, rather than for example survey data sequentially informing interviews or vice versa, case-by-case quantitative data collected from use of the tool in health records – both from patterns of use and discrete clinician feedback - was instead integrated with and expanded by clinicians' qualitative experiences, to develop a rich understanding. These approaches have addressed a key gap in the methods for undertaking a phased development of a prediction model into a clinical tool, and the insights gained into these methods are transferrable to other settings, outcomes and models. The adaptability of electronic health records to facilitate such an approach is also a valuable observation. The value of mixed methods in this work also makes a strong argument for embedding such approaches in any future trials, using the framework of process evaluation to continue to consider contextual factors of implementation and the mechanisms by which impacts are achieved.[198]

More broadly, use of routine data in electronic healthcare records was also shown here to be a feasible way to externally validate a prediction tool in psychiatric services, provided that the required information is routine enough to have been recorded. Given the wide availability of such digital platforms, and improved approaches to handling missing data,[156] there is good reason to continue to increase emphasis on external validation to inform the wider implementation of prediction tools.[148] One reason for this is to adequately consider calibration,[149] the importance of which was highlighted in this thesis along with methods to update and correct this. I used a manual approach to extracting the routine data for external validation. Whilst effective, there is a ceiling to the scalability of this approach and it may not be feasible for rarer outcomes in which larger numbers of individuals are required for adequate power. In such scenarios, techniques such as natural language processing may offer an alternative approach to capture the same information at scale,[189] and this is another avenue of development for the field.

Violence perpetration is highlighted in this thesis as an adverse outcome in EIP services that may benefit from a stratified medicine approach, adding to the outcomes in this setting for which prediction models have been developed.[27,34] There are insights from this thesis that are not specific to violence, and so may be transferrable to other applications of prediction models in EIP services. These include practical feasibility, how clinicians interpret percentage scores and use these to complement their clinical assessments, and the wider impact on knowledge and confidence. EIP services are a natural setting in which to refine the practical integration of prediction models, given that the service model is itself fundamentally based on a prognostic understanding – that allocating resource to offer intensive support and treatment in the early phases of psychotic illness benefits long term outcomes.[71] It is a logical next step to individually refine this prognostic understanding. There has been focus on the application of prediction modelling approaches to outcomes central to the EIP remit, such as

functional, relapse and recovery outcomes.[31-34] This thesis supports the potential feasibility and benefit of translating such approaches into routine practice in EIP services, and offers insight into how such translation can be developed and examined. One other area of focus will be to develop or update models for first episode psychosis for outcomes that have received attention in psychiatry more broadly, such as suicide.[41] Work such as in cardiometabolic risk prediction[30] has highlighted the importance of focussing on the specific setting of EIP services, rather than applying models unchanged which have been developed in other populations. The external validation and updating of OxMIV further highlights the importance of this.

Finally, a specific methodological finding for research into violence risk is the choice of violent outcome measure (Chapter 5). The use of the hybrid measure from healthcare and police sources is discussed in detail in Chapter 5, however this warrants repeating due to the advantages this offers in terms of the clinical relevance of the outcome and the completeness of the information. Again, the linking of police data was achieved manually at a local level with associated data governance frameworks. A need for future development in geographical areas such as the UK that do not have centralised population registers, is how this data linkage can be achieved anonymously and at scale such as between mental health records and police. Although large anonymised databases exist such as within primary care, secondary mental healthcare and within the justice system,[204] pathways for linking healthcare data to crime outcomes are not well established.

Thesis limitations

In individual results chapters I have addressed specific limitations for the constituent studies, such as the difficulties recruiting patients with forensic histories, and the limited geographical

range of the work which covered two English counties in both the validation study and the clinical feasibility work.

An overarching issue for this thesis is that the work was undertaken during the covid-19 pandemic. This did not affect the external validation study (Chapter 5) as this was based on a cohort and time period that predated the pandemic. All work with clinical services however took place against the backdrop of covid-19. In Chapter 4, I discussed the practical implications of this for recruitment, interviews and my communication with the clinical service. It is more difficult to delineate the wider effects that the pandemic may have been having on parameters such as clinicians' receptiveness to new ways of working (having had their standard working model effectively transformed overnight by the pandemic), and their attitudes to violence risk within their service. It is however unlikely that such factors would have had enough of a bearing on results to materially influence the conclusions drawn.

In Chapter 2 I discussed reflexivity and how my own background and perspectives might shape the qualitative data. A related point is that whilst I was not myself involved in the original development of the OxMIV model, my primary supervisor and statistical advisor were. Such transparency is not universal in the violence risk assessment field.[94] I was the only individual with access to any primary data, and undertook all analyses myself, with the role of the supervisory team being precisely that, of supervision. So the potential for this to have had any influence on the outcome of the work is negligible. Nevertheless, it is important to declare that in the strictest sense of the definition, the OxMIV validation was not fully independent from the development team.

Conclusion

In summary, it is hoped that the work presented in this thesis makes a material contribution to improving how risks of violence perpetration are considered in clinical services for emerging

psychotic illness. I have validated and updated a scalable risk prediction tool, demonstrated how this aligns with, and can benefit, a complex clinical system, and provided a framework for its integration and further study. As well as this direct output for clinical practice, methods have been applied and developed to study the domains of external validity, clinical feasibility, and the acceptability and role of a prediction model. It is hoped that these insights and developments will be of value to the wider prediction model field, as it moves towards translating these approaches more widely into clinical tools that impact patient care and outcomes, in EIP services and elsewhere in psychiatry and medicine.

References

1. Riley RD, van der Windt D, Croft P, Moons KGM. Prognosis research in health care: concepts, methods, and impact. Oxford University Press. 2019.
2. Thomas JM, Cooney LM, Jr, Fried TR. Prognosis reconsidered in light of ancient insights—from hippocrates to modern medicine. *JAMA Intern Med.* 2019;179(6):820-823.
3. Christakis NA. The ellipsis of prognosis in modern medical thought. *Soc Sci Med.* 1997;44(3):301-315.
4. Hemingway H. Prognosis research: Why is Dr. Lydgate still waiting? *J Clin Epidemiol.* 2006;59(12):1229-1238.
5. Croft P, Altman DG, Deeks JJ, et al. The science of clinical practice: disease diagnosis or patient prognosis? Evidence about "what is likely to happen" should shape clinical practice. *BMC Med.* 2015;13:20-20.
6. Hemingway H, Croft P, Perel P, et al. Prognosis research strategy (PROGRESS) 1: a framework for researching clinical outcomes. *BMJ.* 2013;346:e5595.
7. Hingorani AD, Windt DAvd, Riley RD, et al. Prognosis research strategy (PROGRESS) 4: stratified medicine research. *BMJ.* 2013;346:e5793.
8. Riley RD, Hayden JA, Steyerberg EW, et al. Prognosis research strategy (PROGRESS) 2: prognostic factor research. *PLoS Med.* 2013;10(2):e1001380.
9. Steyerberg EW, Moons KGM, van der Windt DA, et al. Prognosis research strategy (PROGRESS) 3: prognostic model research. *PLoS Med.* 2013;10(2):e1001381.
10. Rothwell PM, Mehta Z, Howard SC, Gutnikov SA, Warlow CP. Treating individuals 3: from subgroups to individuals: general principles and the example of carotid endarterectomy. *Lancet.* 2005;365(9455):256-265.
11. The Academy of Medical Sciences (AMS). Realising the potential of stratified medicine. AMS. 2013. Available from: acmedsci.ac.uk/viewFile/51e915f9f09fb.pdf (accessed Nov 23, 2021).
12. Damen JA, Hooft L, Schuit E, et al. Prediction models for cardiovascular disease risk in the general population: systematic review. *BMJ.* 2016;353:i2416.
13. Health Education England. The Topol Review. Preparing the healthcare workforce to deliver the digital future. Health Education England. 2019.
14. Lee Y, Ragguett RM, Mansur RB, et al. Applications of machine learning algorithms to predict therapeutic outcomes in depression: a meta-analysis and systematic review. *J Affect Disord.* 2018;241:519-532.
15. Whiting D, Fazel S. How accurate are suicide risk prediction models? Asking the right questions for clinical practice. *Evid Based Ment Health.* 2019;22:125 - 128.
16. Christodoulou E, Ma J, Collins GS, et al. A systematic review shows no performance benefit of machine learning over logistic regression for clinical prediction models. *J Clin Epidemiol.* 2019;110:12-22.
17. Nusinovici S, Tham YC, Chak Yan MY, et al. Logistic regression was as good as machine learning for predicting major chronic diseases. *J Clin Epidemiol.* 2020;122:56-69.
18. Lucaroni F, Cicciarella Modica D, Macino M, et al. Can risk be predicted? An umbrella systematic review of current risk prediction models for cardiovascular diseases, diabetes and hypertension. *BMJ Open.* 2019;9(12):e030234.
19. Wilson PWF, D'Agostino RB, Levy D, et al. Prediction of coronary heart disease using risk factor categories. *Circulation.* 1998;97(18):1837-1847.

20. D'Agostino RB, Vasan RS, Pencina MJ, et al. General cardiovascular risk profile for use in primary care. *Circulation.* 2008;117(6):743-753.
21. Hippisley-Cox J, Coupland C, Brindle P. Development and validation of QRISK3 risk prediction algorithms to estimate future risk of cardiovascular disease: prospective cohort study. *BMJ.* 2017;357:j2099.
22. Hippisley-Cox J, Coupland C, Vinogradova Y, et al. Derivation and validation of QRISK, a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study. *BMJ.* 2007;335(7611):136.
23. National Institute for Health and Care Excellence (NICE). Cardiovascular disease: risk assessment and reduction, including lipid modification. Clinical guideline [CG181]. NICE. 2016.
24. Phung MT, Tin Tin S, Elwood JM. Prognostic models for breast cancer: a systematic review. *BMC Cancer.* 2019;19(1):230.
25. Wishart GC, Azzato EM, Greenberg DC, et al. PREDICT: a new UK prognostic model that predicts survival following surgery for invasive breast cancer. *Breast Cancer Res.* 2010;12(1):R1-R1.
26. Thurtle DR, Greenberg DC, Lee LS, et al. Individual prognosis at diagnosis in nonmetastatic prostate cancer: development and external validation of the PREDICT prostate multivariable model. *PLoS Med.* 2019;16(3):e1002758.
27. Salazar de Pablo G, Studerus E, Vaquerizo-Serrano J, et al. Implementing precision psychiatry: a systematic review of individualized prediction models for clinical practice. *Schizophr Bull.* 2021;47(2):284-297.
28. Malda A, Boonstra N, Barf H, et al. Individualized prediction of transition to psychosis in 1,676 individuals at clinical high risk: development and validation of a multivariable prediction model based on individual patient data meta-analysis. *Front Psychiatry.* 2019;10:345.
29. Moriarty AS, Meader N, Snell KI, et al. Prognostic models for predicting relapse or recurrence of major depressive disorder in adults. *Cochrane Database Sys Rev.* 2021;5(5):Cd013491.
30. Perry BI, Osimo EF, Upthegrove R, et al. Development and external validation of the Psychosis Metabolic Risk Calculator (PsyMetRiC): a cardiometabolic risk prediction algorithm for young people with psychosis. *Lancet Psychiatry.* 2021;8(7):589-598.
31. Leighton SP, Krishnadas R, Chung K, et al. Predicting one-year outcome in first episode psychosis using machine learning. *PloS One.* 2019;14(3):e0212846.
32. Puntis S, Whiting D, Pappa S, Lennox B. Development and external validation of an admission risk prediction model after treatment from early intervention in psychosis services. *Transl Psychiatry.* 2021;11(1):35.
33. Leighton SP, Upthegrove R, Krishnadas R, et al. Development and validation of multivariable prediction models of remission, recovery, and quality of life outcomes in people with first episode psychosis: a machine learning approach. *Lancet Digit Health.* 2019;1(6):e261-e270.
34. Leighton SP, Krishnadas R, Upthegrove R, et al. Development and validation of a nonremission risk prediction model in first-episode psychosis: an analysis of 2 longitudinal studies. *Schizophr Bull Open.* 2021;2(1):sgab041.
35. Senior M, Fanshawe T, Fazel M, Fazel S. Prediction models for child and adolescent mental health: a systematic review of methodology and reporting in recent research. *JCPP Advances.* 2021;1(3):e12034.
36. Tang EY, Harrison SL, Errington L, et al. Current developments in dementia risk prediction modelling: an updated systematic review. *PloS One.* 2015;10(9):e0136181.

37. Belsher BE, Smolenski DJ, Pruitt LD, et al. Prediction models for suicide attempts and deaths: a systematic review and simulation. *JAMA Psychiatry.* 2019;76(6):642-651.
38. Wang SB, Coppersmith DDL, Kleiman EM, et al. A Pilot study using frequent inpatient assessments of suicidal thinking to predict short-term postdischarge suicidal behavior. *JAMA Netw Open.* 2021;4(3):e210591-e210591.
39. Fazel S, Wolf A, Larsson H, Mallett S, Fanshawe TR. The prediction of suicide in severe mental illness: development and validation of a clinical prediction rule (OxMIS). *Transl Psychiatry.* 2019;9(1):98.
40. Carter G, Milner A, McGill K, et al. Predicting suicidal behaviours using clinical instruments: systematic review and meta-analysis of positive predictive values for risk scales. *Br J Psychiatry.* 2017;210(6):387-395.
41. Kessler RC, Bossarte RM, Luedtke A, Zaslavsky AM, Zubizarreta JR. Suicide prediction models: a critical review of recent research with recommendations for the way forward. *Mol Psychiatry.* 2020;25(1):168-179.
42. Hou XH, Feng L, Zhang C, et al. Models for predicting risk of dementia: a systematic review. *J Neurol Neurosurg Psychiatry.* 2019;90(4):373-379.
43. Collins GS, Reitsma JB, Altman DG, Moons KGM. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD statement. *BMJ.* 2015;350:g7594.
44. Moons KGM, Wolff RF, Riley RD, et al. PROBAST: A tool to assess risk of bias and applicability of prediction model studies: explanation and elaboration. *Ann Intern Med.* 2019;170(1):W1-w33.
45. Update to living systematic review on prediction models for diagnosis and prognosis of covid-19. *BMJ.* 2021;372:n236.
46. Wynants L, Van Calster B, Collins GS, et al. Prediction models for diagnosis and prognosis of covid-19: systematic review and critical appraisal. *BMJ.* 2020;369:m1328.
47. Steyerberg EW, Harrell FE, Jr. Prediction models need appropriate internal, internal-external, and external validation. *J Clin Epidemiol.* 2016;69:245-247.
48. Steyerberg EW. Validation of prediction models. In: Clinical prediction models: a practical approach to development, validation, and updating. Cham: Springer International Publishing. 2019;329-344.
49. Justice AC, Covinsky KE, Berlin J. Assessing the generalizability of prognostic information. *Ann Intern Med.* 1999;130:515-524.
50. Siontis GC, Tzoulaki I, Castaldi PJ, Ioannidis JP. External validation of new risk prediction models is infrequent and reveals worse prognostic discrimination. *J Clin Epidemiol.* 2015;68(1):25-34.
51. Reilly BM, Evans AT. Translating clinical research into clinical practice: impact of using prediction rules to make decisions. *Ann Intern Med.* 2006;144(3):201-209.
52. Moons KGM, Altman DG, Vergouwe Y, Royston P. Prognosis and prognostic research: application and impact of prognostic models in clinical practice. *BMJ.* 2009;338:b606.
53. Kappen TH, van Klei WA, van Wolfswinkel L, et al. Evaluating the impact of prediction models: lessons learned, challenges, and recommendations. *Diagn Progn Res.* 2018;2(1):11.
54. World Health Organization. Global status report on violence prevention. Geneva: World Health Organization. 2014.
55. United Nations. Transforming our wold: the 2030 agenda for sustainable development. Available from:

sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf (accessed Nov 24, 2021).
56. Heeks M RS, Tafsiri M and Prince S. The economic and social costs of crime. Second edition. Research Report 99. Home Office. 2018.
57. Whiting D, Lichtenstein P, Fazel S. Violence and mental disorders: a structured review of associations by individual diagnoses, risk factors, and risk assessment. *Lancet Psychiatry.* 2021;8(2):150-161.
58. McGinty EE, Goldman HH, Pescosolido BA, Barry CL. Communicating about mental illness and violence: balancing stigma and increased support for services. *J Health Polit Policy Law.* 2018;43(2):185-228.
59. Fazel S, Gautam G, Linsell L, Geddes JR, Grann M. Schizophrenia and violence: systematic review and meta-analysis. *PLoS Med.* 2009;6(8).
60. Short T, Thomas S, Mullen P, Ogloff JR. Comparing violence in schizophrenia patients with and without comorbid substance-use disorders to community controls. *Acta Psychiatr Scand.* 2013;128(4):306-313.
61. Fazel S, Wolf A, Palm C, Lichtenstein P. Violent crime, suicide, and premature mortality in patients with schizophrenia and related disorders: a 38-year total population study in Sweden. *Lancet Psychiatry.* 2014;1(1):44-54.
62. Fleischman A, Werbeloff N, Yoffe R, Davidson M, Weiser M. Schizophrenia and violent crime: a population-based study. *Psychol Med.* 2014;44(14):3051-3057.
63. Stevens H, Laursen TM, Mortensen PB, Agerbo E, Dean K. Post-illness-onset risk of offending across the full spectrum of psychiatric disorders. *Psychol Med.* 2015;45(11):2447-2457.
64. Casiano H, Hensel JM, Chartier MJ, et al. The intersection between criminal accusations, victimization, and mental disorders: a canadian population-based study. *Can Journal Psychiatry.* 2020;65(7):492-501.
65. Senior M, Fazel S, Tsiachristas A. The economic impact of violence perpetration in severe mental illness: a retrospective, prevalence-based analysis in England and Wales. *Lancet Public Health.* 2020;5(2):e99-e106.
66. Nielssen O, Large M. Rates of homicide during the first episode of psychosis and after treatment: a systematic review and meta-analysis. *Schizophr Bull.* 2010;36(4):702-712.
67. Stevens H, Agerbo E, Dean K, et al. Offending prior to first psychiatric contact: a population-based register study. *Psychol Med.* 2012;42(12):2673-2684.
68. Winsper C, Ganapathy R, Marwaha S, et al. A systematic review and meta-regression analysis of aggression during the first episode of psychosis. *Acta Psychiatr Scand.* 2013;128(6):413-421.
69. Langeveld J, Bjorkly S, Auestad B, et al. Treatment and violent behavior in persons with first episode psychosis during a 10-year prospective follow-up study. *Schizophr Res.* 2014;156(2-3):272-276.
70. Fusar-Poli P, McGorry PD, Kane JM. Improving outcomes of first-episode psychosis: an overview. *World Psychiatry.* 2017;16(3):251-265.
71. Puntis S, Minichino A, De Crescenzo F, et al. Specialised early intervention teams for recent-onset psychosis. *Cochrane Database Syst Rev.* 2020;11(11):Cd013288.
72. NHS England, the National Collaborating Centre for Mental Health and the National Institute for Health and Care Excellence. Implementing the early intervention in psychosis access and waiting time standard (guidance). 1st edition. NHS England. 2015.

73. Tsiachristas A, Thomas T, Leal J, Lennox BR. Economic impact of early intervention in psychosis services: results from a longitudinal retrospective controlled study in England. *BMJ Open.* 2016;6(10):e012611.
74. Winsper C, Singh SP, Marwaha S, et al. Pathways to violent behavior during first-episode psychosis: a report from the UK National EDEN Study. *JAMA Psychiatry.* 2013;70(12):1287-1293.
75. Whiting D, Lennox BR, Fazel S. Violent outcomes in first-episode psychosis: a clinical cohort study. *Early Interv Psychiatry.* 2020;14(3):379-382.
76. Cotton SM, Lambert M, Schimmelmann BG, et al. Predictors of functional status at service entry and discharge among young people with first episode psychosis. *Soc Psychiatry Psychiatr Epidemiol.* 2017;52(5):575-585.
77. Hachtel H, Harries C, Luebbers S, Ogloff JR. Violent offending in schizophrenia spectrum disorders preceding and following diagnosis. *Aust N Z J Psychiatry.* 2018;52(8):782-792.
78. Shrivastava A, Shah N, Johnston M, Stitt L, Thakar M. Predictors of long-term outcome of first-episode schizophrenia: a ten-year follow-up study. *Indian J Psychiatry.* 2010;52(4):320-326.
79. American Psychiatric Association (APA). Practice guideline for the treatment of patients with schizophrenia. 2nd ed. American Psychiatric Association Publishing. 2010. Available from: psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf (accessed Sep 21, 2020).
80. National Institute for Health and Care Excellence. Psychosis and schizophrenia in adults: prevention and management [CG178]. NICE. 2014. Available from: nice.org.uk/guidance/cg178/resources/psychosis-and-schizophrenia-in-adults-prevention-and-management-35109758952133 (accessed Sep 21, 2020).
81. Galletly C, Castle D, Dark F, et al. Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the management of schizophrenia and related disorders. *Aust N Z J Psychiatry.* 2016;50(5):410-472.
82. Lanza ML, Campbell D. Patient assault: a comparison study of reporting methods. *J Nurs Qual Assur.* 1991;5(4):60-68.
83. Webb RT, Lichtenstein P, Larsson H, Geddes JR, Fazel S. Suicide, hospital-presenting suicide attempts, and criminality in bipolar disorder: examination of risk for multiple adverse outcomes. *J Clin Psychiatry.* 2014;75(8):e809-816.
84. Witt K, van Dorn R, Fazel S. Risk factors for violence in psychosis: systematic review and meta-regression analysis of 110 studies. *PloS One.* 2013;8(2):e55942.
85. Witt K, Lichtenstein P, Fazel S. Improving risk assessment in schizophrenia: epidemiological investigation of criminal history factors. *Br J Psychiatry.* 2015;206(5):424-430.
86. Fazel S, Wolf A, Larsson H, et al. Identification of low risk of violent crime in severe mental illness with a clinical prediction tool (Oxford Mental Illness and Violence tool [OxMIV]): a derivation and validation study. *Lancet Psychiatry.* 2017;4(6):461-468.
87. Sariaslan A, Lichtenstein P, Larsson H, Fazel S. Triggers for violent criminality in patients with psychotic disorders. *JAMA Psychiatry.* 2016;73(8):796-803.
88. Fazel S, Wolf A, Chang Z, et al. Depression and violence: a Swedish population study. *Lancet Psychiatry.* 2015;2(3):224-232.
89. Ullrich S, Keers R, Coid JW. Delusions, anger, and serious violence: new findings from the MacArthur violence risk assessment study. *Schizophr Bull.* 2014;40(5):1174-1181.

