

Involving lay and professional stakeholders in the development of a research intervention for the DEPICTED Study

Lesley Lowes PhD,* Michael R. Robling PhD,† Kristina Bennert PhD,‡ Charlotte Crawley BA, PGCE,§ Helen Hambly MSc,¶ Kamila Hawthorne MD,** and John W. Gregory MD,†† and the DEPICTED Study Team

*Senior Lecturer/Practitioner (paediatric diabetes), Nursing, Health and Social Care Research Centre, School of Nursing and Midwifery Studies, Cardiff University, Cardiff, UK, †Senior Lecturer/Associate Director, South East Wales Trials Unit, Primary Care and Public Health, Cardiff University, Cardiff, UK, ‡Research Associate, NIHR School for Primary Care Research, Academic Unit of Primary Care, University of Bristol, Bristol, UK, §Parent of a teenager with diabetes/Lay Representative, c/o South East Wales Trials Unit, Primary Care and Public Health, Cardiff University, Cardiff, UK, ¶Research Associate, Speech and Language Therapy Research Unit, North Bristol NHS Trust, Bristol, UK, **Reader, Department of Primary Care and Public Health, Cardiff University, Cardiff, UK and ††Professor in Paediatric Endocrinology, Department of Child Health, Wales School of Medicine, Cardiff University, Cardiff, UK

Abstract

Correspondence

Dr Lesley Lowes PhD
Department of Child Health
University Hospital of Wales
Heath Park
Cardiff
CF15 9NJ
UK
E-mail: Lowes@cardiff.ac.uk

Accepted for publication

4 July 2010

Keywords: complex research intervention, paediatric diabetes, service user involvement, teenagers and parents, The DEPICTED study

Aim This paper focuses on stakeholders' active involvement at key stages of the research as members of a Stakeholder Action Group (SAG), particularly in the context of lay stakeholder involvement. Some challenges that can arise and wider issues (e.g. empowerment, the impact of user involvement) are identified and explored within the literature on service user involvement in health care research, reflecting on the implications for researchers.

Background In the DEPICTED study, lay and professional stakeholders were actively involved in developing a complex research intervention. Lay stakeholders comprised teenage and adult patients with diabetes, parents and patient organization representatives. Professional stakeholders were from a range of disciplines.

Methods Three 1-day research meetings were attended by 13–17 lay stakeholders and 10–11 professional stakeholders (plus researchers). The SAG was responsible for reviewing evidence, advising on developing ideas for the research intervention and guiding plans for evaluation of the intervention in a subsequent trial. Formal evaluations were completed by stakeholders following each SAG meeting.

Results Throughout the first (developmental) stage of this two-stage study, lay and professional stakeholders participated or were actively involved in activities that provided data to inform the research intervention. Lay stakeholders identified the need for and contributed to the design of a patient-held tool, strongly influenced the detailed design and content of the research intervention and outcome questionnaire, thus making a major contribution to the trial design.

Conclusion Stakeholders, including teenagers, can be actively involved in designing a research intervention and impact significantly on study outcomes.

Introduction

Type 1 diabetes is the third most common chronic condition in childhood and patients risk short- and long-term complications that may affect their development, morbidity and life expectancy. Such risks may be reduced by optimizing medical and behavioural self-management to achieve stable and near-normal ranges of blood glucose levels. However, a systematic review identified a lack of clear evidence regarding the most effective psycho-social or educational approach for optimizing glucose control in young people with diabetes¹ and called for psycho-educational research to be developed in consultation with key stakeholders. Major funders in the UK actively support public involvement in research. The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme have developed an evidence-based approach to involving service users in research and development agenda setting, which includes approaches to reducing barriers to meaningful participation.² Similarly, the James Lind Alliance was established in 2004 to encourage patients, carers and clinicians to work collaboratively to identify research questions.³

Based on the conclusions of the systematic review,¹ the NIHR HTA programme funded the DEPICTED (Development and Evaluation of a Psycho-social Intervention in Children and Teenagers Experiencing Diabetes) Study to develop, through a programme of research, a training programme for health practitioners to facilitate behaviour change in children and teenagers with diabetes.

