

REVERSE TRANSLATION

Increasing the Impact of Behavior Change Intervention Research: Is There a Role for Stakeholder Engagement?

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Objective: There is powerful evidence that changing people's health-related behavior can impact the leading causes of mortality and morbidity. However, despite the significant potential to improve health and clinical outcomes, behavior change interventions frequently fall short of expected reach or impact. **Method:** Stakeholder engagement, which refers to the active involvement of public, patients, health professionals, and other decision makers throughout the research process, has been proposed as a strategy to improve the quality, reach, and impact of research. A user-centered "reverse translation" approach makes it more likely that behavior change interventions are relevant to users' needs, better designed, more likely to be implemented, and, ultimately, more effective. **Results:** In this article, the key concepts of stakeholder engagement are introduced and critically evaluated. Three studies, providing examples of stakeholder engagement, are described and critically evaluated. These include (1) a research prioritization project that sought the views of people with diabetes, services providers, and policy makers to identify research priorities in behavioral diabetes research; (2) a "core outcome set" study, in which consensus methods were used to identify outcomes considered important by patients and health professionals for trials of interventions targeting self-management among young adults with Type 1 diabetes; and (3) an intervention development study, where the intervention targeting self-management among young adults with Type 1 diabetes was coproduced with input from members of a "young adult panel." **Conclusions:** While stakeholder engagement appears promising as a strategy to increase the impact of behavior change research, evidence is sparse and more guidance, tools, and training are needed.

Keywords: behavior change, interventions, stakeholder engagement, patient and public involvement, Type 1 diabetes

Chronic noncommunicable diseases are now the leading causes of mortality and morbidity (Lozano et al., 2012). Changing human behavior—including smoking, alcohol misuse, poor diet, and lack of physical activity—is key to improving global health and reducing these diseases (National Institute for Clinical Excellence, 2014). However, although research testing the effectiveness of behavior change interventions frequently shows some promise, it often falls short of expected reach or impact and regularly delivers inconsistent findings (Fredrix, McSharry, Flannery, Dinneen, & Byrne, 2018; Free et al., 2013; Gardner, Smith, Lorencatto, Hamer, & Biddle, 2016; Maher et al., 2014; O'Hara, Hynes, O'Donnell, Nery, et al., 2017). Similar limitations are evident within implementation research, which targets health professional behavior

change with the aim of implementing new practices and/or change existing practices within health services (Atkins et al., 2017).

Reasons for these limitations in behavior change research include: low investment in this area of research (Michie, Fixsen, Grimshaw, & Eccles, 2009); poor-quality evaluation methods (Gardner et al., 2016); lack of application of behavior change theory in intervention development (Michie, 2008); poor specification of intervention content (Michie, Abraham, et al., 2011); lack of large-scale, interdisciplinary team science in health psychology (Freedland, 2017); and other problems associated with methodological challenges specific to the design and conduct of behavioral trials (Byrne, McSharry, Meade, Lavoie, & Bacon, 2018).

An additional possible reason for limited success is lack of stakeholder engagement (SE) in behavior change research. SE in research refers to the involvement of public, patients, health professionals, service users, payers, and other decision makers, from the early stages of setting priorities and forming research questions through to the final stages of implementing and disseminating results (Concannon et al., 2015). Terminology used in this area is diverse and can be confusing. The term *SE* will be used in this article as it is considered an umbrella term that encompasses

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activities, including patient and public involvement (PPI) and patient engagement. The U.K. National Institute of Health Research, which supports the INVOLVE program to support active public involvement in health and social care research, defines involvement as research being carried out “with” or “by” members of the public, rather than “to,” “about,” or “for” them (INVOLVE, 2012).

SE has become more common in the past decade and is now considered best practice in health research. Indeed, it is a requirement for many research funders internationally (Absolom, Holch, Woroncow, Wright, & Velikova, 2015). The increase in SE is driven by the belief that greater engagement will enhance the quality, relevance, and acceptability of research to all stakeholders (Staniszewska & Denegri, 2013).