90. Singh JP, Serper M, Reinharth J, Fazel S. Structured assessment of violence risk in schizophrenia and other psychiatric disorders: a systematic review of the validity, reliability, and item content of 10 available instruments. *Schizophr Bull.* 2011;37(5):899-912.
91. Fazel S, Wolf A. Selecting a risk assessment tool to use in practice: a 10-point guide. *Evid Based Ment Health.* 2018;21(2):41-43.
92. Fazel S, Singh JP, Doll H, Grann M. Use of risk assessment instruments to predict violence and antisocial behaviour in 73 samples involving 24 827 people: systematic review and meta-analysis. *BMJ.* 2012;345:e4692.
93. Coid JW, Yang M, Ullrich S, et al. Most items in structured risk assessment instruments do not predict violence. *J Forens Psychiatry Psychol.* 2011;22(1):3-21.
94. Singh JP, Grann M, Fazel S. Authorship bias in violence risk assessment? A systematic review and meta-analysis. *PloS One.* 2013;8(9):e72484.
95. Viljoen JL, McLachlan K, Vincent GM. Assessing violence risk and psychopathy in juvenile and adult offenders: a survey of clinical practices. *Assessment.* 2010;17(3):377-395.
96. Douglas KS, Hart SD, Webster CD, et al. Historical-Clinical-Risk Management-20, Version 3 (HCR-20V3): development and overview. *Int J Forensic Ment Health.* 2014;13(2):93-108.
97. Moons KG, Altman DG, Reitsma JB, et al. Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD): explanation and elaboration. *Ann Intern Med.* 2015;162(1):W1-W73.
98. Negatsch V, Voulgaris A, Seidel P, Roehle R, Opitz-Welke A. Identifying violent behavior using the oxford mental illness and violence tool in a psychiatric ward of a german prison hospital. *Front Psychiatry.* 2019;10:264.
99. Craig TK, Garety P, Power P, et al. The Lambeth Early Onset (LEO) team: randomised controlled trial of the effectiveness of specialised care for early psychosis. *BMJ.* 2004;329(7474):1067.
100. Bernardini F, Attademo L, Cleary SD, et al. Risk prediction models in psychiatry: toward a new frontier for the prevention of mental illnesses. *J Clin Psychiatry.* 2017;78(5):572-583.
101. Graney J, Hunt IM, Quinlivan L, et al. Suicide risk assessment in UK mental health services: a national mixed-methods study. *Lancet Psychiatry.* 2020;7(12):1046-1053.
102. Sofaer S. Qualitative methods: what are they and why use them? *Health Serv Res.* 1999;34(5 Pt 2):1101-1118.
103. Greenhalgh T, Taylor R. How to read a paper: papers that go beyond numbers (qualitative research). *BMJ.* 1997;315(7110):740-743.
104. Ritchie J, Lewis J, Nicholls CM, Ormston R. Qualitative research practice: a guide for social science students and researchers. Sage. 2013.
105. Taylor DA, Wallis KA, Feki S, et al. Cardiovascular disease risk prediction in older people: a qualitative study. *Br J Gen Pract.* 2021;71(711):e772-e779.
106. Cowley LE, Maguire S, Farewell DM, et al. Acceptability of the Predicting Abusive Head Trauma (PredAHT) clinical prediction tool: a qualitative study with child protection professionals. *Child Abuse Negl.* 2018;81:192-205.
107. Mullen S, Quinn-Scoggins HD, Nuttall D, Kemp AM. Qualitative analysis of clinician experience in utilising the BuRN Tool (Burns Risk assessment for Neglect or abuse Tool) in clinical practice. *Burns.* 2018;44(7):1759-1766.
108. Lewis ET, Mahimbo A, Linhart C, et al. General practitioners' perceptions on the feasibility and acceptability of implementing a risk prediction checklist to support

their end-of-life discussions in routine care: a qualitative study. *Fam Prac.* 2020;37(5):703-710.
109. Matthias MS, Imperiale TF. A risk prediction tool for colorectal cancer screening: a qualitative study of patient and provider facilitators and barriers. *BMC Fam Prac.* 2020;21(1):43.
110. Glogowska M. Paradigms, pragmatism and possibilities: mixed-methods research in speech and language therapy. *Int J Lang Commun Disord.* 2011;46(3):251-260.
111. Tashakkori A, Creswell JW. The new era of mixed methods. *J Mix Methods Re*s. 2007;1(1):3-7.
112. Tashakkori A, Creswell JW. Exploring the nature of research questions in mixed methods research. *J Mix Methods Re*s. 2007;1(3):207-211.
113. Shorten A, Smith J. Mixed methods research: expanding the evidence base. *Evid Based Nurs.* 2017;20(3):74-75.
114. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ.* 2010;341:c4587.
115. Bryman A. Barriers to Integrating Quantitative and Qualitative Research. *J Mix Methods Re*s. 2007;1(1):8-8.
116. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. *Health Serv Res.* 2013;48(6 Pt 2):2134-2156.
117. McCrudden MT, Marchand G, Schutz PA. Joint displays for mixed methods research in psychology. *Meth Psychol.* 2021;5:100067.
118. Kappen TH, van Loon K, Kappen MA, et al. Barriers and facilitators perceived by physicians when using prediction models in practice. *J Clin Epidemiol.* 2016;70:136-145.
119. Brown B, Cheraghi-Sohi S, Jaki T, et al. Understanding clinical prediction models as 'innovations': a mixed methods study in UK family practice. *BMC Med Inform Decis Mak.* 2016;16:106.
120. Engelhardt EG, Pieterse AH, van Duijn-Bakker N, et al. Breast cancer specialists' views on and use of risk prediction models in clinical practice: a mixed methods approach. *Acta Oncol.* 2015;54(3):361-367.
121. Norvell DC, Suckow BD, Webster JB, et al. The development and usability of the AMPREDICT decision support tool: a mixed methods study. *Eur J Vasc Endovasc Surg.* 2021;62(2):304-311.
122. Campbell P, Hill JC, Protheroe J, et al. Keele aches and pains study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. *J Pain Res.* 2016;9:807-818.
123. Kaushik V, Walsh CA. Pragmatism as a research paradigm and its implications for social work research. *Soc Sci.* 2019;8(9):255.
124. Yvonne Feilzer M. Doing mixed methods research pragmatically: implications for the rediscovery of pragmatism as a research paradigm. *J Mix Methods Re*s. 2010;4(1):6-16.
125. Sim J, Waterfield J. Focus group methodology: some ethical challenges. *Qual Quant.* 2019;53(6):3003-3022.
126. Palinkas LA, Horwitz SM, Green CA, et al. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Adm Policy Ment Health.* 2015;42(5):533-544.
127. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qual Health Res.* 2016;26(13):1753-1760.
128. QSR International Pty Ltd. (2020) NVivo.

129. Boeije H. A purposeful approach to the constant comparative method in the analysis of qualitative interviews. *Qual Quant.* 2002;36(4):391-409.
130. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3(2):77-101.
131. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qual Res Sport Exerc Health.* 2019;11(4):589-597.
132. Glaser BG, Strauss AL. Discovery of grounded theory: strategies for qualitative research. Routledge. 2017.
133. Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. qualitative research in health care A. Are the results of the study valid? *JAMA.* 2000;284(3):357-362.
134. Malterud K. Qualitative research: standards, challenges, and guidelines. *Lancet.* 2001;358(9280):483-488.
135. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care.* 2007;19(6):349-357.
136. Lincoln YG, EG. Naturalistic Inquiry. Sage Publications. 1985.
137. Mays N, Pope C. Assessing quality in qualitative research. *BMJ.* 2000;320(7226):50-52.
138. Fisher RA. Statistical methods for research workers. In: Breakthroughs in statistics. Springer. 1992;66-70.
139. Welch BL. The generalisation of student's problems when several different population variances are involved. *Biometrika.* 1947;34(1-2):28-35.
140. R Core Team. R: a language and environment for statistical computing. R Foundation for statistical computing, Vienna, Austria. URL www.R-project.org/.
141. Wickham H. ggplot2: elegant graphics for data analysis. Srpinger-Verlag New York. 2016.
142. Creswell JW, Clark VLP. Designing and Conducting Mixed Methods Research. SAGE Publications. 2017.
143. Fetters MD, Molina-Azorin JF. The journal of mixed methods research starts a new decade: the mixed methods research integration trilogy and its dimensions. *J Mix Methods Re*s. 2017;11(3):291-307.
144. Guetterman TC, Fetters MD, Creswell JW. Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *Ann Fam Med.* 2015;13(6):554-561.
145. Higgins A, Doyle L, Downes C, et al. There is more to risk and safety planning than dramatic risks: mental health nurses' risk assessment and safety-management practice. *Int J Ment Health Nurs.* 2016;25(2):159-170.
146. Murphy N. An investigation into how community mental health nurses assess the risk of violence from their clients. *J Psychiatr Ment Health Nurs.* 2004;11(4):407-413.
147. Wong L, Morgan A, Wilkie T, Barbaree H. Quality of resident violence risk assessments in psychiatric emergency settings. *Can J Psychiatry.* 2012;57(6):375-380.
148. Collins GS, de Groot JA, Dutton S, et al. External validation of multivariable prediction models: a systematic review of methodological conduct and reporting. *BMC Med Res Methodol.* 2014;14:40.
149. Van Calster B, McLernon DJ, van Smeden M, et al. Calibration: the achilles heel of predictive analytics. *BMC Med.* 2019;17(1):230.

150. Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD Statement. *BMC Med.* 2015;13:1.
151. Ho J, Ralston DC, McCullough LB, Coverdale JH. When should psychiatrists seek criminal prosecution of assaultive psychiatric inpatients? *Psychiatr Serv.* 2009;60(8):1113-1117.
152. Renwick L, Stewart D, Richardson M, et al. Aggression on inpatient units: Clinical characteristics and consequences. *Int J Ment Health Nurs.* 2016;25(4):308-318.
153. Vergouwe Y, Steyerberg EW, Eijkemans MJC, Habbema JDF. Substantial effective sample sizes were required for external validation studies of predictive logistic regression models. *J Clin Epidemiol.* 2005;58(5):475-483.
154. Riley RD, Debray TPA, Collins GS, et al. Minimum sample size for external validation of a clinical prediction model with a binary outcome. *Stat Med.* 2021;40(19):4230-4251.
155. Held U, Kessels A, Garcia Aymerich J, et al. Methods for handling missing variables in risk prediction models. *Am J Epidemiol.* 2016;184(7):545-551.
156. Steyerberg EW. Missing values. In: Clinical Prediction Models: a practical approach to development, validation, and updating. Cham: Springer International Publishing. 2019;127-155.
157. Mack C SZ, Westreich D. Managing missing data in patient registries: addendum to registries for evaluating patient outcomes: a user's guide, third edition [internet]. Rockville (MD): agency for healthcare research and quality (US); 2018. Types of missing data. Available from: www.ncbi.nlm.nih.gov/books/NBK493614/ (accessed Aug 31, 2021).
158. van Buuren S, Groothuis-Oudshoorn K. mice: multivariate imputation by chained equations in R. *J Stat Softw.* 2011;45(3):67.
159. Vergouwe Y, Royston P, Moons KG, Altman DG. Development and validation of a prediction model with missing predictor data: a practical approach. *J Clin Epidemiol.* 2010;63(2):205-214.
160. Rubin DB, Schenker N. Multiple imputation for interval estimation from simple random samples with ignorable nonresponse. *J Am Stat Assoc.* 1986;81(394):366-374.
161. Rubin DB. Multiple imputation for nonresponse in surveys. New York: Wiley. 1987.
162. van Buuren S, Boshuizen HC, Knook DL. Multiple imputation of missing blood pressure covariates in survival analysis. *Stat Med.* 1999;18(6):681-694.
163. Steyerberg EW, Vickers AJ, Cook NR, et al. Assessing the performance of prediction models: a framework for traditional and novel measures. *Epidemiology.* 2010;21(1):128-138.
164. Van Calster B, Vickers AJ. Calibration of risk prediction models: impact on decision-analytic performance. *Med Decis Making.* 2015;35(2):162-169.
165. Steyerberg EW. Evaluation of Performance. In: Clinical prediction models: a practical approach to development, validation, and updating. Cham: Springer International Publishing. 2019;277-308.
166. Riley RD, Ensor J, Snell KIE, et al. External validation of clinical prediction models using big datasets from e-health records or IPD meta-analysis: opportunities and challenges. *BMJ.* 2016;353:i3140.
167. Steyerberg EW. Updating for a new setting. In: Clinical prediction models: a practical approach to development, validation, and updating. Cham: Springer International Publishing. 2019;399-429.

168. Vickers AJ, Cronin AM. Traditional statistical methods for evaluating prediction models are uninformative as to clinical value: towards a decision analytic framework. *Semin Oncol.* 2010;37(1):31-38.
169. Mallett S, Halligan S, Thompson M, Collins GS, Altman DG. Interpreting diagnostic accuracy studies for patient care. *BMJ.* 2012;345:e3999.
170. Vickers AJ, Elkin EB. Decision curve analysis: a novel method for evaluating prediction models. *Med Decis Making.* 2006;26(6):565-574.
171. Vickers AJ, Van Calster B, Steyerberg EW. Net benefit approaches to the evaluation of prediction models, molecular markers, and diagnostic tests. *BMJ.* 2016;352:i6.
172. Steyerberg EW, Vickers AJ. Decision curve analysis: a discussion. *Med Decis Making.* 2008;28(1):146-149.
173. Vickers AJ, van Calster B, Steyerberg EW. A simple, step-by-step guide to interpreting decision curve analysis. *Diagn Progn Res.* 2019;3:18.
174. Van Calster B, Wynants L, Verbeek JFM, et al. Reporting and interpreting decision curve analysis: a guide for investigators. *Eur Urol.* 2018;74(6):796-804.
175. Harrell F E Jr, with contributions from Dupont C and many others. Hmisc: Harrell miscellaneous. R package version 4.5-0. CRAN.R-project.org/package=Hmisc.
176. Kowarik A, Templ M. Imputation with the R Package VIM. *J Stat Softw.* 2016;74(7):1 - 16.
177. Robin X, Turck N, Hainard A, et al. pROC: an open-source package for R and S+ to analyze and compare ROC curves. *BMC Bioinformatics.* 2011;12(1):77.
178. Signorell et mult. al. DescTools: tools for descriptive statistics. R package version 0.9.42.
179. Kuhn M. caret: classification and regression training. R package version 6.0-88. CRAN.R-project.org/package=caret.
180. Mercaldo ND, Lau KF, Zhou XH. Confidence intervals for predictive values with an emphasis to case-control studies. *Stat Med.* 2007;26(10):2170-2183.
181. Schaarschmidt F. bdpv: inference and design for predictive values in diagnostic tests. R package version 1.3. CRAN.R-project.org/package=bdpv.
182. Brown LD, Cai TT, DasGupta A. Interval estimation for a binomial proportion. *Stat Sci.* 2001;16(2):101-133, 133.
183. Brown M. rmda: risk model decision analysis. R package version 1.6 cran.r-project.org/web/packages/rmda/rmda.pdf.
184. Wishart GC, Bajdik CD, Azzato EM, et al. A population-based validation of the prognostic model PREDICT for early breast cancer. *Eur J Surg Oncol.* 2011;37(5):411-417.
185. Hippisley-Cox J, Coupland C, Vinogradova Y, Robson J, Brindle P. Performance of the QRISK cardiovascular risk prediction algorithm in an independent UK sample of patients from general practice: a validation study. *Heart.* 2008;94(1):34-39.
186. Tully J. HCR-20 shows poor field validity in clinical forensic psychiatry settings. *Evid Based Ment Health.* 2017;20(3):95-96.
187. Grann M, Belfrage H, Tengström A. Actuarial assessment of risk for violence: predictive validity of the VRAG and the historical part of the HCR-20. *Crim Justice Behav.* 2000;27(1):97-114.
188. Gray NS, Taylor J, Snowden RJ. Predicting violence using structured professional judgment in patients with different mental and behavioral disorders. *Psychiatry Res.* 2011;187(1):248-253.
189. Senior M, Burghart M, Yu R, et al. Identifying predictors of suicide in severe mental illness: a feasibility study of a clinical prediction rule (Oxford Mental Illness and Suicide Tool or OxMIS). *Front Psychiatry.* 2020;11(268).

190. National Institute for Health and Care Excellence (NICE). Lipid modification. NICE. 2014. Available from: nice.org.uk/guidance/cg181/evidence/lipid-modification-update-full-guideline-pdf-243786637 (accessed Oct 20, 2021).
191. Kappen TH, Vergouwe Y, van Wolfswinkel L, et al. Impact of adding therapeutic recommendations to risk assessments from a prediction model for postoperative nausea and vomiting. *Br J Anaesth.* 2015;114(2):252-260.
192. Miller IW, Camargo CA, Jr, Arias SA, et al. Suicide Prevention in an Emergency Department Population: The ED-SAFE Study. *JAMA Psychiatry.* 2017;74(6):563-570.
193. Troquete NA, van den Brink RH, Beintema H, et al. Risk assessment and shared care planning in out-patient forensic psychiatry: cluster randomised controlled trial. *Br J Psychiatry.* 2013;202(5):365-371.
194. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ.* 2021;374:n2061.
195. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ.* 2008;337:a1655.
196. Greenhalgh T, Papoutsi C. Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC Med.* 2018;16(1):95.
197. Petticrew M. When are complex interventions 'complex'? When are simple interventions 'simple'? *Eur J Public Health.* 2011;21(4):397-398.
198. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.
199. Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. *BMJ.* 2004;328(7441):702-708.
200. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ.* 2005;330(7494):765.
201. Lobach D, Sanders GD, Bright TJ, et al. Enabling health care decisionmaking through clinical decision support and knowledge management. *Evid Rep Technol Assess (Full Rep).* 2012(203):1-784.
202. Jacobs E, Tamayo M, Rosenbauer J, et al. Protocol of a cluster randomized trial to investigate the impact of a type 2 diabetes risk prediction model on change in physical activity in primary care. *BMC Endocr Disord.* 2018;18(1):72.
203. van der Sluijs R, Fiddelers AAA, Waalwijk JF, et al. The impact of the trauma triage app on pre-hospital trauma triage: design and protocol of the stepped-wedge, cluster-randomized TESLA trial. *Diagn Progn Res.* 2020;4:10.
204. Ministry of Justice. Data first: an introductory user guide--harnessing the potential of linked administrative data for the justice system. Ministry of Justice. 2021.

List of Appendices

		Page
Appendix 1.1	Accepted version of subsequently published manuscript of meta-analysis of violence perpetration outcomes in schizophrenia spectrum disorders.	196
Appendix 1.2	Approach to violence risk assessment documentation within electronic health record in Early Intervention in Psychosis services in 12 National Health Service clinical trusts across the south of England.	227
Appendix 2.1	Participant information leaflet (PIL) and informed consent form (ICF) for clinician participants.	228
Appendix 2.2	Invitation letter, participant information leaflet (PIL) and informed consent form (ICF) for patient and carer participants.	233
Appendix 2.3	Draft topic guides for interviews.	248
Appendix 2.4	OxMIV Clinical User Guide.	250
Appendix 5.1	Tripod checklist.	253
Appendix 5.2	Crime/Home Office codes for included violent offences.	255
Appendix 5.3	Poster detailing mechanism for dissent.	262
Appendix 5.4	Patterns of missing data.	263
Appendix 5.5	Associations from univariable models fitted with binary missingness of reference predictor as dependent variable.	264
Appendix 5.6	Prevalence of predictors in observed data and each of 20 imputations.	265
Appendix 5.7	Performance measures across each complete imputed dataset for the original and updated models.	266
Appendix 5.8	Externally validated model with updated intercept.	269

Appendix 5.9	Misclassification measures for OxMIV at 10% cutoff across each of 20 imputed datasets.	270
Appendix 5.10	Net benefit across a range of cutoff preferences when model or assessment used in an "opt-out" strategy.	271
Appendix 5.11	Net benefit across a range of cutoff preferences in an imputed dataset where OxMIV was at a) lower end and b) upper end of its performance range across the 20 imputed datasets.	272

Appendix 1.1

Accepted version of subsequently published manuscript of meta-analysis of violence perpetration outcomes in schizophrenia spectrum disorders.

[Starts on next page]

Schizophrenia Spectrum Disorders and Violence Perpetration: A Systematic Review and Meta-analysis of Observational Studies

Daniel Whiting BM BCh,[a] Gautam Gulati MD,[b] John R. Geddes MD[a,c] and Seena Fazel MD[a,c*]

[a]Department of Psychiatry, University of Oxford, Oxford, England

[b]University of Limerick School of Medicine and Health Service Executive, Limerick, Ireland

[c]Oxford IIealth NIIS Foundation Trust, Warneford IIospital, Oxford, England

This is the accepted version of a subsequently published manuscript:

Whiting D, Gulati G, Geddes JR, Fazel S. Association of schizophrenia spectrum disorders and violence perpetration in adults and adolescents from 15 countries: a systematic review and meta-analysis. *JAMA Psychiatry*. Published online December 22, 2021. doi:10.1001/jamapsychiatry.2021.3721

Correspondence to:

Professor Seena Fazel MD FRCPsych. Wellcome Trust Research Fellow in Clinical Science, University of Oxford Department of Psychiatry, Oxford, England OX3 7JX. Email: seena.fazel@psych.ox.ac.uk Tel: +44 (0) 1865 613165

Date of revision: November 1, 2021

Word count: 3,496

Key Points

Question: What are the absolute and relative risks of perpetrating violence toward others in schizophrenia spectrum disorders compared with the general population?

Findings: Absolute risks of perpetrating violence in register-based studies were below one in 20 in women and one in four in men with schizophrenia spectrum disorders over a 35-year period. The elevated relative risk for all violence perpetration outcomes was around 10 for women and 5 for men with schizophrenia spectrum disorders, which was similar when examining solely sexual offences and arson as outcomes.

Meaning: Violence perpetration outcomes are an important target for prevention and to reduce stigma in people with schizophrenia spectrum disorders.

Abstract

Importance

Violence perpetration outcomes in schizophrenia spectrum disorders contribute to morbidity and mortality at a population level, disrupt care and lead to stigma.

Objective

To conduct a systematic review and meta-analysis of the risk of perpetrating interpersonal violence in schizophrenia spectrum disorders compared with general population controls.

Data Sources

We searched multiple databases for studies in any language from 1970 to March 2021 using the terms violen* or homicid* and "psychosis" or "psychoses" or "psychotic" or "schizophren*" or "schizoaffective" or "delusional" and terms for mental disorder. Bibliographies of included articles were hand searched.

Study Selection

We included case-control and cohort studies that allowed risks of interpersonal violence perpetration and/or violent criminality in individuals with schizophrenia spectrum disorders to be compared with a general population group without these disorders.

Data Extraction and Synthesis

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and the Meta-analyses of Observational Studies in Epidemiology (MOOSE) proposal. Two reviewers extracted data. Quality was assessed using the Newcastle-Ottawa Quality Assessment Scale. Data was pooled using a random-effects model.