The DEPICTED Study, following the commissioning brief, comprised two stages of research: a developmental stage in which options for the research interventions were explored and evaluated with the active involvement of key stakeholders,⁴ and a second stage involving

formal testing of the effectiveness of the research intervention against routine clinical care within a multi-centre randomized controlled trial. This article concerns the first developmental stage. The intervention had to be ultimately deliverable within the context of routine care without the need for additional clinical support (e.g. greater involvement of clinical psychologists) and acceptable to all stakeholders. Thus, the commissioning brief emphasized the requirement for key stakeholders, including children and teenagers with diabetes and parents/carers, to be actively involved in the development of the research intervention.

The aim of this study was to describe the active involvement of stakeholders, particularly in the context of lay stakeholder involvement, in the development of a research intervention, and to identify issues and challenges that have arisen that have wider implications for researchers in health care. These will be explored within the wider literature on service user involvement in health care research. For the purpose of this article, the service user participants (teenage and adult patients with diabetes, parents of children and teenagers with diabetes) are termed 'lay stakeholders' and service provider participants are termed 'professional stakeholders'. Where appropriate in specific discussion, other terms such as 'service user', parent and teenager are used.

Developmental research activities

1. The existing systematic literature review¹ was updated to identify any more recent evidence that could inform development of the research intervention.
2. Throughout the first (developmental) stage of this two-stage study, lay and professional stakeholders participated or were actively involved in activities that provided data to inform the research intervention:

- 2.1. Postal⁵ and telephone surveys were conducted with practitioners working in UK paediatric diabetes clinics to assess common clinical and behaviour change challenges to be addressed by the intervention.
- 2.2. Children and teenagers with diabetes and parents participated in separate focus groups to identify their experiences, concerns and preferences regarding routine clinical care.
- 2.3. Children with diabetes and their families were actively involved in experimental consultations undertaken to evaluate and refine the approach.

However, this article focuses on stakeholders' active involvement at key stages of the research as members of a Stakeholder Action Group (SAG), particularly in the context of lay stakeholder involvement.

The Stakeholder Action Group

The DEPICTED research team worked with a specially constituted SAG, which was to advise on the developing research intervention and on the formal trial evaluating the intervention. The SAG was responsible for reviewing relevant evidence provided by the researchers, considering and advising on developing ideas for the intervention, and guiding the research team about plans for evaluation in the subsequent trial. The group was so named to confirm the *active* role it had in working with the research team.

Lay representatives included teenagers and young adults with type 1 diabetes and parents of affected individuals approached through independent support groups outside the catchment area of the clinical researchers. This was necessary to safeguard confidentiality and professional relations by avoiding the inclusion of patients and parents known to professional attendees. Parents were invited to attend meetings with their children, or on their own. A representative from Diabetes UK (a leading UK diabetes charity) was also invited.

The professional group was selected to represent key professionals with an interest in

children and teenagers with diabetes. Professions represented included paediatrics, specialist diabetes nursing, general practice, child psychiatry, paediatric dietetics, clinical psychology, school nursing and social work.

The research team included clinical and scientific researchers (paediatrician, specialist nurse, psychologists, general practitioner, qualitative researchers, statistician, health economists) and administrators. The research team also included the parent of a teenager with diabetes in her capacity as a user representative.

Setting and context

The SAG met on three full days over the course of 10 months. An independent facilitator – a consultant clinical psychologist not involved in diabetes care – was employed to run the meetings, and the consultant met with the research team before and after each SAG meeting to clarify roles and responsibilities and to review events respectively. Various members of the research team facilitated small group sessions and hosted other plenary sessions. Each SAG meeting was constructed around plenary and parallel small group sessions. Plenary sessions included presentations by the research team about study activities and developmental concepts of the research intervention. Composition of the groups in the small group sessions varied with the task being undertaken. For example, when addressing 'What makes for a successful consultation?', mixed stakeholder groups were used, whilst lay and professional stakeholders were separated to consider 'Choices about service delivery'. Lay stakeholders were further divided into parent and teenager groups to discuss the development of separate patient and parent/carer questionnaires for use in the subsequent trial. Additional materials were made available to view during breaks and over lunch (e.g. scientific and 'meet the team' posters). In all meetings, presentations included examples of the developing intervention and made use of both audio and video materials encouraging further input of ideas and comments.

