ROYAL PHARMACEUTICAL SOCIETY

Involvement, Shared Decision-Making and Medicines

Professor Alan Cribb | **November 2011**
Centre for Public Policy Research
King's College London

Arts & Humanities Research Council

King's College LONDON

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Patient-centred care and shared decision-making between patients and healthcare professionals has been a dominant theme of health policy for many years now. Despite wide acceptance of increased patient involvement as best practice there remains a significant gap between policy ideal and the reality on the ground. The need to bridge this gap has become more apparent with the current government placing patient involvement firmly at the centre of health policy.

Professor Alan Cribb's timely discussion paper explores the inherent complexities of increasing patient involvement in treatment decisions, looking through the lens of prescribed medicines and their use. These complexities resonate strongly with the pharmacy profession; the experts in medicines and their use. The practical and ethical dilemmas involved in increasing patient involvement in medicines use present themselves daily to patient-facing pharmacists.

Alan, in acknowledging that "guidelines can help inform, but they cannot replace context-responsive professional judgement", highlights the challenge of supporting healthcare professionals in exercising their professional judgement.

The Royal Pharmaceutical Society recognises the complexities of patient-centred care and will continue to support pharmacists in exercising their professional judgement. We also recognise and welcome Alan's considerable scholarship in the area of patient involvement and shared decision-making and have heard the mandate to champion educational change and support greater collegial, multidisciplinary leadership for the benefit of patients and the public.

Martin Astbury FRPharmS
President
Royal Pharmaceutical Society

This Royal Pharmaceutical Society discussion paper is a valuable addition to the thinking on shared decision-making. Professor Alan Cribb makes a nuanced and considered argument for shared decision-making, which shares common themes with the Royal College of Physicians' own work on improving communication and understanding between patients and clinicians. His analysis of the potential practical and ethical issues that need to be addressed to enable the successful implementation of shared decision-making will be of strong interest to medical professionals.

Dr Linda Patterson
Clinical Vice President
Royal College of Physicians

FOREWORD

The Health Foundation is delighted to welcome this paper, a rare animal in that it is both practical and erudite. It is an important contribution, revealing the realities and challenges that will inevitably face health systems as we forge a new set of relationships between patients and clinicians. As Professor Cribb argues, it is right and inevitable that we move to a world in which patients are "worked with, rather than worked on"; but eliminating the current policy-practice gap around involvement requires the sort of intelligent, sophisticated analysis and treatment that this paper provides.

It is all too easy to use words such as shared decision-making, patient-centred care and partnership; and there is no shortage of such rhetoric within the current health policy context in the UK. Like Professor Cribb, The Health Foundation welcomes and supports the growing emphasis on this long-neglected driver of quality in healthcare. Indeed, we have been amongst those pushing this agenda. However, we too appreciate that the crude fudging of terminology around involvement by politicians is an impediment to progress; and we too believe that achieving real partnership is not only a question of attitude and desire, or even strategy, but also requires subtle, sophisticated execution: what this paper calls "stepping stones" to change.

It is precisely this need for greater practical learning about what is required to support professionals with this journey that has led the Health Foundation to invest in two demonstration programmes focused on implementation: Co-creating Health and Magic. We are delighted that through his research, Professor Cribb came across Co-creating Health and appreciate his warm endorsement of the Co-creating Health approach within this paper.

It may not have been Professor Cribb's initial intention, but I suspect that reading this paper will greatly increase readers' empathy with the complex position in which professionals now find themselves. That is not, however, to say that it is a reactionary defence of professionals. Rather, it is a call for us to fully understand and address the genuine constraints and concerns that limit the rate at which they can change. Professor Cribb describes the legitimate concerns on the part of professionals about what it means in practice to shift clinical approach in line with the growing shift away from traditional paternalism. This paper clearly illustrates the genuine dilemmas – about risk, patient safety, the professional's own risk management – which constrain professionals' ability to take on these practices. Through our experience with Co-creating Health,

working with over a thousand health professionals across the UK, we have seen that the transition to adopting greater involvement practices by clinicians is an incremental process – a journey over time of integrating new forms of consultation and communication into long-established habits.

Traditionally, professionalism has been seen as a quality of the individual clinician – as opposed to the relationship-based approach that Professor Cribb takes within this report and which The Health Foundation too supports. Relationships with patients, alongside relationships with other health professionals and relationships with the health system, are the qualities that we now understand make up modern professionalism.

The paper calls for a reduction in the "emphasis on abstract models and labels" and an increase in "our attention to the practical and philosophical complications that have to be negotiated in day to day clinical work". One of these practical complications is that health professionals do not practice in isolation or in the abstract, but rather, within the highly complex systems that characterise modern healthcare. The other joy of this paper is its recognition of the critical place of context and conditions on the capacity of the individual to change. This integration of systems-thinking, alongside the insights from philosophy that Professor Cribb brings to this paper, point the way towards the methods and techniques that will work on the ground to support change.

Finally, thanks are due to the Royal Pharmaceutical Society and the Arts and Humanities Research Council for their support for this paper. It could not come at a more important time. The Health and Social Care Bill currently making its way through Parliament in Westminster enshrines patients' rights to a high degree of involvement in their own healthcare. The Bill has had a challenging time in Parliament, but this will be as nothing relative to the challenges of its implementation. North of the border, in Scotland, the national Quality Strategy has "mutuality" at its heart – a similar but different term posing further questions for the professionals required to deliver it. We need as much help as we can get to move to the new world of healthcare to which we all strive, and this paper is a big help. I am delighted to commend it.