Main Outcome and Measure

The main outcome was violence to others obtained either through official records, self- and/or collateral-report, or medical file review and included any physical assault, robbery, sexual offences, illegal threats or intimidation, and arson.

Results

We included 24 studies of violence perpetration outcomes in 15 countries over four decades (n=51,309 individuals with schizophrenia spectrum disorders). There was an increased risk of violence perpetration in men with schizophrenia and other psychoses (pooled OR=4.5, 95% confidence interval [CI] 3.6-5.6), with substantial heterogeneity (I^2=85%, 95% CI 77%-91%). The risk was also elevated in women (OR=10.2, 95% CI 7.1-14.6), with substantial heterogeneity (I^2= 66%, 95% CI 31%-83%). We also investigated odds of perpetrating sexual offences (OR=5.1, 95% CI 3.8-6.8) and homicide (OR 17.7, 95% CI 13.9-22.6). Three studies found relative risks of arson were increased but we did not pool data due to heterogeneity of outcomes. Absolute risks of violence perpetration in register-based studies were below one in 20 in women with schizophrenia spectrum disorders and one in four in men over a 35-year period.

Conclusions and Relevance

This review finds that the risk of perpetrating violent outcomes is increased in schizophrenia spectrum disorders compared with community controls, which has been confirmed in new population-based longitudinal studies and sibling comparison designs.

Key words: schizophrenia, psychosis, violence, crime

Introduction

Schizophrenia spectrum disorders are associated with a range of adverse outcomes. These include suicide,[1] premature mortality,[2] victimisation[3] and contact with the criminal justice system,[4] and deficits across broader social domains.[5] Perpetration of interpersonal violence is also associated with these diagnoses, an outcome with considerable implications for individuals, families and carers, victims, and public services. Examining such links poses particular challenges. Public perceptions around dangerousness in mental illness can contribute to stigma,[6] and a focus on violence risk may inadvertently increase this. The contribution of mental illness to violent crime is often overstated, such as in media reports on mass shootings,[7] which can bias public perceptions, and such issues have been integral to the appraisal of epidemiological evidence.[8] However, failure to acknowledge associations with violence perpetration in turn risks leaving clinical needs unmet in psychiatric services. An accurate and balanced understanding of the nuanced association between mental illness and violence perpetration, and development of effective prevention, alongside balanced communication and contextualization of research evidence is likely to be one approach to reducing stigma.

At a population level, violence is a leading cause of premature mortality and morbidity. Public health approaches to tackling violence focus on prevention and delineating modifiable risk factors, such as mental illness, to inform interventions.[9] In schizophrenia spectrum disorders, the public health importance of violence perpetration has been reinforced by recent estimates of its economic impact.[10] Updated and precise estimates of violence perpetration risk is needed to inform prevention among health services.

A previous systematic review identified 20 primary studies from 11 countries[11] that reported substantially increased risk for violence perpetration in schizophrenia compared with people

without schizophrenia, and a doubling of risk with substance misuse comorbidity. However, the search period for this review ended in February 2009. Since then, several large population investigations have been conducted.[2,12] These newer studies provide improved approaches to examine confounding and testing comorbidities and allow for examination of additional outcomes. Although other systematic reviews have been conducted,[13,14] no recent quantitative analyses have integrated these new data. This longer term perspective provides more precision for risk estimates, subgroup analyses and metaregression.

Therefore, the current study reports an updated systematic review and meta-analysis of the risk of violence perpetration in individuals with schizophrenia spectrum disorders compared with general population controls.

Methods

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines[15] and the Meta-analyses of Observational Studies in Epidemiology (MOOSE) proposal (eFigure 1).[16] The review was registered on PROSPERO (CRD42020224942). Risk of bias was assessed using the Newcastle-Ottawa Quality Assessment Scale.[17]

Search Strategy

In the original review,[11] Medline, Embase and PsycINFO databases were searched from January 1970 to February 2009. For the update, we searched PubMed, PsycINFO and Global Health from 1 March 2009 - 17 March 2021.

Eligibility Assessment

Identification of schizophrenia spectrum disorders in included studies was from clinical diagnosis or based on diagnostic criteria. See eAppendix 1 for full eligibility criteria. Applying these criteria, 416 relevant articles were identified from updated searches, of which 25 (reporting on 24 studies) met eligibility criteria (eFigure 2).

Data Extraction

A standardised form was used to extract data on study design, location, last year of follow-up (study period), case definition, comparison group (including any use of sibling controls), definition and ascertainment of violence, violence perpetration outcomes in cases and controls, outcome period, sample size, mean age, and information on comorbid substance misuse, personality disorder, victimisation, and treatment. If separate data were available for a range of psychoses, we chose schizophrenia spectrum disorders where possible, including schizophrenia and non-schizophrenia psychoses (i.e. ICD-10 F20-F29), and excluding affective, drug-induced and organic psychoses. Where data were available separately for males and females, this was disaggregated for analysis. See eAppendix 1 for details of absolute risk data extraction. Where applicable, authors were contacted for additional data. Two authors extracted data (DW, GG) and discrepancies resolved by consensus.

Meta-analysis

We combined eligible studies from this update with data from the original review for analysis to ensure that the current review presents the most comprehensive synthesis of available information.[18,19] To avoid duplication, where studies included overlapping populations or articles were superseded by updated investigations in the same population, we included the study that employed a longitudinal design, or the study with the largest sample of individuals with schizophrenia spectrum disorders. Applying these methods, 10 studies were excluded from pooled analyses (eTable 1).[3,20-28]

Data for analysis was considered across four violence perpetration outcome classifications. First, a broad interpersonal violence perpetration definition (any physical assault, robbery, sexual offences, illegal threats or intimidation, and arson). Within this classification male, female, and mixed sex data were grouped separately using non-overlapping samples, and subgroup analyses (not in protocol but added based on reviewer suggestion) were undertaken to examine for sources of heterogeneity (substance misuse comorbidity, geographical region of study, study quality, study type, and nature of control group, patient sample and outcome measure). Whilst data from studies that included homicide, sexual offences or arson within their broad violent outcome definition were included within this classification, if a study considered only one of those specific offences in isolation, it was considered separately. Data included within separate classifications for homicide, sexual offences and arson was either disaggregated from these studies that used a broad definition but also reported separated offences or from studies that considered only these outcomes (i.e. no broad violence category). A total of twelve studies of homicide,[21,29-32] arson[33-35] and sexual offences[36-39] were included in these separate classifications that were not otherwise included in the broader violence perpetration classification either due to reporting only that specific offence, or due to issues of population overlap that did not apply within the separate offence classification. Within the arson classification, meta-analysis was not undertaken due to the clinical heterogeneity of the firesetting definitions.

Statistical Analysis

We generated unadjusted pooled odds ratios (ORs) with 95% confidence intervals (CIs) for risk of violence perpetration outcomes using random-effects meta-analysis. Heterogeneity was examined using Cochran's Q and the I^2 statistic. Analyses were undertaken using R (version 3.6.1)[40] and the R package meta.[41] The Mantel-Haenszel method was used to

combine odds ratios from 2*2 tables, with continuity correction of 0.5 in studies with zero cell frequencies.

Results

Interpersonal Violence Perpetration as Outcome

Twenty four studies were included, of which 16 were from the original review (n=9,954 cases with schizophrenia spectrum disorders; 19.4% of the total cases) and 8 were identified from updated searches (n=41,355 cases, 80.6%). Studies were based in 15 countries: 5 from the US,[42-46] 3 from Sweden,[2,47,48] 2 from Israel reported in three publications,[49-51] 2 from Denmark,[52,53] 2 from Finland (reported in three papers),[54-56] one from Switzerland reported in three publications,[57-59] and one from each of Australia,[12] Austria,[60] Canada,[61] Czech Republic,[62] Egypt,[63] Ethiopia,[64] Germany,[65] New Zealand[66] and the UK.[67] See Table 1 for a summary of included studies and eTable 2 for additional details.

Characteristics of Included Studies

For outcomes, 15 used register-based measures of violent criminality[2,12,46-48,51-53,55,56,59-61,65,67] (n=50,250 cases, 97.9%) and 9 used self- or informant-report measures (n=1,059 cases, 2.1%), either solely[42,44,45,50,62-64] or in combination with register-based data.[43,66] Ten studies included only individuals with schizophrenia spectrum disorders who had at least one inpatient hospitalisation[43,46,47,51-53,59,62,65,67] (n=11,011 cases, 21.5%), whereas 14 studies (n=40,298 cases, 78.5%) identified cases in the community or who had been in contact with a broader range of in- and out-patient care settings.[2,12,42,44,45,48,50,55,56,60,61,63,64,66] Thirteen reports were considered overall good quality (scoring 7-9 out of 9 overall and evenly across

domains),[2,12,43,45,47,51-53,55,56,61,62,66] and 11 were poor-fair[42,44,46,48,50,59,60,63-65,67] (eFigure 3). The average quality score was 7.0 (standard deviation 1.5, interquartile range 6-8).

Male Data

There were 19,976 males with schizophrenia spectrum disorders and the random-effects pooled OR for the risk of violence perpetration in cases compared with general population controls was 4.5 (95% CI 3.6-5.6), with substantial heterogeneity (I^2=85%, 96% CI 77%-91%) (Figure 1).

Female Data

Based on the 14,275 females with schizophrenia spectrum disorders, the random-effects pooled OR for the risk of violence perpetration in cases compared with general population controls was 10.2 (95% CI 7.1-14.6), with substantial heterogeneity (I^2= 66%, 95% CI 31%-83%) (Figure 1). Excluding three studies of females with schizophrenia[55,57,67] (n=256 cases) with zero events in either cases or controls made no material difference to risk estimates (pooled OR 10.3, 95% CI 7.0-15.1).

Mixed Sex Data

Data from 11 studies with 17,058 individuals with schizophrenia spectrum disorders was not available separately by sex (Figure 1). Risk of violence perpetration was increased compared with general population controls (random-effects pooled OR 4.6, 95% CI 3.7-5.7), with substantial heterogeneity (I^2= 72%, 95% CI 48%-85%).

Register-based Outcomes and Study Quality

When restricting analysis to studies that used exclusively register-based violence perpetration outcomes (n=50,250 cases; eFigure 4), pooled OR for violence perpetration in males was 4.6 (95% CI 3.6-5.9; I^2=88% [79%-93%]), in females, the OR was 12.8 (95% CI 9.5-17.4;

I^2=48% [0%-78%]) and in mixed sex studies, it was 4.3 (95% CI 3.4-5.4, I^2=78% [47%-91%]). When studies were grouped by quality, pooled OR for studies rated good (n=46,425 cases) was 5.7 (95% CI 4.3-7.5, I^2=96% [95% CI 95%-97%]) and for studies rated poor-fair (n=4,884 cases) was 4.6 (95% CI 3.7-5.9, I^2=48% [95% CI 6%-71%]) (eFigure 5). Subgroup analysis by study design showed that findings were comparable (eFigure 6).

Absolute Risks

Absolute rates of violence perpetration in included studies of register-based violent outcomes ranged from 2.3% to 24.7% in men with schizophrenia spectrum disorders and from 0% to 5.4% in women with schizophrenia spectrum disorders, over outcome periods that ranged from 1 year to lifetime measures spanning up to 35 years (Table 1, Figure 2).

Substance Misuse and Other Comorbidity

Seventeen studies[2,12,42-45,47,50,51,53-55,59,61-65] included data on substance comorbidity among individuals with schizophrenia spectrum disorders, either under a broad substance misuse definition,[12,42,43,45,50,51,53,61,63,65] or separately for drug[2,44,47,59,62,64] and alcohol.[2,44,47,54,55,59,62,64] A variety of descriptors were used to define the comorbidity; in studies that described abuse (without or without dependence),[42-45,50,53-55,59] misuse[51] or use-disorders,[2,12,61] prevalence ranges are reported for men and women (eTable 2). In thirteen studies[12,42-45,50,51,53,54,59,63,65] data allowed violence perpetration in individuals with schizophrenia spectrum disorders with or without substance misuse comorbidity to be compared to general population groups separately. The pooled odds of violence perpetration in cases without substance misuse comorbidity (n=11,079) was 3.5 (95% CI 2.6-4.6, I^2 =81% [95% CI 68%-89%], eFigure 7), and in cases with substance misuse comorbidity (n=3,586), it was 9.9 (95% CI 7.2-13.5, I^2 =82% [95% CI 69%-89%], eFigure 8).

Information on other comorbidities was limited. One study reported on comorbid antisocial personality disorder.[62] No included studies provided treatment information.

Geographical Region

Subgroup analyses were undertaken for studies undertaken in Europe (n=33,836 cases), North America (n=9,856), Australia and New Zealand (n=4,207) and Africa (n=122). Relative risk estimates for violence perpetration compared to general population controls did not significantly vary by region (eFigure 9).

Familial Confounding

Two included studies, conducted in Sweden[2] and Israel,[51] used population registers to examine risk of violence perpetration in individuals with schizophrenia spectrum disorders and their unaffected siblings (n=33,892 unaffected siblings), in addition to comparing cases with general population controls. Both studies found relative risks of violence perpetration in unaffected siblings remained significantly increased versus population controls, but to a lesser degree than in the corresponding patient samples (eFigure 10), indicating familial confounding. When comparing violence perpetration in individuals with schizophrenia spectrum disorders with their unaffected siblings, the first study reported a ratio of ORs of 4.2 (95% CI 3.8-4.5),[2] and the Israeli investigation an OR of 2.8 (95% CI 2.5-3.3).[51]

Inpatient and Community Samples

When data was grouped according to samples identified by a history of psychiatric hospital admission, or using a wider definition of outpatient or inpatient psychiatric settings, there were no significant differences in relative risk estimates (inpatient pooled OR 5.4, 95% CI 4.1-7.0; mixed community/inpatient pooled OR 5.5, 95% CI 4.0-7.4; eFigure 11).

Homicide Perpetration as Outcome

Eight studies were identified (Figure 3, eTable 3). All used official sources for outcomes. There was an increased risk of homicide perpetration in individuals with schizophrenia spectrum disorders compared to those without (Figure 3), leading to random-effects pooled OR of 17.7 (95% CI 13.9-22.6), with substantial heterogeneity (I^2= 70%, 95% CI 39%-85%). Excluding one study (n=282 cases, 0.4%)[59] with zero events in the control group did not materially change the pooled risk estimate (OR 17.9, 95% CI 14.1-22.8). Four studies were rated good quality[21,29,30,51] and four poor-fair[31,32,59,60] (eFigure 3).

Sexual Offence Perpetration as Outcome

Nine studies[22,36-39,51,52,59,64] were included in a meta-analysis of sexual offence perpetration outcomes (Figure 4, eTable 4, eFigure 3). All but two studies[38,64] used a register-based outcome. Risk was increased in individuals with schizophrenia spectrum disorders compared to controls, random-effects pooled OR of 5.1 (95% CI 3.8-6.8), with moderate heterogeneity (I^2= 54%, 95% CI 7%-78%) (Figure 4).

Arson as Outcome

Four studies presented data on risk of arson. Findings ranged from no association between schizophrenia and self-reported firesetting in one study,[64] to two register based studies of arson and related convictions that showed a significant positive association with schizophrenia spectrum disorder diagnosis, with ORs of 18 in males and 23 in females in a Swedish study,[33] and 7 in a mixed-sex Australian study.[34] See eAppendix 2 for details. Meta-analysis was not considered due to the heterogeneity of arson outcomes.

Discussion

This systematic review and meta-analysis included 51,309 individuals with schizophrenia spectrum disorders from 24 studies in 15 countries over four decades and investigated risk of violence perpetration outcomes. Additionally, we examined data on homicide perpetration, and studies reporting sexual offence perpetration and arson as outcomes. Our findings update and extend a previous meta-analysis[11] in four main ways.

First, the study has included more than double the number of individuals with schizophrenia spectrum disorders in the meta-analysis of violence perpetration outcomes than the previous meta-analysis. This is despite deploying strict exclusion criteria to avoid double-counting of individuals in pooled analyses that excluded otherwise eligible studies. The improved precision of the current study is principally due to the inclusion of four large, high-quality register-based studies conducted since the previous review.[2,12,51,61] Despite studies from the last decade contributing the majority of data, estimates for the relative risk of violence perpetration have remained broadly stable based on visual inspection of the forest plots.

Second, we have pooled risks of sexual offence perpetration. Primary studies varied as to whether they include sexual offences amongst an overall definition of violent offending, or provide separate data on these offences. Although there have been descriptive reviews of associations with sexual offending,[68] to our knowledge this is the first quantitative synthesis. Data on arson and firesetting was more limited, although two register-based studies reported a significant increased association with schizophrenia spectrum disorders.

Third, we have summarised information on absolute risks of violent crime perpetration, and on the time period over which these outcomes occurred. Time periods ranged from 1-35 years in register-based studies, and absolute risks varied considerably over time and between sexes. Absolute risks were below one in 20 (or 5%) in females with schizophrenia spectrum disorders and one in four men.

Fourth, large register-based studies undertaken since the original review have provided more power to investigate confounding. We have replicated in pooled analyses the finding that violence perpetration risk is reduced but remains increased relative to control samples when individuals with substance misuse comorbidity are excluded.[12,51] The increased odds of around 3-fold in non-comorbid schizophrenia spectrum disorder samples compared with general population controls was different and around 10-fold in those with substance misuse comorbidity. Additionally, the contribution of familial factors has now been estimated in studies that have compared risks of violence perpetration in individuals with schizophrenia spectrum disorders, their unaffected siblings, and general population controls. These investigations have reported residual risk amongst unaffected siblings, and therefore some familial confounding, but that risk remains elevated among affected individuals compared to their unaffected siblings.[2,51] The latter finding further confirms the independent association between schizophrenia and violence perpetration.

There are several implications of our findings for clinical services and future research. In clinical settings, risks in absolute terms, particularly in young men, are typically high enough to be considered of routine clinical importance to prevent. This is reflected to a limited extent in clinical guidelines, but guidance on assessing and managing risk could be improved.[69] Likewise, the importance of comorbid substance misuse has been further highlighted, and reinforces the need to prioritise the assessment and treatment of comorbid substance misuse disorders in clinical services. A limitation of pooling data from individuals at different stages of illness and treatment, in a variety of geographical and healthcare settings, is the applicability of findings to a particular clinical setting. The amount of data included has allowed exploration of some relevant factors however, such as the variation by region, patient samples and substance misuse comorbidity. This improves the ability of clinicians to consider to what extent findings apply to their practice.

For research, this replication of relative risk estimates for violence perpetration with the inclusion of larger datasets suggests that further small studies of the relative risk of violence in schizophrenia are not priorities. Future epidemiological research could focus on specific offences or outcomes, such as sexual offences and arson. Violence perpetration as an outcome is necessarily broad, but there may be important differences in clinical and risk profiles between more specific violence perpetration outcomes.

This meta-analysis found robust associations between schizophrenia spectrum disorders and violence perpetration, but does not answer the question of the nature of causal pathways and whether they are present. Empirical studies have suggested that symptoms such as persecutory delusions may be causally linked to violence.[70] The current study found that the association between schizophrenia spectrum disorders and violence perpetration remained, albeit with reduced estimates, after adjusting for substance misuse and familial confounders, which can exist on the causal pathway and explain a proportion of the association. Other background, psychiatric and socio-economic factors, unaccounted for in these pooled analyses, can contribute to this pathway however, and there is research in support of early conduct problems,[71] adverse childhood experiences[72] and economic disadvantage.[73] Large prospective studies are needed to further evaluate causality.[74] For clinicians, the multifactorial relationship means that a key priority should be to refine approaches to individualised risk assessment and management. Scalable prediction tools offer one way to translate contemporary knowledge on risk factors (including sociodemographic, familial and treatment factors) into clinical practice, and achieve a more stratified approach to assessing and managing clinical needs around violence risk.[75]

There was little information on treatment effects. There is evidence from pharmaco-epidemiological studies that antipsychotics can reduce violence perpetration outcomes.[76-79] This needs confirmation in randomised trials, and violence perpetration should be a routine

outcome in effectiveness trials of pharmacological and non-pharmacological interventions. One question is how risk of violence perpetration in individuals with schizophrenia spectrum disorders treated with antipsychotic medication compares to general population samples. One Swedish population study found rates of violent offences of 33 per 1000 person years during treatment with olanzapine, compared with 96 offences per 1000 person years prior to treatment.[77] To what extent these treatment effects bring rates of violence perpetration down towards baseline population levels requires comparison with matched groups.

The majority of data in pooled analyses used register-based violence perpetration outcomes, which offer advantages over self- or informant-rated measures in that they objectively cross a severity threshold for clinical relevance and resource implications, do not rely on ongoing contact with health services, and avoid inter-rater variability and recall bias. A limitation, however, is to what extent these measures may be confounded by differential treatment of individuals with mental disorders by the justice system. However, a study examining the Dunedin cohort found that associations with mental disorders were similar when using self/informant report and official court records, suggesting that the degree of underreporting is similar in cases and controls when using either outcome.[66] In terms of other limitations, only three studies presented information on victimisation[61,62,64] and one on the contribution of childhood trauma.[62] The importance of the overlap between risk of violent victimisation and perpetration is increasingly recognised.[3,61,80] Further, although analyses did not reveal significant differences in risk estimates when studies were grouped by quality, variation between studies in the level of matching of comparison groups is an additional consideration to explain heterogeneity, as this was only partially captured by the quality rating. Finally, a study of over half a million individuals using Danish population registers replicated findings of increased risk of violence perpetration in individuals with schizophrenia spectrum

disorders (with incident rate ratios of 6 in men and 18 in women),[81] but could not be included in pooled analyses due to lacking the necessary tabular data.

Conclusion

Prevention of violence perpetration should be a target for clinical services that assess and treat individuals with schizophrenia spectrum disorders. This review has quantitatively summarised the association between these disorders and violence perpetration outcomes, with more precision than previous reviews and the inclusion of higher quality investigations. New work should consider preventive approaches, including the improvement of the clinical assessment of risk and targeted resource allocation to treat modifiable factors. Violence perpetration outcomes should be routinely collected in studies of the effectiveness of clinical services and therapeutic interventions.

Acknowledgements

The authors are grateful to Hygiea Casiano, Charlotte Hanlon, Ruth Tsigebrhan and Nomi Werbeloff-Becker for providing additional information from their studies.

Funding

Daniel Whiting is funded by the National Institute for Health Research (NIHR) (Doctoral Research Fellowship DRF-2018-11-ST2-069). John Geddes is supported by NIHR Oxford Health BRC. Seena Fazel is funded by the Wellcome Trust (202836/Z/16/Z). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Role of Funder Statement

The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Access to Data and Data Analysis

DW had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflict of Interests Disclosures

None reported.

