Assessment of the benefits of user involvement in health research from the Warwick Diabetes Care Research User Group: A qualitative case study

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 Abstract

Objective: To assess the benefits of involving health care users in diabetes research

Design and Participants: Qualitative case study. Semi-structured interviews were conducted with researchers who had worked extensively with the group. During regular meetings of the Research User Group, members discussed their views of the group's effectiveness as part of the meeting's agenda. Interviews and discussions were transcribed, coded using N-Vivo software and analysed using constant comparative methods.

Results: Involvement of users in research was generally seen as contributing to effective and meaningful research. However, the group should not be considered to be representative of the patient population or participants of future trials. An important contributor to the group's success was its longstanding nature, enabling users to gain more insight into research and form constructive working relationships with researchers. The user-led nature of the group asserted itself especially in the language used during group meetings. A partial shift of power from researchers to users was generally acknowledged. Users' main contribution was their practical expertise in living with diabetes, but their involvement also helped researchers to remain connected to the 'real world' in which research would be applied. While the group's work fulfilled established principles of consumer involvement in research, important contributions relying on personal interaction between users and researchers were hard to evaluate by process measures alone.

Conclusions: We demonstrated the feasibility, acceptability and effectiveness of this longstanding, experienced, lay-led research advisory group. Its impact on research stems from the continuing interaction between researchers and users, and the general ethos of learning from each other in an ongoing process. Both process measures and qualitative interviews with stakeholders are needed to evaluate the contributions of service users to health research.

Key words: Patient participation, consumer participation, diabetes mellitus, qualitative research, health services research

Introduction

Since 1999, Department of Health policy has encouraged the involvement of users/ consumers[i] in health research.[1,2] However, although involvement is increasing,[3] the involvement rarely encompasses all stages of the research process.[4] The Medical Research Council expects funding applicants to involve and disseminate findings to consumers.[5] Users can be participants, consultants, advisors, and, in a few cases, co-producers who are involved in every stage of the research.[3,6,7] They can improve research efficiency by ensuring that potential barriers for those who hope to benefit from the research are understood.[8] The greatest benefit involving users can add may be their experiential knowledge, that is, the experience of living with a condition, developing coping skills and interacting with others.[9] A consensus was developed on the structures, roles, training for users and researchers and acknowledgment of contributions.[10] However, initiatives to involve users are dogged by the difficulty of evaluating their impact on research.[4]

We seek to address the questions of what makes user involvement successful, effective and meaningful, and how these benefits might be constructively evaluated by presenting a case study.

Design and Participants

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[i] There have been debates whether those to be involved in research should be referred to as users, consumers or the public. For the context of this article, we will mainly refer to users, as this was the term used when the Research User Group was founded. Moreover, group members are literally 'users' of specific services and interventions that are the outcome of diabetes research.

Warwick Diabetes Care (http://www.warwick.ac.uk/go/diabetes/) aim to improve the quality of diabetes care by delivering a high standard of diabetes education for professionals, and using behavioural sciences in research on providing diabetes care. In response to the priority given to consumer involvement,[2,3] the Research User Group was launched in July 2001. This has enabled long-term participation of users in diabetes research in a meaningful and challenging partnership. The group currently comprises 59 people living with diabetes who, as a minimum, ask to be kept informed about our research. Of those, 32 are willing to be consulted up to 10 times per year for their research advice by email or post. Up to 26 attend bi-monthly meetings chaired by a layperson and attended by researchers. Those unable or unwilling to attend meetings are kept informed about meetings. This offers different levels of commitment for members to choose. Members provide feedback on research proposals and questionnaires, research participant recruitment and the focus of analysis, as well as generating lay dissemination of diabetes research findings.