All stakeholders received re-imbusement of their travel expenses, and lay stakeholders also received £30 vouchers for each meeting they attended. Newsletters were used between meetings to update stakeholders about study progress. At the final meeting, stakeholders were asked whether they wanted to continue being informed about the study as it progressed into its trial phase.

Evaluation of SAG meetings

Stakeholders' views expressed during the day were audio-recorded, and the data were transcribed and analysed following each SAG meeting to inform the research. Summary written notes were also taken by researchers observing the group sessions and these were made available to stakeholders during the remainder of the day and were formally transcribed as additional data to facilitate record keeping and inform the process. Each SAG meeting was evaluated using an anonymous stakeholder feedback form that nevertheless identified whether the respondent was a patient, parent or professional. The feedback form addressed expectations about the day, whether these had been met, what they did/did not enjoy, their views on information provision, meeting format and practical arrangements. Suggestions for how future SAG meetings could be modified were also sought. The evaluation form for the third meeting was modified and included a question about how the stakeholder would like to continue being involved in the study.

Ethics

Ethical approval for the study was granted by the South East Wales Research Ethics Committee (ref: 05/WSE02/2). All lay stakeholders provided written informed consent at the start of each SAG meeting.

Outcomes

Between 13 and 17 lay stakeholders (both teenagers and adults with diabetes, and parents) and 10–11 professional stakeholders attended each

meeting. In addition, there were between 13 and 15 research team members present.

How the SAG influenced the design of the research intervention

Three key outputs arose from the SAG meetings, all of which have been implemented in the trial phase of the DEPICTED study⁶:

1. *The Talking Diabetes Course*. A training programme of web-based learning and face-to-face workshops for paediatric diabetes teams drawing upon strategies developed from Motivational Interviewing.⁷
2. *The shared agenda setting tool* ('3T: Time ToTalk'). The concept of a shared agenda-setting tool arose from earlier focus groups with lay stakeholders, and was reinforced during SAG meetings, where lay stakeholders played an important role helping the research team with choices related to the tool design (Table S1; available online). Advice from both lay and professional stakeholders was used to develop guidelines for subsequent use of the tool in trial centres. Finally, at the third meeting, a naming competition was held for the tool in which all stakeholders and researchers had the opportunity to suggest and select names for the new tool (3T: Time to Talk).
3. *A Discrete Choice Experiment (DCE) questionnaire* to evaluate patient preferences for consultation style and content was developed in conjunction with lay stakeholders. To generate attributes for the questionnaire (i.e. what questions to ask), to understand what would be appropriate levels to choose (i.e. what response options to provide) and to help draft instructions and wording, two nominal group exercises were conducted with the lay stakeholders (adults and teenagers separately). Within each group, lay stakeholders were encouraged to consider what an ideal consultation and a 'nightmare' consultation would be like. Group facilitators helped distil these comments into a list of key attributes and how they could vary (i.e.

attribute level). Additional attributes derived from earlier patient focus groups were subsequently introduced for lay stakeholders to consider. Members of groups then selected and ranked their top five attributes to produce a listing of most important attributes to be considered for inclusion in the DCE questionnaire (Table S2 available online).

Evaluation of the SAG process

Feedback from stakeholders in the first two SAG meetings (Table S3; available online) resulted in longer discussion groups being introduced and formal presentation slots being shortened in subsequent SAG meetings. Greater numbers and variety of lay stakeholders were suggested, although this was harder for the research team to modify. Several professional stakeholders commented upon the timing of the meeting (on a weekend) which was unpopular, although no such comments were raised by lay stakeholders.

The second meeting started and finished earlier due to observations that some lay stakeholders were tired or less engaged towards the end of day one. However, some disagreed with this change, requesting longer discussion and a longer day. One also commented upon the unease felt when being put on the spot in a discussion session. Linked to this was the observation at the first SAG meeting that mixing related parent and teenagers within the same group inhibited discussion. In subsequent meetings, related parents and children were separated for the small group discussions and more attention was given to the facilitation process to ensure avoidance of discomfort in stakeholders when eliciting their views.