Table 1. Summary of studies reporting violence perpetration outcomes in people with schizophrenia spectrum disorders compared to general population controls included in meta-analysis. For additional study details see Table S2.

Study	Sex	N Scz	% Viol Scz	Outcome period	Ascertainment of violence	Definition of cases	Nature of case sample	Country	Study period	Definition of violence
Sosowsky,[46] 1980	Mixed	171	4.7%	Up to 6.5 years	Register	Schizophrenia	Admitted to and released from state hospital	US	1975	Violent crimes
Ortmann,[52] 1981	Male	86	2.3%	8 years	Register	Schizophrenia and ICD-8 paranoid states, other psychoses and unspecified psychosis (excluding alcoholic, organic and affective psychosis)	Psychiatric hospitalisation by age 26	Denmark	1978	Violent offences (excluding sexual)
Swanson,[45] 1990	Male	114	12.7%	1 year	Self-report	Schizophrenia or schizophreniform disorder	Community sample	US	1983	Diagnostic Interview Schedule items indicating self-reported violent behaviour
Lindqvist,[48] 1990	Male	330	8.5%	15 years	Register	Schizophrenia	Community sample	Sweden	1986	Assault, unlawful deprivation of liberty, unlawful threats
	Female	314	1.3%							
Modestin,[59] 1996	Male	282	5.3%	21 years	Register	Schizophrenia	Hospitalised at least once during study period	Switzerland	1987	Violent crimes (excluding sexual)
Modestin,[57] 1995	Female	226	0.4%	26 years	Register	Schizophrenia and other psychoses	All patients hospitalised in 1987	Switzerland	1985-7	Violent crimes (excluding sexual)
Rasanen,[55] 1998/ Tiihonen,[54] 1997	Male	67	11.9%	12 years	Register	Schizophrenia, schizophreniform and schizoaffective disorders, paranoid and other psychoses (excluding affective and orgaric)	Birth cohort members with diagnoses on hospital discharge register (treated in all mental and general hospitals)	Finland	1992	Homicide, assault, robbery, arson, violation of domestic peace
	Female	25	0%			Schizophrenia				
Stueve,[50] 1998	Male	51	25.5%	5 years	Self-report	Psychotic or bipolar disorders	Community-based	Israel	1992	Self-reported measures of fighting and weapon use
	Female	50	24.0%							
Arseneault,[66] 2000	Mixed	39	33.3%	1 year	Register & self-report	Schizophrenia spectrum disorder	Community-based (in year before interview only 1.6% of study members overall spent on average 25 days in a psychiatric hospital)	New Zealand	1994	Violent convictions (including illegal threats, presenting an offensive weapon, rape, manual assault, assault, robbery and homicide), and self-reported violence scale (simple assault, aggravated assault, robbery, rape and gang-fighting)
Brennan,[51] 2000	Male	2,185	11.0%	29 years	Register	Schizophrenia and other psychoses (including reactive, paranoid and unspecified, excluding organic and affective)	Members of a birth cohort hospitalised with schizophrenia	Denmark	1991	Murder, attempted murder, rape, violence against authority, assault, domestic violence, robbery
	Female	2,473	1.7%							

Monahan,[61] 2000	Mixed	189	9.5%	20 weeks	Register, collateral & self - report	Schizophrenia and other psychotic disorders (schizophreniform, schizoaffective, delusional disorder, brief reactive psychosis)	Inpatients post-discharge	US	1995	Acts of battery that resulted in physical injury, sexual assaults, assaultive acts that involved the use of a weapon, or threats made with a weapon in hand
Haller,[60] 2001	Mixed	1,325	3.9%	12 years	Register	Schizophrenia, schizoaffective and delusional disorders	Previous in- or out-patient treatment	Austria	1997	Violent crime
Corrigan,[44] 2005	Mixed	42	11.9%	1 year	Self-report	Non-affective psychosis	Community sample	USA	1992	Serious trouble with the law or physical fight resulting in injury
Hodgins,[67] 2007	Male	10	35.0%	31 years	Register	Schizophrenia & other psychoses	Inpatients	UK	2005	Violence against the person, sexual offences minus prostitution related offences and robbery
	Female	5	11.8%							
Elonheimo,[56] 2007	Male	14	7.1%	4 years	Register	Psychotic disorder (including schizophrenia and schizophreniform psychosis)	Community sample (assessed at military call-up)	Finland	2004	Assault ('various kinds'), battery, robbery
Soyka,[65] 2007	Mixed	1,662	3.7%	7-12 years	Register	Schizophrenia	Post-discharge former inpatients	Germany	2002	Physical assault, aggravated assault or battery, threatening/invasion of privacy, sexual abuse of a child, robbery, attempted manslaughter, illegal restraint, involuntary manslaughter, manslaughter, murder, sexual assault, rape, to hold someone at gunpoint
Elbogen,[42] 2009	Mixed	294	9.2%	3 years	Self-report	Schizophrenia and other psychoses	Community sample	US	2005	Self-reported violence including using weapons in a fight, arson, forcible sex, substance-related violence, domestic violence
Eriksson,[47] 2011	Male	377	24.7%	35 years	Register	Schizophrenia	Discharged at least once from hospital	Sweden	2005	Serious violent conviction (homicide, manslaughter, assault, robbery, assaulting or threatening an officer, forcible confinement, and sexual assault excluding attempts)
Short,[12] 2013	Mixed	4,168	10.0%	35 years	Register-based	Schizophrenia disorder (including schizoaffective disorder, paraphrenia, shared psychotic disorder, delusional disorders, unspecified non-organic psychosis)	All persons diagnosed with psychosis on public mental health system.	Australia	2005	Guilty of a violent offence, including all contact sex offences and any physical assaults involving force or causing harm to the victim
Fazel,[2] 2014	Male	14,621	3.5%, 6.0% and 10.7% 16.6%	1, 2 and 5 years post-diagnosis Over mean 9.5 years	Register	Schizophrenia and other non-affective psychosis	National patient register identifying any hospital admission 1972 onwards, outpatient appointments from 2001	Sweden	2009	Violent conviction (homicide, attempted homicide, aggravated assault, common assault, robbery, arson, any sexual offence [rape, sexual coercion, child molestation, sexual harassment], illegal threats or intimidation)

	Female	9,676	0.8%, 1.5%, 2.7% 5.4%	1, 2 and 5 years post-diagnosis Over mean 9.5 years						
Fleischman,[51] 2014	Male	1,746	23.9%	13.6 years	Register (court records)	Schizophrenia	Persons admitted to psychiatric hospitals, day hospitals or psychiatric units in general hospitals	Israel	-	Violent crimes (murder, attempted murder, assault, rape, threats and robbery) for which convicted (controls), or either convicted or deemed mentally incompetent to stand trial
	Female	1,441	4.3%							
Tsigebrhan,[61] 2014	Mixed	92	27.2%	1 year	Self-report	Schizophrenia and schizoaffective disorder	Community sample	Ethiopia	2011	MacArthur interview for past-year violence against others (used a weapon, hit someone hard, purposely set a fire, forced sexual intercourse, fought when drinking alcohol or chewing khat, involved in a fight that came to blows, started a fight)
Refaat,[63] 2015	Mixed	30	86.7%	1 week	Self-report	Schizophrenia	Outpatients either in acute relapse or on maintenance antipsychotic treatment coming for follow-up	Egypt	-	Physical violence grade 3-5 on Modified Overt Aggression Scale (stroked, pushed, scratched or pulled hair of others without injury; attacked others causing mild injury, or serious injury)
Cerny,[62] 2018	Male	93	41.9%	6 months	Self-report, collateral & file review	Schizophrenia, delusional disorder, acute polymorphic psychotic disorder, schizoaffective disorder	Inpatients hospitalised >3 days	Czech Republic	2009	MacArthur Community Violence Interview for past 6 months moderate violence (simple assault without injury or weapon use) and serious violence (any assault with a lethal weapon, any threat with a lethal weapon in hand, any sexual assault)
	Female	65	38.5%							
Casiano,[61] 2020	Mixed	9,046	3.4%	1 year	Register	Psychotic disorder (including schizophrenia, delusional disorders, acute and transient psychotic disorders, schizoaffective disorder, drug-induced psychosis and other and non-specified psychosis)	Community based sample (diagnoses coded on inpatient or outpatient health care contact)	Canada	2012	Violent criminal accusations defined as charges laid down by police and tracked by Manitoba Justice's Prosecution Information and Scheduling Management database; violence inclusive of assault, sexual, and other violent crimes (all included Canadian criminal codes listed in study appendix)

Figure 1. Forest Plot of Association Between Schizophrenia Spectrum Disorders and Violence Perpetration.

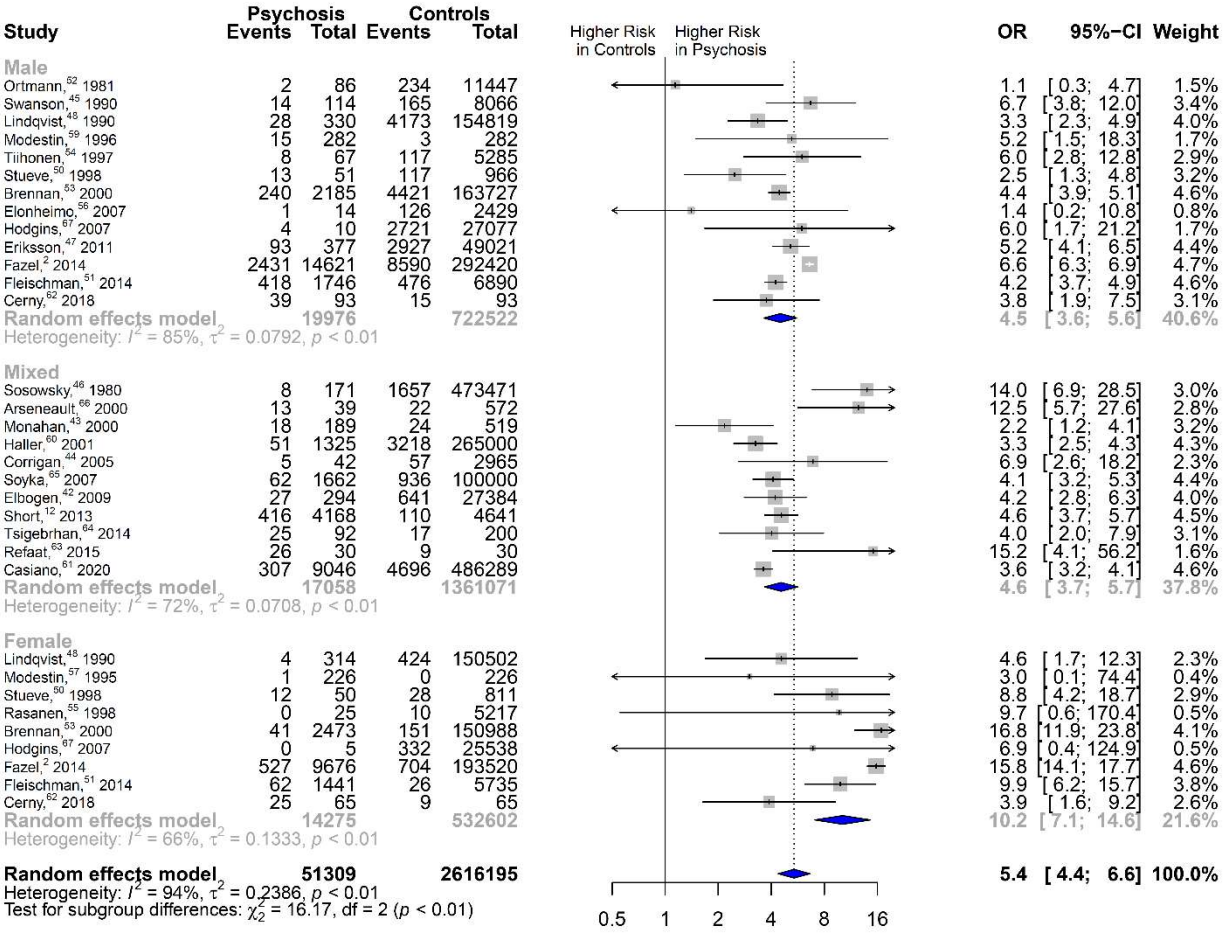
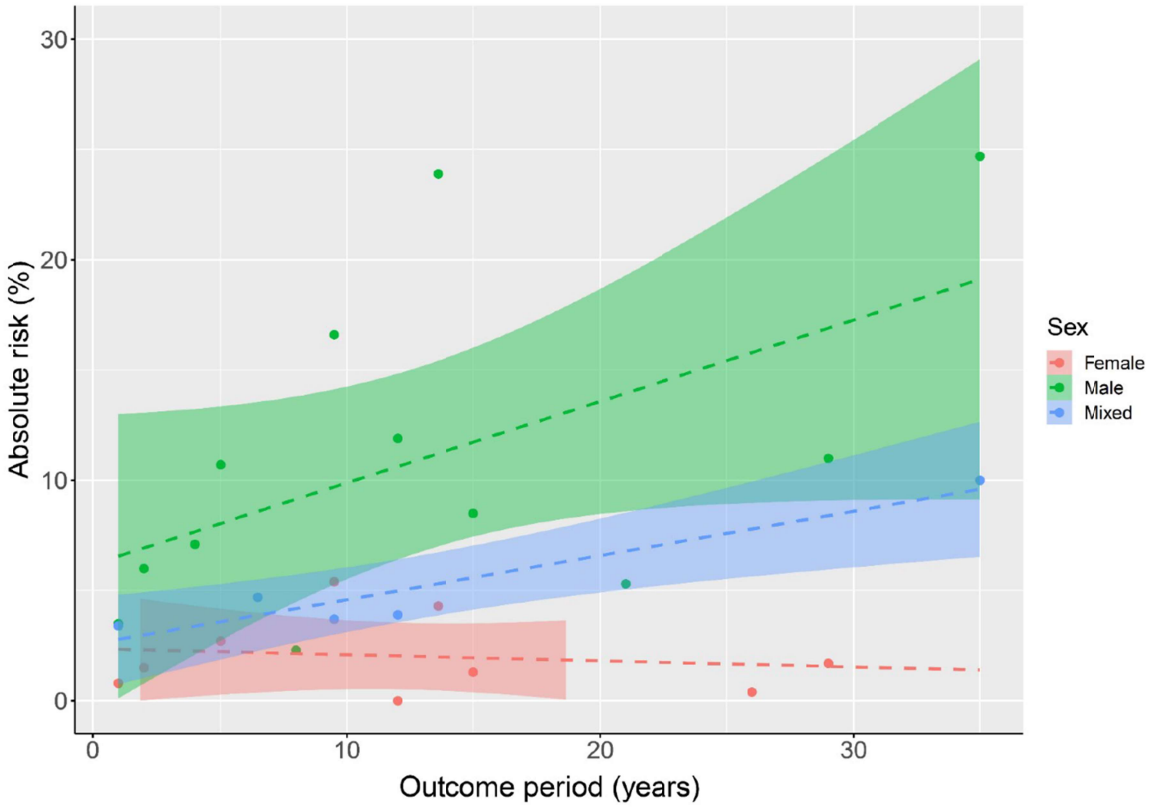


Figure 2. Absolute Risks of Violence Perpetration in Schizophrenia Spectrum Disorders



Outcome period and absolute risk of violence perpetration in people with schizophrenia spectrum disorders in studies included in meta-analysis reporting register-based violent outcomes. Data using self- and collateral-report measures excluded from comparison due to lower severity threshold. Linear regression lines with 95% confidence intervals presented by sex.

Figure 3. Forest Plot of Association Between Schizophrenia Spectrum Disorders and Homicide Perpetration.

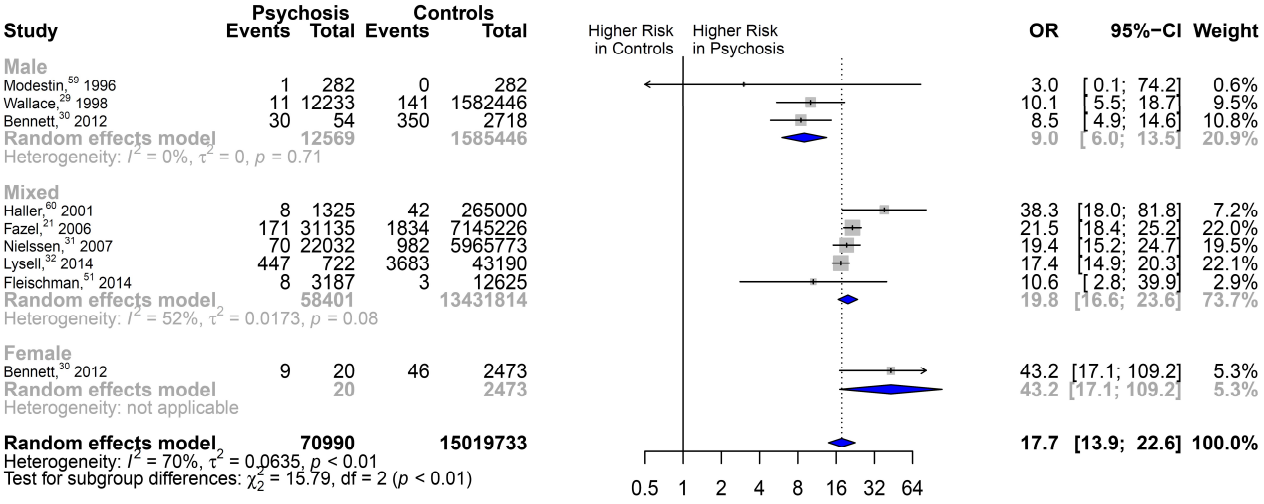
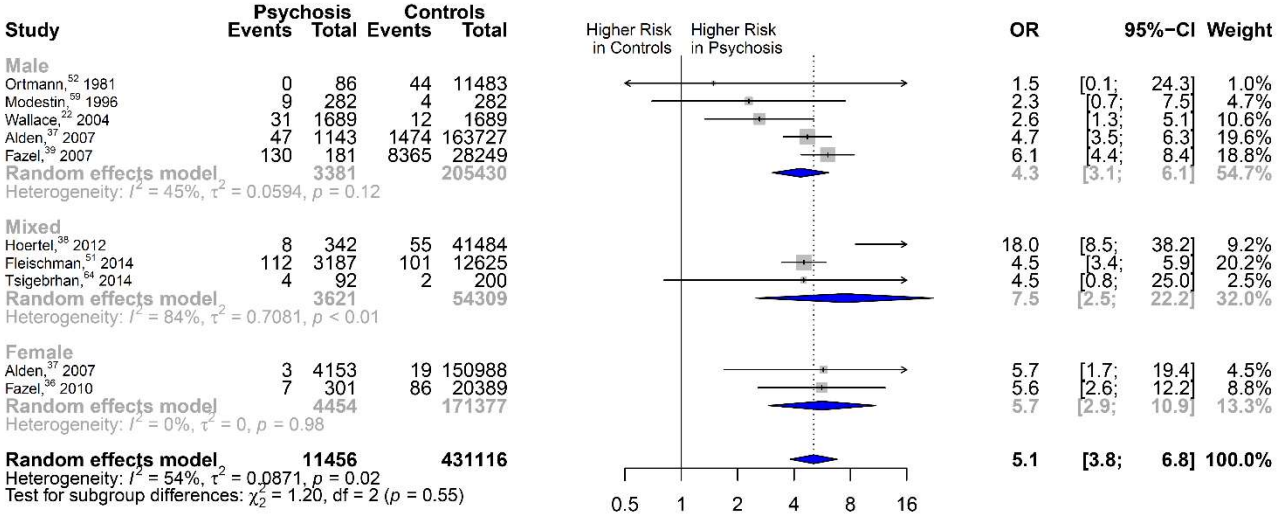


Figure 4. Forest Plot of Association Between Schizophrenia Spectrum Disorders and Sexual Offence Perpetration



References

1. Hor K, Taylor M. Suicide and schizophrenia: a systematic review of rates and risk factors. *J Psychopharmacol.* 2010;24(4_suppl):81-90.
2. Fazel S, Wolf A, Palm C, Lichtenstein P. Violent crime, suicide, and premature mortality in patients with schizophrenia and related disorders: a 38-year total population study in Sweden. *Lancet Psychiatry.* 2014;1(1):44-54.
3. Sariaslan A, Arseneault L, Larsson H, Lichtenstein P, Fazel S. Risk of subjection to violence and perpetration of violence in persons with psychiatric disorders in Sweden. *JAMA Psychiatry.* 2020;77(4):359-367.
4. Yee N, Matheson S, Korobanova D, et al. A meta-analysis of the relationship between psychosis and any type of criminal offending, in both men and women. *Schizophr Res.* 2020;220:16-24.
5. Immonen J, Jääskeläinen E, Korpela H, Miettunen J. Age at onset and the outcomes of schizophrenia: a systematic review and meta-analysis. *Early Interv Psychiatry.* 2017;11(6):453-460.
6. Lok P, Dijk S. Violence and mental illness: five minutes with . . . Seena Fazel. *BMJ.* 2019;366:l5199.
7. US Department of Justice Federal Bureau of Investigation. A study of pre-attack behaviors of active shooters in the United States between 2000-2013. www.fbi.gov/file-repository/pre-attack-behaviors-of-active-shooters-in-us-2000-2013.pdf/view?mod=article_inline. Accessed September 15, 2021.
8. Varshney M, Mahapatra A, Krishnan V, Gupta R, Deb KS. Violence and mental illness: what is the true story? *J Epidemiol Community Health.* 2016;70(3):223-225.
9. World Health Organization. Global status report on violence prevention 2014. Geneva: World Health Organization.
10. Senior M, Fazel S, Tsiachristas A. The economic impact of violence perpetration in severe mental illness: a retrospective, prevalence-based analysis in England and Wales. *Lancet Public Health.* 2020;5(2):e99-e106.
11. Fazel S, Gulati G, Linsell L, Geddes JR, Grann M. Schizophrenia and violence: systematic review and meta-analysis. *PLoS Med.* 2009;6(8):e1000120.
12. Short T, Thomas S, Mullen P, Ogloff JR. Comparing violence in schizophrenia patients with and without comorbid substance-use disorders to community controls. *Acta Psychiatr Scand.* 2013;128(4):306-313.
13. Nederlof AF, Muris P, Hovens JE. The epidemiology of violent behavior in patients with a psychotic disorder: a systematic review of studies since 1980. *Aggress Violent Behav.* 2013;18(1):183-189.
14. Lamsma J, Harte JM. Violence in psychosis: conceptualizing its causal relationship with risk factors. *Aggress Violent Behav.* 2015;24:75-82.
15. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med.* 2009;6(7):e1000097.
16. Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. *JAMA.* 2000;283(15):2008-2012.
17. Wells GA, Shea B, O'Connell D, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp. Accessed April 15, 2021.
18. Moher D, Tsertsvadze A, Tricco A, et al. When and how to update systematic reviews. *Cochrane Database Syst Rev.* 2008;(1):MR000023.
19. Moher D, Tsertsvadze A. Systematic reviews: when is an update an update? *Lancet.* 2006;367(9514):881-883.