Natalie Grazin
Assistant Director
Health Foundation

INVOLVEMENT, SHARED DECISION-MAKING AND MEDICINES

This discussion paper builds on the deservedly influential work of the Royal Pharmaceutical Society on concordance. It is concerned with putting concordance into context in two senses. First, it discusses the importance of concordance (or what is known more generally as shared decision-making) as part of a wider family of 'involvement' concerns; and second, it explores the challenge of applying ideas about, or models of, involvement in the real and very diverse contexts of professional practice. This paper also has some strong resonances with the very recent report and recommendations of the Royal College of Physicians on *Why people matter in medicines*. The authors of that report stress the importance of partnership not only between professionals and patients but also between groups of health professionals, writing that, '[w]e cannot emphasise enough the need for collaboration between health professionals and between doctors and pharmacists' (2011, p3). These forms of collaboration are not the focus of this discussion paper, but it is hoped that, nonetheless, the changes it calls for may also play a small part in encouraging such professional partnerships.

Executive Summary

The central argument of this paper can be summarised as follows:

1. There is increasingly a new policy orthodoxy that:

- more partnership working between clinicians and patients is fundamentally important and, in particular, that shared decision-making about treatment choices is needed for reasons of both effectiveness and ethics;

- despite many efforts there is a big gap to close between these general ideals and routine practice;

- further steps need to be taken to close this gap.

2. The new policy orthodoxy is to be welcomed. However it is also important to recognise that not all of the gap between ideals and practice should be seen as mere 'resistance' or 'drag' on the part of healthcare professionals. In particular:

- the right infrastructure and tools need to be put in place if calls for widespread partnership working are to be realistic;

- some of the gap between ideals and practice stems from valid concerns and from the inherent complexities of involvement- or partnership-related values.

3. Policy attempts to 'push' the involvement agenda – including the implementation of ideas such as concordance or shared decision-making – will not succeed, and may even be counter-productive, unless the practical and ethical challenges and dilemmas surrounding this agenda are explicitly addressed and fully reflected in policy initiatives and practice development.

The report aims to make a contribution to addressing these challenges and to formulating more realistic (i.e. context-sensitive and practicable) policy. It draws upon conversations and interviews with professionals and on academic work in applied philosophy (summaries of which are presented in two appendices), as well as on the existing literature on involvement and shared decision-making. Each of these three sources highlights important shortcomings behind well meaning but simple 'policy solutions' in this area. In particular both the experience of professionals and philosophical analysis show that, in addition to significant practical and infrastructural challenges, there are dilemmas inherent in models of shared decision-making which need to be recognised as part of effective implementation. Similarly, academic proponents of shared decision-making are often advocating a much more subtle and internally complex approach than the one reflected in policy. A crucial insight from this work is that narrow 'technicist' models – either in the construction or the implementation of approaches such as shared decision-making will not work and may even be counter-productive.

Key conclusions are:

1. Progress depends upon achieving greater clarity about the range of different purposes and agendas being pursued in the area of medicines and patient involvement. Fudging these different purposes and agendas together under single headings such as 'shared decision-making' (or 'choice') is often unhelpful and masks the diversity of approaches needed to tailor involvement to specific circumstances and cases and to address practice dilemmas.

2. The gap between policy ideals and routine practice can only be narrowed if both policy and practice are reformed. In particular:

■ Educational change and collegial leadership are needed to underpin new, more responsive, models of professionalism and to encourage the 'practical wisdom' that is the essential component of professionalism.

■ If new models of working are to be feasible, infrastructural 'stepping stones' need to be identified and put in place. In so doing, the important and carefully researched traditions of practice development that already exist in this area need to be drawn upon and built upon.

■ It is also necessary to prompt 'systems re-thinking' and systemic changes in health services, but there is a circumscribed role for managerial, 'incentive based' or other 'technicist' interventions in this area. Similarly, arguments from cost-effectiveness can play a role – in addition to the central arguments about care quality and ethics – but arguments based upon cost savings should be used carefully.

3. Policy in this area must maintain the strongly reformist, even transformative, zeal of the advocates of patient involvement and shared decision-making. But this zeal needs to be combined with: (i) a carefully differentiated account of the nature and values of involvement; and (ii) an approach to change that supports and protects these values.

Overall the paper is designed to map and clarify the various purposes and agendas at stake in patient involvement policies in relation to medicines, and the practical and ethical challenges of translating these purposes into practice. The appendices are designed not only to help illuminate and support the content of the paper but also to inform educational developments in this area.

1. BACKGROUND

Over the past three decades, the notion that 'patients', 'lay people' or 'the public'[1] should be 'involved' in healthcare provision has become increasingly prominent and influential. It is no exaggeration to say that patient involvement is now established as 'policy orthodoxy', and it has even been described as a 'policy imperative' (Thompson, 2007). Patient involvement is unquestionably a very important agenda for health policy and healthcare professional practice but – as the continual emphasis and re-emphasis on the need for reform in the area also indicates - it is also an extremely challenging agenda. The main sections of this discussion paper analyse some of the difficulties of translating involvement ideals into routine practice and consider some possible ways forward. To begin with, however, this section will provide a little more background - underlining the strength of the new policy orthodoxy, and introducing the importance, and some of the complexity, of the idea of involvement and the relevance of this theme to the broad area of prescribing and medicines use.

The new policy orthodoxy

This discussion paper focuses on issues related to the involvement of individual patients in prescribing decisions and the use of prescribed medicines. However, it is important to recognise that ideas about this have developed alongside thinking about both the involvement of individuals in their own healthcare more generally[2] and about the involvement of patients or (potential) service users collectively.[3] Over recent years many overlapping policy labels have been used to capture and promote these ideas: as well as patient and public involvement we have, for example, had talk of patient-centredness or person-centredness, personalisation, partnership and shared decision-making.