Advocates of SE claim that it can improve research quality by ensuring that research is more relevant to research end users’ needs. SE enables researchers to identify and conduct research in areas considered priority by stakeholders (Gray-Burrows et al., 2018), identify intervention outcomes that are considered important by stakeholders (Staniszewska, Haywood, Brett, & Tutton, 2012), design interventions and research materials that are appropriate and sensitive to stakeholders’ needs (Brett et al., 2014), and recruit more successfully into research studies and disseminate research findings more effectively (Brett et al., 2014). In addition, some have argued that the public has a right to be involved in the conduct, management, and governance of publicly funded research to ensure public accountability and safeguarding (Gray-Burrows et al., 2018).

Conducting large and expensive randomized controlled trials of interventions with inadequate SE increases the chances of contributing to the significant societal problem of research waste. In 2010, expenditure on life sciences (mostly biomedical) research was U.S.\$240 billion (Røttingen et al., 2013). Waste across medical research (clinical or other types) has been estimated as consuming 85% of the billions spent each year (MacLeod et al., 2014), and commentators have criticized clinical research suggesting that most research is not useful (Ioannidis, 2016).

For example, in the Stanford Girl’s Health Enrichment Multisite Studies, researchers conducted a randomized controlled trial of a culturally tailored afterschool dance program intervention to reduce excessive weight gain in African American girls aged 8–10 years (Robinson et al., 2010). No difference in body mass index trajectories across the 2-year study was found between intervention and control group participants. The research team accounted for this finding by pointing to an “implementation failure” within the study: Median attendance rates among intervention participants at dance classes were only 12%, one fifth of the goal rate. If this study had used SE during the development of the intervention, it is unlikely that the research team would have developed an intervention that appears to have had so little traction with the target population and they could have avoided the waste of a full-scale randomized controlled trial costing millions of dollars and significant effort on the part of the researchers and participants.

In this article, I will present three examples of efforts I have led or been involved in to use SE to improve the quality of the behavior change research conducted within the Health Behavior Change Research Group. This group is a Health Research Board (Ireland)–funded national hub and internationally recognized center of excellence in health behavioral intervention development,

evaluation, and implementation in Ireland. The first example is a research prioritization project in which we worked with key stakeholders to identify, and achieve consensus on, the most important target behaviors for research in diabetes in Ireland. The second example is an international, e-Delphi consensus study to identify a core outcome set (COS) that key stakeholders (young adults with Type 1 diabetes [T1D], diabetes health professionals, diabetes researchers, and diabetes policy makers) consider as essential outcomes for future intervention research. The third example describes how we have embedded a user-centered approach in the development of a complex behavior change intervention to improve outcomes for young adults living with T1D, the D1 Now Study. For each example, I will reflect on the experience of using SE and highlight any lessons learnt. I will conclude by evaluating the current evidence base for the value and impact of SE and offer guidance for future attempts to embed SE in behavior change research based on the state of the evidence and my own experiences.

Example 1: Prioritizing Target Behaviors for Research in Diabetes: Using the Nominal Group Technique to Achieve Consensus From Key Stakeholders

At the outset of a 5-year program of research, which aimed to promote the routine application of behavioral science to the development and evaluation of behavioral interventions in population health and health services research, the research group needed to decide which patient, public, and health professional behaviors relevant to prevention and management of diabetes should be prioritized. Previous work has highlighted the lack of stakeholder and diabetes community links as key barriers in the implementation of diabetes research (Garcia de Quevedo, Siminerio, L’Heveder, & Narayan, 2012). Engaging stakeholders in the research process, by seeking input from patients and health care professionals in the prioritization of research, is recommended (Petit-Zeman, Firkins, & Scadding, 2010). We aimed to work with key stakeholders to identify, and achieve consensus on, the most important target behaviors for research in diabetes in Ireland and develop a research agenda for the research group (McSharry, Fredrix, Hynes, & Byrne, 2016). By adopting this collaborative approach to coproducing a research agenda, we sought not only to identify important research topics but also to enhance partnerships between researchers and key stakeholders to accelerate translation of research into benefits for patients and the population.