20. Fazel S, Långström N, Hjern A, Grann M, Lichtenstein P. Schizophrenia, substance abuse, and violent crime. *JAMA.* 2009;301(19):2016-2023.
21. Fazel S, Grann M. The population impact of severe mental illness on violent crime. *Am J Psychiatry.* 2006;163(8):1397-1403.
22. Wallace C, Mullen PE, Burgess P. Criminal offending in schizophrenia over a 25-Year period marked by deinstitutionalization and increasing prevalence of comorbid substance use disorders. *Am J Psychiatry.* 2004;161(4):716-727.
23. Eriksson A. Schizophrenia and criminal offending - risk factors and the role of treatment. [PhD dissertation] 2008. Stockholm: Karolinska Institutet.
24. Sariaslan A, Larsson H, Fazel S. Genetic and environmental determinants of violence risk in psychotic disorders: a multivariate quantitative genetic study of 1.8 million Swedish twins and siblings. *Mol Psychiatry.* 2016;21(9):1251-1256.
25. Kuja-Halkola R, Pawitan Y, D'Onofrio BM, Långström N, Lichtenstein P. Advancing paternal age and offspring violent offending: a sibling-comparison study. *Dev Psychopathol.* 2012;24(3):739-753.
26. Moberg T, Stenbacka M, Tengström A, et al. Psychiatric and neurological disorders in late adolescence and risk of convictions for violent crime in men. *BMC Psychiatry.* 2015;15:299..
27. Okuda M, Olfson M, Wang S, et al. Correlates of intimate partner violence perpetration: results from a National Epidemiologic Survey. *J Trauma Stress.* 2015;28(1):49-56.
28. Lysell H, Dahlin M, Långström N, Lichtenstein P, Runeson B. Killing the mother of one's child: psychiatric risk factors among male perpetrators and offspring health consequences. *J Clin Psychiatry.* 2016;77(3):342-347.
29. Wallace C, Mullen PE, Burgess P, et al. Serious criminal offending and mental disorder. *Br J Psychiatry.* 1998;172(6):477-484.
30. Bennett D, Ogloff J, Mullen P, Thomas S. A study of psychotic disorders among female homicide offenders. *Psychol Crime Law.* 2012;18(3):231-243.
31. Nielssen OB, Westmore BD, Large MM, Hayes RA. Homicide during psychotic illness in New South Wales between 1993 and 2002. *Med J Aust.* 2007;186(6):301-304.
32. Lysell H, Runeson B, Lichtenstein P, Långström N. Risk factors for filicide and homicide: 36-year national matched cohort study. *J Clin Psychiatry.* 2014;75(2):127-132.
33. Anwar S, Långström N, Grann M, Fazel S. Is arson the crime most strongly associated with psychosis?--A national case-control study of arson risk in schizophrenia and other psychoses. *Schizophr Bull.* 2011;37(3):580-586.
34. Ducat L, Ogloff JR, McEwan T. Mental illness and psychiatric treatment amongst firesetters, other offenders and the general community. *Aust N Z J Psychiatry.* 2013;47(10):945-953.
35. Hoertel N, Le Strat Y, Schuster J-P, Limosin F. Gender differences in firesetting: results from the national epidemiologic survey on alcohol and related conditions (NESARC). *Psychiatry Res.* 2011;190(2):352-358.
36. Fazel S, Sjöstedt G, Grann M, Långström N. Sexual offending in women and psychiatric disorder: a national case-control study. *Arch Sex Behav.* 2010;39(1):161-167.
37. Alden A, Brennan P, Hodgins S, Mednick S. Psychotic disorders and sex offending in a Danish birth cohort. *Arch Gen Psychiatry.* 2007;64(11):1251-1258.
38. Hoertel N, Le Strat Y, Schuster JP, Limosin F. Sexual assaulters in the United States: prevalence and psychiatric correlates in a national sample. *Arch Sex Behav.* 2012;41(6):1379-1387.
39. Fazel S, Sjöstedt G, Långström N, Grann M. Severe mental illness and risk of sexual offending in men: a case-control study based on Swedish national registers. *J Clin Psychiatry.* 2007;68(4):588-596.
40. R Core Team. R: a language and environment for statistical computing. Vienna ARFfSC, 2019 https://www.R-project.org/.

41. Balduzzi S, Rücker G, Schwarzer G. How to perform a meta-analysis with R: a practical tutorial. *Evid Based Ment Health.* 2019;22(4):153-160.
42. Elbogen EB, Johnson SC. The intricate link between violence and mental disorder: results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Arch Gen Psychiatry.* 2009;66(2):152-161.
43. Monahan J. Reducing violence risk: diagnostically based clues from the MacArthur Violent Risk Assessment Study. In: Hodgins S. Effective prevention of crime and violence among the mentally ill. Amsterdam: Kluwer, 2000.
44. Corrigan PW, Watson AC. Findings from the National Comorbidity Survey on the frequency of violent behavior in individuals with psychiatric disorders. *Psychiatry Res.* 2005;136(2-3):153-162.
45. Swanson JW, Holzer CE, 3rd, Ganju VK, Jono RT. Violence and psychiatric disorder in the community: evidence from the Epidemiologic Catchment Area surveys. *Hosp Community Psychiatry*. 1990;41(7):761-770.
46. Sosowsky L. Explaining the increased arrest rate among mental patients: a cautionary note. *Am J Psychiatry.* 1980;137(12):1602-1605.
47. Eriksson A, Romelsjö A, Stenbacka M, Tengström A. Early risk factors for criminal offending in schizophrenia: a 35-year longitudinal cohort study. *Soc Psychiatry Psychiatr Epidemiol.* 2011;46(9):925-932.
48. Lindqvist P, Allebeck P. Schizophrenia and crime. A longitudinal follow-up of 644 schizophrenics in Stockholm. *Br J Psychiatry.* 1990;157:345-350.
49. Stueve A, Link BG. Violence and psychiatric disorders: results from an epidemiological study of young adults in Israel. *Psychiatr Q.* 1997;68(4):327-342.
50. Stueve A, Link BG. Gender differences in the relationship between mental illness and violence: evidence from a community-based epidemiological study in Israel. *Soc Psychiatry Psychiatr Epidemiol.* 1998;33(1):S61-S67.
51. Fleischman A, Werbeloff N, Yoffe R, Davidson M, Weiser M. Schizophrenia and violent crime: a population-based study. *Psychol Med.* 2014;44(14):3051-3057.
52. Ortmann J. *Psykisk afvigelse og kriminel adfærd : en undersøgelse af 11.533 mænd født i 1953 i det metropolitane område København.* [Mental disorder and criminal behaviour. An investigation of 11,533 men born in 1953 in Copenhagen metropolitan area]. Copenhagen: Justitsministerie, 1981.
53. Brennan PA, Mednick SA, Hodgins S. Major Mental Disorders and Criminal Violence in a Danish Birth Cohort. *Arch Gen Psychiatry.* 2000;57(5):494-500.
54. Tiihonen J IM, Rasanen P, Koiranen M, Moring J. Specific major mental disorders and criminality: a 26-year prospective study of the 1966 northern Finland birth cohort. *Am J Psychiatry.* 1997;154(6):840-845.
55. Räsänen P, Tiihonen J, Isohanni M, et al. Schizophrenia, alcohol abuse, and violent behavior: a 26-year followup study of an unselected birth cohort. *Schizophr Bull.* 1998;24(3):437-441.
56. Elonheimo H, Niemelä S, Parkkola K, et al. Police-registered offenses and psychiatric disorders among young males: the Finnish "From a boy to a man" birth cohort study. *Soc Psychiatry Psychiatr Epidemiol.* 2007;42(6):477-484.
57. Modestin J, Ammann R. Mental disorders and criminal behaviour. *Br J Psychiatry.* 1995;166(5):667-675.
58. Modestin J, Wuermle O. Criminality in men with major mental disorder with and without comorbid substance abuse. *Psychiatry Clin Neurosci.* 2005;59(1):25-29.
59. Modestin J, Ammann R. Mental disorder and criminality: male schizophrenia. *Schizophr Bull.* 1996;22(1):69-82.
60. Haller R, Kemmler G, Kocsis E, et al. Schizophrenie und Gewalttätigkeit Ergebnisse einer Gesamterhebung in einem österreichischen Bundesland. *Der Nervenarzt.* 2001;72(11):859-866.

61. Casiano H, Hensel JM, Chartier MJ, et al. The intersection between criminal accusations, victimization, and mental disorders: a Canadian population-based study. *Can J Psychiatry.* 2020;65(7):492-501.
62. Černý M, Hodgins S, Kučíková R, et al. Violence in persons with and without psychosis in the Czech Republic: risk and protective factors. *Neuropsychiatr Dis Treat.* 2018;14:2793-2805.
63. Refaat N, Fahmy M, El-Leithy W, Hassan H, El-Moez A. Frequency, severity and types of aggressive behavior among patients with schizophrenia at psychiatry outpatients clinic in comparison to normal controls. *Arab J Psychiatry.* 2015;44(2151):1-8.
64. Tsigebrhan R, Shibre T, Medhin G, Fekadu A, Hanlon C. Violence and violent victimization in people with severe mental illness in a rural low-income country setting: a comparative cross-sectional community study. *Schizophr Res.* 2014;152(1):275-282.
65. Soyka M, Graz C, Bottlender R, Dirschedl P, Schoech H. Clinical correlates of later violence and criminal offences in schizophrenia. *Schizophr Res.* 2007;94(1):89-98.
66. Arseneault L, Moffitt TE, Caspi A, Taylor PJ, Silva PA. Mental disorders and violence in a total birth cohort: results from the Dunedin Study. *Arch Gen Psychiatry.* 2000;57(10):979-986.
67. Hodgins S, Alderton J, Cree A, Aboud A, Mak T. Aggressive behaviour, victimization and crime among severely mentally ill patients requiring hospitalisation. *Br J Psychiatry.* 2007;191:343-350.
68. Lewis ET, 3rd, Dwyer RG. Psychosis and sexual offending: a review of current literature. *Int J Offender Ther Comp Criminol.* 2018;62(11):3372-3384.
69. Whiting D, Lichtenstein P, Fazel S. Violence and mental disorders: a structured review of associations by individual diagnoses, risk factors, and risk assessment. *Lancet Psychiatry.* 2021;8(2):150-161.
70. Coid JW, Ullrich S, Kallis C, et al. The relationship between delusions and violence: findings from the East London first episode psychosis study. *JAMA Psychiatry.* 2013;70(5):465-471.
71. Lichtenstein P, Cederlöf M, Lundström S, et al. Associations between conduct problems in childhood and adverse outcomes in emerging adulthood: a longitudinal Swedish nationwide twin cohort. *J Child Psychol Psychiatry.* 2020;61(7):798-806.
72. Duke NN, Pettingell SL, McMorris BJ, Borowsky IW. Adolescent violence perpetration: associations with multiple types of adverse childhood experiences. *Pediatrics.* 2010;125(4):e778-e786.
73. Pickett KE, Wilkinson RG. Income inequality and health: a causal review. *Soc Sci Med.* 2015;128:316-326.
74. Appelbaum, PS. In Search of a new paradigm for research on violence and schizophrenia. *Am J Psychiatry.* 2019;176(9):677-679.
75. Fazel S, Wolf A, Larsson H, et al. Identification of low risk of violent crime in severe mental illness with a clinical prediction tool (Oxford Mental Illness and Violence tool [OxMIV]): a derivation and validation study. *Lancet Psychiatry.* 2017;4(6):461-468.
76. Fazel S, Zetterqvist J, Larsson H, Långström N, Lichtenstein P. Antipsychotics, mood stabilisers, and risk of violent crime. *Lancet.* 2014;384(9949):1206-1214.
77. Bhavsar V, Kosidou K, Widman L, et al. Clozapine treatment and offending: a within-subject study of patients with psychotic disorders in Sweden. *Schizophr Bull.* 2019;46(2):303-310.
78. Chang Z, Lichtenstein P, Långström N, Larsson H, Fazel S. Association between prescription of major psychotropic medications and violent reoffending after prison release. *JAMA.* 2016;316(17):1798-1807.
79. Sariaslan A, Leucht S, Zetterqvist J, Lichtenstein P, Fazel S. Associations between individual antipsychotics and the risk of arrests and convictions of violent and other crime: a nationwide within-individual study of 74 925 persons. *Psychol Med.* 2021:1-9.
80. Sariaslan A, Lichtenstein P, Larsson H, Fazel S. Triggers for violent criminality in patients with psychotic disorders. *JAMA Psychiatry.* 2016;73(8):796-803.

Appendix 1.2

Approach to violence risk assessment documentation within electronic health record in Early Intervention in Psychosis services in 12 National Health Service clinical trusts across the south of England.

Clinical service	Format single tick box or free-text?	Structure or subdivision?	Distinguish past and current risk?	Risk descriptor	Lists risk factors or guides formulation?	Summary formulation free-text only?	Divides into timescale of risks?	Categorical rating
A	No	Yes	Yes	Broad violence, risk to others or aggression	No	No	No	High/Med/Low
B	No	No	Yes	Lists specific risks e.g. arson etc.	No	No	Yes	High/Med/Low
C	Yes	No	No	Broad violence, risk to others or aggression	Yes	Yes	No	None
D	No	No	No	Lists specific risks e.g. arson etc.	Yes	Yes	No	None
E	Yes	No	No	Broad violence, risk to others or aggression	No	Yes	No	None
F	No	Yes	Yes	Broad violence, risk to others or aggression	Yes	Yes	No	None
G	Yes	No	No	Broad violence, risk to others or aggression	No	Yes	No	None
H	No	No	No	Broad violence, risk to others or aggression	No	Yes	No	None
I	No	No	No	Broad violence, risk to others or aggression	No	No	Yes	Numeric
J	No	No	No	Lists specific risks e.g. arson etc.	No	Yes	No	None
K	No	Yes	No	Lists specific risks e.g. arson etc.	Yes	No	No	High/Med/Low
L	Yes	No	No	Broad violence, risk to others or aggression	No	No	No	None

Appendix 2.1

Participant information leaflet (PIL) and informed consent form (ICF) for clinician participants.

Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

PARTICIPANT INFORMATION SHEET – CLINICIAN INTERVIEWS

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

We'd like to invite you to take part in our study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this leaflet, and discuss it with others if you wish. If anything is unclear, or you would like more information, please ask us.

What is the purpose of the study?

We want to find out about clinicians' current approaches and attitudes to assessing risk of violence, preconceptions about using a structured tool for this, and subsequent experiences of using the 'OxMIV' risk assessment tool.

Why have I been invited?

You have been invited because the clinical team in which you work (Early Intervention in Psychosis [EIP] services) will soon have the OxMIV tool available to use, and in your clinical role you have some responsibility for assessing risk (such as in new assessments or reviews). We want to interview people with different perspectives and experience and our aim is to interview around 12 patients under the care of EIP services, 20 clinicians who work within EIP services, and 6 carers of patients under the care of EIP services.

Do I have to take part?

No, taking part is voluntary. Whether you take part or not will in no way affect your work, or whether or not you are able to use the OxMIV tool when it becomes available. You can also withdraw at any point if you change your mind, without giving a reason.

What will happen to me if I decide to take part?

If you decide to take part, you will be invited to two interviews – one before OxMIV is made available to your team, and one 4 months after it is made available. These interviews can be face to face or over the phone.

Before the first interview, the researcher will ask if you have read this leaflet, if you have any questions, and if you still want to take part. They will then ask you for consent, either by signing a consent form, or doing this verbally if the interview is being conducted over the telephone. You will be given a copy of the signed form to keep, or where verbal consent is given, a consent form signed by the researcher.

Each interview will last a maximum of one hour, and will be audio-recorded. The audio-recording will be stored securely on a laptop until the interview is typed-out (transcribed), and will then be destroyed.

At the first interview, the researcher will ask questions such as about your views on the assessment of violence risk in your clinical setting, any difficulties with this, and your thoughts the potential usefulness of a supportive tool. Although the researcher guides the interview, you will be able to talk about aspects most important to you.

Before the second interview, the researcher will ask if you still want to participate. If so, the interview will focus on your experiences of using the OxMIV tool.

What are the benefits and possible disadvantages of taking part?

We cannot promise that the study will help you, but the information that we get from the study may help improve the care of patients in the future. Being interviewed will involve you giving up some of your time.

The topic can be sensitive, especially if you have had relevant experiences that are upsetting. If so, it is possible you may find the interview difficult or distressing. Before starting, the researcher will ask what you would like to happen if you do become distressed. You are also free to stop the interview at any point, and can choose not to answer certain questions.

Will my taking part in the study be kept confidential?

Yes it will. We will follow all ethical and legal practices to ensure information about you is handled confidentially. Your personal information will be held securely. Access will be restricted to the research team based at the University of Oxford. Information we collect will be stored in line with the University's data storage policy.

Audio-recorded interviews will be transcribed and de-identified by removing names that might identify anyone. Original recordings will be destroyed after transcription, and the dataset will be destroyed three years after the results of the study are published.

Responsible members of the University of Oxford and Oxford Health NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Expenses and payments

You will not receive any payment for taking part in this research. However, reasonable travel expenses will be paid, on production of receipts, or a mileage allowance provided as appropriate.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for less than 3 months after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for three years after the end of the study.

The audio-recordings of interviews will be typed-out by a transcriber service (Appen UK Transcription Services). The recordings passed to the transcriber will be identified by a study-ID number rather than any of your personal details. The transcriber will not retain the recording after it has been typed out and returned to the research team. This processing of data will be formalised in a written agreement to ensure it is undertaken confidentially and securely.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, and don't need to tell us why. This would not affect your work. If you withdraw, we would like to use the data collected up to that point.

What will happen to the results of this study?

When the research study is finished the findings will be used to help improve future clinical care. We will publish the study findings through journal articles, reports, presentations and conference papers. You will not be able to be identified in any written or verbal reports from the study, including anonymous quotations that may be used. You will be sent a leaflet giving a summary of the study findings. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (a PhD thesis).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Daniel Whiting, daniel.whiting@psych.ox.ac.uk or 01865 613165, or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, ctrg@admin.ox.ac.uk.

Who is organising and funding the study?

This study is funded by the National Institute for Health Research as part of a research fellowship undertaken by the Chief Investigator Dr Daniel Whiting (Award Ref DRF-2018-11-ST2-069). It is sponsored by the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the West Midlands – Solihull Research Ethics Committee.

Further information and contact details:

For more information please contact Dr Daniel Whiting by email, telephone or in writing:

Dr Daniel Whiting (Chief Investigator)
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

Thank you for taking the time to read this leaflet

Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM – CLINICIAN INTERVIEW

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

Name of Researcher:

If you agree, please initial each box

1. I confirm that I have read the information sheet dated..... (version.....) for this 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, without my work or legal rights being affected.	
3. I understand that relevant sections of data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities and from Oxford Health NHS Trust(s), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
4. I agree to audio recording and the use of anonymised quotes in research reports and publications.	

5. I agree to take part in this study.	

Name of Participant	*Date*	*Signature*
Name of Person taking Consent	*Date*	*Signature*

**1 copy for participant; 1 copy for researcher site file; for recorded verbal consent: researcher to complete form and email or post copy to clinician.*

Appendix 2.2

Invitation letter, participant information leaflet (PIL) and informed consent form (ICF) for patient and carer participants.

Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

LETTER OF INVITATION – PATIENT/CARER INTERVIEWS

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

We would like your permission for our researchers to contact you by telephone or email regarding an interview study.

What would the study involve?

We want to find out what it is like for patients and carers when clinicians assess someone's individual risks and needs regarding the safety of other people, and whether using an assessment tool called 'OxMIV' can make the experience better. The study would involve a single one-to-one interview that can be done in person or over the phone.

If you are happy to be contacted, please fill in the details below and pass them back to your clinician, and a member of the research team will be in touch within a week with further information to help you decide whether you might want to take part.

Do I have to agree to being contacted?

No, you do not have to agree to be contacted. Taking part is voluntary and you can withdraw at any time without giving a reason. If you change your mind before we contact you and would

rather not hear from us, you can let Dr Daniel Whiting know using the details below. None of this would affect any aspect of your clinical care, either now or in the future.

Thank you for taking the time to read this.

Dr Daniel Whiting (Chief Investigator)
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk 01865 613165

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

I agree to be contacted about an interview

Name _____ Signature_____

Email _____ And/or telephone _____

Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

PARTICIPANT INFORMATION SHEET – PATIENT INTERVIEWS

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

We'd like to invite you to take part in our study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this leaflet, and if you wish discuss it with others. If anything is unclear, or you would like more information, please don't hesitate to ask us.

What is the purpose of the study?

We want to find out what it is like for patients and carers when clinicians assess someone's individual risks and needs regarding behaving violently, and whether using an assessment tool called 'OxMIV' can make the experience better.

Why have I been invited?

You have been invited because your clinical team (Early Intervention in Psychosis [EIP] services) are using the OxMIV tool, and this may have been discussed with you in a recent assessment or review.

Importantly, the study is about your views on how mental health services assess risk.

We want to interview people with different perspectives and experience and our aim is to interview around 12 patients under the care of EIP services, 20 clinicians who work within EIP services, and 6 carers of patients under the care of EIP services. Patients and carers can take part separately – you do not have to have a carer to take part.

Do I have to take part?

No, taking part is voluntary. Whether you take part or not will in no way affect any aspect of your clinical care, either now or in the future. You can also withdraw at any point if you change your mind, without giving a reason.

What will happen to me if I decide to take part?

If you decide to take part, you will be invited to a one-off interview. This can be face to face, at a location you feel comfortable with (including your home), or over the phone. This is separate to any contact with your clinical team. A friend or carer is welcome to be present during the interview if you would like.

Before the interview, the researcher will ask if you have read this leaflet, if you have any questions, and if you still want to take part. They will then ask you to consent to the study, either by signing a consent form, or doing this verbally if the interview is being conducted over the telephone. You will be given a copy of the signed form to keep, or where verbal consent is given, a consent form signed by the researcher.

The interview itself will last a maximum of one hour, and will be audio-recorded. The audio-recording will be stored securely on a laptop until the interview is typed-out (transcribed), and will then be destroyed. The researcher will ask questions about your views on the assessment of violence risk and about the OxMIV tool. Although the researcher guides the interview, you will be able to talk about those aspects most important to you.

What are the benefits and possible disadvantages of taking part?

We cannot promise that the study will help you, but the information that we get from the study may help improve the care of other patients. Being interviewed will involve you giving up some of your time.