These involvement-related concerns, and the broader discourses behind them, have been in mainstream circulation for at least thirty years. They were deeply embedded in official government policies throughout the 'New Labour' era and have been equally prominent in the policy climate of the Coalition government formed in 2010. Indeed, if anything, this policy emphasis is being intensified.[4] Both in the first health White Paper of the Coalition era (DoH, 2010) and in associated speeches by the Secretary of State for Health the importance of patient involvement, and, in particular, the language of shared decision-making, were placed at the centre of health policy, and represented as the 'first principle' of the new NHS:

> *"Many of you will already treat your patients as partners. Involving them in decisions, giving them as much choice as is possible within the bounds of appropriate treatment. This should be the case for everyone."*

Secretary of State for Health's speech to the National Association of Primary Care's annual conference, 21 October 2010

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1 *There is, notoriously, no single satisfactory term to use here. Each term has advantages and disadvantages, and the use of 'patients' most of the time in what follows is purely for reasons of simplicity and does not detract from these complications.*

2 *For example, by their 'speaking up' about threats to their safety in healthcare contexts and by a growing emphasis on self-management and healthy lifestyles more widely.*

3 *For example, in the governance of health professionals, the licensing and regulation of medicines, and the planning, organisation and evaluation of services.*

4 *The very short policy summary provided here relates primarily to England. There are of course significantly different policy settlements in the countries of the UK. However, most of the diversity is arguably connected to different structural and ideological emphases in the organisation of health services rather than to differing conceptions of healthcare professionalism. Indeed the shift towards the greater involvement of patients in clinical decision-making, including partnership models of professional-patient working, is part of a very long-term and international trend in healthcare. One recent example of the spread of discourses of shared decision-making can be seen, for example, in the statement produced by the Salzburg Global Seminar (2011):*

see press.psprings.co.uk/bmj/march/SalzburgStatement.pdf.

"For the NHS, through the White Paper, we set out those principles: first, a patient-centred NHS. Patients not just as beneficiaries of care, but as active partners in its design and delivery. Shared decision-making. Patients feeling that invariably, when they encounter the health service, it's a case of 'no decision about me, without me.'"

Secretary of State for Health's speech to the National Clinical Assessment Service conference, 5 November 2010

This stress on decision-making partnerships is explicitly retained in the government's more recent response to the 'listening exercise' and the Future Forum report in particular:

"Our White paper declaration, 'no decision about me without me' aspires to an NHS where patients are involved fully in their own care, with decisions made in partnership with clinicians, rather than by clinicians alone."

*"[S]hared decision-making must become the norm and not the exception. As suggested by the Future Forum, we will amend commissioners' duties to involve patients and carers in their own care to **better reflect the principle of 'no decision about me without me**.'" (Original emphasis.)*

Government response to the NHS Future Forum report (Department of Health, June 2011, p39)

In addition to government and government agencies, other influential health policy bodies have helped to clarify and champion the importance of patient involvement. For example, the Picker Institute, the Royal College of Physicians and the King's Fund have contributed important work on new models of clinical professionalism that stress the need for 'patient-oriented' working and patient-professional partnerships (Askham & Chisholm, 2006; Levenson, Dewar, & Shepherd, 2008; RCP, 2005).

In the area of medicines and patient involvement the landmark work on developing and disseminating the notion of 'concordance' – partnership working in prescribing and medicines taking – stems from the RPSGB report of 1997 (Royal Pharmaceutical Society of Great Britain, 1997). But this current of work on medicines and concordance has continued through the activities of other agencies,

especially the Medicines Partnership and the National Prescribing Centre (Cox, Stevenson, Britten, & Dundar, 2004; Clyne, Granby, & Picton, 2007) and has been usefully explicated in recent books (Bond, 2004; Dowell, Williams, & Snadden, 2007). This current directly fed into the 2009 National Institute for Health and Clinical Excellence (NICE) guidelines on 'Medicines Adherence' (NICE, 2009; Nunes et al., 2009). These guidelines represent a recent milestone in medicines policy making because they give an official articulation and endorsement of the crucial importance of patient involvement in medicines decision-making. The expectation endorsed and reinforced by the guidelines is, once again, that patients should be seen less as 'passive' and more as 'partners' in prescribing as well as medicines taking. (These guidelines are discussed further in section 3).

What is involvement? Why does it matter? Why medicines?

The question 'What is involvement?' is more difficult to answer than might be first thought and much of this discussion paper is given over to illustrating the complexity of involvement. However, before going any further it is worth offering a summary answer to it. Some notion of what patient involvement means is obviously indicated by the discussion thus far; i.e. it indicates relatively active rather than passive patients or service users, and thereby something like a partnership between professionals and lay people – patients being 'worked with' rather than simply 'worked on'. However, beyond this very broad sketch, the notion of patient involvement is a highly complex one (as is also indicated by the different kinds of labels and languages associated with it and referred to above).

Patient involvement can be seen as an umbrella category that covers a diverse range of possibilities, emphases, models and practices. To begin to open up this diversity it is worth spelling out two sets of basic distinctions alluded to above, distinctions between: individual and collective forms of involvement; and the involvement of patients in clinical practices and their involvement in broader health-related practices.