Since this study aimed to address the effect of researcher-user interaction and the development of user expertise over time, we opted for a qualitative case study in order to trace the interactions and cultures that give shape to the organisation.[11] Qualitative case studies have been used successfully to understand the complex realities of user involvement[12] and other voluntary and community groups.[13] Although these case studies do not draw on a representative sample or large numbers of respondents, they have the potential to sensitise policy makers and practitioners to more complex realities of voluntary action than suggested by quantitative approaches.[13]

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One of the authors (AL) conducted semi-structured interviews with the 5 researchers who had worked extensively with the group. Four were from Warwick Medical School; one was external. The interviews covered what difference consultation with users had made to their research projects, whether user involvement made any difference to funding, and in what ways research would be different without the users' input. Secondly, during two of the group's regular meetings, group members held a discussion, facilitated by HH and the lay chairman, comprising open questions on their views of the group's effectiveness. These discussions were tape recorded and transcribed. Thirdly, other external researchers who had consulted the group, and members not attending either of the two meetings, were sent a brief letter or e-mail, asking their opinion on the group's effectiveness to make sure that their experiences did not strongly differ. Two external researchers and two users responded, and their responses were added to the data. Lastly, the minutes of all Research User Group meetings were analysed for content. All data entered in N-Vivo software for ease of retrieval and was thematically coded and analysed using the constant comparative method.[14] Since this case study explores the impact of user involvement on research and researchers, they were interviewed more extensively than the users. The results were presented by the researchers to the user group, and a draft of this paper was emailed to all group members for comments, and their responses incorporated.

We used the 8 principles and 16 indicators of user involvement developed by through a Delphi process by Telford, Boote and Cooper[10] as a framework to assess the management and infrastructure of the group. Table 1 shows how each of the indicators were achieved, demonstrating the planned and systematic

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approach of the group. In addition, other aspects of successful user involvement emerged. Table 2 lists the activities itemised. Group activities described in the tables were documented in the meeting minutes and other related documents, e.g. lists of changes made after User Group input. Themes that emerged from the interviews and group discussions are presented below, with examples. Quotes are extensive since this paper aims to explore the experiences with user involvement voiced by both researchers and users. Researchers' quotes are marked (R) and users' (U).

Results

1. Membership

It is important to recognise that users are not representative, nor advocates, but instead individual examples. The members were predominantly white, male retired professionals. Issues may be appealing or problematic to them, and this could influence the research, but lead to biases.

> *Actually, I never made this connection before, but the profile of the Research User Group has always been and remains ex-professional, retired males. And the profile of the people that we recruited in the [named] study, principally via the media, they were exactly the same demographic, which is quite unusual for a qualitative, health-related study. (R4)*

On the other hand, the group has attempted to reach out to other patient groups by attending lay events and contributing to and attending a diabetes educational event in Punjabi. In the words of one researcher, this helped to lend validity to the event:

Although the language used was Punjabi, they [non-Punjabi-speaking Research User Group members] did manage to take part. As co-ordinator for the project, I feel they added an air of authority to it. That it wasn't just the University talking at people. It was—not authority, it gave it validity. (R3)

Another aspect of representativeness is that most members of the group have had diabetes for a long time, and many have been members of other diabetes voluntary groups.

[Blood glucose self-testing] is one of the things where the panel is not a representative sample in any way. But the reason they were on the panel in the first place was because they had an enormous interest in their own diabetes. …There were disagreements between members of the group about matters of detail on how to manage your diabetes, but the one thing they all had in common is that they all were extremely conscious of their diabetes. (R5)

2. Language

The Research User Group is inclusive and user-led. Meetings are held alternately during afternoons and evenings to enable both working and retired users to participate, and are chaired by a lay person (RO). The user-led nature of the group asserted itself especially in struggles over language and research 'jargon'.

When the [Research] User Group is predominantly user, and researchers are the invited bodies, it's successful, because that has informed their language and their understanding of the [Research] User Group. It fails when the group is not predominantly user, you have user representatives, and I have never yet seen that group conform to the language of the user. It carries on, speaking

the language of its own discipline, and therefore it's incredibly hard for the users to assimilate to that. (R1)

This issue of research terminology has been addressed by a researcher presenting a glossary covering a few technical terms at each group meeting, explaining terms like 'quantitative/ qualitative' or 'Cochrane review'.

3. Balance of Power

Involving users in a sustained manner raised issues about the balance of power between researchers and users. For researchers, involving users meant giving up some power.

