

Title: Mind the Gap Methods: Steps to making Participatory Action Analysis with Citizen Collaborators Work

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Abstract

RESEARCH QUESTION

This question explored the strengths, weaknesses, opportunities and threats in clinical trials as represented through online communications. In this follow up analysis we share learning points for successful research involvement.

AIM

The aim was to use participatory action research to prioritize the research question and to explore projected solutions as citizens and researchers with equal voices in research.

INTRODUCTION

Participants in health research want to be involved in the research. Researchers struggle with how to approach citizens as co-researchers, train them, tactfully reduce contributions that are less useful, and what to do about compensation and where to include citizen input in a manuscript.

METHODS

Researchers and citizens worked in a participatory research framework. They searched the Internet using key words to locate social media conversations and Internet interviews about clinical trials over four months until a saturation point was reached. Data was de-identified and coded into a SWOT analysis and further coded into themes and analyzed. The findings and solutions were discussed using a circle chart for problem solving. The data was prioritized by consensus and report the process is reported here.

RESULTS

Investigators and participant researchers were not conflicted in assigning themes because the data was clearly stated and the same sentiments were repeated consistently. The teams reached consensus about which quotes to include to support the findings. These themes ranged from supportive researcher-to-participant and participant-peer relationships to experiences of shame, research disparity, intimidation and personal loss.

CONCLUSIONS

This research engages citizen participants as equal partners in all aspects of this study. Public and patient involvement as co-production in research can be used to identify and suggest resolutions in research. The use of participatory action in research can improve consistency, communication, innovation and quality in clinical trials.

What is New

The research for this paper was done in collaboration with members of the public as full authors who worked to collect, code, analyze, contribute to the discussion, edit and write up the data. In the Mind the Gap manuscript results were found to point to links between poor trials management and participant experiences of rejection or exclusion. The participants were emphatic about the need to make inclusion and exclusion criteria clear if researchers want to maintain community respect. The citizen authors identified shame and displaced loyalty in their data analysis as factors in failed reporting of adverse events.

The same principles of respect, good management and inclusion are applicable to the methodology for research involvement. This manuscript adds to what is known by inviting citizen authors to problem solve pressing issues in the running of clinical trials and serves to demonstrate that citizen volunteers are useful and insightful collaborators in multiple areas even when methods are adapted and simplified. For a viable bridge between research involvement and methodology the careful consideration of methods to engage citizens can be explored from the onset of the research.

Introduction

In the Primary Mind the Gap manuscript, citizens and researchers analyzed social media transcripts and brainstormed ways to increase engagement in clinical trials using a Participatory Action Research (PAR) framework[1]. In this manuscript we share our methods and lessons. Freely available social media was used as a source of data analysis because it is widely noted for reshaping worldviews[2], represents a current opinion about clinical trials participations, and served as a medium that volunteers could be invited to analyze without complex ethical approval. We note that the World Health Organization and Centers for Disease Control use social media to predict disease patterns, to provide survival advice and to share links that can reunite loved one in major disasters. Increasingly major research funders have developed a presence on social media and this growing use of social media in health seemed a logical place to start and triggered interest in using this as a source of data [3,4].

Public Research Involvement

A minority of the public have managed to contribute to citizen and health researcher co-production to design heart and brain valves, devices to save women in childbirth, inexpensive 3D plastic artificial limbs and markers for the early detection of pancreatic cancer[5]. For the majority of people inroads for collaboration remain inadequate and there is limited methodological guidance to pave the way forward[6]. Trials participants struggle to make their voices understood [7]. Researchers claim to speak for participants, but content is frequently chosen to enhance the researchers priorities rather than the needs of participants[8]. This power imbalance is widely reported and even though attempts exist to limit the scope to deficiencies of evidence based medicine (EBM) the literature reports this bias as not limited to EBM, but instead it is far reaching[9], longstanding[10], potentially harmful[11] and is embedded in medical research and medicine[12]. Our goal is to encourage others to integrate citizen research involvement and to enjoy working together as funders, researchers, regulators patients and members of the public. There is not an instant recipe for success but rather provides one map in the journey for identifying best methods to contribute to excellence in research involvement. We asked researchers and citizens at conferences, teaching sessions, on social media and through publishing groups about working together. We include some of the main queries and our responses and then we go on to describe the methods we used in the companion Mind the Gap paper.

Eight Questions Researchers and Citizens Ask

“How do we get started finding contributors?”