These distinctions are not entirely sharp or clear-cut. For example, collective involvement can help shape the terms of individual involvement: if patients participate in a group – perhaps representing their perspectives on conditions and treatments, and advising on, or advocating for, service reform – then they can help shape the participation opportunities open to themselves as individual service users. Similarly the distinction between a clinical practice and a health-related practice is not a clear-cut one. Roughly speaking, we can stipulate that clinical practices are those that have traditionally been regarded as falling within the domain, and responsibility, of clinicians and other professionals (for example, diagnosis, treatment and referral judgements at an individual level, and service planning, management, audit etc. at a collective level); and we can stipulate that health-related practices are those that have traditionally been regarded as falling within the domain, and responsibility, of patients or citizens (for example, treatment adherence and lifestyle practices at an individual level and lobbying, campaigning etc. at a collective level). But these boundaries are neither clear nor fixed. The familiar example of someone choosing to buy certain medicines over the counter rather than seeking a consultation and a prescription for the same medicines illustrates this, as does the fact that a number of medicines have been reclassified so that they are no longer prescription-only but are available over the counter. Equally, if someone is prescribed some medication to take in the 24 hours running up to an operation, then adherence to this medication seems to count both as involvement in a clinical practice and as one of the health-related practices of the patient.

These rough distinctions generate four broad possibilities

	In clinical practices	In broader healthcare practices
Individual involvement	**A**	**B**
Collective involvement	**C**	**D**

Examples of these possibilities are:

A. An individual patient playing some active role in his or her treatment decisions within clinical consultations.

B. An individual patient attending a health promotion or self-management course.

C. Service users participating in service planning activities.

D. A patient organisation lobbying for public policy change.

The main emphasis of this discussion paper is on 'category A' forms of involvement. But, as has just been noted, this needs to be seen in the broader context of the other three sets of possibilities.

This simple - A to D - taxonomy also indicates that as well as patient involvement in clinical practices (A and C) there is also the need for what might be thought of as 'clinical involvement' in patients' broader health-related practices (B and D); i.e. in addition to fulfilling their own clinical role, clinicians (and other professionals and services) can help foster, support and participate in people's health-related practices. Involvement might thus be seen as allowing for the possibility of a 'two way' movement. Just as the patient can enter into, and somehow participate in, the clinical sphere, clinicians can enter into, and participate in, the 'non-clinical' sphere; i.e. the lives, life circumstances and lifeworlds of patients. Recognising the potential for this 'two way' movement is important. If our focus is on something like partnership working, then this entails potential adjustments and accommodations for everyone. This 'two way' idea is to some extent embedded in the work on concordance by the stress that is placed both on clinicians *including patients* in prescribing decisions and on clinicians *supporting patients* in medicines use.

The contemporary emphasis on involvement is underpinned by two fundamental and linked concerns. The first is a concern with effectiveness: involving people in decisions about the medicines they will be prescribed, for example, has the potential to improve their understanding, medicines use, health and satisfaction. The second is a concern with ethics: if service provision, either at an individual or a collective level, is to be legitimate and properly respectful of patients then it ought to be responsive to and reflect the perspectives and values of patients. In short, involvement can be seen as both practically useful and as intrinsically worthwhile. Lying behind the 'policy imperative' of involvement, therefore, is what can be thought of as both a 'quality imperative' and an 'ethical imperative'. Linked with these things, but more contentiously, there are sometime allusions to what might be called an 'economic imperative', i.e. the thought that health resources are likely to be used more cost effectively and allocated more efficiently if patients are involved in their choice of treatment - both because they may resist

accepting (sometimes distressing or otherwise demanding) treatments when these treatments have unclear benefits and because they are more likely to participate effectively in treatments that are actively agreed to because these treatments feel 'chosen' rather than 'imposed'. These core ideas - that involvement produces higher standards (in healthcare quality and ethics) and potentially also improves cost-effectiveness – were cited in the Secretary of State for Health's speech to the National Association of Primary Care, referred to above:

> *"There is a vast amount of research that clearly demonstrated what every one of you will know instinctively. That a patient's treatment is always better and often cheaper when they are more than just a passive recipient of care, but an active participant in it."*

Is there any particular reason to focus on involvement in relation to medicines, rather than the many other areas of healthcare? In one sense medicines can be seen simply as one very important example of a healthcare intervention. But medicines are also a particularly useful example because, as noted above, they sit at the interface of clinical practices and health practices; i.e. they operate between the clinical and the personal realms. In other words, medicines are very often clinical interventions in people's lives but the operationalisation of these interventions typically depends upon the active participation of these people. It is for this reason that 'adherence' (and related ideas such as concordance) has become such an important focus of concern and research.

Medicines thus provide one particularly valuable lens through which to view the challenges of patient involvement. At the same time it is worth noting there are some *relatively* distinctive challenges facing involvement policy in the area of prescribed medicines which can be summarised here in four broad points. Although these points are certainly not unique to medicines, taken in combination, they apply especially to medicines:

(i) medicines are typically self-administered and managed, sometimes over long periods of time in which patients move through different service settings, illness phases and life phases; (ii) the mechanisms by which medicines work are, for the most part, extremely technical and hard to explain; (iii) knowledge about medicines (specifically, different kinds and uses of medicines) is very unequally shared by the various health professionals who may be called upon to discuss medicines with patients; (iv) knowledge about the likely positive and negative effects of medicines is largely population based and sometimes very difficult to apply to individuals. To some extent this can be overcome by adopting 'trial and error' approaches to prescribing, which frequently have an important role to play in matching medicines to patients, but these in turn depend on managing information across service settings and also pose their own problems for managing involvement. In summary, medicines-related involvement is a very useful area to analyse but, of course, we should be wary of automatically extrapolating such analyses to other areas.

