Patient and public involvement in clinical treatment guideline development and implementation: Learning from mental health service users in the UK.

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Abstract

The participation of patients and the public in the development of clinical treatment guidelines is increasingly valued in international guideline programmes. This paper extends the findings of Harding *et al.* (2010) exploration of the views of service users of mental health resources who participated in NICE guideline development groups developing UK clinical treatment guidelines for mental health related disorders. In this research, service users reported not unduly obstructed by some of the concerns raised about their involvement as lay members, influencing the relevance of recommendations to the individual consumer of the service, and grappling with the opaque nature of

decision-making processes and asymmetries in power. We argue that these insights, combined with observations from research in guideline development and advances in the recovery movement and in the shared decision-making clinical model leads to progress in the guideline development topics of translation of evidence to recommendations, optimising the acceptability of treatment recommendations to service users, participants in the treatment decision being different but equal and reconciling different types of knowledge.

Context

The past decade has seen significant progress in the contributions of patients and members of the public to clinical treatment guidelines. Besides the active patient involvement in guideline development groups (GDGs) fostered in NICE guidelines in the UK, there exists today a wide variety of guideline programmes across the world, along with an international cooperative initiative, the Guideline International Network Patient and Public Involvement Working Group (GIN-Public), and plans for international cooperation to develop priorities for research and collaboration on patient and public involvement (PPIP) (Boivin, Currie et al. 2010). Internationally, several studies have sought to explore the mechanisms, value and impact of patient and public involvement more broadly. NICE's successful involvement of patients (and/or service users, as termed in mental health and as used in this articleⁱ) in guideline development is seen in an evaluation of guideline excellence in which 24 schizophrenia guidelines from 18 countries were compared. (Gaebel, Weinmann et al. 2005) found that NICE scored highest overall and on 5 of 6 domains of quality. Nineteen of the guidelines in this study did not include contributions from service users and few had separate 'patient' versions – components in the NICE guidelines that NICE has produced since the first NICE guideline was published in 2002. Moreover, service user involvement results in guidance that is more relevant, readable and understandable to them, as reported in a recent Cochrane review (Nilsen, Myrhaug et al. 2006)

Alongside these developments, in mental health over the last decade, attention has been drawn to new approaches to improve the wellbeing of people with mental health problems, arguably among the most disempowered of patient populations. Notably, interest has grown in the 'recovery' model, with recovery defined as 'what people experience themselves as they become empowered to manage their lives in a

manner that allows them to lead a meaningful life, and a contributing positive sense of belonging in their communities' (NIMHE 2005) This is achieved by helping service users determine their own holistically valued outcomes (e.g. vocational, recreational, spiritual, interpersonal and educational) as well as those relating to symptom reduction. This concerns planning, supporting and co-producing movement towards these goals. A related development is the concept of 'shared decision-making' that has been gaining ground in the USA, which outlines that both the service user and practitioner should agree specifically what the 'problem' is, how to treat it and what the outcomes of this treatment ought to be. Expertise from both the medical and psychiatric evidence-base and lived experience contribute to each of these discussions. Incorporating recovery and shared decision making principles in the development and implementation of guidelines presents a challenge.

The experience of mental health service users in guideline development

One of the first empirical studies to directly examine user involvement in guideline development (van Wersch and Eccles 2001) was published when the first NICE guideline, Schizophrenia, was starting development. It painted a picture of limited service user participation in GDGs, and found that service users made relatively few contributions to the finished product, the guideline itself, and that they commented on relatively limited areas while struggling with technical language and not appearing to value scientific evidence in the same way as professional GDG members (those recruited to GDGs by virtue of being trained and practicing in health disciplines).

At the National Collaborating Centre for Mental Health (NCCMH), as guideline development proceeded over the years, there has been considerable interest in understanding service user influence on the guideline development process. In 2007-2008, we investigated service users' own views of their involvement (Harding, Brown et al. 2010), interviewing 10 individuals with mental health conditions who had participated in completed or ongoing mental health GDGs. The period of time elapsed since involvement in guideline development varied, with some individuals still engaged in guideline development at the time of interview whereas other guidelines had been completed and published in 2005. Interview transcripts were analysed using grounded theory (Glaser and Strauss 1967).