This study invited volunteers from high schools, community colleges and universities and offered them community service credits in return for participation. There are other options for finding volunteers such as searching the topic of interest in social media and Google to find interested individuals and groups. Many universities and industries have dedicated research involvement staff who will match researchers to patients in the community for working together. Some health professionals ask their own patients or leave leaflets or posters in the waiting room with a contact number or person to ask if

they want to volunteer. Patient interest and advocacy groups are a good way to find volunteers. An initial phone call will help your information reach those most able to assist. Follow-up contact is essential, especially when working with organizations or groups. Thanking those who have helped promotes continuity in partnership and community goodwill.

At what point do we involve citizens in the research and how involved should they be?

This will vary according to the research question, project resources, availability of researchers and volunteers, however the literature recommends early involvement. A clear plan is vital to avoid volunteers becoming confused about their roles or levels of expected commitments. Consider the resource costs of potential volunteers and think about how they could be rewarded. Some volunteers may be sick patients with physical limitations, while others may be young retired persons with time on their hands. It works well to engage volunteers one task at a time. In this way contributions can still be recognized if volunteers are unable to continue. This reduces the fear and guilt of letting the “team” down and leaves volunteers with their personal dignity intact. Another advantage of using the one task at a time approach is to define areas of volunteer interest. This strategy can work to weed out those who may not be able to work as a team.

“What can we ask research volunteers and how can we explain what we are doing?”

Volunteers may be helpful to identify transitions from research to getting an intervention into practice for use in every-day life. Ask for feedback concerning important outcomes and have them consider areas that may have been missed or neglected. When questions in the study are too long, hard to understand or something in the platform or intervention goes wrong, volunteers can communicate this when used as early testers. Volunteers can share how they manage inevitable side effects and ways it improves usability of the research site and the intervention. They may have suggestions to make it better.

When explanations are necessary, it is good practice to invite participants to explain what they have understood in their own words. This will expose gaps in understanding. Have volunteers share the task with someone else and listen. This way, what is understood well will be apparent and it will be easier to see where adapting materials and approaches is required. Follow up on assigned tasks early to insure volunteers are able to complete them and are not struggling. It can take individuals three sessions to be comfortable with a new task and to be able to work independently.

Volunteers can help with editing and will quickly find jargon to remove. This will make the research easier to understand for everyone. There are times when things go wrong, be truthful, forgiving and inclusive. Let volunteers know that they are part of something new and that feelings, values and contributions are respected and that they matter. Volunteers frequently respond in kind, letting researchers know how the work has led to positive outcomes, fresh understanding or changed lives.

Are their ways we can encourage each other?

Give praise, encouragement and thanks often. Be specific, rather than saying thanks, good job, or you are so logical, creative or kind try using praise that is situation specific, such as when I saw you manage that situation, your diplomacy was exemplary and when I saw what you have written I was so pleased with how far you have come, and state the differences, adding thanks, you are such an important member of our team. Display reminders and encouragement of why the research is important. Research is delving into the work of uncertainty, it is hard work and not always comfortable. The people we work with can make research a joy or a torment.

“How can we honor volunteers when we are on a limited budget?”

Bring volunteers to conferences and other events as partners in presenting the work. Share results with the research team before it is announced to the world. Just as in a family important announcements are given family first so in the research climate, research volunteers are part of the “family”. Be generous with letters of thanks and recommendation. Share a celebration meal together. Buy gifts to say thank you. Offer a research participant certificate. Be there to help volunteers with other research interests. Include volunteers as co-authors if they meet the criteria and alternatively acknowledge them as contributors in an acknowledgement section.

“What is the procedure for adding citizen research involvement? In the manuscript”

New and emergent methods will need to be fully explained and introduced gently without condemning methods already in use. Editors and reviewers are trained in specific methodologies and these are the frameworks to which they have become accustomed. It is the work of the researcher and author to present the results in ways that they will be heard. In a traditional manuscript a good place to include citizen research involvement is at the bottom of the methods section under the heading “*Public Involvement*” The BMJ has an excellent declaration that can be adapted to any manuscript and we include it here by permission:

Mind the Gap Summary

The research question asked was “*What are the strengths, gaps, expectations and barriers to research engagement in clinical trials as communicated through social media?*” This question was chosen because trials can act as building blocks of history where what is reported on social media might be used to improve the way we interact with the clinical trials climate. What is learned from earlier research can be used to build on current treatments and provide evidence for alternative options. Studying what people say about trials can demonstrate ways to make trials more person centered by improving the quality of life within the research environment.

Earlier research indicates the priorities of those running the trials can differ from those of participants[6]. Researchers and participants shared that roles for public research involvement lack clarity so that even when people want to get involved they are not sure how to get started or what to do[13]. We explored these gaps through the use of a Participatory Action Research (PAR) framework where citizens can be equal partners in the research working to problem solve barriers to access. Citizens can explore and report ways collaboration has progressed research.