Methods have been reported in detail elsewhere (McSharry et al., 2016). Briefly, 24 participants, including people with diabetes, diabetes health care professionals, and policy makers, took part in a nominal group technique consensus process. Participants generated lists, through an online survey, of important target behaviors in three areas: managing T1D, managing Type 2 diabetes (T2D), and preventing T2D. Participants then attended a research prioritization meeting and ranked target behaviors in two rounds, with group discussion between ranking rounds. For each of the three key areas, the six top-ranked behaviors relevant to people with diabetes and health care professionals were identified. The top behavior relevant to people with T1D was “taking insulin as required” and for people with T2D was “attending and engaging with structured education programs.” “Engage in collaborative goal setting with patients” was the top-ranked behavior relevant to

health care professionals for managing both T1D and T2D. For preventing T2D, “engage in healthy behaviors as a family” was the highest ranked population behavior and “attend and engage with behavior change training” was the highest ranked professional behavior.

It proved possible to work with a diverse group of stakeholders to inform the diabetes research agenda for our research group. Following this process, we have developed programs of research in two priority areas: first, research to increase attendance at structured education in T2D (Humphreys, McSharry, Dinneen, & Byrne, 2017) and, second, research to explore the implementation and effectiveness of goal-setting techniques in diabetes self-management interventions (Fredrix et al., 2018). By adopting a collaborative approach to the coproduction of the research agenda, our experience was that the relationships developed through this process significantly facilitated the conduct of the program of research, made it easier to recruit participants, and increased stakeholders’ interest in the work. By identifying a key national priority, as was the case for increasing attendance at structured education for people with T2D, the research team was able to benefit from new national initiatives and investments in this area. For example, a national structured patient education coordinator was appointed soon after the research prioritization exercise was conducted, and this person (who was one of the participants in the research prioritization!) has been instrumental in facilitating access and recruitment of participants for this research. Practice and policy stakeholders were keen to access, disseminate, and use the results of the research, increasing the chances that the research findings will impact practice.

The process was not without its problems, however. It was challenging to facilitate the discussions among the key stakeholders in the research prioritization meeting. People with diabetes in the study were recruited via Diabetes Ireland, an Irish national charity dedicated to supporting people with diabetes. Participants, once recruited, were contacted by the researcher by phone in advance of attending the research prioritization meeting. They were provided information about the research and had an opportunity to ask questions. However, the diversity of backgrounds and wide range of expertise within the group made discussions challenging to moderate. People with diabetes contributed less to the meeting than members of other stakeholder groups, and two of the patient participants, in feedback following the meeting, stated that they felt they had not been adequately prepared and had not known what to expect. It is important that patient representatives within the research process, who have little or no background to research and the types of activities involved in the research process, are supported and provided with training to ensure that they have the skills needed to participate fully (INVOLVE, 2009). In addition, skill and training are needed for facilitators of discussions about research prioritization, and facilitators must be able to unite different groups, translating between different languages or spheres of expertise and enabling interactions (Cartwright & Crowe, 2011).

Another challenge for the research group was around maintaining networks and engagement of key stakeholders in the program of research beyond the research prioritization exercise. This appears to be a common pattern: Stakeholders, if they are engaged at all, are more frequently engaged in the earlier stages of research when priorities are set and evidence is generated (Concannon et

al., 2015). Research teams should seek to establish formal structures to maintain engagement throughout the research process and maintain interest and contact by regularly updating stakeholders about activities and outputs from the program of research, for example, by regular dissemination of policy briefs (INVOLVE, 2009).

Example 2: A Core Outcomes Set for Clinical Trials of Interventions for Young Adults With T1D: An International, Multiperspective Delphi Consensus Study