The analysis suggests a nuanced view of service user contributions, with four categories of influence on guideline development emerging, offering a preliminary basis for further theory development. These are:

1. ***Developing expertise from experience***: service users report an awareness of ways that relative values of experience and professional knowledge contrast. Although both service users and professionals report their personal experience in GDG meetings, the experience and knowledge of living with a disorder is arguably a broad experience that complements discussion of research evidence in meetings.
2. ***Overcoming stereotypes to demonstrate value***: service users report playing a useful role in guideline development; and doing so requires surmounting barriers through translation of unfamiliar technical language, redistribution of power in the group, and making debates accessible for all
3. ***Unwritten rules influence deliberation*** – unspoken ‘customs’ concerning decision-making and developing recommendations are influential in GDG deliberations
4. ***Social comparisons affect confidence***: service users may undermine their confidence by comparing themselves with others in the group; political and social skills are needed to enable individuals to contribute

We suggest that these insights, combined with observations from research in guideline development and advances in the recovery movement and in the shared decision-making clinical model can lead to progress in the following guideline development topics:

- translation of evidence to recommendations,
- optimising the acceptability of treatment recommendations to service users,
- participants in the treatment decision as different but equal and
- reconciling different types of knowledge.

Influences on the translation of evidence to recommendations

The process of developing guidelines is not a direct conversion of an evidence base to recommendations. Socio-political and other influences also impact on the end product; this emphasises the importance of understanding interaction in the development process. For example, in a study of value judgements in the development of oncology guidelines, (de Kort, Burgers et al. 2009) found that value judgements such as what constitutes minimum patient outcomes and preference for tailored treatment, influenced the development process, but was not actually reported in the finished guidelines, It was unclear whether these value judgements came from patients who were

included in both the GDGs and study. This points to the influence of group dynamics and to the need to determine how evidence and judgements are wielded in the development process.

In guidelines, treatment recommendations has been found to not necessarily agree with the research evidence. (Raine, Sanderson et al. 2004) found that little over than half of the treatment recommendations agreed with the evidence (51% of 192 scenarios) in GDGs studied, surmising that contextual or clinical experience and beliefs about research evidence influenced recommendations. Service user judgement is arguably developed from lived experience, and as such may be dismissed as circumscribed or idiosyncratic. However evidence itself (as in systematic reviews) may also be discernibly skewed towards discrete interventions that are easier to examine in randomised controlled trials (RCTs) - often not those advocated by service users, which may problematise the mechanisms by which they may influence deliberations. "Professional" GDG members may value service user experience differently to their own, and as such it may not be equally influential.

(Pagliari and Grimshaw 2002) argued that the role of professional status has a marked effect on the level of contribution to group discussions with increased focus on scientific evidence rather than on personal opinion. The most frequently endorsed was 'giving information, clarification or confirmation', with generic experts / advisors (including a health economist, patient advocate, clinical auditor and librarian) making a higher level of contribution than general practitioners (GPs) /nurse/professions allied to medicine (PAMs) with the patient advocate contribution being the second greatest of their group of experts. The influences they postulated on this process were peer support, being in the majority, gender and status (compounded by numbers).