It has helped us keep going when we've had rejections. … Because here, when I'm the boss, I can say, well, we give up. But if it's the [Research] User Group, I'm not their boss. (R3)

I remember XX, she came to our meeting and you could hear her knees knocking! [laugh] And she said, 'I'm going to do this [questionnaire]' and we said 'well…' So we tore it apart and put it together for her… (U1)

The users were empowered by developing expertise as a group. Peer support and increasing understanding of research gave users the confidence to ask fundamental questions of the research:

If you're just being used as a pilot in a questionnaire, you might not actually say to the researcher, what's the point of it? You might, but you'd have to be a fairly, sort of [laugh] confident person to say that, because most people would assume that there is a point to it. Why else would the researcher be doing it?

[Laugh] Not realising that an awful lot of research has no point! So I think that's a big thing that having them as a group can bring (R2).

4. Interaction between users and researchers

Interpersonal dynamics are a major part of the collaboration between researchers and users[1]. Users and researchers learned from each other, knowing and respecting each other's skills and perspectives. The continuity of the Research User Group was important.

U1: …and when you think what it was like in 2002 when we were all groaning and moaning what it was all about and all the rest of it and…

U3: …Well, again it's a learning curve.

U1: It is, it's a learning curve.

One researcher took a theoretical qualitative approach which regarded the input of the Research User Group as part of the research data and not separate from it:

I see what the [Research] User Group say as part of the data, as research that develops on the hoof. That's why I always record the meetings. (R2)

This close interaction between users and researchers enabled the researchers' to predict user responses.

Working with the [Research] User Group probably helps us put their hat on better than we would do if we hadn't worked with the user group. So when we're doing things, although they're not there, we can half put their hat on and think how it would be if they were there, because we know them. We know who they are. We've interacted with them. (R2)

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However, sometimes researchers were disappointed when the Research User Group did not find enough to criticise and confined their comments to correcting spelling errors. This might mean that, for the group to work effectively, a balance needs to be struck between close collaboration with researchers and the distance necessary for critical feedback.

5. Funding matters

Researchers were certain that the activities of the group improved the chances of research being funded, although it was hard to know how much. There is no clear consensus among funding organizations about whether and how researchers' proposals for consumer involvement should influence decisions about which projects are funded.[15] However, in meeting the funders' requirements, the ongoing nature of the group was again seen as beneficial:

> *So many of the forms want to know upfront, not just how you are going to involve users, but how you have already involved users in designing the proposal you are submitting. … And of course, for us, that's easy. (R4)*

Users' contribution to help funding include acting as volunteers for feasibility work and piloting questionnaires for research proposals.

> *We can demonstrate that it's going to work, if you see what I mean. Because you've done a feasibility study … I think the funders are getting hotter and hotter on that, because so often the studies' designs don't work, because they're not feasible. (R2)*

However, one researcher's disconfirming experience was criticism by a funding body related to giving too much power to users.

I don't think there are many user groups that are set up like WDC. When we went for [a national funding body] bid, it was actually evaluated. ... They asked what role the user group had, is it to approve? ... They were very, very unhappy that we had a user group that they perceived to have some form of power over the research that was carried out. Even though I had explained that it didn't have direct power, but that we did respect their views and therefore they were a component part of research which was carried out in diabetes. They were unhappy with this. Now, I think that is fascinating. …That's utter hypocrisy. (R-anonymous)

6. Research User Group expertise

Researchers and users considered the members' expertise as their experience of living with diabetes (see Box 1). Users stressed the ongoing necessity to achieve a balance between tight diabetes control and enjoying life, or the existence of 'stages' in diabetes self-management. Though this practical expertise might lead only to minor changes in the questionnaire or intervention, these minor changes could have a major impact on the success of the research:

Therefore, when I organised these [questionnaire] questions, I organised them theoretically. They organised them logically and practically, with an understanding of the condition. It is so simple, but it is the kind of thing that puts someone [a respondent] off. (R2)

The researchers stressed that the group had pointed out ideas that had not occurred to them before. For example, extensive sections on stress management and relaxation techniques were added to the Diabetes Manual, a workbook that aims to improve self-management of type 2 diabetes.[16] This was done because group

members insisted that stress was an important issue for people with diabetes. In a questionnaire on obstacles to adherence to diabetes treatment, potentially sensitive questions about weight and alcohol intake were moved to the end of the questionnaire, and a statement 'I do not take my medication on principle because I do not agree with it' was added. Users broadly agreed they made a difference, but stressed their wish for more feedback from the researchers on their effectiveness.

