Title: Mind the Gap in Clinical Trials: A Participatory Action Analysis
with Citizen Collaborators

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Abstract

RESEARCH QUESTION

What are the strengths, gaps, expectations and barriers to research engagement in clinical trials as communicated through social media?

BACKGROUND

Clinical trials test treatments to provide reliable information for safety and effectiveness. Trials are building blocks where what is learned in earlier research can be used to improve treatments, compare alternatives and improve quality of life. For twenty years the percentage clinical trials volunteers have decreased while costs of running clinical have multiplied. Participants enroll in trials to access latest treatments, to help others and to advance science, but there is growing unrest. The priorities of those running the trials differ from those of participants and roles for public research involvement lack clarity. Changes to bridge these gaps in the research culture are proposed through the use of Participatory Action Research (PAR) where stakeholders collaborate to improve research methodology, galvanize citizen participation, multiply health knowledge, problem solve barriers to access and to explore the value of research volunteers as collaborators.

METHODS

PAR enabled inclusion of citizens as full collaborators. Social media data was gathered over 120 days until saturation was reached. De-identified data was organized

into a SWOT framework and coded into themes for analysis. Following analysis authors prioritized potential solutions for improving research engagement.

RESULTS

Strengths and opportunities remained constant through trial phases, disease burdens, and interventions. Threats included alienation, litigation, disparity and shaming. Poor management and barriers to inclusion were identified as weaknesses. Opportunities included improving resource management and information quality. Barriers were minimized when relationships between staff and participants were inclusive, respectful, tolerant and open to change.

CONCLUSIONS

Participants' communications ranged from fulfillment through trial involvement to disparities and rights violations. PAR provides a safe space without power imbalances where researchers and citizen worked as equals rather than as researcher and objects of research.

Keywords: Research involvement, thematic analysis, research methods, patient experience, participatory action research, citizen research impact

Ethics Registration in compliance with University of Oxford, CUREC # MSD IDREC-C1-2013-174

Protocol Registration: This study is registered with the Research Registry with the unique identification number, UIN: 670, Principal Investigator Amy Price, Title; Mind the Gap in Clinical Trials: A Participatory Action Analysis with Citizen Collaborators <http://www.researchregistry.com>

Introduction

The clinical trials field is facing unprecedented challenges even as the curative potential for medicine and health science multiplies. For over a decade, aggressive marketing has not worked to increase recruitment or retention¹ of participants. In the UK, 45% of trials apply for extensions to recruit participants and yet 55% of trials still fail to reach the required sample size². In the last decade, 21% fewer people enrol in trials and retention rates have plummeted by 30% in the US. This is in stark contrast to the 58% increase in participant eligibility and the three-fold increase in clinical trials registered at clinical trials.gov from 2001-2014¹. Canadians reports a similar decline in cancer trials coupled with mounting costs and an increase of 50 to 150 days to trial activation³.

In order to address this issue, a reframing of the culture of research to build a bridge between methodological excellence and public engagement is required. One approach to engage patients and the public may be to utilize participatory action research (PAR). The PAR approach uses active collective inquiry by working with research volunteers whose perspectives and priorities may differ from those of researchers to adapt methodology for participation, collaboration and social change⁴. To facilitate accessibility and collaboration in PAR, the team works to reduce the use of theoretical jargon. The research volunteers are both participants and researchers whose input and experience are reflected in the publication⁵. PAR was initially used in education to reflect the changing values and experience in learning models. This approach is equally useful in health science as this allows the true inclusion of the values, experiences and strategies of all stakeholders⁶. PAR differs from traditional research

in that participants are active researchers⁷. PAR is well fitted for this time in health research as it is a window into the insights of all stakeholders and it is a bridge to a collective working methodology. The public is the end-user of any healthcare intervention thus making it imperative that research evidence guiding the use of healthcare interventions is relevant and useful to them^{8,9}.