The Mind the Gap study found shared strengths and opportunities throughout trial phases, disease burdens, and types of treatment. Trial participants praised trial investigators, saying they gained strategies and learned more about their disease during the trial than from their physicians. Other participants welcomed the opportunity to make healthcare better by volunteering for research. Of course some felt that the trial would be the magic cure and for some it was. Conversely, respondents report alienation and litigation threats for speaking out about inconsistencies or disparities. Some participants felt shamed and disparaged. They struggled with seeing doctors as objective researchers rather than compassionate clinicians and were at odds with no one assuming responsibility for their clinical welfare throughout the trial. The data showed barriers were minimized where relationships between staff and participants were inclusive, respectful, tolerant and open to adapt to unexpected circumstances. The data was collected and analyzed using the PAR framework.

More About the Participatory Action Framework

The PAR framework 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 change[14]. The research volunteers are both participants and researchers whose input and experience are reflected in the publication[15]. PAR was initially used in education to reflect the changing values and experience in learning models. This approach is equally useful in health science where the aim is to include the values and experiences of all stakeholders[16]. To facilitate accessibility and collaboration, coding structures were in plain language and free of theoretical jargon. In the remaining sections of the paper the methods and how they were applied are shared.

Aims and Objectives

The aim of Mind the Gap was to explore benefits, practical breakdowns and unfulfilled expectations in clinical trials participation with citizen collaborators using a participatory action framework[1] . The objectives were to identify the expectations and experiences of clinical trials participants as identified through a SWOT (strengths, weaknesses, opportunities and threats) analysis of online conversations and interviews and then to find and troubleshoot gaps in methodology and engagement for clinical trials research as identified by the SWOT analysis and to discuss potential solutions.

Equipment

The authors used NVIVO[17] software to code the anonymized, aggregated materials from personal computers. Researcher and co-author Amy Price (AP) trained participants to use the software over several three hour sessions. The data was saved and uploaded to a secure online location. Discussion about coding, analysis and authoring took place via personal contact, SKYPE, email, and telephone.

The Research Team

The research team consisted of three graduate research authors and three volunteer citizen collaborators. For this manuscript the authors remain the same. Everyone contributed to the work using a participatory action research framework.

Data Collection

Data was collected as described elsewhere until a saturation point was reached[18]. The research team elected to code the data according to strengths weaknesses, opportunities and weaknesses, rather than employing themes that assumed prior knowledge of emotional context. This was done to avoid misunderstanding and to direct the focus to problem solving the practical issues.

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. Three authors, Amy Price (AP), Jazmin Price (JP), and Taylor Lopreto (TL) independently coded the data, came to consensus and agreed on themes. NVIVO software was used to code the data and the coding structure was based on a SWOT (strengths, weaknesses, opportunities and threats) analysis with categories pre-agreed by authors[19]. The themes that emerged from the coding categories were expanded in the results sections with proposed solutions offered in the discussion (Fig 1).

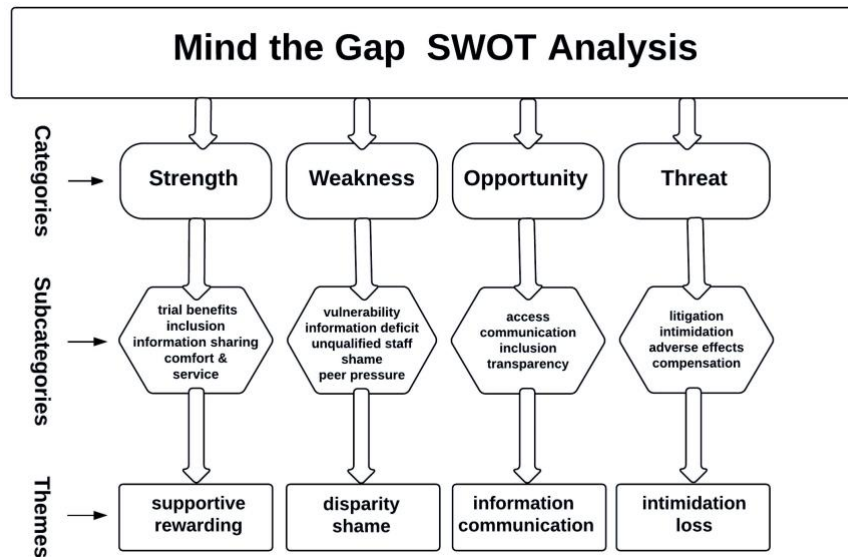


Fig 1 SWOT Diagram and sub categories used by coders

The subcategories were used to capture the nuances of individual narratives such as participation in the trial, family life influence, and lessons learned through trials participation. Following the analysis researchers and citizen authors used a “circle technique” commonly used in conflict negotiation to facilitate problem solving of weaknesses and threats identified through a data analysis[20]. The steps are illustrated in Table-1

