

Patient involvement: from guidelines to good practice

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Figure 1. It is widely believed that medicines adherence is more likely in patients that agree a prescription is appropriate and when they are warned of the potential side-effects

NICE guidance on medicines adherence puts particular focus on greater involvement of patients in decision making. Here, the authors discuss the reasons why this might not always be fully justified and cannot be solely achieved by good communication skills.

In 2009 the National Institute for Health and Clinical Excellence (NICE) published guidelines on medicines, adherence and patient involvement.^{1,2} These guidelines give an official articulation to widely rehearsed arguments about the need to see patients as ‘partners’ in prescribing.

Until recently the emphasis has been on whether and how patients take medicines. It is estimated that patients with long-term conditions take less than a half of medicines as prescribed.³ This is clearly a major public policy issue. It represents billions of pounds worth of fruitless expenditure and, assuming that much prescribing is ‘clinically appropriate’, a substantial shortfall in potential health improvement.

It also raises questions about involvement in prescribing – because it is widely believed that

patients are more likely to take medicines when they agree a prescription is appropriate and when they are aware of and prepared to deal with potential side-effects.⁴

Terminology

The terms used to discuss these issues have shifted in recent years. The language of ‘compliance’ has been displaced by talk about ‘adherence’ and/or ‘concordance’. The terms have different meanings, and have ‘built in’ conceptions of the patient’s role in prescribing and medicines use.

Compliance is the earliest and simplest concept; it can be defined as ‘the extent to which the patient’s behaviour matches the prescriber’s recommendations’.⁵ But compliance has unfortunate connotations. It constructs the patient as a passive follower of the prescriber’s pre-

scription and as lacking independent judgement and agency.

The idea of adherence introduces the need for agreement between patient and prescriber in the definition.^{6,7} In principle the concept of adherence thus shifts the emphasis away from the notion of obeying a prescription to the notion of choosing to follow a prescription. In practice, however, the terms are often used interchangeably.

The idea of concordance takes this shift one step farther. The concept was introduced in a report that sought to consider how prescribers and patients could work in partnership to achieve both appropriate and effective prescribing and medicines use.^{8–10}

NICE guidance

Although NICE settled on the language of adherence for its guide-

lines, concordance-related ideas are central in the document. In essence they offer advice on how to manage both intentional and unintentional nonadherence.

In addition to providing recommendations on supporting medicines taking (*eg* by simplifying dosing regimens or using alternative packaging) and encouraging better communication between professionals, the advice focuses on enhanced communication in prescribing and medicines reviews and puts particular emphasis on the greater involvement of patients in decision making.

It includes what might be seen as a checklist of communication 'tips' and techniques, *eg* asking patients open-ended questions. However, beneath this attention to communication skills is a clear concern with fostering a set of attitudes and values among prescribers.

Prescribers are reminded that 'patients have a right to decide not to take a medicine' (assuming the patients have 'capacity') and, more generally, to accept 'that patients may have different views from healthcare professionals about risks, benefits and side-effects'.² The importance of prescribers being adaptable and responsive to patients is stressed and advice is given about 'tailoring' communication to individual patients (in terms of content, style and the level of involvement wanted), attending to patients' concerns and providing opportunities for patients to express their perspectives and views. Last, but not least, all of this is to be accomplished in a 'non-judgemental' spirit.

Justifying patient involvement

But is it possible to justify NICE's calls for more active patient involvement in medicines decision making? We are disposed to answer this

question affirmatively, but we think it is important to ask it, to consider possible objections and also to explore how an affirmative answer might need to be qualified.

Patient involvement is underpinned by two linked concerns. First, a concern with effectiveness: involving people in prescribing, for example, might improve their understanding, medicines use, health and satisfaction. Second, a concern with ethics: if service provision is to be properly respectful of patients, then it ought to be responsive to their perspectives and values. Although these two types of justification overlap (because effectiveness is relevant to ethics), they have different implications.

If we want to cite effectiveness as a reason then we need to examine the relevant research evidence. If we want to make ethical claims in support of involvement then we have to articulate and assess the value judgements that underpin them. Here we will offer a very brief summary of the research evidence but then focus in a little more depth on the ethical arguments.

Research evidence

There is a substantial body of research that provides evidence of nonadherence and its negative impact on effectiveness.^{3,6,11} In addition, hundreds of studies¹² have identified a diverse range of factors that help to explain medicines-taking behaviour including intentional and unintentional nonadherence. Many of these factors could, in principle, be addressed by better prescriber-patient communication leading both to revisions in prescribing and/or to more supported medicines taking.