This research explores the strengths, gaps, expectations and barriers to public and patient participation in clinical trials as communicated through social media. Up to 78% of those taking part in a clinical trial will find a trial through the internet or by email^{10,11}. Increasingly, trials participants use social media to share their clinical trials experiences¹² and this is an unexplored aspect of the patient voice.¹³ Brice and colleagues noted in their descriptive analysis of online trials that current practice in research involvement offers limited methodological guidance to pave the way forward¹⁴. This paper presents an example of citizen volunteers and researcher professionals working together to analyze trial participant experiences and to propose viable solutions to bridge some of the gaps in clinical trials research. This research adds to what is known by using a Participatory Action Research (PAR) approach to increase research knowledge for improving participation in clinical trials and by reporting on the value of research volunteers as equal collaborators.

Methods:

Research Question

What are the strengths, gaps, expectation and barriers to public and patient participation in clinical trials?

Data Collection

The authors used Internet search engines from January 2015 until April of 2015 to search freely available content from blogs, LinkedIn, Twitter, and Research Gate and via Symplur hash tags. Keywords used to locate data sources included; clinical trials, research participants, patient preference, shared decision making, public and patient involvement. The data used for exploration and analysis included summarized findings from the body of narrative interview studies on clinical trials by the Health Experiences Research Group at the University of Oxford, illustrated by video, audio and written extracts from the interviews, published on healthtalk.org¹⁵. Snowball techniques were employed to expand the pool of relevant information until a saturation point was reached ¹⁶.

The Research Team

The research team consisted of three graduate research authors and three volunteer citizen collaborators. Everyone contributed equally to the work using a participatory action research framework. The volunteer citizen collaborators were trained to code and to use NVIVO software over weeks in multiple three hour sessions using pilot sample data.

The Coding Process

Following the data collection but prior to coding, all identifiers pertaining to organizations or individuals were removed. The data sources were randomized

before the analysis to minimize bias and as a safeguard against a disproportionate amount of material from any one source. Data was organized according to Strengths Weaknesses, Opportunities and Threats (SWOT), a framework that has been used in qualitative health research^{17–20}. This framework helped coders to better organise the data and develop themes. NVIVO software was used to code the data with each entry independently coded by two researchers²¹. Discussion about coding, analysis and authoring took place via personal contact, SKYPE, email and telephone.

Results

The results for data coding and analysis are outlined using a SWOT framework²² with the main categories as described under the headings of Strengths, Weaknesses, Opportunities and Threats (Figure-1).

SWOT Framework in Theme Development

Figure-1 Strength perspectives were coded as themes of trial benefits, feeling included, information sharing, levels of comfort and service. Weaknesses were coded as vulnerability, information deficits, under

qualified staff, shame in research, and peer pressure. Opportunities themes included access issues, improvements in communication, inclusion and transparency. Threat based themes were litigation, intimidation, harm or adverse effects, and compensation challenges.

The parent themes reserved for organizing the discussion were; Strength through the lens of support and rewards; Weakness was linked to disparity and shame; Opportunities related the need for information and communication; Threats encompassed the themes of intimidation and loss.

Strengths

The two main themes to emerge in Strengths were supportive and rewarding. The respondents described positive experiences. Respondents welcomed research feedback, new information on managing conditions and positive reinforcement. Peer-to-peer support provided via online chats and forums was considered helpful but contact information available only for troubleshooting emergencies was not. The support and interaction were not expectations of the participants. They embraced the support and felt it increased their knowledge, feeling of safeness and some said the extra education and support helped them with the self-care to manage their conditions more effectively. Participants that experienced this support reported being open to participate in future trials even when the experimental intervention was ineffective or the trial was stopped. This pattern of response was constant across severity of conditions and stage of the trial even when patients were facing a terminal diagnosis and the trial was high risk.

“DA felt he got excellent care from the doctor running the trial and enjoyed being able to talk to him. He would if anything have liked more scientific information, even

if it was hard to understand, to help him look into the press stories in more detail and understand how accurate they were” [healthtalk.org].