The topic is sensitive, especially if you have had experiences to do with it that are upsetting. If so, it is possible you may find the interview difficult or distressing. Before starting, the researcher will ask whether there is anyone you would like to be told if you do become distressed, like a relative or friend. You are also free to stop the interview at any point, and can choose not to answer certain questions.

Will the clinical team be informed of my participation?

If you are a patient, your care co-ordinator will be informed that you participated. No details of the interview will be shared, this is kept confidential. The only scenario in which something other than your participation would be shared with them would be if the researcher had concerns about your immediate wellbeing.

Will my taking part in the study be kept confidential?

Yes. We will follow all ethical and legal practices to ensure information about you is handled confidentially. Your personal information will be held securely. Access will be restricted to the research team based at the University of Oxford. Information we collect will be stored in line with the University's data storage policy.

Audio-recorded interviews will be typed out and de-identified by removing names that might identify anyone. Original recordings will be destroyed, and the dataset will be destroyed three years after the results of the study are published.

Responsible members of the University of Oxford and Oxford Health NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Expenses and payments

You will receive a voucher worth £10 for taking part in this research. Reasonable travel expenses will also be paid, on production of receipts, or a mileage allowance provided as appropriate.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for less than 3 months after the study has finished. We will store the de-identified research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for three years after the end of the study. Oxford Health NHS Foundation Trust will only collect your name and contact details to pass on to the research team, if you are happy to be contacted about being involved in the study. They will not keep identifiable information about you from this study.

The audio-recordings of interviews will be typed-out by a transcriber service [name and details of transcription company]. The recordings passed to the transcriber will be identified by a study-ID number rather than any of your personal details. The transcriber will not retain the recording after it has been typed out and returned to the research team. This processing of data will be formalised in a written agreement to ensure it is undertaken confidentially and securely.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, and don't need to tell us why. This would not affect any care or treatment. Your interview would not be removed from the study if you withdraw after it has already been typed out and de-identified.

What will happen to the results of this study?

When the research study is finished the findings will be used to help healthcare professionals to better provide care for patients. We will publish the study findings through journal articles, reports, presentations and conference papers. You will not be able to be identified in any written or verbal reports from the study, including anonymous quotations that may be used. Your clinical team will provide you with a leaflet giving a summary of the study findings if you wish. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (a PhD thesis).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Daniel Whiting, daniel.whiting@psych.ox.ac.uk or 01865 613165, or you may contact the

University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

A patient and public involvement group consisting of both patients and carers has inputted into the design of the study, such as the topics of interest for interviews, and has reviewed written materials associated with the study, including this leaflet.

Who is organising and funding the study?

This study is funded by the National Institute for Health Research as part of a research fellowship undertaken by the Chief Investigator Dr Daniel Whiting (Award Ref DRF-2018-11-ST2-069). It is sponsored by the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the West Midlands – Solihull Research Ethics Committee.

Further information and contact details:

For more information please contact Dr Daniel Whiting by email, telephone or in writing:

Dr Daniel Whiting (Chief Investigator)
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

Thank you for taking the time to read this leaflet





Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

PARTICIPANT INFORMATION SHEET – CARER INTERVIEWS

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

We'd like to invite you to take part in our study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this leaflet, and if you wish discuss it with others. If anything is unclear, or you would like more information, please don't hesitate to ask us.

What is the purpose of the study?

We want to find out what it is like for patients and carers when clinicians assess someone's individual risks and needs regarding behaving violently, and whether using an assessment tool called 'OxMIV' can make the experience better.

Why have I been invited?

You have been invited because the clinical team of the person you care for (Early Intervention in Psychosis [EIP] services) are using the OxMIV tool, and this may have been discussed with you in a recent assessment or review.

Importantly, the study is about your views on how mental health services assess risk.

We want to interview people with different perspectives and experience and our aim is to interview around 12 patients under the care of EIP services, 20 clinicians who work within EIP services, and 6 carers of patients under the care of EIP services. Patients and carers can take part separately – you can take part as a carer without the person you care for taking part.

Do I have to take part?

No, taking part is voluntary. Whether you take part or not will in no way affect any aspect of clinical care, either now or in the future. You can also withdraw at any point if you change your mind, without giving a reason.

What will happen to me if I decide to take part?

If you decide to take part, you will be invited to a one-off interview. This can be face to face, at a location you feel comfortable with (including your home), or over the phone. This is separate to any contact with the clinical team.

Before the interview, the researcher will ask if you have read this leaflet, if you have any questions, and if you still want to take part. They will then ask you to consent to the study, either by signing a consent form, or doing this verbally if the interview is being conducted over the telephone. You will be given a copy of the signed form to keep, or where verbal consent is given, a consent form signed by the researcher.

The interview itself will last a maximum of one hour, and will be audio-recorded. The audio-recording will be stored securely on a laptop until the interview is typed-out (transcribed), and will then be destroyed. The researcher will ask questions about your views on the assessment of violence risk and about the OxMIV tool. Although the researcher guides the interview, you will be able to talk about those aspects most important to you.

What are the benefits and possible disadvantages of taking part?

We cannot promise that the study will help you or the person you care for, but the information that we get from the study may help improve the care of other patients. Being interviewed will involve you giving up some of your time.

The topic is sensitive, especially if you have had experiences to do with it that are upsetting. If so, it is possible you may find the interview difficult or distressing. Before starting, the researcher will ask whether there is anyone you would like to be told if you do become distressed, like a relative or friend. You are also free to stop the interview at any point, and can choose not to answer certain questions.

Will my taking part in the study be kept confidential?

Yes. We will follow all ethical and legal practices to ensure information about you is handled confidentially. Your personal information will be held securely. Access will be restricted to the research team based at the University of Oxford. Information we collect will be stored in line with the University's data storage policy.

Audio-recorded interviews will be typed out and de-identified by removing names that might identify anyone. Original recordings will be destroyed, and the dataset will be destroyed three years after the results of the study are published.

Responsible members of the University of Oxford and Oxford Health NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Expenses and payments

You will receive a voucher worth £10 for taking part in this research. Reasonable travel expenses will also be paid, on production of receipts, or a mileage allowance provided as appropriate.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for less than 3 months after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for three years after the end of the study. Oxford Health NHS Foundation Trust will only collect your name and contact details to pass on to the research team, if you are happy to be contacted about being involved in the study. They will not keep identifiable information about you from this study.

The audio-recordings of interviews will be typed-out by a transcriber service [name and details of transcription company]. The recordings passed to the transcriber will be identified by a study-ID number rather than any of your personal details. The transcriber will not retain the recording after it has been typed out and returned to the research team. This processing of data will be formalised in a written agreement to ensure it is undertaken confidentially and securely.

What will happen if I don't want to carry on with the study?

You or the person you care for can withdraw from the study at any time, and don't need to tell us why. This would not affect any care or treatment. Your interview would not be removed from the study if you withdraw after it has already been typed out and de-identified.

What will happen to the results of this study?

When the research study is finished the findings will be used to help healthcare professionals to better provide care for patients. We will publish the study findings through journal articles, reports, presentations and conference papers. You will not be able to be identified in any written or verbal reports from the study, including anonymous quotations that may be used. The clinical team will provide you with a leaflet giving a summary of the study findings if you wish. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (a PhD thesis).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Daniel Whiting, daniel.whiting@psych.ox.ac.uk or 01865 613165, or you may contact the

University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

A patient and public involvement group consisting of both patients and carers has inputted into the design of the study, such as the topics of interest for interviews, and has reviewed written materials associated with the study, including this leaflet.

Who is organising and funding the study?

This study is funded by the National Institute for Health Research as part of a research fellowship undertaken by the Chief Investigator Dr Daniel Whiting (Award Ref DRF-2018-11-ST2-069). It is sponsored by the University of Oxford.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the West Midlands – Solihull Research Ethics Committee.

Further information and contact details:

For more information please contact Dr Daniel Whiting by email, telephone or in writing:

Dr Daniel Whiting (Chief Investigator)
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

Thank you for taking the time to read this leaflet





Oxford Health
NHS Foundation Trust

Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM – PATIENT INTERVIEW

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

Name of Researcher:

If you agree, please initial each box

6. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
7. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
8. I understand that relevant sections of data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities and from Oxford Health NHS Trust(s), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
9. I agree to audio recording and the use of anonymised quotes in research reports and publications.	

10. I agree to my clinical team being informed of my participation in the study and understand they may be notified in the event of the researcher having concerns about my immediate wellbeing.	
11. I agree to take part in this study.	

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

**1 copy for participant; 1 copy for researcher site file; for recorded verbal consent: researcher to complete form and email or post copy to patient/carer.*

Chief Investigator:
Dr Daniel Whiting
University of Oxford, Department of Psychiatry
Warneford Hospital, Oxford OX3 7JX
daniel.whiting@psych.ox.ac.uk
01865 613165

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM – CARER INTERVIEW

Use of a violence risk assessment tool (OxMIV) in Early Intervention in Psychosis services: a qualitative study of acceptability to patients and clinicians

Name of Researcher:

If you agree, please initial each box

12. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
13. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
14. I understand that relevant sections of data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities and from Oxford Health NHS Trust(s), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
15. I agree to audio recording and the use of anonymised quotes in research reports and publications.	
16. I agree to take part in this study.	

Name of Participant	*Date*	*Signature*
Name of Person taking Consent	*Date*	*Signature*

**1 copy for participant; 1 copy for researcher site file; for recorded verbal consent: researcher to complete form and email or post copy to patient/carer.*

Appendix 2.3

Draft topic guides for interviews.

Clinician interview 1

General questions about violence risk assessment

- Do you routinely assess violence risk?
- How important do you feel this is in your service?
- How do you assess violence risk?
- How much do you involve patients in assessing violence risk?
- How do you communicate your assessment to patients? (probe whether discussed or recorded in letters / CPA documents)
- How confident are you at assessing risk of violence?
- Have you received any training on how to assess violence risk?
- What are the main difficulties with assessing violence risk in your setting?

Questions about short clinical vignettes

- How would you rate the risk of violence in each case?
- What factors are you mainly basing your views on?
- What other things you would you most want to know in each case?

Questions about structured risk assessment tools

- Have you ever used some kind of tool to structure your violence risk assessments?
- Do you think having a structured tool would be helpful?
- What would make you want to use a tool? (probe different properties)
- What would make you not want to use a tool?
- What kind of % risk of violence would reassure, or worry you?
- Do you have any other thoughts or reflections about anything we have discussed?

Clinician interview 2

Questions about the use of OxMIV

- How frequently have you used OxMIV?
- Was there anything that stopped you using it more often?
- When did you use it?

- How long did it take to complete?
- How easy was it to use?
- Did the information required seem relevant?
- How did you involve patients in the process?
- How did the OxMIV ratings compare with your own judgements of risk? What did you do if they differed?
- How did OxMIV affect your clinical decisions?
- Which output (% or category) did you find most helpful?
- Did any problems arise due to using OxMIV?
- Do you think OxMIV was useful?
- Do you plan to continue using it?
- What would make you more likely to use it in the future?

Patient and carer interviews

- Is a routine process of clinicians assessing the risk of violence something that you've been conscious of?
- Can you ever remember seeing this mentioned in a clinical letter or careplan, or heard it mentioned in a review?
- How do/did you feel about this risk being mentioned?
- How do you feel about clinicians routinely thinking about this risk?
- Do you feel you were/are as involved in the process of assessing risk as you want to be?
- How would you feel about clinicians involving patients and their families more in this kind of assessment?
- Were/are you worried that these assessments might lead to something unhelpful?
- What do you think about the language, is "violence" an acceptable word for clinicians to use?
- Do you remember an assessment tool called OxMIV being mentioned?
- What do you make of that kind of approach?
- Could you imagine being more involved in the process by using the tool?
- Would you worry about the potential stigma of violence being discussed more openly?
- Do you have other good or bad experiences of clinicians assessing risk?
- What advice would you give to clinicians about assessing and discussing risk of violence?
- Do you have any other thoughts or reflections?

Appendix 2.4

OXMIV
MENTAL ILLNESS AND VIOLENCE

CLINICAL USER GUIDE FOR EARLY INTERVENTION IN PSYCHOSIS SERVICES

Version 2.0 – January 2020

OxMIV is a risk calculator for assessing risk of violent offending in individuals with schizophrenia-spectrum or bipolar disorder. It is intended to be used to support full clinical assessments of risk. This tool was developed by the Forensic Psychiatry and Psychology group at the University of Oxford and is also available for free on the oxrisk.com website.

How was it developed?

OxMIV was developed and validated in Sweden, using data from 75,158 individuals aged 15-65 with a diagnosis of schizophrenia -spectrum or bipolar disorder. Potential risk factors for inclusion in OxMIV were drawn from carefully reviewing the evidence for the association between violence and different factors - including previous history, sociodemographic factors, family history and clinical factors - and considering only those that were both reliable risk factors and relatively easy to score.

First, the OxMIV prediction model was developed using data from 58,771 patients. In this data, the strongest risk factor for violence was a history of previous violent crime, which increased the odds of violence by a factor of 5.0 (known as the odds ratio). The other strongest risk factors were being male (odds ratio 2.3), previous drug use (odds ratio 1.5), previous alcohol use (odds ratio 1.8), recent treatment for dependence (odds ratio 1.8), current inpatient treatment (odds ratio 1.4) and being in receipt of benefits (1.4). Some of these risks may seem lower than in other studies because in this study all the different risk factors were adjusted for each other. A prediction model was then developed that included 16 risk factors weighted according to these findings.

The final model was then tested in a different group of 16,387 patients from another region in Sweden to check that it also performed well in a new sample (a process known as "external validation"). The model was translated into a simple risk calculator (OxMIV) that gives the percentage chance of a violent offence in 12-months, and also categorises this risk as either "low" or, if risk is 5% or greater, "increased".

The research behind OxMIV has been peer-reviewed and published in the Lancet Psychiatry journal (Open Access). OxMIV has also been externally validated in a different setting, a psychiatric ward of a German prison hospital and the validation paper is published in the Frontiers in Psychiatry journal. Further validations in other countries are planned. For a full bibliography related to OxMIV, visit the oxrisk.com website.

When should OxMIV be used?

OxMIV is designed to predict violent offending within 12 months in individuals with schizophrenia-spectrum or bipolar disorder.

Who should use OxMIV?

The OxMIV tool should only be used by healthcare staff, as scoring to specific cases requires interpretation of some of the risk factors. The current project is making OxMIV available within the 'carenotes' system for clinicians working in Early Intervention in Psychosis services in Oxford Health NHS Foundation Trust. Only clinicians working in these services should use the tool, as specific guidance, support and monitoring will be in place for these services.

How should each item be scored?

There are item descriptions on the form where this may be unclear. The best and most recent source of information should be used if possible. Some variables can be scored as unknown, in which case OxMIV will give a range of scores in the final rating.

How should the output of OxMIV be used?

OxMIV can be used to support full clinical assessments of risk. It can help ensure that important indicators of risk are considered, and give context to assessments and discussions. The calculator provides a 'best guess' of likely outcomes based on current

knowledge, but cannot provide an accurate prediction for every individual. It should not therefore be used in isolation, but as part of an overall assessment. Whilst it may help inform clinical practice, no specific interventions or decisions are currently linked to the tool.

How should the percentage risk score be interpreted?

The OxMIV calculator gives a percentage score for the risk of violent offending within 12-months. So a score of 5% means that, on average, in 100 individuals with the same combination of risk factors, 5 will commit a violent crime over the next 12 months. This is a similar interpretation to the chance of rain in a weather app, where a 5% chance of rain means that on 100 days with the same characteristics, it will rain on 5 occasions.

How should the "low" or "increased" risk category be interpreted?

The calculator also provides a risk category, based on pre-specified cut-offs (Low: <5%; Increased: ≥5%). Using these categories, the tool has a high "negative predictive value" of 99.5% – which means that in the validation study, for every 200 individuals identified as "low" risk by the tool, 199 did not offend violently within 12-months (i.e. the low risk rating was correct). This suggests that the tool may be most helpful for screening out low risk people in combination with clinical judgement. The "positive predictive value" is 11%. This means that for every 100 people categorised as "increased" risk in the validation study, 11 violently offended in 12-months.

Can I use OxMIV more than once with the same patient?

Many of the factors used in the OxMIV tool are "static", i.e. they do not change over time. The tool has been validated as a one-off assessment of risk, rather than one that is repeated at different times to measure changes in risk.

Where can I go for more information?

The oxrisk.com website has a full list of background literature about the tool. The project in Oxford Health NHS Foundation Trust is led by Dr Daniel Whiting. For any issues relating to this and the use of the tool in carenotes, please contact

daniel.whiting@oxfordhealth.nhs.uk

Appendix 5.1

Tripod checklist.

Section/Topic	ı	Checklist Item	Page
Title and abstract			
Title	1	Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted.	121
Abstract	2	Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions.	122
Introduction			
Background and objectives	3a	Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models.	Chapter 1
	3b	Specify the objectives, including whether the study describes the development or validation of the model or both.	122
Methods			
Source of data	4a	Describe the study design or source of data (e.g., randomized trial, cohort, or registry data), separately for the development and validation data sets, if applicable.	122
	4b	Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up.	122
Participants	5a	Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres.	122-123
	5b	Describe eligibility criteria for participants.	122-123
	5c	Give details of treatments received, if relevant.	n/a
Outcome	6a	Clearly define the outcome that is predicted by the prediction model, including how and when assessed.	124
	6b	Report any actions to blind assessment of the outcome to be predicted.	123
Predictors	7a	Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured.	125-128
	7b	Report any actions to blind assessment of predictors for the outcome and other predictors.	123
Sample size	8	Explain how the study size was arrived at.	128
Missing data	9	Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method.	129-130
Statistical analysis methods	10c	For validation, describe how the predictions were calculated.	130
	10d	Specify all measures used to assess model performance and, if relevant, to compare multiple models.	130-131
	10e	Describe any model updating (e.g., recalibration) arising from the validation, if done.	132
Risk groups	11	Provide details on how risk groups were created, if done.	146
Development vs. validation	12	For validation, identify any differences from the development data in setting, eligibility criteria, outcome, and predictors.	137
Results			
Participants	13a	Describe the flow of participants through the study, including the number of participants with and without the outcome and, if applicable, a summary of the follow-up time. A diagram may be helpful.	137
	13b	Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome.	137-139
	13c	For validation, show a comparison with the development data of the distribution of important variables (demographics, predictors and outcome).	139
Model performance	16	Report performance measures (with CIs) for the prediction model.	143
Model-updating	17	If done, report the results from any model updating (i.e., model specification, model performance).	143-144
Discussion			
Limitations	18	Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data).	155-156
Interpretation	19a	For validation, discuss the results with reference to performance in the development data, and any other validation data.	152

	19b	Give an overall interpretation of the results, considering objectives, limitations, results from similar studies, and other relevant evidence.	151-157
Implications	20	Discuss the potential clinical use of the model and implications for future research.	153-154, Chapter 6
Other information			
Supplementary information	21	Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets.	24
Funding	22	Give the source of funding and the role of the funders for the present study.	Preface

Appendix 5.2

Crime/Home Office codes for included violent offences.

001/01	1	Murder - victim one year of age or older
001/02	1	Murder - victim under one year of age
002/00	2	Attempt murder - victim aged under 1 year
002/00	2	Attempt murder - victim aged 1 year or over
019/02	19A	Sex - Sexual intercourse with woman / girl mental defective
019/17	19H	Sex - Rape of a boy under 13 - SOA 2003
019/18	19E	Sex - Attempt rape of a girl under 13 - SOA 2003
019/19	19H	Sex - Attempt rape of a boy under the age of 13 - SOA 2003
021/02	21	Sex - Offender of any age cause / incite a girl under 13 to engage in sexual activity - penetration - SOA 2003
021/12	21	Sex - Offender under 18 engage in penetrative sexual activity with girl under 13 - SOA 2003
021/13	21	Sex - Offender under 18 engage in penetrative sexual activity with boy under 13 - SOA 2003
021/14	21	Sex - Offender under 18 cause / incite a girl under 13 to engage in sexual activity - penetration - SOA 2003
070/01	70	Sex - Sexual activity with a mentally disordered male - penetration - SOA 2003
070/02	70	Sex - Sexual activity with a mentally disordered female - penetration - SOA 2003
070/05	70	Sex - Cause / incite sexual activity with a mentally disordered male - penetration - SOA 2003
070/06	70	Sex - Cause / incite sexual activity with a mentally disordered female - penetration - SOA 2003
071/02	71	Sex - Paying for the sexual services of a girl under 13 - penetration - SOA 2003
071/03	71	Sex - Paying for the sexual services of a boy under 13 - penetration - SOA 2003
005/14	05E	Possess firearm with intent to endanger life
005/15	05E	Possess shotgun with intent to endanger life
005/07	05E	Cause explosion with intent to burn / maim / grievous bodily harm etc
005/10	05E	Administer poison with intent to endanger life / inflict grievous bodily harm
005/13	05E	Do an act with intent to cause an explosion likely to endanger life / injure property
023/14	23	Sex - Adult sexual activity with a girl under 13 family member - penetration - SOA 2003
023/15	23	Sex - Adult sexual activity with a boy under 13 family member - penetration - SOA 2003
023/18	23	Sex - Adult incite sexual activity with a girl under 13 family member - penetration - SOA 2003
023/19	23	Sex - Adult incite sexual activity with a boy under 13 family member - penetration - SOA 2003
023/30	23	Sex - Offender under 18 sexual activity with a girl under 13 family member - penetration - SOA 2003
023/31	23	Sex - Offender under 18 sexual activity with a boy under 13 family member - penetration - SOA 2003
023/34	23	Sex - Offender under 18 incite sexual activity with a girl under 13 family member - penetration - SOA 2003
023/35	23	Sex - Offender under 18 incite sexual activity with a boy under 13 family member - penetration - SOA 2003
056/01	56A	Arson with intent to endanger life
071/12	71	Sex - Control a child under 13 involved in prostitution / pornography - SOA 2003
005/17	05E	Make use / attempt to make use of a firearm with intent to resist arrest
008/13	10A	Firearms - Possess firearm on arrest for Schedule 1 offence
008/13	10A	Firearms - Possess firearm while committing Schedule 1 offence
008/13	10A	Firearms - Possess imitation firearm on arrest for Schedule 1 offence
008/16	10A	Firearms - Have a firearm with intent to commit an indictable offence
008/16	10A	Firearms - Have an imitation firearm with intent to resist arrest
008/16	10A	Firearms - Have a firearm with intent to resist arrest