Research also shows that prescribers do not routinely foster concordant approaches to decision making. A systematic review of communication between patients and

- What if patients do not want to be involved in particular ways?
- What if attempts to involve patients cause them anxiety or distress?
- What if actions or interventions to promote involvement undermine the trust patients have in clinicians, or the comfort and reassurance that clinicians can offer?
- What if 'involved' patients make choices that are harmful to them, or to others, or damage the public realm more generally, *eg* because they are very expensive, or otherwise adversely affect public health?

Table 1. Important questions to address when promoting patient involvement

professionals showed that the 'building blocks' of concordance were not in place.¹³

However, the very strong evidence base that is available to support the claims that there are problems with prescribing and medicines use is not matched by evidence about the effectiveness of particular solutions. Some research does support interventions based on greater involvement in prescribing processes, but the kinds of intervention studies that clinical epidemiological standards of evidence privilege are, for good reason, thin on the ground.

A Cochrane review showed some interventions – mostly those related to better information and communication – were potentially effective, but suggested these effects were often modest.³ A more recent overview of systematic reviews of 'strategies for informing, educating and involving patients' shows a similarly mixed picture.¹⁴ Good evidence exists for the benefits of 'patient decision aids' that have been developed for a variety of conditions and treatments to enhance the involvement of patients. Similar positive findings suggest that communication skills teaching

and the provision of coaching enhance the capabilities and confidence of patients.

However, most of the demonstrated benefits relate to comparatively 'soft' (albeit important) outcomes. For example, communication interventions can improve participation in decision making, and decision aids have been shown to improve patients' knowledge and understanding and 'to improve agreement between patients' preferences and subse-

quent treatment decisions'. These are very important but there is comparatively little clear evidence of similarly positive impacts on subsequent health behaviours and health status.

Nonetheless there is no reason to be completely sceptical about calls for more active patient involvement on the basis of these sets of findings. There are many barriers to implementing change in this domain, and innovations in involvement are thus inevitably sporadic and partial.¹⁴ It

is impossible to know what effect much more widespread and systemic reform might produce.

Ethics and professional practice

It is easy to assume that any scepticism about patient involvement springs from simple conservatism. This is wrong. Ethical scepticism about patient involvement springs from many thoughtful and responsible sources. Table 1 outlines some questions that need to be confronted. There is not space here to

deal with each of these questions in depth, but we can offer some brief responses.

First, what if patient involvement is unwanted? Respect for persons is a central plank of healthcare ethics. Respecting people involves not only treating them with consideration but also respecting their autonomy – *ie* recognising their capacity and entitlement to lead their own life in their own way. Of course respect for personal autonomy can sometimes be in tension with other values (such as patient protection or the public interest), and this is the backcloth against which arguments about the involvement of patients in clinical decision making take place.

Respect for autonomy entails that a patient's preferences about the level and form of his or her involvement should be respected (this is reflected in the NICE guidelines). There are thus genuine dilemmas about how to encourage involvement while avoiding oppressive 'enforced involvement'.¹⁵

But even if a patient clearly signals they are not interested in actively participating in prescribing decisions, it is still possible to aim for forms of professional recommendation and leading of decision making that optimise respect for patients and support their autonomy.¹⁶ At minimum, respect for persons requires a willingness to share clinical information and thinking with patients.

Second, if involvement strategies cause distress in certain cases then there may be an argument for dropping or moderating them in those cases. However, there should be no presumption that anxiety and distress are necessarily bad things, and they can even be seen as appropriate responses in some situations – side-effects that are, on occasions, unavoidable in the sometimes painful processes of facing and making decisions.

Key points

- the idea of concordance considers how prescribers and patients can work in partnership to achieve both appropriate and effective prescribing and medicines use
- NICE guidance puts emphasis on the greater involvement of patients in decision making and reminds prescribers that patients have the right to not to take a medicine and may have different views on risks, benefits and side-effects
- good evidence exists for the use of patient decision aids and good communication skills in improving patient participation, but there is comparatively little evidence for subsequent improved health behaviours and health status
- there are ethical considerations for limiting patient involvement, as outlined in Table 1, and these should be used to tailor the level of involvement
- clinicians should still retain their own responsibility for decision making and should remain professionally accountable for decisions made about prescription-only drugs
- clinicians must balance the promotion of adherence with that of greater partnership in decision making

Eliciting patients' values and preferences is often an important element of determining what is 'clinically appropriate'. Unless prescribers have some sense of individual patient's values and preferences then they are often not in a position to make the right judgements, because what counts as 'right' can depend upon knowing what patients hope and expect to get from treatment (and what they want to avoid, for example, in terms of side-effects).