Our research suggests that power imbalances are indeed perceived within GDGs. The category *Social comparisons affect confidence* relates directly to the differences between GDG members that service users detected within, and between disciplines in a group. One participant sums up a view of a power imbalance detected between themselves and professional GDG members, and suggests that he expected that this would happen:

I think to start off with, um there was as I said a bit of posturing and a bit of power positioning, and I think um that can be a lot of problems because as a service user there are always these power differentials between the professionals and the service users. Participant 4

[about another service user representative]...He didn't have the sort of skills – his contribution could only be, you know banging on about the same old points from his experience that couldn't meaningfully be fed into that process. Participant 6

Here, differences within the service user 'camp' suggests an uncomfortably elitist approach might be required in developing the recruitment, support and training of service user GDG members. Though it is acknowledged that 'professional' members of GDGs tend to be those leading the relevant field who possess the concomitant personal and professional skills, there is no analogous and established training route into being a service user professional. It may be inferred that political and social skills are required to 'meaningfully' contribute at this level. Whereas the involvement of service users tends to be an inclusive practice, to be successful at this level and to avoid tokenism service user representatives may benefit from having relevant prior occupational or personal experience that others may not possess.

The shared decision-making clinical model observes that joint decision-making may be feasible to a lesser extent where the individual is in crisis or lacks capacity, but it is still possible. (Deegan and Drake 2006) suggest that training individual professionals in collaborative communication and developing decision support aids can aid in this endeavour. Similarly, we suggest that this approach could form useful components of the guideline development process and the resulting guidelines, to enable those with less practiced skills to be meaningfully involved in important personal treatment decisions. The lack of agreement between service user contributors within the guideline development process emphasizes the idiosyncratic nature of personal preferences and priorities, both highlighting the complexity of making meaningful treatment decisions and the need to focus on the process as well as the outcome of making them.

Improving implementation: Optimising the acceptability of treatment recommendations to service users.

The majority of recommendations made in guidelines relate to the use of pharmaceutical interventions. In mental health related guidelines; this is problematised by the frequency with which medication is not taken as prescribed. (Deegan and Drake 2006) refer to the 'grey zone' of uncertain evidence and point to the reality that, despite the efficacy of a drug being supported by scientific evidence, its exact benefit to the

specific individual for whom it is prescribed cannot be absolutely known in advance. In addition, many issues may influence an individual's decision to not 'obey' the prescriber's directions – the disorder treated may be preferable to the drug; taking medication can be stigmatising and serves to remind the individual of their 'illness'; medication may not target the symptoms the individual experiences as distressing, and the person may have an alternate explanation than that their difficulties are related to an illness, making the idea of taking a medicine nonsensical. Finally, the medication may simply be ineffective. Deegan and Drake (2006:1637) outline that to be successful, medication must not interfere with 'personal medicine' ('self-initiated, non-pharmaceutical strategies to improve wellness and prevent unwanted outcomes... [Including] activities and interventions that give life meaning and purpose', but it must support and allow the pursuit of valued goals (in line with the recovery movement). The esoteric nature of some examples of 'personal medicine' precludes recommending specific activities (as they are, by definition, self determined), but enhancing choice and the process by which treatment goals and decisions are made is possible.

In GDGs, Harding *et al.*'s (2010) participants referred to a lack of communication about the process of determining treatment recommendations, perhaps reflecting power dynamics present in the individual consultation, from which conflicts and power imbalances might arise - 'Unwritten rules influence deliberations' - a lack of clarity that surrounded the guideline development process.

I was a little bit unclear about the process for decision-making because you know I don't think it was ever set out from the beginning how, how decisions were going to be reached and whether there was going to be a you know voting process or something like that. - Participant 6

The uncertainty about the formal process of making recommendations reportedly left some service users wondering how to contribute:

Sometimes it feels that you put a point of view from experience and they come back at you and say 'That's not what the research shows' and I'm thinking like well that's not what my contribution is about . . . I've wondered about that sometimes, well what's the point of me being here if that's what you are going to do . . . ?
Participant 2

The shared decision model (Deegan and Drake 2006) proposes that when joint decision-making replaces the compliance enhancement approach, characterised by

paternalistic notions of obedience and the 'professional knows best', both parties learn about the 'problem' through education and valuing different types of expertise and determine valued goals and select interventions that do not obstruct but actively support movement towards this outcome. The decision-making team includes two experts: one who knows the scientific literature and has clinical experience, and one who knows his or her preferences and subjective experience': (p1638).