008/16	10A	Firearms - Have an imitation firearm with intent to commit an indictable offence
008/23	10A	Firearms - Possession of imitation firearm with intent to cause fear of violence
008/23	10A	Firearms - Firearm - possession with intent to cause fear of violence
008/24	10A	Firearms - Shotgun - possession with intent to cause fear of violence
019/07	19D	Sex - Rape a girl aged 13 / 14 / 15 - SOA 2003
019/08	19C	Sex - Rape a woman 16 years of age or over - SOA 2003
019/09	19G	Sex - Rape a male under 16
019/10	19F	Sex - Rape a man 16 or over - SOA 2003
019/11	19A	Sex - Attempted rape of a female under 16
019/12	19C	Sex - Attempt to rape a woman 16 or over - SOA 2003
019/13	19G	Sex - Attempted rape of a male under 16 years of age
019/14	19F	Sex - Attempt to rape a man aged 16 or over - SOA 2003
019/16	19E	Sex - Rape a girl under 13 - SOA 2003
021/04	21	Sex - Offender of any age cause / incite a boy under 13 to engage in sexual activity - penetration - SOA 2003
021/06	21	Sex - Offender 18 or over engage in penetrative sexual activity with girl under 13 - SOA 2003
021/07	21	Sex - Offender 18 or over engage in penetrative sexual activity with boy under 13 - SOA 2003
021/08	21	Sex - Offender 18 or over cause / incite a girl under 13 to engage in sexual activity - penetration - SOA 2003
021/09	21	Sex - Offender 18 or over cause / incite a boy under 13 to engage in sexual activity - penetration - SOA 2003
021/15	21	Sex - Offender under 18 cause / incite a boy under 13 to engage in sexual activity - penetration - SOA 2003
070/17	70	Sex - Care worker engage in sexual activity with mentally disordered male - penetration - SOA 2003
070/18	70	Sex - Care worker engage in sexual activity with mentally disordered female - penetration - SOA 2003
070/21	70	Sex - Care worker cause / incite sexual activity with mental disordered person - penetration - SOA 2003
071/14	71	Sex - Paying for the sexual services of a girl 13 to 15 - penetration - SOA 2003
071/15	71	Sex - Paying for the sexual services of a boy 13 to 15 - penetration - SOA 2003
005/01	05D	Assault - S18 - GBH grievous bodily harm with intent
005/01	05D	Assault - S18 - GBH cause grievous bodily harm with intent to resist / prevent arrest
005/04	05E	Attempt to choke / suffocate / strangle with intent
005/05	05E	Administer drug with intent to commit an indictable offence
008/03	10A	Firearms - Set a man trap with intent to inflict grievous bodily harm - Offences against the Person Act 1861
017/14	17B	Sex - Assault a boy under 13 by penetration with a part of your body / a thing - SOA 2003
020/04	20B	Sex - Assault a girl under 13 by penetration with a part of your body / a thing - SOA 2003
070/12	70	Sex - Sexual activity with mentally disordered person by inducement / threat / deception - no penetration - SOA 2003
070/14	70	Sex - Cause sexual activity with mentally disordered person by inducement / threat / deception - no penetration - SOA 2003
005/16	05E	Possess air weapon with intent to endanger life
023/04	23	Sex - Adult sexual activity with a girl 13 - 17 family member - penetration - SOA 2003
023/05	23	Sex - Adult sexual activity with a boy 13 - 17 family member - penetration - SOA 2003
023/08	23	Sex - Adult incite sexual activity with a family member - victim girl 13 to 17 - penetration - SOA 2003
023/09	23	Sex - Adult incite sexual activity with a family member - victim boy 13 to 17 - penetration - SOA 2003
023/32	23	Sex - Offender under 18 sexual activity with a girl 13 - 17 family member - penetration - SOA 2003
023/33	23	Sex - Offender under 18 sexual activity with a boy 13 - 17 family member - penetration - SOA 2003
023/36	23	Sex - Offender under 18 incite sexual activity with a girl 13 -17 family member - penetration - SOA 2003

023/37	23 4282	Sex - Offender under 18 incite sexual activity with a boy 13 -17 family member - penetration - SOA 2003
004/01	6	Manslaughter
008/13	10A	Firearms - Possess imitation firearm - committing Schedule 1 offence
028/02	28A B	Burglary dwelling - With intent to inflict GBH
008/15	10A	Firearms - Possess air weapon while committing Schedule 1 offence
008/25	10A	Firearms - Air weapon - possession with intent to cause fear of violence
073/02	73	Sex - Sex offences - abuse position of trust - engage in sexual activity
073/01	73	Sex - Sex offences - abuse position of trust - have sexual intercourse
073/13	73	Sex - Adult abuse position of trust - sexual activity with a girl U.13 - SOA 2003
073/14	73	Sex - Adult abuse position of trust - sexual activity with a boy U.13 - SOA 2003
073/15	73	Sex - Adult abuse of position of trust - cause / incite sexual activity with girl U.13 - SOA 2003
073/16	73	Sex - Adult abuse of position of trust - cause / incite sexual activity with boy U.13 - SOA 2003
073/17	73	Sex - Adult abuse of position of trust - sexual activity in presence of child U.13 - SOA 2003
073/18	73	Sex - Adult abuse of position of trust - cause child under 13 to watch a sexual act - SOA 2003
005/07	05E	Cause taking / receiving of dangerous / noxious thing
005/07	05E	Send / deliver noxious thing with intent
008/04	08N	Cause bodily harm by wanton / furious driving
008/04	08N	Cause bodily harm by wilful neglect - vehicle
008/04	08N	Cause bodily harm by wilful misconduct
017/13	17A	Sex - Assault a male 13 or over by penetration with part of body / a thing - SOA 2003
020/03	20A	Sex - Assault a female 13 and over by penetration with part of body / a thing - SOA 2003
021/03	21	Sex - Offender of any age cause / incite a girl under 13 to engage in sexual activity - no penetration - SOA 2003
021/05	21	Sex - Offender of any age cause / incite a boy under 13 to engage in sexual activity - no penetration - SOA 2003
022/02	22A	Sex - Cause a female 13 or over to engage in a penetrative sexual activity - SOA 2003
022/03	22A	Sex - Cause a male 13 or over to engage in a penetrative sexual activity - SOA 2003
022/06	22B	Sex - Offender 18 or over engage in penetrative sexual activity with a girl 13 to 15 - SOA 2003
022/07	22B	Sex - Offender 18 or over engage in penetrative sexual activity with a boy 13 to 15 - SOA 2003
022/08	22B	Sex - Offender 18 or over cause / incite a girl 13 to 15 to engage in sexual activity - penetration - SOA 2003
022/09	22B	Sex - Offender 18 or over cause / incite a boy 13 to 15 to engage in sexual activity - penetration - SOA 2003
022/12	22B	Sex - Offender under 18 engage in penetrative sexual activity with a girl 13 to 15 - SOA 2003
022/13	22B	Sex - Offender under 18 engage in penetrative sexual activity with boy 13 - 15 SOA 2003
022/14	22B	Sex - Offender under 18 cause / incite a girl 13 to 15 to engage in sexual activity - penetration - SOA 2003
022/15	22B	Sex - Offender under 18 cause / incite a boy 13 to 15 to engage in sexual activity- penetration - SOA 2003
030/02	30A B	Burglary other than dwelling - With intent to inflict GBH
031/00	31	Aggravated burglary - other than dwelling
056/01	56A	Arson - recklessly endangering life
057/00/01	58A	Criminal damage to a dwelling - endangering life
057/00	58B	Criminal damage to a building other than a dwelling - endangering life
057/00	58C	Criminal damage to a vehicle - endangering life
057/00	58D	Criminal damage other - endangering life
059/11	59	Threaten to destroy / damage own property - endanger life
059/13	59	Have article with intent to destroy / damage property - endanger life
059/14	59	Make explosive substance for unlawful purpose

059/15	59	Possess explosive substance for unlawful purpose
071/11	71	Sex - Cause / incite a child under 13 to prostitution / pornography - SOA 2003
088/05	88C	Sex - Administer a substance with intent - SOA 2003
088/06	88C	Sex - Commit an offence with the intention of committing a relevant sexual offence - SOA 2003
088/07	88C	Sex - Knowingly / recklessly trespassed on premises with intent to commit a relevant sexual offence - SOA 2003
013/02	13	Child abduction - other person
036/01	36	Kidnap - common law
036/03	36	False imprisonment - common law
037/01	37/1	Aggravated vehicle taking - death caused by accident
008/59	08P	Racially / religiously aggravated wounding / GBH without intent
086/02	86	Make indecent photograph / pseudo-photograph of a child
086/02	86	Take an indecent photograph / pseudo-photograph of a child
088/01	88A	Sex - Adult meet girl under 16 following sexual grooming - SOA 2003
088/02	88A	Sex - Adult meet boy under 16 following sexual grooming - SOA 2003
004/02	42827	Infanticide
004/03	42828	Child destruction
029/00	29	Aggravated burglary - dwelling
1934/01/01	34A	Robbery - Business
1934/01/02	34B	Robbery - Personal
034/02	34A	Assault with intent to commit robbery - business
034/02	34B	Assault with intent to commit robbery - personal
035/00	35	Blackmail
066/03	66	Bomb hoax - place article with intent
066/04	66	Bomb hoax - communicate false information
071/09	71	Sex - Control a child 13 - 17 involved in prostitution / pornography - SOA 2003
071/10	71	Sex - Arrange / facilitate the prostitution / involvement in pornography of a child 13 - 17 - SOA 2003
071/13	71	Sex - Arrange / facilitate the prostitution / involvement in pornography of a child under 13 - SOA 2003

034/01		Robbery
008/02	08N	Cause administer poison with intent to injure / aggrieve / annoy
008/61	10C	Threaten with an offensive weapon in a public place
008/62	10D	Threaten person with blade or pointed article on school premises
008/64	10D	Threaten person with blade or pointed article in public place
008/65	08Q	Stalking - Involving fear of violence
008/66	08Q	Stalking - Involving serious alarm / distress
008/67	105 A	Engage in controlling / coercive behaviour in an intimate / family relationship
005/24		Use of noxious substances or things to cause harm and intimidate
008/60	08P	Racially / religiously aggravated assault occasioning ABH
017/16	17B	Sex - Assault a boy under 13 by touching - SOA 2003
020/06	20B	Sex - Assault a girl under 13 by touching - SOA 2003

021/10	21	Sex - Offender 18 or over engage in sexual activity in presence of a child under 13 - SOA 2003
021/16	21	Sex - Offender under 18 engage in sexual activity in presence of a child under 13 - SOA 2003
021/18	21	Sex - Offender 18 or over engage in non penetrative sexual activity with girl under 13 - SOA 2003
021/19	21	Sex - Offender 18 or over engage in non penetrative sexual activity with boy under 13 - SOA 2003
021/20	21	Sex - Offender 18 or over cause / incite a girl under 13 to engage in sexual activity - no penetration - SOA 2003
021/21	21	Sex - Offender 18 or over cause / incite a boy under 13 to engage in sexual activity - no penetration - SOA 2003
021/22	21	Sex - Offender under 18 engage in non penetrative sexual activity with a girl under 13 - SOA 2003
021/23	21	Sex - Offender under 18 engage in non penetrative sexual activity with a boy under 13 - SOA 2003
021/24	21	Sex - Offender under 18 cause / incite a girl under 13 to engage in sexual activity - no penetration - SOA 2003
021/25	21	Sex - Offender under 18 cause / incite a boy under 13 to engage in sexual activity - no penetration - SOA 2003
022/10	22B	Sex - Offender 18 or over engage in sexual activity in presence of a child 13 to 15 - SOA 2003
022/16	22B	Sex - Offender under 18 engage in sexual activity in presence of a child 13 to 15 - SOA 2003
070/03	70	Sex - Sexual activity with a mentally disordered male - no penetration - SOA 2003
070/04	70	Sex - Sexual activity with a mentally disordered female - no penetration - SOA 2003
070/07	70	Sex - Cause / incite sexual activity with a mentally disordered male - no penetration - SOA 2003
070/08	70	Sex - Cause / incite sexual activity with a mentally disordered female - no penetration - SOA 2003
070/19	70	Sex - Care worker engage in sexual activity with mentally disordered male - no penetration - SOA 2003
070/20	70	Sex - Care worker engage in sexual activity with mentally disordered female - no penetration - SOA 2003
070/22	70	Sex - Care worker cause / incite sexual activity with mentally disordered person - no penetration - SOA 2003
071/04	71	Sex - Paying for the sexual services of a girl 13 to 15 - no penetration - SOA 2003
071/04	71	Sex - Paying for the sexual services of a girl under 13 - no penetration - SOA 2003
071/05	71	Sex - Paying for the sexual services of a boy 13 to 15 - no penetration - SOA 2003
071/05	71	Sex - Paying for the sexual services of a boy under 13 - no penetration - SOA 2003
071/06	71	Sex - Paying for the sexual services of a girl aged 16 / 17 - SOA 2003
071/07	71	Sex - Paying for the sexual services of a boy aged 16 / 17 - SOA 2003
071/08	71	Sex - Cause / incite a child 13 - 17 to prostitution / pornography - SOA 2003
008/58	08M	Racially / religiously aggravated harassment with fear of violence
037/02	37/2	Aggravated vehicle taking - (initial taker) and dangerous driving
037/02	37/2	Aggravated vehicle taking - and vehicle damage of £5000 or over
008/30	08L	Public Order - S4 Harassment - put in fear of violence
008/55	09B	Racially / religiously aggravated intentional harassment / alarm / distress
008/56	08M	Racially / religiously aggravated harassment without violence
066/91	09B	Racially or religiously aggravated fear of violence

125/8		
2	09B	Racially / religiously aggravated harassment / alarm / distress
195/1		
2	08Q	Stalking - Pursue a course of conduct
008/0		
1	08N	Assault - S20 - GBH Grievous bodily harm without intent
017/1		
2	17A	Sex - Indecent assault on a man aged 16 or over
017/1		
5	17A	Sex - Sexual assault on a male - SOA 2003
020/0		
5	20A	Sex - Sexual assault on a female - SOA 2003
022/0		
4	22A	Sex - Cause a female 13 or over to engage in a non penetrative sexual activity - SOA 2003
022/0		
5	22A	Sex - Cause a male 13 or over to engage in a non penetrative sexual activity - SOA 2003
022/1		
8	22B	Sex - Offender 18 or over engage in non penetrative sexual activity with girl 13 to 15 - SOA 2003
022/1		
9	22B	Sex - Offender 18 or over engage in non penetrative sexual activity with boy 13 to 15 - SOA 2003
022/2		Sex - Offender 18 or over cause / incite a girl 13 to 15 to engage in sexual activity - no penetration -
0	22B	SOA 2003
022/2		Sex - Offender 18 or over cause / incite a boy 13 to 15 to engage in sexual activity - no penetration -
1	22B	SOA 2003
022/2		
2	22B	Sex - Offender under 18 engage in non penetrative sexual activity with a girl 13 to 15 - SOA 2003
022/2		
3	22B	Sex - Offender under 18 engage in non penetrative sexual activity with a boy 13 to 15 - SOA 2003
022/2		Sex - Offender under 18 cause / incite a girl 13 to 15 to engage in sexual activity - no penetration -
4	22B	SOA 2003
022/2		Sex - Offender under 18 cause / incite a boy 13 to 15 to engage in sexual activity - no penetration -
5	22B	SOA 2003
056/0		
2	56B	Arson - not endangering life
003/0		
1	03B	Threats to kill
008/0		
6	08N	Assault - S47 - AOABH assault occasioning actual bodily harm
021/1		Sex - Offender 18 or over cause a child under 13 to watch / look at an image of sexual activity - SOA
1	21	2003
021/1		
7	21	Sex - Offender under 18 cause a child under 13 to watch a sexual act - SOA 2003
022/1		Sex - Offender 18 or over cause a child aged 13 to 15 to watch / look at an image of sexual activity -
1	22B	SOA 2003
022/1		
7	22B	Sex - Offender under 18 cause a child 13 to 15 to watch a sexual act - SOA 2003
023/0		Sex - Offender under 18 sexual activity with a girl 13 - 17 family member - no penetration - SOA
6	23	2003
023/0		Sex - Offender under 18 sexual activity with a boy 13 - 17 family member - no penetration - SOA
7	23	2003
023/1		Sex - Offender under 18 incite sexual activity with a family member - victim girl 13 to 17 - no
0	23	penetration - SOA 2003
023/1		Sex - Offender under 18 incite sexual activity with a family member - victim boy 13 to 17 - no
1	23	penetration - SOA 2003
023/1		
2	23	Sex - Offender 16 or over sexual activity with an adult relative over 18 - penetration - SOA 2003
023/1		Sex - Offender 16 or over consenting to sexual activity by an adult relative over 18 - penetration -
3	23	SOA 2003
023/1		Sex - Offender under 18 sexual activity with a girl under 13 family member - no penetration - SOA
6	23	2003
023/1		
7	23	Sex - Offender under 18 sexual activity with a boy under 13 family member - SOA 2003
023/2		Sex - Offender under 18 incite sexual activity with a girl under 13 family member - no penetration -
0	23	SOA 2003
023/2		Sex - Offender under 18 incite sexual activity with a boy under 13 family member - no penetration -
1	23	SOA 2003

023/2		
2	23	Sex - Adult sexual activity with a girl 13 - 17 family member - no penetration - SOA 2003
023/2		
3	23	Sex - Adult sexual activity with a boy 13 - 17 family member - no penetration - SOA 2003
023/2		
4	23	Sex - Adult sexual activity with a girl under 13 family member - no penetration - SOA 2003
023/2		
5	23	Sex - Adult sexual activity with a boy under 13 family member - no penetration - SOA 2003
023/2		Sex - Adult incite sexual activity with a family member - victim girl 13 to 17 - no penetration - SOA
6	23	2003
023/2		Sex - Adult incite sexual activity with a family member - victim boy 13 to 17 - no penetration - SOA
7	23	2003
023/2		
8	23	Sex - Adult incite sexual activity with a girl under 13 family member - no penetration - SOA 2003
023/2		
9	23	Sex - Adult incite sexual activity with a boy under 13 family member - no penetration - SOA 2003
125/0		
9	09A	Public Order - S4A sign etc to harass alarm distress
125/0		
9	09A	Public Order - S4A words / behaviour to cause harassment / alarm / distress
125/1		
1	09A	Public Order - S4 display sign etc intend unlawful violence
125/1		
1	09A	Public Order - S4 words / behaviour - fear unlawful violence
125/6		
8	08L	Harassment of a person in their home
008/2		
0	08N	Assault with intent to resist arrest
104/2		
3	104	Assault a constable in the execution of his / her duty
104/2		
5	104	Assaulted a designated person / assistant - SOCA 2005
105/0	105	
3	A	Assault person assisting constable in execution of duty
105/0	105	
4	A	Assault prisoner custody officer
105/0	105	
6	A	Assault court security officer
105/0	105	
8	A	Assault designated / accredited person - Police Reform Act 2002
105/1	105	
0	A	Assault a traffic officer in the execution of his / her duty
105/0	105	
1	A	Assault - S39 - Common assault
125/1		
2	09A	Public Order - S5 Display writing / sign - harassment alarm distress
125/1		
2	09A	Public Order - S5 Use threatening words / behaviour to cause harassment alarm or distress
008/0		
5		Assault with Injury

Appendix 5.3

Poster detailing mechanism for dissent.



DEPARTMENT OF
PSYCHIATRY
Medical Sciences Division

Information for patients

Use of routine data for the 'OxMIV' Study

When you are in contact with mental health services, a **routine log** of information is recorded in electronic medical notes. This might include important things about you and your care, summaries of discussions you have with your team, or copies of letters sent to you and your GP.

As well as being important for your treatment, this information might also help **research projects** that aim to improve care in the future.

To do this, researchers might sometimes need to access information without asking your permission. For this to happen, the project needs approval by a **Research Ethics Committee** – a panel of people (including lay members representing patients and the public) who are separate to the study. They make sure that it is in the **public and patient interest**, and that **data is managed securely** and made anonymous as soon as possible.

The 'OxMIV' study has been reviewed and approved by the London-Bromley NHS Research Ethics Committee, and by the Health Research Authority's Confidentiality Advisory Group. It is developing better ways of predicting who might benefit from help to reduce physical aggression. The study will take information from previous assessment reports (such as about past history and treatment), and then see if police or mental health services have a record of that person behaving aggressively towards people in the year following assessment.

Although records will be looked up by name to get information, all identifiable data will be deleted once this is collected, and no new information is passed back to the clinical team.

If you do not want your data being used in this, or in any future similar studies, please simply let your team know, or email daniel.whiting@psych.ox.ac.uk. This will in no way affect your clinical care.

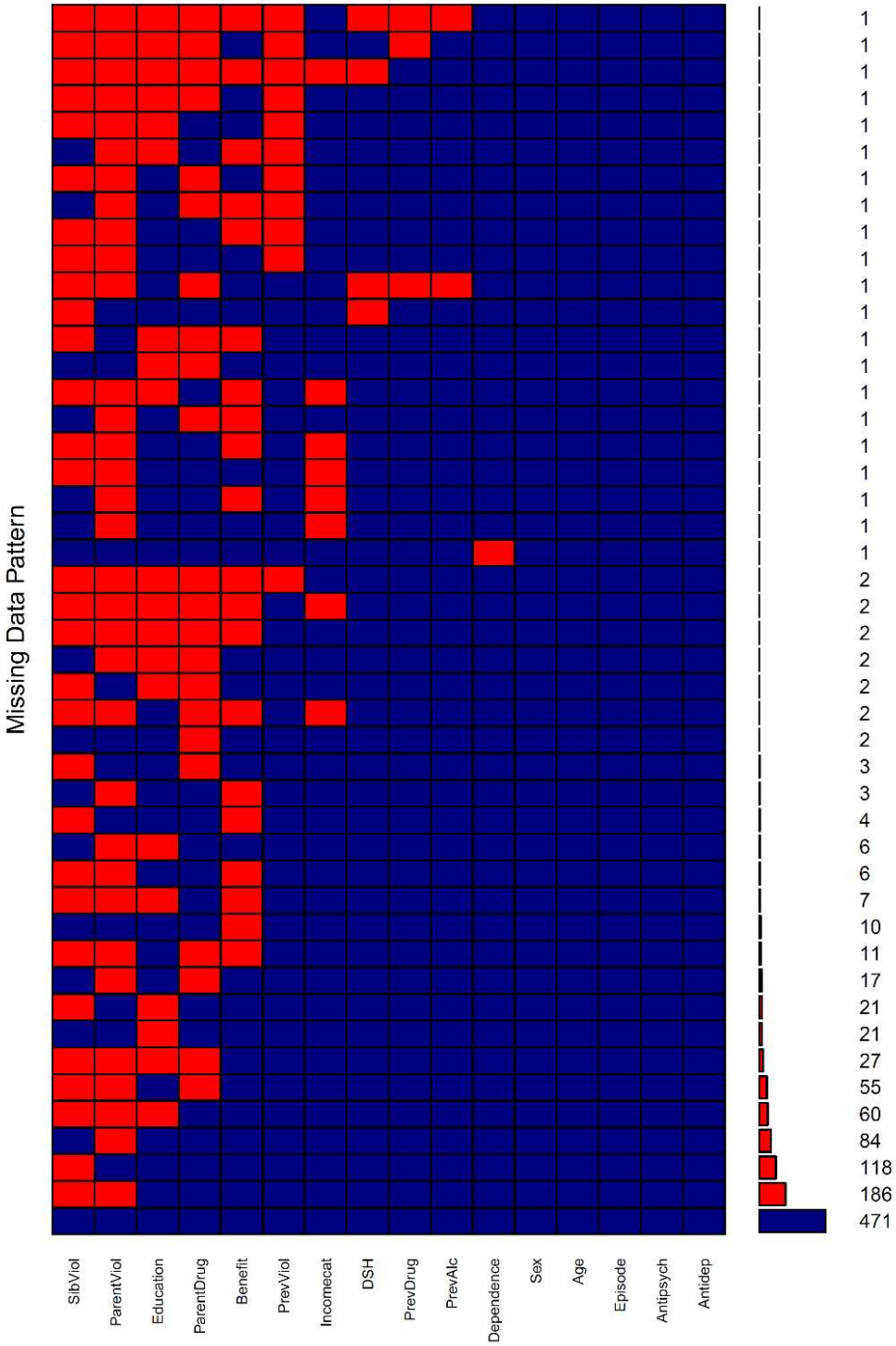
Dissent poster v1.0 21/02/2019

The 'OxMIV' violence risk assessment tool: an external validation study in patients referred to Early Intervention in Psychosis services using routine documentation in Electronic Patient Records.