A possible criticism of the continuing involvement of users in research is that, in order to be taken seriously by researchers, they have to become 'proto-professionals'[9], losing the special quality of independent, experiential knowledge. It was felt this group avoided that, mostly because of the variety of approaches to research discussed in the group:

> *The types of people in the [Research] User Group, they're making a retirement of it, they're not making a career of it. ... But the other thing that our [Research] User Group does is a lot of different types of research. I can imagine, if they were just seeing clinical trials, for example, or just seeing something else, they could get wrapped up in it. But they have a good range of stuff coming through (R2)*

7. Evaluation issues

The collaboration resulted in a blurring of the boundaries between professionals' and users' contributions to research which could lead to difficulties in evaluating the contributions of the users. Simply treating the group as another member of the research team could lead to their contributions not being recorded (Box 2). This issue has now been addressed by routinely keeping a summary of changes made

by a researcher as a result of Research User Group feedback, while avoiding unnecessary labelling of users' or researchers' contributions. While formal minutes of meetings were seen as important to preserve the continuity of the group and recognise its value, less formalised interactions such as sub-committee meetings, or rapid email response, were also seen as important contributions to research.

8. Contribution to meaningful research

The Research User Group's involvement in research is not restricted to supporting existing research, but also shaping research and interventions from the very beginning. Research proposals, from the first 'ideas paper' onwards, are discussed by group members, often by email between meetings. Users contribute by changing the researchers' mind-sets, thus increasing their confidence in the relevance of this research. Proposals are, from the very beginning, drafted with the users in mind. Researchers also view their interaction with the group as essential for conducting research that is feasible in practice (see Box 3). In order to make this real-world connection meaningful, researchers said they needed to put work and commitment into their relationship with the users. One researcher expressed this as the group being the 'shareholders' to whom the research needed to be justified. The Research User Group impelled researchers to think about why the research needed to be done in the first place. This was not done by seeing the group as a 'proxy' for future users, but in keeping researchers attuned to the many different issues related to living with diabetes. The users themselves expressed

pride in their contributions making a difference and the 'heck of a lot of work' put in. Being told that their contribution was instrumental in gaining funding made it clear that they were valued outside the Warwick research community.

Discussion

This study demonstrates the feasibility, acceptability and effectiveness of this longstanding, experienced, lay-led research advisory group. It is also clear that much of its impact on research stems from the continuing interaction between researchers and users, and the general ethos of learning from each other in an ongoing process. The stakeholder roles of almost all the authors (HH, JS, RO, GA), and our potential wish to present the involvement of users in research in a positive light could be regarded as a limitation of this paper. Nevertheless, the data were gathered using standard case study methods, by a non-stakeholder researcher (AL), and there was very little evidence of negative views about the Research User Group's existence and role. The presentation of evidence against published criteria and indicators shows that the group is systematic and self-monitoring in its activities supporting research, through practical contributions to all stages of the research process (see table 1).

From this case study, we have demonstrated first that user involvement in health research adds value by forcing researchers to address why they wanted to conduct their research in the first place. Second, user involvement benefits research by adding credibility to a proposal thus (usually) making it more likely to be funded. This comes from the users' unique practical expertise. Structures and training need to be in place to enable users to interact with researchers effectively.

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Structures are also needed to enable users to be equal partners and be effective contributors to research. In this study the group was user-led which was widely seen as contributing to this equality of interaction.

Although it is difficult to evaluate effectiveness of user involvement, feedback from funding bodies should be made available, recorded and analysed for this purpose. Similarly, the contribution of users in the form of changes to research protocols, questionnaires, patient information etc. should be routinely logged. The influence of users' practical expertise could be explored by interviewing users and researchers about specific projects. However, users should not be evaluated as representatives of the patient population in general, nor of the target population of interventions researched. They are individual examples of people, who are users in this context.

The greatest benefit involving users can add to the research process has been described as the patients' experiential knowledge, that is, the experience of living with a condition, developing coping skills and interacting with others.[9] There is no doubt that those findings were borne out in this case study, and that Research User Group members made that contribution.