Integrating the two types of expertise through decision support aids such as information gathering and sharing tools has been demonstrated to be effective; in an RCT with 4783 participants (Deegan 2010), a software package decision aid was found to enhance collaboration on next-step treatment decisions between medication clinic clients and their prescribers 82% of the time. Besides traditional means to support patients in guideline development, such as patient inclusion in GDGs, condensed patient versions of full guidelines and sharing guidelines via patient organisations, new directions include developing decision support aids (for use at the abovementioned individual consultation level), grading the level of importance of the intervention recommended for patients and highlighting treatment recommendations that are particularly sensitive and as such require discussion, as well as outlining appropriate techniques for enabling communication about these areas (Boivin, Currie et al. 2010). Working with relevant service users to develop these support aids through guideline development may benefit the end service user in the consulting room. Shared decision-making suggests reconciling different types of knowledge but recognises that this is not easy for either service user or professional.

Shared decision-making: participants in the treatment decision as different but equal

Involvement of service users may promote the rights of people often disempowered by health services, particularly those receiving treatment for mental health problems. There is increased international support (Boivin, Currie et al. 2010), for the view carried out by NICE since its inception that involvement of the recipients of treatment and other stakeholders is valuable in its own right and is an essential element of the development, implementation and use of treatment guidelines. Demonstrating other benefits, such as increased acceptability of recommendations is likely to build support for further improving involvement technologies and the extent to which they are embedded in guideline development and implementation processes.

Legare *et al.* (2009) suggest that not including the preferences and values of patients can impede the implementation of treatment recommendations. They refer to 'grey' or scientifically uncertain 'preference sensitive' decisions (i.e. where scientific evidence does not clearly support one course of action over another in terms of the potential harms and benefits) and suggest clinicians and patients need to resolve such conflicts. A further potential source of conflict is between individual and collective goals, as observed at an international guideline development workshop from 14 countries on service user involvement (Boivin, Currie *et al.* 2010). Organisations such as professional and third sector bodies may be concerned with social accountability whereas individuals are more inclined to promote their rights as individuals, to autonomy and choice. Reconciling the two requires change by both parties.

Service user involvement can occur at different points - the macro, meso and micro levels, respectively during the guideline development process; when the guideline is implemented and in the individual consultation between patient and practitioner itself (Legare, Boivin *et al.* 2009). . Arguably, the differing priorities of the individual patient and the organisation regulating or campaigning for the treatment of their condition may variously be more useful and / or relevant one of these levels than another.

The success of implementation may well be relevant to the discussion that occurs between the patient and practitioner when a treatment is recommended and agreed. Many service users 'expect' a power imbalance at this stage, and a parallel process may be observable within the GDG. In our previous research, in overcoming stereotypes to demonstrate value, service users observed that power imbalances could be ameliorated by, for instance, drawing attention to the opaque nature of the terms discussed:

We had a very good chair who said 'explain that' or would actually say 'I don't understand what you mean by that' when I knew jolly well that they (professionals on the group) did know and it put them in their place.
Participant 4

The analysis suggested that in practice, by virtue of being less constrained by assumptions about shared understanding implicit in training or practicing as a mental health professional, service users may challenge 'taken-for-granted' knowledge. Instead of the use of 'accepted' terminology becoming a barrier, as has been suggested previously, this category refers to ways they used it to make deliberations more

accessible. However the epistemology as well as the terminology contained within communication is relevant. As one service user observed:

I have called myself like the language police really.