T1D requires people with the condition to engage in a complex regimen of self-management, including intensive self-monitoring of blood glucose and administering insulin, as well as regulating diet and exercise, to maintain optimal glycemic control (Chiang, Kirkman, Laffel, Peters, & the Type 1 Diabetes Sourcebook Authors, 2014). Young adults, aged 15–30 years, in particular struggle with the demands of self-management and are identified as being at high risk of clinical complications as a result (Bryden, Dunger, Mayou, Peveler, & Neil, 2003). One problem with research seeking to identify effective interventions to improve self-management among this high-risk population is the heterogeneity of outcomes used (O’Hara, Hynes, O’Donnell, Nery, et al., 2017). In addition, intervention research frequently does not include outcomes that are considered most important to people living with the condition and professionals making decisions about health care, limiting the relevance and applicability of research (Williamson et al., 2012). To address these problems, trialists advocate the identification of COS, defined as agreed standardized collections of outcomes that should be measured and reported in all trials, for specific clinical areas (Clarke, 2007). These outcomes constitute a *minimum* set of outcomes, which are recommended for inclusion in all intervention trials in the relevant clinical area. The involvement of key stakeholders in the identification of a COS is considered critical to ensure that outcomes are relevant to all stakeholder groups (Williamson et al., 2012). Our aim was to identify a COS for intervention research aiming to improve clinical, behavioral, or psychosocial outcomes for young adults with T1D (Byrne et al., 2017).

Methods have been reported in detail elsewhere (Byrne et al., 2017) and followed recently published guidelines on conduct of COS studies (Kirkham et al., 2016). Briefly, using a list of 87 outcomes generated from a previously published systematic review (O’Hara, Hynes, O’Donnell, Nery, et al., 2017), we administered two online surveys to a sample of international key stakeholders (Survey 1, $n = 132$, and Survey 2, $n = 81$) who rated the importance of the outcomes on a 9-point Likert scale. Participants included young adults with T1D, diabetes health professionals, diabetes researchers, and policy makers in diabetes services who were recruited by the international research team distributing the study invite via e-mail to lists and networks within their countries and internationally. In Survey 2, which was administered only to those who had completed Survey 1, participants received information on total mean rating for each outcome and a reminder of their personal outcome ratings from Survey 1. They were asked to complete Survey 2, taking this information into account. Survey 2 results were discussed at a consensus meeting and participants ($n = 12$: three young adults with T1D, four diabetes health

professionals, four diabetes researchers, and one diabetes policy maker) voted on outcomes. Final core outcomes were included provided that 70% of consensus group participants voted for their inclusion. Eight core outcomes were agreed for inclusion in the final COS: measures of diabetes-related stress, diabetes-related quality of life, number of severe hypoglycemic events, self-management behavior, number of instances of diabetic ketoacidosis, objectively measured glycated hemoglobin, level of clinic engagement, and perceived level of control over diabetes.

It was possible to engage a diverse range of stakeholders to produce and agree a COS for research targeting young adults with T1D. Diabetes research tends to emphasize quantifiable biomedical outcomes (such as standard metrics related to survival and physiological outcomes) over patient-oriented outcomes (outcomes that are important to patients such as quality of life; Hurley et al., 2017). It is likely that the inclusion of a broad range of stakeholders contributed to the production of a COS, which included a diverse set of outcomes, including stress, quality of life, self-management behavior, and level of engagement with health services, in addition to the “traditional” medical or biological markers. Within the discussions during the consensus meeting, young adults with T1D strongly advocated for the importance of psychosocial outcomes relative to clinical outcomes.

While consensus methods have been criticized (Beretta, 1996) and the study had some limitations (Byrne et al., 2017), we have produced the first COS for intervention trials targeting young adults with T1D. In addition, we believe that the process of patient involvement in this study worked well, and the interactions during the consensus meeting were more successful than those during the meeting in the research prioritization study described above. Members of a young adult panel (YAP) of 18- to 30-year-olds with T1D that had been formed for another study (O'Hara, Cunningham, et al., 2017) worked with the COS study research team to ensure that the surveys were acceptable to younger adults and to disseminate the surveys using methods, such as social media, which increased the chances of the surveys reaching young adults. Members of the YAP participated in the consensus meeting and, as they had received research and communications training as part of the YAP formation process, demonstrated the skills and confidence to fully engage with the discussion within the consensus meeting.