Table 1 circle process illustration for problem solving[20]

Circle Steps	Process for problem solving
Problem	Diagnose problem, categorize symptoms, note barriers
Analysis	Sort symptoms into categories, suggest causes
Approach	Explore disliked facts, brainstorm preferred solutions
Action Ideas	Seek strategies and list steps for potential solutions

Re-Identification of Data

The data sources were re-identified following coding and analysis with the use of the freeware corpus analysis application AntCont[21]. This was to enable the later identification of comments by source with italics and quotes for publication. Interview based participants seemed to remember more positive aspects of research than those who contributed using free form social media comments [49]. This alerted us to the possibility that an unbalanced ratio of interviews to social media content could disrupt the balance between positive and negative content. When individuals who were quoted could be identified, we invited them to edit the quote or revise the context. This served as a consistent check and balance that the participant voice was sustained throughout the coding.

In the original paper recommendations for change were abbreviated to make room for the results. They are now included to show the possibilities for depth and innovation that collaboration with citizens can bring.

Recommendations for Change

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

Enable Reusable Demographic Trials Data

Participants confided being rejected for a clinical trial was taken personally rather than regarded as not meeting inclusion criteria. CISC RP[22] reported that only 35% of excluded persons will go on to find another clinical trial for which they are a better fit. Citizen volunteers suggest building a registry to match participants to trials. Information could be stored in an international demographic data bank where online consent for any registered trial might be auto-populated with pre-entered data. One challenge that patients and participants face is the ability to access and share their data in a portable way across systems[23]. Mandatory registration and reporting of all trials as recommended by the All Trials initiative[24] could lead to a more transparent climate where clinical trials registries are standardized and information is shared.

Enrolment, Consent and Adverse Events Management

Volunteers suggested aligning medical and research consent so research could be merged within clinical practice [25]. Autonomy could be protected through the use of an opt-out process as is used for organ donation in multiple countries[26] and also in the UK to share aggregated primary care data[27]. Models of interactive consent and concepts used to facilitate shared decision-making that includes values and preferences might be used to revamp patient information sheets to provide improved explanations for risks, benefits and medical conditions[28,29]. To address adverse event management, citizens suggest trial sponsors could post bonds or have adequate funds held in trust for addressing adverse events compensation. Sponsors who fail to meet these obligations could be excluded from funding, trial registration, publication and commercialization until these discrepancies are resolved. Mediators could evaluate adverse event claims to protect both parties.

Profit Sharing for Participants

The volunteers considered profit sharing with participants as shareholders. They referenced the example of Henrietta Lacks who died of aggressive ovarian cancer. Her cell line was used without consent for decades while her impoverished motherless family struggled to survive. The family received no financial consideration even though her cells were used to develop life extending expensive cancer medicines[30]. Authors agreed with the justice of compensation however the concern was that profit-sharing might increase tendencies to under-report adverse events or over-report benefits and that this could compromise public safety[31].

The volunteers suggested a work around to deposit a percentage of trial profits in a national or internationally held trust fund run by stakeholders including research participants where prospective participants could apply to meet unfunded participation and researchers could apply to this fund for help with meeting volunteer research expenses[32]. Previous participants might be granted priority access funding for them or a family member. The fund could continue to accumulate equity until the funds were applied for.

Online Trials and Citizen Collaboration

With an increase in life expectancies, more people with complex needs and limited mobility will participate in clinical trials[22]. Reduced costs, global access and electronic data transfer tracking makes online trials an attractive option where participants could enroll from home using an Internet connection. Participatory online trials could be adopted for citizen health science research particularly in fields of wellness and self-management. Volunteers expressed concerns about data ownership, portability and safety. 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 all forms of participant populated clinical trials[33].

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 participants was not usable. The final protocol was adapted with the help of citizen researchers. From this it was learned piloting studies with the same population that will be involved in research is essential and that technical piloting with topic experts is not sufficient.

Conclusion and Reflections

“The first thing we need is a list of those things that make people feel powerless and a set of limited achievable objects to start removing the barriers to people taking control of the scientific process” (Research Gate)

The quote was chosen by the volunteers as their “action statement.” It serves as a poignant reminder that much could be done to resolve problems by standard application of the patient’s preferences, values and priorities throughout the clinical trials process[12]. The citizen collaborators, our co-researchers added perception and sensitivity with their insights. They noted that even in the face of great personal suffering participants found joy in helping others.

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Ethics: The research used public information however the volunteer authors were also consented participants in the primary research and in this work. The study was approved by the Central University Research Ethics Committee (CUREC)[34], The University of Oxford # MSD IDREC-C1-2013-174

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

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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