After the third meeting, feedback on stakeholder involvement in the study as a whole focusing on what aspects of the study they enjoyed most and what they would have liked the research team to have done differently are summarized descriptively in Table S4 (available online). For most stakeholders, it was a positive experience. For lay stakeholders, the opportunity to meet others in the same situation and

to be listened to by others was valued. Overall, parents wanted greater opportunity to discuss their views and some expressed dissatisfaction about the level of lay/professional integration. When asked whether they wished to have any further involvement in the study, only one lay stakeholder declined. Both lay and professional stakeholders valued exposure to each others' views and perspectives and knowing that they were contributing to a worthwhile endeavour. Professional stakeholders mentioned a desire to experience the research intervention. Some professional stakeholders also stated a wish to have choice about group allocation. An initial challenge related to engagement of some professional stakeholders with the behavioural science behind the proposed intervention and its clinical utility. The involvement of practitioners in the research team who had been involved in the developmental work underlying the research intervention was important in overcoming this challenge.

Discussion

The requirement by the funding body to involve actively key stakeholders, including children and teenagers with diabetes and their parents/carers, reflects the increasing focus on patients and the public being involved at all stages of the research process.^{8,9} Kirby proposes that service user involvement can occur at three different levels: consultation, collaboration and user-controlled research.¹⁰ Service user involvement in DEPICTED was primarily at the second level, collaboration, and was viewed as a reciprocal partnership between stakeholders, including service users and researchers. In the study reported here, stakeholder involvement resulted in major contributions to the design of the research intervention, including reassurance to the research team of the intervention's utility by ensuring that practical aspects proved acceptable to practitioners, patients and parents. Furthermore, stakeholders' identification of the need for, and contribution to the design of, an agenda-setting tool (3T: Time to Talk), and their specific contribution to the patient preference

questionnaire (DCE) have been shown to be valuable given their successful piloting and the subsequent central nature of '3T' to the intervention. Involving stakeholders was not simply a philosophical driver in this process; it also directly addressed the validity of the research being delivered.^{11,12}

These findings confirm that research proposals may benefit from service user involvement at an early stage in their development rather than simple identification of the research topic and dissemination of research findings, which are the levels of service user involvement in research most commonly reported¹³ and are in contrast to the conclusions of a recent consensus study.¹⁴

A survey in 2007 concluded that only a small proportion of NHS researchers were actively involving service users when evaluated against eight consensus-derived indicators of successful service user involvement.^{14,15} As recognized by Barber *et al.*, this is partly due to the evaluated projects being undertaken at an early stage in the development of policies on service user involvement. Nevertheless, whilst principles for successfully involving service users in health research have been clarified by Telford *et al.*, there is less reported evidence of actual user involvement in NHS research,^{14,15} although this deficiency has been partly addressed in a formal evaluation of patient and public involvement in the UK Clinical Research Collaboration.⁹ The lack of reported evidence may be due to the fact that service user involvement in research is patchy and inconsistent.^{16,17} It is still in its relative infancy, with many practical, ethical, moral, methodological and philosophical questions unanswered.¹⁷

There is a lack of clarity concerning the extent to which service users can influence and benefit the research process and low levels of consensus about what it means to involve service users successfully in research.^{15,18} The work by Telford *et al.*¹⁴ in identifying clear and valid principles to guide good practice, and the subsequent survey by Barber *et al.*,¹⁵ are important developments in an under-researched area, but raise questions regarding how 'successful' involvement can or should be measured. Furthermore,

the eight indicators only relate to process and do not attempt to measure the impact of successful user involvement upon research outcomes. This concern is raised by other researchers working in the field of involvement, who purport that the lack of an evidence base concerning the impact of involving service users can mean that this endeavour is seen as relatively low status, and labelled as an 'add-on'.¹⁹ They further suggest that the existence of a strong evidence base would significantly contribute to the 'business case' for involvement, encourage more general recognition and help protect continued funding.