“They gave two different lots of information. One for “J”, the book was “J’s” to read, which was designed really for the children to read and, and look at. And then they gave the adults other information, which went into it in more depth really. So we were both informed of the same things but in different ways really” [healthtalk.org].

Rewards provided by trial participation went beyond the compensation provided by taking part. Rather, participants spoke about the satisfaction of taking part, that they enjoyed hoping with others that the intervention was successful and how they felt they were accessing the best available care.

“So, you know, the whole thing was a new, new experiment, but it was all done with using drugs that had been used at least, you know, for some time. So I was always quite happy. I always felt I was in good hands and never really worried at all, you know.” [Healthtalk.org]

“The trial improved my son, gave us hope, we would do it again” [Twitter]

“I felt like, yes, I did feel like that if I could help someone and someone could have, you know, a much easier road to recovery because of something that I did, it made me feel a bit better about it and that my suffering, being sick was worth it for someone else.” [healthtalk.org].

Weaknesses

The themes that contributed to weakness in the trial were those that triggered a sense of disparity and shame. Respondents were frustrated with the disparity between themselves and other stakeholders. Participants felt like objects mined for selective information if they were the “right” package. They imply human needs for validation, respect and care were unmet and they contrasted this with sponsors who enjoyed a voice, profits, and prestige.

“Health disparities will persist until intent and methods and practice change.”

[PCORI Twitter-chat]

“Crowd-source to define the exclusion characteristics common in our specific disease; Listen and learn. The goal is to allow participants to answer only a few questions, but with those questions to eliminate a majority of trials for which they fail to meet eligibility criteria.” [Twitter-chat via Symplur]

“While they get a pay check to live, we are paying with our lives” As one volunteer aptly stated, *“Sponsors are making an investment from which they expect a return and staff is paid to make a living, their risk is small compared to ours, we gamble with our lives.”* [LinkedIn]

The trials participants expressed fear, desperation, shame and inner pain. The sense of exclusion and frustration was clearly communicated.

“They only want perfect patients, if you have more than one thing wrong with you, you can’t get in a trial. In our MS group we all tried and none of us matched the inclusion criteria, we were all rejected.” [BioEthx Twitter-chat] “How do researchers expect treatment to work outside of the lab if they only take perfect patients?” [F1000 Twitter-chat]

“If it was simple we would just go to the doctor and get a pill, don’t they understand our sickness makes us ill in other ways too”. [Regenerative medicine forum]

During a Twitter chat one Parkinson disease (PD) patient and a veteran of multiple RCTs gave an eloquent example followed by a video showing the gait freezing that comes when PD patients are off their medications for more than 24 hours. This happens because some studies need the patients to have their systems free from the medication that prevents gait freezing to prevent overlap with effects of the experimental intervention. Patients found crossing the road or walking through a parking lot was dangerous and humiliating. They repeatedly requested admission to a clinic the night before and aides to help them navigate within the facility however the courtesy was denied as “too expensive”.

“A” is so keen to be involved in trials that he says sometimes he has worked very hard to persuade trial staff to accept him even if he does not quite meet the eligibility criteria. If they say no the first time, he will ask to be put on a reserve list, and will keep ringing back.” [healthtalk.org]

“If the intervention is only effective for some of the people we will all be denied the treatment in future;” [blood cancer, emphysema and ALS online groups]. *“We patients have all the skin in the game”* [LinkedIn].

The participants shared how shame and fear heightened their sense of exclusion and disparity. They felt responsible for the trial and feared that reporting an adverse event might cause the trial to be closed down. In their minds this destroyed the hope of a “cure” for others. Many admit they were ashamed to ask for help when they could not understand the directions. Others say they dropped out of a trial because they lacked funds to continue. It was common for participants to fear being labeled as difficult, blacklisted and banned from further trials. When asked on Twitter why participants don’t report serious adverse events during trials the responses were:

“I’m afraid of getting kicked out”

“Too sick to know what is a side effect and what is dying”

“We were told it will ruin it for others if we say anything”

Our doctors will be mad because they would lose “the recruitment reimbursement monies” and they will drop us as patients.”