In particular, in all those cases where the relative costs and benefits of different treatments are broadly comparable or uncertain, then it makes sense to attach considerable weight to eliciting and reflecting the preferences of patients in determining the 'right' treatment (including no treatment).

The third, broader concern about possible damage to professional-patient relationships is harder to respond to, but any possible damage is likely to depend on how involvement is accomplished. It is easy to imagine clumsy 'involvement interventions' that would undermine patient-professional relationships and trust, but there is

no reason to suppose that all approaches to involvement would have these consequences.

Indeed there is reason to suppose that, done well, the facilitation of patient involvement would tend to enhance the quality of patient-professional relationships. In other words, the ethical justification of attempts to improve patient involvement in prescribing depends on the 'style' in which involvement is enacted. From patients' perspectives, the right 'style' can be particularly significant for a sense of involvement.¹⁷⁻¹⁹

Fourth, there is the question about whether the promotion of involvement, particularly if this involves offering patients more options and/or more influence over which medicines are prescribed for them, could result in bad outcomes for the health of the individuals concerned, the public health or the public purse, *eg* if patient choice led to more widespread use of antibiotics and compromised herd immunity. Once again this raises several complex problems that we can address only briefly.

The concern behind the question certainly provides an argument

against unfettered patient choice of medicines. But choice and involvement are not the same thing, and arguments for patient involvement in the form of concordance are not arguments for excluding clinicians from decision making. As the closely related language of shared decision making suggests,²⁰ clinicians would still retain their own responsibility for decision making and would remain professionally accountable for decisions made about prescription-only drugs.

In other words, concordant approaches to prescribing would mean that professionals retained broadly the same kind of control over access to potentially harmful medicines.

But these approaches discourage unthinking paternalism by requiring clinicians to attend to the ways in which patients evaluate benefits and harms, and to give more weight than has sometimes been the case to patients' preferences. In the context of ethics, it is worth adding, paternalism is not inherently good or bad.

Two questions can be separated out: is this a case of paternalism and can it be justified? In some instances clinical paternalism can be justifiable. Indeed the whole medicines decision-making framework in the NHS is framed by a paternalistic restriction of access to medicines. Patient involvement does not replace paternalism but simply modifies its exercise.

In short, all of the above questions can be related to good arguments for limiting patient involvement – at least in certain forms – but none are good arguments for the wholesale rejection of increased patient involvement. Rather they are arguments for placing limits on the medicines that people can choose to have and, more generally, for tailoring approaches to involvement in ways that reflect these legitimate concerns.

It is important to note, however, that the arguments we present for tailoring involvement could equally plausibly be presented, using a more contentious language, as arguments for restricting involvement depending upon cases and purposes.

The tailoring of involvement also has to reflect the different purposes of involvement. The NICE guidelines are designed to promote both adherence and greater partnership in prescribing decision making. In practice, when professionals come to interpret involvement in particular cases they will sometimes have to balance these different purposes together.

For example, to decide what to do when it seems that more emphasis on exploring option sets and promoting shared decision making may, for a particular patient, risk undermining the adherence benefits to be gained by a narrower focus on information sharing and responding to patients' questions and concerns.

Conclusion

Our suggestion is that the promotion of patient involvement in prescribing can certainly be justified in general terms, but that this leaves a multitude of complex balancing acts that can only be understood or managed by professional judgement.

Appropriate patient involvement cannot be accomplished solely by enhanced technical communication skills. It requires clinicians to manage complex dilemmas and balancing acts about the various goods at stake. It also calls upon clinicians' personal and emotional resources and, in some cases, may require fundamental changes to habits and styles of relating.

While we very much welcome the NICE guidelines, we would be wary of any assumption that the multiple purposes they champion are always compatible and fully practicable.

Finally we should stress that patient involvement responsibilities should not be placed on the shoulders of individual prescribers alone. Professional working habits are bound up with a range of structural and service constraints. Any realistic and defensible call from policy makers for a substantially increased role for patients in prescribing must also address these structural factors.

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