Conclusions

Users or consumers are increasingly involved in health research and service delivery. As Telford et al have stated, agreed roles, an appropriate budget, available training, respect for users' skills and reporting of users' contributions are important for meaningful involvement.[10] However, it remains difficult to evaluate the actual difference that users have made to research. In our case study, we found that successful involvement of users should result in more funded research that is relevant to the experience and requirements of service users. Moreover, this contribution of users resulted in explicit changes to elements of research, but also in shaping the research through interaction with researchers. Therefore, we would like to conclude that this interaction with researchers in forming a 'research ethos', much of it informal, is a crucial element in the work of a user group. This means that user members of research steering groups which are appointed for single studies will not provide the opportunity for continuity which may be a valuable aspect of a user group's function. Moreover, the possibly most valuable contribution of the group, focusing the researchers' minds on making a difference for future health care users, could not be captured by a process evaluation alone. Auditing of group records and interviewing of stakeholders should both form part of any evaluation of user involvement in research.

Table 1: Principles and indicators of successful user involvement,[10] with examples from Warwick Diabetes Care Research User Group minutes

	Indicators	Examples
Principle 1: Roles of consumers are agreed between researchers and consumers		
1	The roles of consumers in the research were documented	• The Research User Group drafted its own 'job description' during the first meeting • Roles of users are agreed in Research User Group meetings and documented in the minutes
Principle 2: Researchers budget appropriately for the costs of consumer involvement		
2	Researchers applied for funding to involve consumers	• A formula was found for costing user involvement at £75 per month in the life of the study, to fund ongoing Research User Group activities
3	Consumers were reimbursed for their travel costs	• The Research User Group discussed the issue and found it appropriate to reimburse users for travel expenses but not their time
4	Consumers were reimbursed for their indirect costs (e.g. carer costs)	• This necessity has not yet arisen
Principle 3: Researchers respect differing skills, knowledge and experience of consumers		
5	The contribution of consumers' skills, knowledge and experience was included in research reports and papers	• Contributions of users were included in research reports and publications • Users were co-authors on posters, presentations and papers
Principle 4: Consumers are offered training and personal support		
6	Consumers' training needs were agreed between consumers and researchers	• Users' training needs were identified in Research User Group meetings
7	Consumers had access to training to facilitate their involvement in research	• A workshop was held to identify training needs, resulting in a one-day training event on appraising evidence • Researchers have contributed to a work-in-progress 'Glossary of Jargon' explaining research terms • An induction pack is available for new members
8	Mentors were available to provide personal and technical support to consumers	• Researchers are available to provide support to users at Research User Group meetings • A mentor system has been discussed; Research User Group members may be asked become mentors for new members in the future
Principle 5: Researchers ensure that they have the necessary skills to involve consumers		
9	Researchers ensured that their own training needs were met in relation to involving consumers	• Training for researchers in this area is not yet formalised, but WDC researchers and one Research User Group member have shared their expertise at several conference workshops, e.g. Royal College of General Practitioners 2003, King's Fund 2004.

	Principle 6: Consumers are involved in decisions about recruitment of participants and dissemination of information to participants	
10	Consumers gave advice to researchers on how to recruit participants to the research	• Research User Group's suggestion for recruiting strategies have been successfully implemented (e.g. posters in surgery, advertising in local media) • The Research User Group has provided feedback on patient information material to be used for recruitment
11	Consumers gave advice to researchers on how to keep participants informed about the progress of the research	• The Research User Group has been involved in lay events and conferences disseminating research findings. • The progress of research is outlined in the regular Newsletter produced by Research User Group members.

	Principle 7: Consumer involvement is described in research reports	
12	The involvement of consumers in research reports and publications was acknowledged	• Final report to Diabetes UK, funders of a study identifying the educational and support needs for self-management of people with type 2 diabetes. • All papers submitted include acknowledgement of Research User Group contributions (e.g. Sturt et al 2005) [16]
13	Details were given in the research reports and publications on how consumers were involved in the research process	• Details on user involvement are given in this paper, which will be cited.