“If we withdraw from the trial we have to pay for medical treatment to fix it ourselves or sue and we do not have the money.”

Opportunities

The major themes were information and communication. Respondents wanted their input to be given equal consideration with that of other stakeholders and saw no reason why copies of their data could not be made available to them in a portable

format. Participants wanted to be informed ahead of the general public about trial results.

“But patients are being harmed every day because of a lack of information sharing that could detect harmful side effects and drug reactions that would never be picked up by clinical trials. It is really this that we should all be working towards” [Lily Twitter-chat].

“ First they tell us any decent trial will be listed in <http://clinicaltrials.gov> and when people they don’t like get approved they tell us that trial is unethical, they keep changing the rules because they have a conflict of interest” [LinkedIn]

“If you are upfront and explain to patients that there is genuine uncertainty about which treatment is best, they will understand the need for research. Greater public awareness would help.” [healthtalk.org]. Participants wanted *“Helpful websites to learn about our conditions, find available treatments, and sign up for trials.”* [LinkedIn]

Threats

The themes were intimidation and loss. Participants were alarmed and angry that consequences for those that harmed them were non-existent. They wanted accountability from trial sponsors and investigators. Many participants state they were enrolled in trials by doctors but were treated only as participants and not cared for as patients.

One participant stated *“I anonymously shared the terms of the contract they photographed on the Internet only to be tracked by the sponsor through an IP number and threatened”* (LinkedIn).

“When I tried to report my problems to the FDA it was way too complicated and when I finally got someone on the phone from there, they made me feel stupid and like I was the criminal” [LinkedIn].

Participants wanted to know about adverse events or bad outcomes. They expressed concern trials staff were not adequately trained in their disease. They shared experiences of trials being closed without notice and not hearing about how the trial ended or what other research was completed as a follow-up to trials.

“If they are going to research us shouldn’t they know more about our needs and be better trained about the conditions. Sure, there are doctors in clinical trials but they are usually not there and the people that are don’t have that training?” [LinkedIn].

“Shouldn’t these organizations have an obligation to provide insurance coverage for study volunteers? I was truly shocked when I learned that a clinical trial sponsored by the NIH (National Institutes of Health) would do nothing to pay for long-term care needed as a result of serious trial-caused injury or disability” [CISCRP-blog].

Discussion

The conversations of trials participants ranged from expressions of strength and support for trial personnel to harrowing accounts of shame and disparity. Similar

results of variable quality in clinical trials were found in the PIRICOM²³ systematic review where authors focused on the degree and quality of public and patient involvement in terms of impact to all stakeholders. Although their research was published in 2010 many disparities and opportunities for improvement remain²⁴.

The identification of themes in weaknesses and threats can prepare researchers to consider these elements in their methodology. The themes of disparity and loss show experiences of rejection and exclusion are magnified through inadequate trials management. Participants were emphatic about the need to make inclusion and exclusion criteria clear to prevent such negative experiences. Similarly, other studies report participants deal with significant financial loss and a sense of rejection when they are excluded from trials adding those who are excluded are less likely to participate in another clinical trial²⁵.

Particularly shocking was the multi-faceted expressions of shame, intimidation and the fear of reporting adverse events which was also confirmed in other research²⁶. These disparities represent clear violation of the rights of participants²⁷. If these weaknesses and threats are not curbed, participation rates will continue to fall¹⁰ Ethics committee would do well to consider these weaknesses and threats as violations of participant rights and stop trials where these are occurring. These concerns were shared in US congress and the National Institutes of Health grand rounds events by one of our volunteer content contributors²⁸.

In spite of challenges strengths were apparent, the themes supportive and rewarding participants report inclusion, support and feeling rewarded. This is in synchrony with

research where patients regularly share knowledge and contribute to empowerment in clinical trials through the healthtalk.org website¹⁵. Here researchers serve as facilitators while patient interviews offer information and support. Healthtalk.org are recipients of multiple British Medical Association awards indicating their positive influence spans disciplines and social groups²⁹.