The experience of the DEPICTED research team demonstrates that lay and professional stakeholders can make a significant contribution to the design of a complex research intervention even at relatively early developmental stages. This finding provides evidence that involving lay and professional stakeholders can produce relevant and valid interventions which benefit substantially from their combined experiences. This is consistent with outcomes reported by others investigating the benefits of involving people with diabetes in research.²⁰ Furthermore, the experiences of the DEPICTED research team, and the lay stakeholders involved in the study, seem to conflict with the belief that one of the fundamental barriers to the empowerment of service users is researchers' fear of losing their power and status as 'experts'.¹⁶ Of course, it is important that equality of power is considered at the planning stage of research. In DEPICTED, for example, an adequate number of service users in the SAG balanced the influence that professionals might exert on the process,²¹ particularly when a question (e.g. What are the characteristics of a 'successful' consultation) potentially posed a tension between lay and professional viewpoints. The nature of stakeholder involvement reported in this article strongly suggests that both lay stakeholders and researchers can work together as experts, but in complementary dimensions of the research project: expertise by experience and expertise by profession.²²

An indicator of successful service user involvement in DEPICTED is that, despite travel and time commitments, no collaborating

young person or parent withdrew from the study. This could reflect their inherent interest in the topic under investigation, or perhaps the value they placed on being able to influence service improvements, a significant motivating factor for people involved in research.^{23,24} It could be argued therefore that the lay stakeholders felt empowered through their involvement at this level in the research process. Peter Beresford identifies two aspects to empowerment: personal and political. Personal empowerment is concerned with strengthening the 'individual's position through capacity and confidence building, skills and assertiveness training to be able to gain more power', whereas political empowerment is concerned with 'seeking to make broader change that will increase the objective power...available to people'.¹⁶ The lay stakeholders in DEPICTED had views about their experiences of clinic consultations and identified strategies to improve existing services. These views were listened to and directly informed the development of the 3T and DCE questionnaire, strongly influenced the design of the research intervention and the subsequent trial design, all of which confirmed for lay stakeholders the value and purpose of their involvement. This exemplifies how active involvement in research can engender the personal and political empowerment of service users, and also suggests that service users do not always need to receive training, for example, in research methods, to experience empowerment. However, this outcome may be specific to the process of involvement used in DEPICTED, in which lay stakeholders were provided with input to orient them to the specific tasks involved, but did not receive training to develop them as researchers *per se*. Thus, they were socialized and professionalized to an extent, but without compromising the validity of the lay perspectives they provided; experiential knowledge is purported to be the greatest added benefit of involving service users.²⁰

Nevertheless, guidelines for involvement recommend that service users should receive research training to ensure their preparedness for effective involvement,²⁵ and academic

researchers continue to question the nature of meaningful service user collaboration in relation to how many aspects of the research process they are involved in²⁶ or are *able* to contribute to in the context of research knowledge. It is probable therefore that some training is preferable in different models of collaboration. The TRUE project, commissioned by INVOLVE to examine the issue of training for service users, found that training had enormous value to participants' personal development and confidence and, without exception, participants in this study found that the training was 'hugely valuable, worthwhile and empowering'.²⁵

For the teenagers involved in the DEPICTED study, it could be argued that their sustained involvement was potentially attributable to their honorarium of £30. This was not considered coercion, but rather a strategy to demonstrate that their input was valued.¹⁰ It is worth noting that some service users expressed surprise about receiving such tokens for their input. Whilst the research team would defend their approach, there is a risk that payments could be seen to devalue the altruistic intentions of service users (particularly from the perspective of the users themselves). Furthermore, payment for research activity could be classed as employment, which may affect benefit entitlement and requires careful consideration.^{10,27}

It is probable that lay and professional stakeholders had different drivers for involvement. Although individuals from both parties viewed their involvement in research as an opportunity to impact on clinical care in the future, lay stakeholders were more likely to value meeting other service users and being able to interact with health professionals. The finalized plan for the meetings did not allow for much informal interaction between service users and professionals. As families were recruited from two parent support groups and most of the professionals knew each other, there was also a natural gravitation during breaks into distinct peer groups. This inhibited integration of service users and professionals. Such expectations could have been better identified and managed. In the future, eliciting expectations at the outset may help.