	Principle 8: Research findings are available to consumers in formats they can easily understand	
14	Findings were disseminated to consumers in appropriate forms (e.g. Braille, large print)	• Large print material is available to Research User Group members who require it. Other formats will be used as appropriate
15	The distribution of the research findings was in appropriate formats and easily understandable language	• Research findings are distributed to the Research User Group in information sheets written in layperson's language. • Research User Group members' experience and training enables them to cope with complex research issues.
16	Consumers gave advice on the choice of methods used to distribute the research findings	• The Research User Group discussed and implemented several methods of research dissemination (e.g. lay conferences and events, lay publications, a possible lay-oriented Open Studies course in diabetes)

Table 2: Roles taken on by members of the Research User Group

Pre-research	• Bring up research ideas • General discussions about usefulness of research • Quick feedback for pre-proposal 'ideas papers', in meetings or by e-mail
Proposals	• Feedback on wording of proposals, especially 'lay language' summaries • Encouragement with re-applying for funding
Feasibility studies	• Volunteer for completing questionnaires, for face validity tests and suggestions e.g. on the order of the questions • Help with finding volunteers for piloting questionnaires or interview schedules
Research design	• Participate in intervention design, especially for interventions aimed at people with diabetes • Feedback on questionnaires and interview schedules. Changes made include substitution of 'healthy eating' for 'diabetic diet' or the addition of the statement 'I do not take my medication on principle because I do not agree with it' to a diabetes questionnaire
Recruitment	• Contribute ideas to increase recruitment, e.g. put posters up in practice or use local radio to advertise a study • Feedback on patient information material
Analysis	• In one study, Research User Group members have co-analysed qualitative data to find out whether they could add additional themes
Distribution	• Attend lay conferences and diabetes events • Have presented at national conferences to share experiences
Other	• Have helped to develop and attended educational event for people with diabetes in Punjabi • Input into new education projects at Warwick Diabetes Care • Have presented the user experience to students at Warwick Medical School • Send 2 representatives to the Warwick Diabetes Care Research Group and Advisory Group • Have sat on interview panels for new staff members to Warwick Diabetes Care • Formally appointed to steering groups for specific research studies, both at Warwick and externally.

Box 1: <u>Practical expertise of users</u>

'Some of their criticisms were wrong, because they didn't understand research, but some of their criticisms were correct, because I did not understand diabetes.'(R1)

'It started off as being called the 'expert panel' and the 'lay panel' [in one specific study]. Of course, it is the people with the diabetes who are the experts, because they know what it's like to have type 2 diabetes.' (R5)

'to comment from a layman's viewpoint using practical experiences' (U2)

'to give an informed opinion; know the problem' (U1)

'I can only imagine how useful it is to the researchers to have users on hand to refer to, since not all researchers have first hand knowledge if they themselves do not suffer from diabetes' (U4)

Box 2: <u>Evaluation issues arising from researcher-user interaction</u>

'I think I find it quite difficult to remember, because I'm so close to it. And I just sort of take it all for granted. It no longer has this big impact. These are not critical incidents for me any more, because they're happening all the time, and I'm used to it. ... I implement the suggestion and the advice and the changes, and then I throw that bit of paper away, because I've incorporated it.' (R4)

'It's difficult to remember how much of that I learned from the patients and how much I learned from the professionals, and how much I got from reading.' (R5)

'Recruitment soared, because we made 3 big changes, but because it's a complex intervention in itself, it will not be possible to pinpoint that that was the reason why. ... And that's why user involvement is so impossible to assess the impact of, unless you try each of these things individually, which you don't have time to do.' (R3)

Box 3: <u>Contribution to meaningful research</u>

'I think it does actually improve the research design by having them involved. The big way, I think, it involves—it improves research design is, it actually makes it practical, it actually makes it real. And people can see that in the research design.' (R2)

'The Research User Group are a way of creating a centre ground, a communication channel between the disease, or understanding of the disease, and research.'(R1)

'It reassured me that my methodological interest was not completely divorced from their own actual experience.'(R2)

'The Research User Group keep my feet on the ground. They are my contact with the real world of living with diabetes, in a way that I would have were I still practising as a nurse as well as being a researcher.'(R4)

'It's very supportive to know that someone out there cares about what we do'. (R2)

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