2. UNDERSTANDING THE POLICY-PRACTICE GAP

The gap between policy orthodoxy and routine practice is well known and persistent. For example, the data that the Picker Institute collect from hospitals continue to show that, although there are some promising signs of improvement in some domains, patients do not feel as involved in their treatment as they would like to be and do not get as much information about their medicines as they would like to have (Richards & Coulter, 2007; Sizmour & Redding, 2010). There is also a wealth of research that shows that concordant approaches to prescribing are not routinely in place (Cox et al., 2004; Horne et al., 2005).

One reading of this gap rests upon a – sometimes explicit but often implicit – deficit picture of health professionals. According to this reading, professionals are simply not willing or able to move away from a traditional paternalistic approach to treatment in which their own expertise and professional judgement is centre stage and the job of patients is essentially to co-operate or even to 'comply' with these professional judgements. This deficit story is most often ascribed to doctors but can also be ascribed to other health professionals, and, in more explicitly critical accounts, is seen as simply a function of professional power and of practices that preserve and protect professional power. (There are also, of course, deficit pictures of patients that are sometimes used to explain the gap.)

It would take a foolish person to argue that this deficit reading of professionals is a total irrelevance, based upon a complete misreading of reality. Nonetheless, there is a real danger that too much emphasis is placed upon this reading and that it effectively acts as a smokescreen that prevents us from confronting the full range of factors that explain the policy-practice gap. The question that really needs to be addressed is this one: 'Why is the policy-practice gap seen as pervasive and persistent in a system in which there are very many conscientious health professionals who subscribe to the broad principles of patient-centred healthcare and are increasingly educated in settings where these principles are strongly emphasised?' A full answer to this question might quite reasonably include reference to professional conservatism or professional power, but other elements would need to be included. The argument of this

section of the report is, in summary, that the gap between policy orthodoxy and routine practice is in major part produced by two overlapping factors:

(i) patient involvement in clinical settings is 'hard to do' – *it is very difficult to translate principle into practice;* and

(ii) patient involvement in clinical settings gives rise to substantial dilemmas – *in many instances the resistance to forms of involvement does not spring from simple conservatism but from legitimate concerns about what is for the best.*

In the rest of this section these two factors will be unpacked and discussed further. However, as has already been noted, the two factors cannot be neatly separated out. Part of what makes patient involvement difficult to implement is the fact that it involves the management of dilemmas. For this reason the two factors will be discussed in parallel.

Understanding the policy-practice gap starts from the recognition that 'involvement' in practice is complicated – it can refer to a broad range of things and has to be interpreted in a broad range of contexts – and so there can be no standard answers to the challenges of involvement; this is true with regard both to the practicalities and the principles of involvement.

The components of involvement

As noted above, 'patient involvement' is really an umbrella category that covers a wide range of concerns and practices. Others have helpfully illustrated the open-ended nature of involvement, for example by indicating some of the questions that would need answering, case-by-case, before we would be clear about what kind of involvement we are talking about. For example: *What kinds of activities should individuals be involved in? What kinds of relationships and people should individuals be involved with? Who are we imagining are the agents of involvement? i.e. who is supposed to initiate or support involvement for whom?* (Entwistle & Watt, 2006).

In this paper the central focus is on the potential contribution of patients to clinical exchanges involving medicines, including related clinical and health-related decision-making, and on the potential role that professionals have in facilitating this contribution. However, it is important not to define this focus too rigidly, not only because this agenda merges into other ones, as noted above, but also because the way any such agenda is constructed makes assumptions about 'who is in charge' or 'who is responsible' which is precisely the issue that is raised by involvement debates.

To indicate some of the diverse things a professional who wishes to strengthen their 'involvement practices' may have to address, it is worth abstracting out eight different components of patient involvement practices. These components are designed to be indicative, and not in any way meant to be definitive or exhaustive (although they are based upon analysis of fieldwork on involvement and are thus certainly of relevance[5]):

1. creating the conditions for communication;

2. informing and educating patients;

3. promoting self management;

4. being responsive to patient perspectives;

5. joint agenda-setting;

6. joint decision-making;

7. relationship building; and

8. re-working relationships and systems.

These components are discussed and illustrated in much greater depth in Appendix 1. They are introduced here because they help to indicate some of the complexity of involvement and provide a platform for further discussion.

Not least, setting out this indicative list of components makes it evident that involvement is not just one thing

(let alone one simple thing). For a professional to involve a patient can mean, for example, that they must engage with them, inform them, encourage and support them, listen to them, work collaboratively with them on defining problems and determining solutions, build rapport and trust with them and, at least some of the time, break out of the moulds which typically shape the ways in which professionals and patients interact. Even under the best of circumstances, none of these things are easy. To achieve a suitable combination of them in the 'real world' of healthcare is extremely demanding.

One major element of this challenge is that increasing levels of patient involvement requires the forging of new patterns and habits of relating in contexts where other patterns and habits of relating are institutionally and personally embedded. This can be seen by looking at what might seem like the 'easy end' of the involvement components listed above – the need to create and 'open up' channels of communication. Of course, all health professionals must have some level of communication skills and, of course, there are plenty of opportunities for communication between professionals and patients. However, the kinds of communication that are possible are structured, and limited, by the settings and circumstances of particular interactions. Even in primary healthcare settings – which are often seen as sites conducive to more open-ended and ongoing forms of communication – there are well-known time limits upon consultations, and patients (even if not professionals) often come to consultations with strong and long-reinforced notions of what is expected from each party. According to some of the leading conceptions of patient involvement - e.g. various models of 'shared decision-making' - patients ought to be helped to share their values and preferences about their experiences and possible treatment risks and outcomes and to collaboratively explore and deliberate about clinical and health-related decisions. This obviously requires specific forms and conditions of communication; i.e. if patients are to feel truly secure enough and to be sufficiently forthcoming and confident

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5 *More details of the fieldwork are provided in Appendix 1.*

to participate effectively. (And, as will be illustrated in more detail below and Appendix 1, the exact forms and styles of communication needed will vary depending on which of the various components of involvement - or which combinations – are stressed.)