It was also difficult to balance the practical needs of lay stakeholders with those of professionals, in particular, the requirement to hold meetings on a Saturday – although attendance of professional stakeholders was nevertheless good. There was also some tension between professional SAG members and researchers not involved in clinical practice, resulting in criticism from some professionals about theoretical concepts not being grounded ‘in the real world’. Nevertheless, we would argue that such differing professional perspectives are what stakeholder involvement is designed to elicit and address.²⁸

There were specific issues related to working with families. The decision to include parents of participating teenagers was made partly for logistic reasons (parents needed to transport/accompany their youngsters to the meetings). In most cases, teenagers were accompanied by two parents, resulting in excess numbers of parents contributing to the discussion groups. Furthermore, it became clear that teenagers should be in separate discussion groups from their parents to promote their active engagement, to allow them to step outside their usual generational roles, and to disclose information that they might not wish to share with their parents. This arrangement proved successful, allowing teenagers to become more vocal within the groups and is an important lesson for research teams proposing to work with young people and their families in the future.

Although problems were not encountered, it is important to anticipate tensions when research is steered by service users (collaboration) as opposed to seeking their opinion (consultation) as occurred, for example, in the naming of the agenda-setting tool. Although consensus was reached with little difficulty, this process could have proved problematic if there had been a disparity between the research team’s choice of name and that of other stakeholders. Greater transparency in decision-making, including clarity about individual roles, should ensure that all can make a valid and recognized contribution. Establishing a consensus-based ‘terms of reference’ for the group at the outset would be a useful future strategy.

Although guidelines for service user involvement exist in terms of ethical and practical issues, there is a dearth of research evaluating this phenomenon and different challenges inevitably arise when service users are involved in research as active, rather than passive, participants.^{10,27,29} One such issue, particularly when health research focuses on a specific condition such as diabetes, concerns the ability of service users to see beyond their own experiences to view the ‘bigger picture’. Whilst service user involvement could be used as a platform for airing particular grievances about service provision, such experiences are also part of the value of public engagement.³⁰ In this study, some lay stakeholders attended poorly-resourced diabetes clinics and their initial contributions were understandably focused by their own experiences of the adverse effects of such limited resources. However, with a greater understanding over time of the purpose of their involvement, assisted by careful facilitation of discussion groups whose leaders were aware of this issue, the lay stakeholders were able to consider the implications of the research and its effects on patients in a wider context other than their own clinic, which significantly increased the value of their contribution to this part of the research project.

Considerable attention was paid to the constituency of the professional stakeholders within the SAG to ensure representation across professional groups. For lay stakeholders, sampling was based on status as either patient (teenager or young adult) or parent (of child or teenager). For both lay and professional groups, such sampling was purposive and not intended to produce generalizable data. This in part reflects the pragmatic challenge of constituting a standing group of diverse participants. However, broad input from lay and professional stakeholders was achieved via the various preparatory activities (e.g. patient focus groups and professional surveys). The real value of the SAG was the direct, considered and immediate response to such data and to the researchers’ plans from the unique perspective of the ‘service user’ and ‘service provider’.

Stakeholder involvement is more broadly represented in this study by inclusion in the research management team of a mother of a teenage patient who participated in a number of roles throughout the study including co-facilitator in SAG meetings. Despite her enthusiasm and commitment, it is important to recognize that such an unfunded contribution requires her to prioritize competing commitments with consequent risks of guilt at being unable to respond to overwhelming numbers of requests from the research team. In retrospect, although her involvement was not tokenistic, it would have been better to have more than one service user at this level of involvement. Consideration should also have been given to including adequate funding of her time commitment in the grant proposal, which, others suggest, is important in maximizing the potential of user-involvement in research.³⁰