Recommendations

The authors considered recommendations for change in four areas; (1) reusable demographic trials data, (2) managing adverse effects, (3) participant profit sharing, and (4) self-recruited online participatory clinical trials.

As only 35% of excluded persons will go on to find another clinical trial for which they are a better fit, a registry to match participants to trials may reduce rejection of participants. This along with improved trial management in areas such as enrolment, consent and adverse events can lead to better participant experience. Profit sharing for participants is an issue that should also be considered in the principle of fair compensation although ethical problems such as undue influence can arise from this.

True participation of citizen collaborators may be the way forward. Engaging the public in all aspects of research inclusive of trial design may well improve the quality of trials, lead to greater transparency and generate practical insights for clinical trials³⁰.

Strengths and Limitations

While this research offers the unfiltered voices of clinical trials participants it is limited to a slice of history and to populations captured through social media during that era. These findings reveal current meaning and experiences participants attach to

clinical trials. However social construction is fluid and dynamic. The concerns expressed may change over time and means that although methods are replicable, conversations around clinical trials are subject to change. The original protocol built without using citizen research volunteers was not usable. It was adapted with the help of citizen researchers. From this we learned it is important to pilot the process with the same population that will be involved in research and that technical piloting with topic experts is not sufficient.

Limitations of the Population Sample

Social media and online commentary was used to capture the voice of issues that are widespread across clinical trials as expressed through online communications between patients and research participants. The search was not limited by severity of condition, size of a trial or common populations. Using this approach allows explorations of common experience in clinical trials across cultures, interventions and operations. The goal of this research was not to compare experiences of interventional versus observational research or to stratify for issues of engagement related to disease, prognosis or treatment burden. It is expected these qualities will differ across trials and our aim was to explore common participant experience across trials. Social media collection allowed the research team to explore publicly available data that could be shared with our citizen researchers without incurring excessive costs or the data protection complications that would arise if we used clinic, hospital or national health service records³¹.

We acknowledge that the findings may exclude research participants who do not use the internet to communicate health or research information. However, exploring a

broad overview of experience through online experience can expose areas worthy of future targeted intervention for public health research and online trials.

Conclusions

Trial participants' communications ranged from praise about support and acknowledgement about the sense of fulfillment trial participation brought them to the reality of facing disparities and loss that violated their rights. The participatory action research framework provided a safe space without power imbalances where professional researchers and citizen volunteers could work as equals rather than as researcher and objects of research³².

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Declarations

Ethics

Informed Consent

The Oxford Central University Ethics Committee gave ethics approval for the overall study. The IRB approval number is MSD IDREC-C1-2013-174. Informed consent was not needed to collect the social media data as it was in the public domain and no private password protected data was used. The data were collected in specific accordance with the Terms of Service that are listed on the website of each social media outlet (Linked In, Twitter, and Research Gate). The principal investigator anonymized social media data one month prior to coding in order to reduce the possibility of brand bias. Informed Consent was obtained for sharing the data of the citizen authors.

Consent for Publication

The citizen authors gave consent for their participation and were informed they were free to withdraw from the study at any time without giving reasons and without any penalty. The participants had the opportunity to review and edit their contributions to the data and content was agreed prior to submission.

Availability of data and materials

Results for analyses are published within the study. Any further information is available from the corresponding author.

Competing Interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare they received no support from any additional organization for this work.

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This research received no funding and no author has any competing interests to declare.

Author Contributions

Amy Price (AP) had the original idea for this study. AP and Su May Liew (SML) developed the methods sections. All authors contributed to the study, AP wrote the paper and SML critically reviewed the contents. All authors approved the submitted version.

Research Reporting

The Critical Appraisal Skills Programme (CASP) making sense of evidence: 10 questions to help you make sense of qualitative research³³ and GRIPP checklist³⁴ were used to report the study

Transparency

The lead author and the manuscript's guarantor (AP) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

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