There is no desire here to suggest that these broader forms of communication are impossible or that appropriate conditions do not exist. The intention is purely to stress that these forms of communication are definitely not easily achieved and to note that some conditions in which professionals and patients come together (e.g. in busy hospital clinics designed with specific functions in mind) are unlikely to support these richer kinds of patient involvement practices.

Moving from the general to the particular

Ideals such as 'partnership working', 'shared decision-making' or 'concordance' serve a range of important purposes. They encapsulate and help to explicate important principles, they signal and steer policy directions and models of professional practice, and they provide general frameworks and languages for research and development. However they are of only limited value when it comes to bringing about change on the ground. The reasons for this are mostly obvious. These terms are inherently abstract[6]. To know the terms, and even to embrace the broad ideas and principles they represent, does not resolve the question, 'What should we do here and now, in this particular setting, in this particular instance?' Still less does it resolve the question of how we make it possible (or easier) to do whatever it is we think should be done.

Much important work has been done on this practice development agenda (see section 3), and this work suggests

possible ways forward. As well as time, other resources need to be available – not least suitable 'spaces' for potentially more personally and emotionally invasive or more open-ended interactions, new and/or extended forms of expertise for some professionals (and patients) and, in some instances, specific 'tools' (information sources, decision-aids, record keeping tools etc) to support involvement efforts. The point being underscored here is merely that practice development is something supplementary to, and rather different from, the articulation and dissemination of ideals.

A core problem with the dissemination of patient involvement ideals, therefore, is that it effectively involves translating 'one big idea' to a countless set of very diverse contexts. Patient involvement has to be translated into practices in different sectors and settings, for different professionals and patients, and for different kinds of health conditions and treatments. In the case of prescribing decisions, for example, there are very significant differences in what it is appropriate to call for in different cases. Just to indicate some relatively clear-cut differences: (a) the legitimate limits to professional influence or persuasion would seem to be different in relation to those medicines where there is the potential for addiction, abuse or public health risks[7]; (b) in some scenarios patient choice of medicines is much less practically or personally meaningful than in others (compare, for example, choice of rejection drugs as part of a transplant procedure and choice of HRT[8] - in the former case there may be no real choice about *whether* to take medicines and no significant personal factors relevant to the choice of *which* medicines to choose; whereas in the latter case both kinds of choice are often both possible and personally meaningful); (c) professionals have their own prescribing philosophies and styles and it is unreasonable to expect them to accomplish things in exactly the same style providing they are broadly striving to achieve the same kinds of balances (especially in areas where the personhood of the professional is a key resource – see

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6 *This abstraction incidentally means that such terms can easily be dismissed from the start as empty 'policy jargon' by practitioners. This is shown, for example, in studies conducted within the King's Fund 'Point of Care' programme; an excellent source for thoughtful and penetrating ideas about what matters beyond the jargon (see Goodrich & Cornwell, 2008; and Goodrich, 2009). This work shows that professionals much prefer ordinary 'human' words for caring such as respect, dignity, sensitivity, understanding or compassion.*

7 *For example, see the very careful and responsible discussion of 'involuntary isolation' as a last resort in TB care, following sustained efforts to explore effective and person-centred approaches to non-adherence in the WHO guidance on the ethics of tuberculosis prevention, care and control (WHO, 2010). Also see the debate about the ethical desirability and problems of 'opioids contracts' between doctors and patients in The American Journal of Bioethics, 2010(11).*

8 *See, for example, Légaré & Brouillette (2009); Murtagh & Hepworth (2003).*

section 3); (d) patients, of course, have different information and support needs in relation to medicines, and very varied perspectives and preferences including involvement preferences. (Some of this diversity, based upon practice examples, is illustrated in Appendix 1).

Thus what patient involvement can and should look like will vary from case to case, and the same applies to what counts as appropriate kinds of decision support or record-keeping tools and systems and, to some degree, the appropriate 'skill set' of professionals. As already noted, these things partly depend upon the immediate setting and the dominant 'function' of the encounter between professional and patient. Some institutional settings and consultations lend themselves to richer forms of engagement and involvement than others. But equally important, different settings and functions suggest different involvement *purposes* and possibilities. To return to the components of involvement listed above, it seems sensible to suggest that these components might need to be prioritised (and interpreted) in different ways on different occasions. If the immediate job at hand is to support the patient's self-management of their chronic condition through the most effective use of already prescribed medicines, then – crudely – components 1 to 4 are arguably the most salient. If the principal task is to initially identify a suitable medicines regime (or to review and rethink a regime), then components 4 to 6 are obviously central. Similarly, if professionals and patients are likely to have a more long-term and open-ended relationship – for example either working on a treatment trajectory over a long period and/or collaborating on service improvements, then components 7 and 8 (along with others, depending upon the instance) become particularly prominent.