Example 3: Developing and Engaging a Young Adult Patient and Public Involvement Panel to Develop a Health Behavior Change Intervention: The D1 Now Study

As described above, young adults with T1D often struggle with the demands of self-management of their condition and are identified as being at high risk of clinical complications as a result. Evidence is lacking around effective interventions for this population (O'Hara, Hynes, O'Donnell, Nery, et al., 2017). The importance of including key stakeholders, such as patients and members of the public, to create and implement high-quality, impactful interventions has been highlighted (Armstrong, Herbert, Aveling, Dixon-Woods, & Martin, 2013). Our aim was to develop the D1 Now intervention, which aims to improve outcomes for young adults living with T1D. The research was underpinned by a comprehensive approach to SE while synthesizing theoretical and best practice guidelines for intervention development (Craig et al.,

2008; Michie, Atkins, & West, 2014). We involved research users—young adults with T1D, service providers, and policy makers—in a systematic and meaningful way to increase the likelihood of developing a feasible, implementable, applicable, and effective intervention.

Methods have been reported in detail elsewhere (O'Hara, Cunningham, et al., 2017; Walsh et al., 2018). Briefly, we recruited young adults to join a Young Adult Panel (YAP) in the study through a multimedia campaign. A public consultation event was organized to generate interest in the research, and interested young adults were interviewed to determine their suitability to join the YAP. A panel of eight members was selected, and members were trained in committee skills and an introduction to different research methods and terms. The YAP members participated in all stages of the research process: They were members of the research study steering group and attended research meetings, developed research materials, reviewed and interpreted research findings, were involved in result dissemination, and helped develop the online platform within the intervention to enhance engagement between young adults and their diabetes health care providers. Members of the YAP assisted in the interpretation of results of a systematic review of interventions targeting young adults (O'Hara, Hynes, O'Donnell, Nery, Byrne, et al., 2017). For the qualitative study to understand young adults' diabetes self-management behavior, YAP members coproduced interviews and focus group scripts. They co-led an international conference on health services delivery for young adults with T1D and participated in an expert panel consensus meeting to refine the intervention content (O'Hara, Hynes, O'Donnell, Keighron, et al., 2017). They wrote specific sections of a further research grant application (which was successful) to pilot test the D1 Now intervention.

We are currently pilot testing the D1 Now intervention, which includes three primary components: an interactive online system to facilitate more flexible appointment booking and communication between service users and providers, a “key worker” role identified within the diabetes service to promote better relationships and greater continuity between services users and providers, and an agenda-setting tool to promote greater shared decision making.

We engaged meaningfully with a range of stakeholders, including young adults with T1D, service providers, and policy makers for T1D, in order to increase the likelihood of developing a feasible, implementable, and effective intervention. The SE approach was instrumental in moving from theory-based concepts identified through the systematic review of the evidence (O'Hara, Hynes, O'Donnell, Nery, et al., 2017) and the qualitative research to operationalizing core intervention components. In our experience, integrating a SE approach into a phased intervention development approach (Craig et al., 2008) to identify evidence-based, acceptable, and feasible ways of operationalizing theoretical constructs that we identified using the Behavior Change Wheel framework for intervention development (Michie, van Stralen, & West, 2011) was critical to delivering the final product: the D1 Now intervention.

The SE approach within this study was not without challenges, however. Forming the YAP was time-intensive and required commitment from the research team to drive recruitment and maintain relationships. Meetings with the YAP often took place out of office hours, so flexibility was needed from the research team. It was challenging to identify training content suitable for the YAP mem-

bers in the absence of guidance in this area. Acting as a member of the YAP was also demanding and required regular meetings and exposure to new ideas, skills, and language. YAP members were required to read different and unfamiliar types of material (participant information sheets, grant applications, and articles being prepared for publication). Delivering research impact into services can be a slow process, and YAP members were required to engage with an iterative research process over a period of 2 years, which at times may have seemed frustrating. This involved managing expectations of both the YAP and the research team in terms of what was feasible, and implementable, and being realistic about how quickly change can happen given research designs and processes. We benefited greatly from support by a neutral local “knowledge broker,” Jigsaw, a community youth mental health service with experience in young adult panels (Illback et al., 2010). The process of understanding and integrating the ethos of SE, or patient and public involvement, occurred gradually over the duration of the study, and trust between the research team and the YAP grew through multiple interactions. Inclusion of opportunities to support the development of relationships in informal contexts, such as traveling together to meetings or having lunch following meetings, can be useful in enhancing the quality of stakeholder and research team relationships (Armstrong et al., 2013).

