

Highlights from the literature on user involvement in diabetes research

Introduction

We reviewed user involvement in diabetes research. The review included scientific literature relating to user involvement in all stages of research related to management of diabetes. This implies that emphasis was on all stages of patient and public involvement in diabetes research. In some of the studies this included studies evaluating user involvement in relation to diabetes prevention as well as treatment. The review disclosed 10 relevant review papers of which 8 were considered *highly relevant*. The most relevant papers were those that most explicitly described the relationship between the nature of involvement and the possible impact on outcomes and considered facilitators and barriers of user involvement. Some of these papers explicitly addressed user involvement in all stages of clinical research from idea, to execution, analysis and dissemination, while others addressed community based interventions such as screening or lifestyle intervention related to diabetes and other chronic health conditions including obesity or cancer, often with focus on minorities such as American Indians, or males of black color. One review focused on increasing enrolment of participants into clinical studies with involvement of users, but also health care providers and other relevant stakeholders, and one study focused on considerations for development of mobile phone apps to support diabetes self-management. Finally, one was not a review as such, but a three staged evaluation of patient and public involvement (PPI) in publicly funded research in different areas including diabetes conducted in England, where PPI has been a requirement for funding for over a decade. This report started with a scoping exercise, followed by an online survey to principal investigators and finally longitudinal evaluation of PPI in selected case studies.

Main conclusions on the impact of user involvement

There are different arguments for user involvement in research in diabetes (and in general), including a moral argument as citizens should have a voice in publicly funded research, and an ethical perspective as individuals have a right to be involved in any research intervention potentially done “to” them. In addition, a methodological argument suggests PPI will lead to higher quality research with greater impact and more reliable data.

In a review it was concluded that understanding of community context, developing trusting relationships across sectors and developing productive partnerships were prerequisites for designing research that was feasible and locally relevant. Benefits of user involvement have been reported to potentially help the development of the research agenda, the study design and process. All other reviews agreed to the potential benefits of user involvement with community engagement and culturally centred approaches being very important for the studies particularly in minorities. Not all analyses were able to confirm the benefits with certainty, partly because number of studies were few and partly because descriptions of the process for user involvement was often not detailed. Although some reviews compared the success of different strategies between studies, there were no studies comparing different degrees of user involvement within a study and we were not able to identify studies concerning the effectiveness of involving patients and the public in adapting diabetes interventions to reduce diabetes risk or achieve better diabetes self-management. Community based participatory research projects were in one review scored for user involvement according to the Reliability-Tested Guidelines for Assessing Participatory Research Projects developed by Mercer in 1998. The guidelines outline 4 key domains: 1) Participants and the Nature of Their Involvement; 2) Shaping the Purpose and Scope of the Research; 3) Research Implementation and Context; and 4) Nature of the Research Outcomes. The review suggested that a CBPR orientation yields improved community outcomes but could not conclude that community participation was directly associated with an improvement in health outcomes.

Key factors, enabling or hindering user involvement

There are many important factors for successful user involvement, but key factors identified enabling positive outcomes and impact of user involvement were a shared understanding of the purpose of PPI among researchers and lay representatives, a key individual co-ordinating PPI, and lay representatives having a strong connection with the target study population. Relationships should be established and maintained over time,

which is critical but also time and resource consuming. Identification of relevant local people could be difficult but rewarding. Resources may be an issue for long-term projects and relations, but with increasing focus from funders on user involvement this may be overcome. Whereas funders and researchers see randomised controlled clinical trials as an optimal design the use of a placebo control group is usually not possible/ethical in community-based research, but alternatives could be applied.

It is important that the whole research team is onboard and positive about PPI and evaluation of PPI should be proactive and systematic.

Key questions, gaps and challenges

As few studies in diabetes research have involved users in the research process from priority setting, designing the study, enrolling participants, developing study materials, data collection and analysis and dissemination there are multiple gaps, challenges and unanswered questions.

Key gaps are:

- Agreeing on the framework for PPI, and for reporting of PPI research projects in a way that enables comparison across studies or implementation of proposed tools such as GRIPP2 (<https://www.bmj.com/content/358/bmj.j3453>) or alternative updated version with lay coresearchers (<https://pubmed.ncbi.nlm.nih.gov/34294148/>).
- Training researchers in PPI, creating a curriculum framework.
- Whereas the focus has been on lifestyle and diabetes self-management in previous studies, we should explore user involvement also in basic diabetes research as well as in clinical intervention trials. In collaboration researchers and users should set priorities for research and develop shared endpoints also in these areas.
- The potential implications and outcomes of being a participant researcher should be further explored.
- We also need longer-term evaluation of outcomes on research findings and implementation.
- A cost analysis of different models of PPI will be important for optimal resource utilization

Authors: Peter Rossing and Kirsten Lomborg