Reflections on the process

The research team has learnt important lessons for the future (See Table S5; available online). Such engagement has to be well-planned and resourced (note that up to 15 researchers worked on each day). Meeting formats should vary to accommodate a range of stakeholder interests and preferences, and to suit the task requirements. We found an external facilitator especially helpful as he provided a challenge to the potentially insular perspective of the research team, helped the research team clarify their objectives for each SAG meeting and had expertise in managing mixed group dynamics. Support for the stakeholders (e.g. exploring and providing for their requirements, providing plenty of information before and during meetings) also seemed to be successful and acknowledged. What we would do differently includes initial eliciting of role expectations from both stakeholders and the research team, which could be formalized in a jointly developed terms of reference. This would include clarity about responsibility for decision-making and safeguarding all stakeholders' valid contribution. Integration of all stakeholder groups should be

addressed perhaps by an explicit initial exercise, and supported thereafter by adequate opportunities to mix. Finally, working with families requires even further consideration to enable optimal involvement and experience for both children and their parents.

Summary

Service user involvement in health care research is increasingly being required by funding bodies. However, the evidence base concerning the impact of involvement, particularly on research outcomes, is minimal. This is an important issue that needs to be addressed if involvement in health care research is to achieve higher status and attract continuing funding. This article describes the active involvement of lay and professional stakeholders in the developmental stage of a two-stage seminal study. Challenges encountered during the course of the research are identified and reflected upon. Importantly, it is also clearly demonstrated how stakeholder involvement positively affected the study outcomes; that a research intervention was only successfully developed because stakeholders, including teenagers with diabetes, were actively involved.

Acknowledgements

We are grateful to the service users (teenagers, adult patients with diabetes and parents) and the service providers who participated so constructively in this research. We are grateful to NIHR Health Technology Assessment Programme for their funding and ongoing support for The DEPICTED Study. We would also like to convey our thanks to our research administrator Mrs Veronica Dunning for her work in organizing the events, to Joss Hutchinson who also provided invaluable support, and especially to Professor Neil Frude who facilitated each meeting. The authors acknowledge the support of the South East Wales Trials Unit, and its funding from the Welsh Assembly Government through the Wales Office of Research and Development for Health and Social Care (WORD).

Contributorship

This study is a constituent part of the work plan and output from the DEPICTED study. L Lowes and M Robling were responsible for drafting the manuscript. All named authors contributed to the design and delivery of the SAGs and were responsible for reading, commenting upon, and approving the final manuscript. J Gregory and M Robling were co-principal investigators and guarantors of the DEPICTED study in its entirety. The DEPICTED Study Team includes JW Gregory, M Robling, K Hood, K Bennert, S Channon, D Cohen, E Crowne, H Hambly, K Hawthorne, M Longo, L Lowes, R Playle, S Rollnick, C Butler, I Russell and R McNamara. L Lowes is the guarantor for the paper.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Stakeholder feedback on design for agenda-setting tool.

Table S2. Ranking of desirable consultation attributes from SAG nominal group discussion (meeting 2).

Table S3. Stakeholder feedback from meetings one and two.

Table S4. Stakeholder feedback on their involvement (following meeting 3).

Table S5. Summary of our experiences.

Please note: Wiley-Blackwell are not responsible for the content or functionality of any supporting materials supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.

References

- Hampson S, Skinner T, Hart J *et al.* Effects of educational and psychosocial interventions in adolescents with diabetes mellitus: a systematic review. *Health Technology Assessment.*, 2001; **5**: 1–79.
- Oliver S, Clarke-Jones L, Rees R *et al.* Involving consumers in research and development agenda setting for the NHS: developing an evidence-based