Participant 2

Reconciling different types of knowledge

The process of involving service users requires their input in assessing the evidence base. Scientific evidence may be more accessible to those trained and practicing within this framework and service users' personal experience is rarely captured quantitatively in large scale studies. Moreover, RCT evidence included in systematic reviews supporting the development of treatment recommendations rarely includes service user led research. (Rose, Wykes et al. 2008) argue that the outcome measures that underpin such RCTs cannot be as neutral as their positivist epistemology dictates as long as they are derived solely from the perspective of the providers of treatments -clinicians and academics. For example, participants with mental health problems rate the Global Assessment of Functioning (GAF) poorly on the criterion of reflecting outcomes that are important to them (Crawford, Robothom et al. submitted). Moreover, this problem is not rectified by Patient Reported Outcome Measures (PROMS), an approach that is increasingly used to evaluate health service provision in the UK by gathering patient self reports. Instead, Rose, Wykes et al advocate user *generated* outcome measures and have developed a mechanism for deriving them. The resulting measures have appropriate psychometric properties and are are suitably reliable and valid to warrant their inclusion in large-scale studies.

In reconciling different types of knowledge, it should first be pointed out that in 'Drawing expertise from experience', as service users – and professionals – do in GDG meetings, illustrates the link between value judgements and the utilization of different types of evidence. The value of drawing expertise from experience in reifying concepts was demonstrated by the finding that professionals also gave examples from experience. For example:

Some of them [professionals] worked very much by talking about people they are actually working with at the time ...

Participant 1

This suggests similarities in the ways service users and professionals value their experience and in what they consider important ingredients in debate. For instance, service users were able to influence decisions on relevant and meaningful outcomes for others experiencing difficulties similar to their own, in a way that the evidence base could not.

I think the actual experience of living with [disorder] is always so much broader than coming down to technical research issues which might be about which [medication] worked better, which one do we have the evidence that shows one seems to be more effective than another and you start getting that technical evidence that comes down to such small points and you think the living experience is . . . much bigger.

Participant 7

At the same time, participants demonstrated an appreciation of the value of professional knowledge:

. . . It is kind of knowhow and experience, someone who is really experienced in treating the condition can say 'Well this is what the evidence is but that didn't work so there is no point in trying that again' or 'This tends to work quite well with you but there's not a lot of research' its special, the benefit of experience . . .

Participant 6

Nonetheless, that the two types of knowledge could be compatible rather than mutually exclusive was appreciated, as perhaps might have been assumed by a more paternalistic model of treating mental health problems.

They [other group members] I think took the view that what they weren't going to get was somebody who had a very vertical view on a particular aspect of the subject of [disorder] . . . but that I had a broad expertise . . . and it complemented theirs.

Participant 5

The notion of collective knowledge or experiential expertise (where experiences of living with a particular disorder and interventions provided "are converted, consciously or unconsciously, into a personal insight" (Caron-Flinterman, Broerse et al. 2005) p. 2576 responds to the criticism often leveled at personal experience and qualitative data, that it is idiosyncratic. Instead, it is possible that knowledge transmitted between service users informs individuals' judgement.

In my case I have had lots of personal experience but also lots of personal contact with lots of other service user reps . . . so I am not just talking from my own personal experience but a whole marshalling of anecdotal evidence . . .

Participant 3

The use of supervision and other communications between mental health professionals suggests this is not limited to the recipients of treatment.

Conclusion

Shared decision-making seeks to resolve power imbalances and moves instead towards a position appreciating heterogeneity along with the merits of different types of knowledge in determining and implementing treatment goals and interventions. The involvement of patients and the public, but specifically users of mental health services, in determining treatment recommendations and the way they are made may then strengthen the integrity of s and improve their implementation whilst advancing recovery and shared decision-making models. Whilst it may be argued that guidelines should restrict themselves to listing optimal treatments for specific disorders, the human factors involved in deciding what these might be make the process of deliberation as significant as the outcome, within both the guideline development and the individual clinician-patient consultation. Involving patients and service users in developing treatment recommendations may itself improve the relevance and acceptability (to service users and patients) of the resulting guideline. By also considering the implementation of guidance at the point it is used, by developing decision aids and considering both parties' involvement in the process of determining treatment goals and interventions is consistent with recovery values currently permeating mental health services internationally.

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ⁱ Also frequently used is patient and public involvement (PPIP)