Some key lessons for researchers who wish to engage stakeholders in their research are listed as follows:

- Engage key stakeholders early in the research process to enhance the likelihood of impact. This enhances stakeholders’ feelings of ownership of, responsibility for, and interest in the program of research.
- Research teams can maintain SE throughout the research process by regularly updating stakeholders on progress, for example, by dissemination of policy briefs.
- It takes time to build trust and relationships between members of the research team and other key stakeholders. When planning research meetings, it can help to build in time to facilitate informal interactions to develop relationships; for example, it may be possible to travel to meetings together or organize a shared lunch before or after meetings.
- Stakeholder engagement requires commitment from all members of the research team, as well as flexibility, as meetings may have to take place outside of normal “office hours.”
- Stakeholders, especially patient and public members, should have protected time within research meetings where their views are sought, as they may not be confident enough to interrupt other speakers to volunteer their views.
- Abbreviations and technical language should be avoided as much as possible within research meetings involving stakeholders, as these can be off-putting and can act as barriers to engagement.
- Patients and public within the research process, who have little or no background to research and the types of activities involved in the research process, should be trained in relevant research and committee skills to enable them to participate fully and conduct the tasks.
- Researchers also may need communication training to facilitate interactions and discussions between teams of people from mixed backgrounds.

Discussion

So, does SE increase the impact of behavior change intervention research? The answer is probably yes, but the evidence base is still underdeveloped (Brett et al., 2014; Domecq et al., 2014; Shippee et al., 2015).

Public and patient SE in research seems feasible across a wide range of settings (Domecq et al., 2014). Based on evidence reviewed by INVOLVE in the United Kingdom, public involvement in research positively impacts the quality of the research, as well as impacting members of the public who are involved in research, the researchers themselves, and members of the wider community (INVOLVE, 2009). Public involvement in research has been reported as leading to improvements in the research, for example, in the research question, study design, communication with potential participants, study recruitment, confidence to carry out or complete a study, interpretation and communication of results, and influence on future research (South et al., 2016). In a systematic review of the impact of PPI on the impact of health and social care research, PPI was associated with enhanced quality and appropriateness of research, with impacts reported at all stages of research (Brett et al., 2014). Researchers who adopt PPI in their research report the benefits of doing so (Vale, Thompson, Murphy, Forcat, & Hanley, 2012).

Guidance in how to do stakeholder-engaged research is sparse. Training and user-friendly tools and methods for stakeholder recruitment, engagement, and evaluation are needed to help researchers embrace SE in their research projects (Concannon et al., 2014).

Critical factors to ensure success include long-term involvement of stakeholders, involvement throughout the duration of a project, and adequate training and support for the people involved (INVOLVE, 2009). To effectively engage patients in the research process, it is essential to ensure early involvement (ideally at the protocol-design stage), establish effective communication channels between patients and other team members (e.g., creating opportunities for more informal discussion outside of meeting times), and promote a nonhierarchical structure by valuing each team member’s opinions (Armstrong et al., 2013). Researchers are advised to consider a broad range of approaches to PPI and select their approach according to the desired impact and the people they wish to engage (South et al., 2016). The need to tailor PPI activities according to the nature of research to ensure authentic and appropriate involvement is important. A framework to guide the planning, conduct, and reporting of PPI within implementation research, which generally focuses on health professional behavior, has been recently published (Gray-Burrows et al., 2018).

This article aims to share and learn from the experience of adopting a SE approach across a number of studies within a program of behavior change intervention research. However, none of the studies actually set out to experimentally *test* the impact of SE. Within this article, I have presented our experience of using these approaches; future research is needed to develop a solid evidence base for the impact of SE (Shippee et al., 2015) and to estimate where engagement and involvement have the greatest

impact. Research devoted to identifying the best methods to achieve engagement is absent and needed (Domecq et al., 2014). Tools have been developed to encourage more standardized reporting on collaboration with stakeholders, and research teams are encouraged to conduct additional research to evaluate the impact of engagement on the relevance, transparency, and adoption of research (Concannon et al., 2015).

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