This could be formalised by referring to different 'models' of involvement – some of which have been given names in the literature. Roughly speaking, as we move through the eight components, we are moving from what have been called 'informed adherence' models to 'self-management' models to 'shared decision-making' models. These are all attempts to improve on an old-fashioned expert-based compliance model. The first part of this process is to help patients 'get on board' with clinical agendas – to involve them, for example, through education. This can merge into another part of the process, which is to recognise patients' involvement in, indeed ownership of, their own health-related practices (which includes 'adherence' issues of course) and the need to focus on patients' health-related perspectives and practices. This merges into the process of making decisions, including prescribing decisions, *with* patients as is represented in the

idea of 'the meeting of experts' assumed by concordance or shared decision-making ideals. Through these various steps there is some re-negotiating of the boundaries between professional and patient roles and responsibilities. The emphasis in component 8 on 'relationships and systems', in the plural, serves as a reminder that the patient-professional dyad (which is the main focus here) always needs to be seen in a social and institutional context.

Components 5 to 8 might be seen in some ways as potentially (and increasingly) more radical steps, because they suggest the scope for – at least to some degree – diminishing or even dissolving the boundaries that typically define the professional-patient relationship. However, it is worth cautioning against the simple idea that some components or models are inherently 'lower' or 'higher' in an involvement hierarchy, or of seeing more unconventional professional-patient relationships as necessarily more 'radical' or as necessarily representing 'more' and therefore 'better' involvement. To repeat the point just made, what counts as appropriate or 'better' involvement, and how the components (summarised above) should be interpreted and applied, depends very much upon the particularities of specific settings, purposes and cases. This means that there are two different axes to the complications of involvement: as well as a diversity of practice settings there is a diversity of possible conceptions and models of involvement

Understanding the ethical obstacles

Thus far the emphasis has been on what might be thought of as the instrumental or 'organisational' obstacles to closing the policy-practice gap; i.e. the need for various kinds of planning and resources, and problems in 'operationalising' involvement in ways that is appropriate to specific contexts. But nested within the above discussion are potential challenges of a different sort – relating to what might be thought of as ethical or principled concerns.

The debate about suitable models of involvement can be interpreted in either a technical or an ethical way – as a debate about technical questions or about questions of principle. The above discussion puts the emphasis on the former; i.e. in order to optimise the benefits of patient involvement, bearing in mind the demands of different settings and cases, what is likely to be an effective and a 'fitting' model of involvement in various instances? But, of course, the debate about models is about more than this. It is also partly about what we should think of as the

benefits and costs of involvement or what should *count* as effectiveness; i.e. it is also about purposes and principles. In other words, it is quite possible that two people could agree that an approach to involvement could be implemented in a particular context and even agree, to a large extent, about what the likely outcomes of implementing such an approach might be and yet disagree about whether or not such implementation would be a good or a bad thing.

Professionals can have a variety of principled worries about practical approaches to involvement and it is a mistake to see all reservations about patient involvement as a simple expression of professional conservatism or paternalism. If this fact is not understood and addressed, there is no hope of optimising levels of patient involvement, because policy makers may appear to professionals to be 'pushing' them in directions which they see as unprofessional and wrong. The result of this can only be a stalemate between two well-intentioned sets of agents.

This is not to say that the general practical and ethical importance of patient involvement is in any doubt. As summarised above, patient involvement is ethically important because it treats individuals (and groups) with respect and because it can have beneficial consequences in relation to quality of care and health outcomes. The legitimate concerns about whether, where and to what extent involvement is 'a good thing' only arise when we focus in more closely. To summarise these concerns: first, there is the question of whether and how far the ideals which underpin broad conceptions of involvement are actually made manifest when involvement is translated into practice; and second, there is the question of how to balance together different ethically relevant considerations when they come into conflict.

A responsible professional needs to be able to confront the following value-based questions:

- What if there is some doubt about the capacity of patients to represent themselves effectively?

- 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 themselves, or to others, or damage the public realm more generally (for example, because they are very expensive, or otherwise adversely affect public health)?[9]

There is not space, and it is not appropriate, to offer an in-depth response to these questions here, but it is worth unpacking them each a little further to show their importance and some of the challenges of responding to them. It is also worth repeating in advance that none of the questions are meant to undermine the general case for involvement; rather they simply indicate concerns which taken together show the ethical importance of 'tailoring' involvement carefully.

Problems of capacity - It is well known, in relation to informed consent processes, that patients' autonomous (unpressurised) choice to consent to, or refuse, treatment must be respected, assuming that patients meet necessary thresholds of competence and understanding. It is also well known that in some real world cases clinicians have to make careful professional judgements about whether these thresholds are met and, in either case, how to tailor information and conversations to best meet the varying needs of different patients. In practice, these judgements cannot be based on some exact formula but are necessarily based upon professional experience, sometimes including 'educated guesstimates'. There is also not one fixed level of capacity for each individual patient because the capacity for independent autonomous judgement can vary depending upon the social and emotional conditions individuals find themselves in and the kinds of circumstances and choices they are faced with.

In essence, professionals are faced with deciding when a degree of paternalism may be called for; i.e. when it might be justifiable to promote the interests of patients in ways that effectively ignore rather than follow patients' expressed preferences. In the case of informed consent, it is clear that setting aside patient preferences has to be the exception rather than the rule and that, even then, steps must be taken to limit exercises of paternalism (for example, by involving family members to help represent the interests of patients). The crux of informed consent is that it should protect

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9 *See Cribb, Donetto & Entwistle (2011) for a similar list of questions – the discussion here was written in parallel with the discussion there.*

patients from unwarranted paternalism and that patients should not be subjected to clinical interventions which they say they don't want, unless exceptional conditions apply.

However, the situation is less clear-cut with much richer, and more demanding, models of involvement. If more full-blown shared decision-making models are applied to prescribing decisions, for example, there is the potential for high levels of exchange of information and perspectives between patients and professionals, including the sharing of clinical expertise on the evidence base relating to specific medicines. Patients will have very varied capacities (and desires – discussed next) to engage in these exchanges including, for example, in detailed technical discussions. Here clinicians have to make analogous professional judgements about when it is unrealistic and unproductive to pursue certain lines of communication. This is especially important because there is a real risk that some approaches to communication may not only be unproductive but may also be ethically counter-productive – because in practice they may generate confusion and thereby undermine the clear lines of communication that are necessary to ensure that the basic conditions of informed consent are met.