IRAS ID 257332

Appendix 5.4

Patterns of missing data. Blue cells represent observed predictors and red cells missing predictors. Right hand column and histogram correspond to number of cases with that pattern of missing predictors.



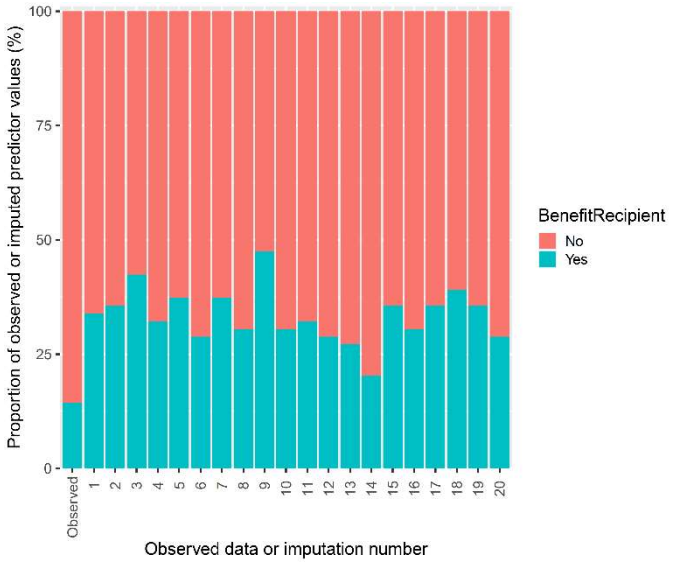
Appendix 5.5

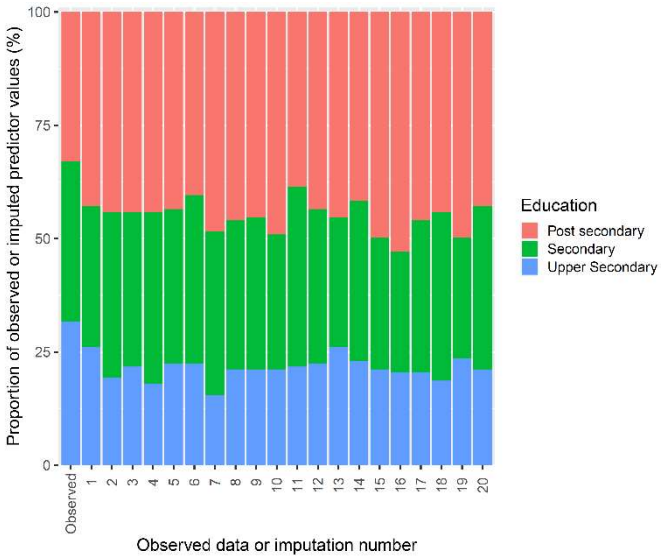
Associations from univariable models fitted with binary missingness of reference predictor as dependent variable.

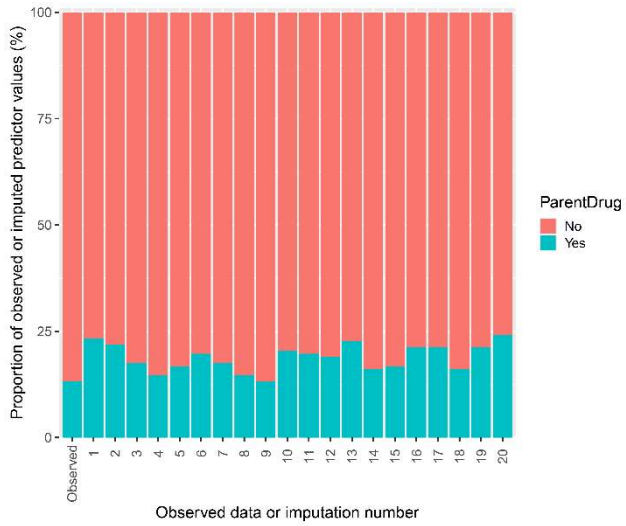
Model	Odds ratio	95% CI	P-value
Education missing ~ Age	1.09	1.07-1.10	**<0.001*** **
ParentDrug missing ~ Age	1.02	1.00-1.04	**0.01***
ParentViol missing ~ Age	1.04	1.02-1.05	**<0.001*** **
SibViol missing ~ Age	1.07	1.05-1.08	**<0.001*** **
Education missing ~ Episode	1.42	0.95-2.11	0.09
ParentDrug missing ~ Episode	0.91	0.57-1.46	0.71
ParentViol missing ~ Episode	1.06	0.79-1.43	0.69
SibViol missing ~ Episode	1.01	0.75-1.36	0.95

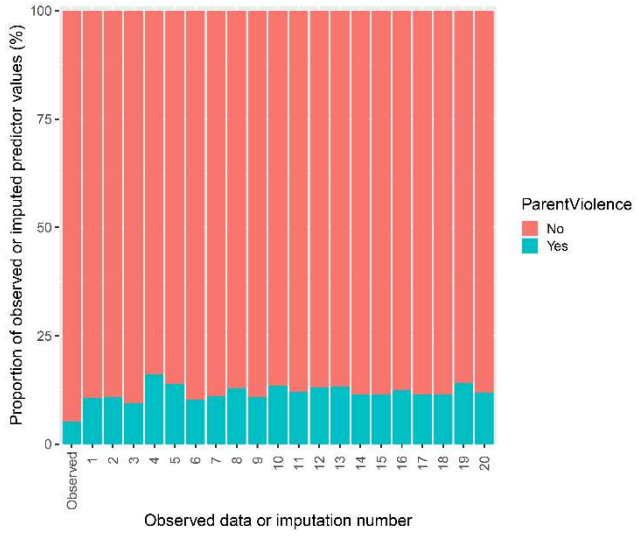
Appendix 5.6

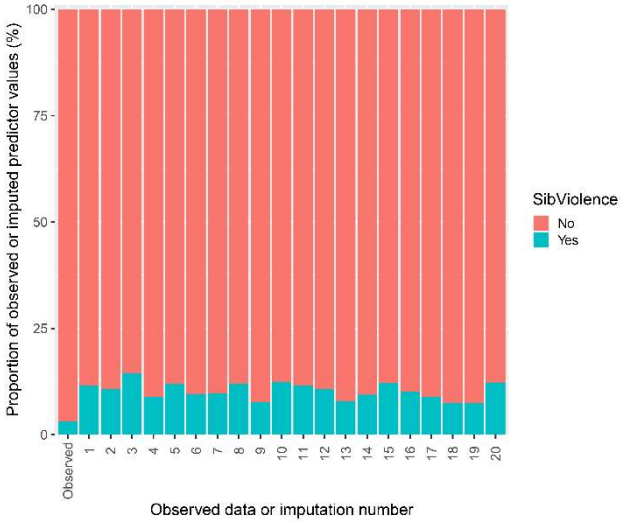
Prevalence of predictors in observed data and each of 20 imputations.











Appendix 5.7

Performance measures across each imputed dataset for the original and updated models.

Original model

Imp.	AUC	AUC 95% CI lower	AUC 95% CI upper	E/O ratio	Brier score	CITL	CITL variance	Calibration slope	Calibration slope variance
1	0.753	0.708	0.799	0.181	0.106	2.001	0.010	0.839	0.008
2	0.754	0.709	0.800	0.181	0.106	2.000	0.010	0.855	0.009
3	0.755	0.710	0.801	0.182	0.106	1.994	0.010	0.852	0.008
4	0.753	0.707	0.798	0.184	0.106	1.988	0.010	0.841	0.008
5	0.748	0.703	0.794	0.181	0.106	1.997	0.010	0.819	0.008
6	0.754	0.708	0.800	0.183	0.106	1.993	0.010	0.840	0.008
7	0.751	0.706	0.797	0.182	0.106	1.997	0.010	0.830	0.008
8	0.754	0.709	0.800	0.180	0.106	2.004	0.010	0.862	0.009
9	0.755	0.709	0.800	0.184	0.106	1.987	0.010	0.829	0.008
10	0.756	0.712	0.801	0.184	0.106	1.992	0.010	0.826	0.008
11	0.754	0.709	0.800	0.181	0.106	1.999	0.010	0.853	0.008
12	0.749	0.704	0.794	0.179	0.106	2.007	0.010	0.831	0.008
13	0.760	0.715	0.806	0.182	0.106	1.992	0.010	0.884	0.009
14	0.754	0.708	0.799	0.181	0.106	2.000	0.010	0.849	0.008
15	0.757	0.711	0.802	0.184	0.106	1.989	0.010	0.849	0.008
16	0.756	0.711	0.801	0.181	0.106	2.000	0.010	0.853	0.008
17	0.751	0.705	0.797	0.181	0.106	1.999	0.010	0.844	0.008
18	0.755	0.709	0.800	0.182	0.106	1.992	0.010	0.861	0.008
19	0.752	0.706	0.797	0.183	0.106	1.990	0.010	0.836	0.008
20	0.752	0.707	0.798	0.183	0.106	1.996	0.010	0.838	0.008

Updated intercept (AUC and calibration slope unchanged)

Imp.	E/O ratio	Brier score	CITL	CITL variance
1	0.996	0.093	0.005	0.010
2	0.997	0.093	0.004	0.010
3	1.002	0.093	-0.002	0.010
4	1.006	0.093	-0.008	0.010
5	0.999	0.094	0.001	0.010
6	1.002	0.093	-0.002	0.010
7	0.999	0.093	0.001	0.010
8	0.994	0.092	0.008	0.010
9	1.007	0.093	-0.009	0.010
10	1.003	0.094	-0.004	0.010
11	0.998	0.093	0.003	0.010
12	0.991	0.094	0.011	0.010
13	1.003	0.091	-0.004	0.010
14	0.997	0.093	0.005	0.010
15	1.005	0.093	-0.007	0.010
16	0.997	0.093	0.004	0.010
17	0.998	0.093	0.003	0.010
18	1.003	0.092	-0.003	0.010
19	1.005	0.093	-0.006	0.010
20	1.000	0.093	0.000	0.010

Updated intercept and rescaled coefficients (AUC unchanged)

Imp.	E/O ratio	Brier score	CITL	CITL variance	Calibration slope	Calibration slope variance
1	0.997	0.093	0.003	0.010	0.993	0.012
2	0.998	0.092	0.003	0.010	1.012	0.012
3	1.002	0.092	-0.002	0.010	1.009	0.012
4	1.006	0.092	-0.007	0.010	0.996	0.012
5	1.000	0.093	0.000	0.010	0.970	0.012
6	1.002	0.092	-0.002	0.010	0.995	0.012
7	1.000	0.093	0.000	0.010	0.983	0.012
8	0.996	0.092	0.006	0.010	1.021	0.012
9	1.006	0.093	-0.008	0.010	0.982	0.011
10	1.003	0.093	-0.003	0.010	0.978	0.011
11	0.999	0.092	0.002	0.010	1.010	0.012
12	0.993	0.093	0.008	0.010	0.984	0.012
13	1.003	0.091	-0.003	0.010	1.047	0.012
14	0.998	0.092	0.003	0.010	1.005	0.012
15	1.005	0.092	-0.006	0.010	1.005	0.012
16	0.998	0.092	0.002	0.010	1.009	0.012
17	0.999	0.092	0.002	0.010	1.000	0.012
18	1.003	0.092	-0.004	0.010	1.020	0.012
19	1.004	0.092	-0.005	0.010	0.989	0.012
20	1.001	0.092	-0.001	0.010	0.992	0.012

Appendix 5.8

Externally validated model with updated intercept.

Predictor	Coefficient
Constant	-1.7314
Male sex	0.8400
Age	-0.0468
Previous violent crime	1.6149
Previous drug use	0.3737
Previous alcohol use	0.5603
Previous self-harm	0.2049
Highest education	
Upper-secondary	-0.1264
Post-secondary	-0.0703
Parent drug or alcohol use	0.1044
Parent violent crime	0.1464
Sibling violent crime	-0.1076
Recent antipsychotic treatment	-0.4708
Recent antidepressant treatment	-0.2209
Recent dependence treatment	0.5783
Current episode inpatient	0.3143
Benefit recipient	0.3508
Income category stable	-0.1642

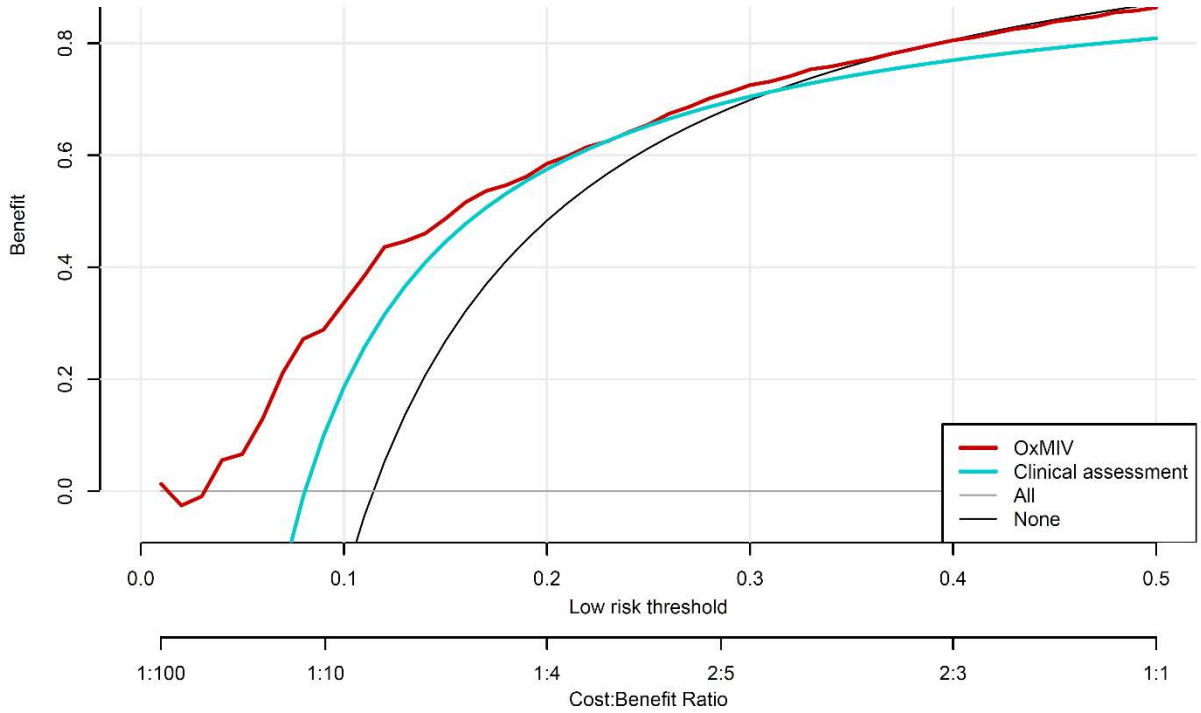
Appendix 5.9

Misclassification measures for OxMIV at 10% cutoff across each of 20 imputed datasets.

Imp.	Sens.	95% CI lower	95% CI upper	Spec.	95% CI lower	95% CI upper	PPV	95% CI lower	95% CI upper	NPV	95% CI lower	95% CI upper
1	0.718	0.632	0.793	0.665	0.635	0.694	0.216	0.193	0.240	0.948	0.933	0.960
2	0.725	0.640	0.800	0.666	0.636	0.695	0.218	0.196	0.242	0.937	0.934	0.961
3	0.725	0.640	0.800	0.664	0.634	0.693	0.217	0.195	0.241	0.949	0.934	0.961
4	0.718	0.632	0.793	0.664	0.634	0.693	0.215	0.193	0.240	0.948	0.933	0.960
5	0.702	0.616	0.779	0.661	0.631	0.690	0.210	0.188	0.235	0.945	0.930	0.957
6	0.718	0.632	0.793	0.667	0.637	0.696	0.217	0.194	0.241	0.948	0.933	0.960
7	0.710	0.624	0.786	0.669	0.639	0.698	0.216	0.193	0.241	0.947	0.932	0.959
8	0.718	0.632	0.793	0.664	0.634	0.693	0.215	0.193	0.240	0.948	0.933	0.960
9	0.710	0.624	0.786	0.663	0.633	0.692	0.213	0.191	0.237	0.947	0.931	0.959
10	0.725	0.640	0.800	0.667	0.637	0.696	0.219	0.196	0.243	0.950	0.934	0.962
11	0.710	0.624	0.786	0.666	0.636	0.695	0.215	0.192	0.239	0.947	0.931	0.959
12	0.695	0.608	0.772	0.659	0.629	0.688	0.208	0.185	0.232	0.944	0.928	0.956
13	0.725	0.640	0.800	0.662	0.632	0.691	0.216	0.194	0.240	0.949	0.934	0.961
14	0.718	0.632	0.793	0.664	0.634	0.693	0.215	0.193	0.240	0.948	0.933	0.960
15	0.710	0.624	0.786	0.666	0.636	0.695	0.215	0.192	0.239	0.947	0.931	0.959
16	0.710	0.624	0.786	0.668	0.638	0.697	0.216	0.193	0.240	0.947	0.932	0.959
17	0.702	0.616	0.779	0.666	0.636	0.695	0.213	0.190	0.237	0.946	0.930	0.958
18	0.718	0.632	0.793	0.663	0.633	0.692	0.215	0.193	0.239	0.948	0.933	0.960
19	0.718	0.632	0.793	0.665	0.635	0.694	0.216	0.193	0.240	0.948	0.933	0.960
20	0.718	0.632	0.793	0.665	0.635	0.694	0.216	0.193	0.240	0.948	0.933	0.960

Appendix 5.10

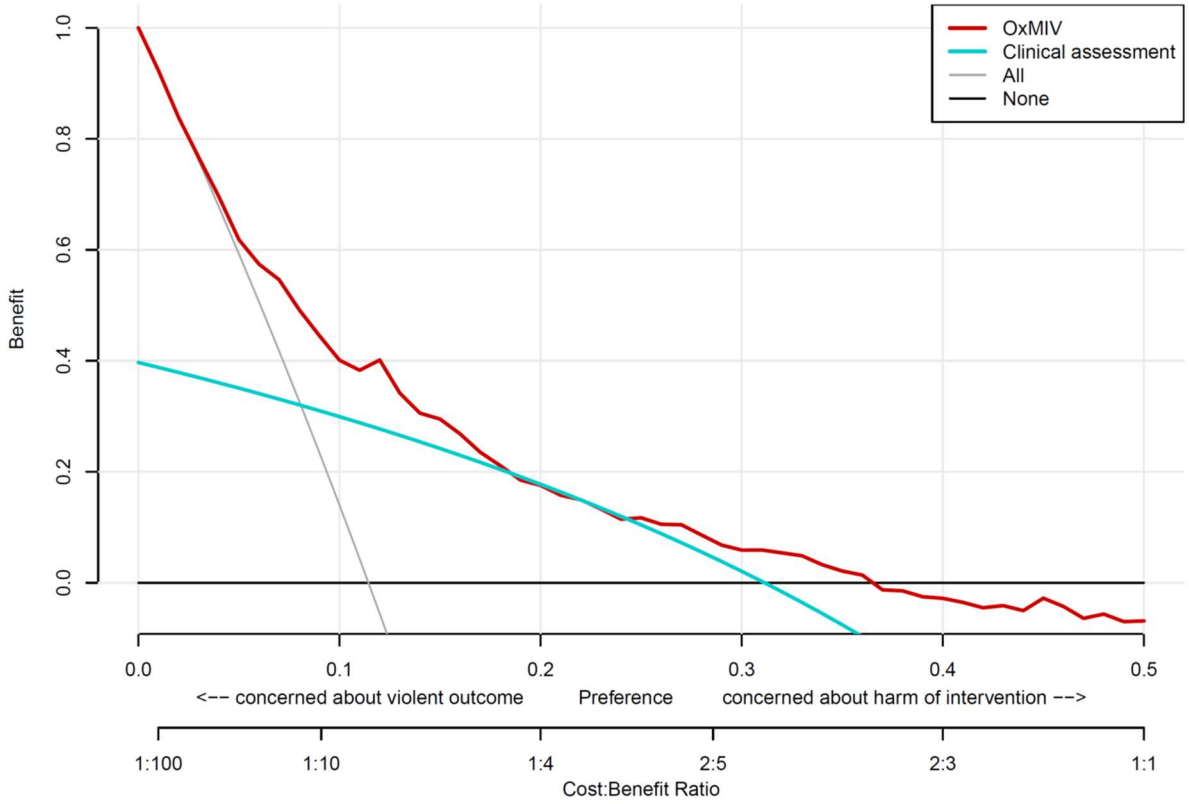
Net benefit across a range of cutoff preferences when model or assessment used in an "opt-out" strategy. Plotted for OxMIV, unstructured clinical judgement, and default strategies of "treat all" or "treat none".



Appendix 5.11

a) Net benefit across a range of cutoff preferences in an imputed dataset where OxMIV was at lower end of its performance range across the 20 imputed datasets.

Cost:Benefit Ratio represents the acceptable number of individuals identified as high risk in order to identify each true positive. Plotted for OxMIV, unstructured clinical judgement, and default strategies of “treat all” or “treat none”.



b) Net benefit across a range of cutoff preferences in an imputed dataset where OxMIV was at upper end of its performance range across the 20 imputed datasets. Cost:Benefit Ratio represents the acceptable number of individuals identified as high risk in order to identify each true positive. Plotted for OxMIV, unstructured clinical judgement, and default strategies of “treat all” or “treat none”.