- approach. *Health Technology Assessment.*, 2004; **8**: 1–148.
- Buckley B, Grant AM, Firkins L, Greene AC, Frankau J. Working together to identify research questions. *Continence*, 2007; **1**: 76–81.
- Craig P, Dieppe P, Macintyre S *et al.* Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal*, 2008; **337**: 979–983.
- Hambly H, Robling M, Crowne E, Hood K, Gregory JW, and The DEPICTED Study Team. Communication skills of health-care professionals in paediatric diabetes services. *Diabetic Medicine*, 2009; **26**: 502–509.
- The DEPICTED Study Team. The DEPICTED Trial Protocol 2008. Available at: <http://www.controlled-trials.com/ISRCTN61568050/depicted>.
- Miller W, Rollnick S. *Motivational Interviewing: Preparing People to Change*, 2nd edn. New York: Guilford Press, 2002.
- NIHR Health Technology Assessment Programme. Planning patient and public involvement in HTA. 2008. Available at: <http://www.hta.ac.uk/ppiguide/>.
- TwoCan Associates. *An Evaluation of the Process and Impact of Patient and Public Involvement in the Advisory Groups of the UK Clinical Research Collaboration: Final Report*. London: UK Clinical Research Collaboration, 2009.
- Kirby P. A Guide to Actively Involving Young People in Research: for researcher commissioners, and managers. INVOLVE. 2004 September 2004:33
- Entwistle VA, Renfrew MJ, Yearley S, Forrester J, Lamont T. Lay perspectives: advantages for health research. *British Medical Journal*, 1998; **316**: 463–466.
- Hanley B, Truesdale A, King A, Elbourne D, Chalmers I. Involving consumers in designing, conducting, and interpreting randomised controlled trials: questionnaire survey. *British Medical Journal*, 2001; **322**: 519–523.
- Chambers R, O'Brien LM, Linnell S, Sharp S. Why don't health researchers report consumer involvement? *Quality in Primary Care*, 2004; **12**: 151–157.
- Telford R, Boote J, Cooper C. What does it mean to involve consumers successfully in NHS research? A consensus study. *Health Expectations*, 2004; **7**: 209–220.
- Barber R, Boote J, Cooper C. Involving consumers successfully in NHS research: a national survey. *Health Expectations*, 2007; **10**: 380–391.
- Hanley B for the Toronto Seminar Group. Research as Empowerment? Report of a series of seminars organised by the Toronto Group. York: Toronto Group, 2005
- Minogue V, Boness J, Brown A, Girdlestone J. The impact of service user involvement in research.

- International Journal of Quality Assurance*, 2005; **18**: 103–112.
- 18 Boote J, Telford R, Cooper C. Consumer involvement in health research: a review and research agenda. *Health Policy*, 2002; **61**: 213–236.
 - 19 Staniszewska S, Herron-Mars S, Mockford C. Editorial. Measuring the impact of patient and public involvement: the need for an evidence base. *International Journal for Quality in Health Care*, 2008; **20**: 373–374.
 - 20 Lindenmeyer A, Hearnshaw H, Sturt J, Ormerod R, Aitchison G. Assessment of the benefits of user involvement in health research from the Warwick Diabetes Care Research User Group: a qualitative case study. *Health Expectations*, 2007; **10**: 268–277.
 - 21 Jones J, Hunter D. Consensus methods for medical and health services research. *British Medical Journal*, 1995; **311**: 376–380.
 - 22 Faulkner A, Thomas P. User-led research and evidence-based medicine. *British Journal of Psychiatry*, 2002; **180**: 1–3.
 - 23 Telford R, Faulkner A. Learning about service user involvement in mental health research. *Journal of Mental Health*, 2004; **13**: 549–559.
 - 24 Wright D, Corner J, Hopkinson J, Foster C. Listening to the views of people affected by cancer about cancer research: an example of participatory research in setting the cancer research agenda. *Health Expectations*, 2006; **9**: 3–12.
 - 25 Lockey R, Sitzia J, Gillingham T *et al.* Training for service user involvement in health and social care research: a study of training provision and participants' experiences (The TRUE Project). Hants: INVOLVE; 2004
 - 26 McLaughlin H. Keeping Service User involvement in research honest. *British Journal of Social Work*, 2010; **40**: 1591–1608.
 - 27 Steel R. A guide to paying members of the public who are actively involved in research: for researchers and research commissioners. INVOLVE, 2003:14.
 - 28 Grant-Pearce C, Miles I, Hills P. *Mismatches in Priorities for Health Research Between Professionals and Consumers*. Manchester: PREST Manchester University, 1998.
 - 29 Lowes L, Hulatt I. *Involving Service Users in Health and Social Care Research*. London: Routledge, 2005.
 - 30 Trivedi P, Wykes T. From passive subjects to equal partners: qualitative review of user involvement in research. *British Journal of Psychiatry*, 2002; **181**: 468–472.