Unwanted involvement - One factor in determining the right kind and level of involvement is the question of how much involvement is wanted by individual patients. Respect for the patient's autonomy means that, not only patients' expressed preferences about treatments should be respected, but also that similar consideration should be given to their preferences about involvement. As with treatment decisions, there may be some room for joint discussion and negotiation about the right levels of involvement (it cannot just be assumed that whatever preferences about involvement are encountered or expressed in the first instance necessarily represent the patient's considered, stable and autonomous decision about involvement), but patients' considered preferences need to be taken seriously. This creates potential dilemmas for professionals who may have very good reasons to wish to encourage greater levels of patient involvement (in prescribing decisions, for example), but at the same time need to avoid oppressive forms of 'enforced involvement'. Of course involvement is not an 'all or nothing' thing and, 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 (Entwistle, Carter, Cribb, & McCaffery, 2010).

Creating distress - If involvement strategies cause distress in certain cases, then that might be a reason for dropping or moderating them in those cases. However, there should not be a presumption that anxiety or distress are necessarily and always 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. This is certainly a common feature of non-clinical life choices. Attempting to elicit patients' values and preferences is often a critically important element of determining what is 'clinically appropriate'. Unless prescribers have some sense of individual patients' 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 it makes sense to attach considerable weight to eliciting and reflecting the preferences of patients in determining the 'right' treatment (including no treatment). This is the central rationale for shared decision-making approaches. So, whilst it is clear that the creation of anxiety or distress is an ethically relevant factor here, as above, there are genuine dilemmas about how far a degree of anxiety might be outweighed by the advantages of greater patient involvement, providing, of course, that the level of anxiety is not so high as to preclude the possibility of effective involvement.

Undermining trust and support - Another legitimate concern about the unqualified promotion of greater levels of patient involvement in clinical decision-making is that this has the potential to undermine the trust that patients have in professionals and the opportunities for professionals to offer support and reassurance to patients. As has already been suggested in relation to each of the three concerns already discussed, it would be counter-productive to insist on forms of involvement in those instances where doing so would undermine the foundations of effective professional-patient relationships. However the possible damage to professional-patient relationships depends 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.

From patients' perspectives, the right 'style' can be particularly significant for a sense of involvement (Burkitt-Wright, Holcombe, & Salmon, 2004; Entwistle, Prior, Skea, & Francis, 2008; Fraenkel & McGraw, 2007; Levinson, Kao, Kuby, & Thisted, 2005).

Bad outcomes - Finally, there is the question of 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, in practice, result in 'bad outcomes'. The phrase 'bad outcomes' is being used here as shorthand for a broad range of phenomena – the 'badness' of some of which would be contested - including costs and risks to the health of the individuals concerned, the public purse or the public health (for example, if patient choice led to more widespread and costly use of antibiotics and also compromised herd immunity). The risks, in some instances at least, to the professional-patient relationship (just discussed) provide another potential example, as does the possibility that certain approaches to involvement may actually reinforce health inequalities (for example, by further advantaging those who are the most assertive 'consumers' of healthcare). Once again, there is only space here to indicate this family of concerns and risks, rather than to further unpack or analyse the many complexities and controversies they generate. But these concerns certainly help to provide an argument against unfettered patient choice of medicines.

However choice and involvement are not the same things, and arguments for patient involvement in the form of shared decision-making or concordance are not arguments for excluding clinicians from decision-making. Concordant approaches to prescribing mean that professionals maintain essentially the same kind of control over access to potentially harmful medicines. Indeed, as the language of 'shared decision-making' makes explicit, clinicians would still retain their own responsibility for decision-making and would remain *professionally accountable* for decisions made about prescription only drugs. This final point merits underlining. Responsible professionals have to be ready to attend to the value-based questions reviewed here, and to navigate the ethical dilemmas raised by involvement practices, because they are professionally accountable for their participation in decision-making. In fact, another way of indicating the practical and ethical obstacles facing the implementation of shared decision-making, and of summarising the overall

ethical challenge, is to ask, 'how can we *both* extend patient involvement *and* protect professional accountability?'

In summary, all of the ethical concerns reviewed here 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.[10]

The issues rehearsed here show how misleading a simple deficit picture of professionals can be. The notion that the 'drag' on the promotion of more patient involvement is simply the conservative attitudes of professionals (or patients) obscures many crucial matters. Increasing levels of patient involvement entail considerable practical challenges and amongst these are the ethical challenges of tailoring involvement practices in ways that balance competing considerations together. The operationalisation of patient involvement is shot through with professional dilemmas. Of course one of the central values in healthcare ethics is that professionals should respect the autonomy of patients, but (a) it is not always straightforward to know what that entails in specific cases, and (b) following the choices of patients (even when we feel reasonably confident that these are autonomous choices) can, on occasions, conflict with other important values such as patient protection or the public interest. Professionals are accountable for the practices they engage in, including the forms of involvement they facilitate, and they cannot choose these practices lightly.

If we are interested in closing the policy-practice gap in this area, then we need a good understanding of the factors that produce it. Repeating abstract policy ideals and slogans will not be enough. This is especially so if, as sometimes happens, ideas with very different meanings, and with a range of possible interpretations, are 'fudged together' as if they all essentially mean the same thing and require the same strategies (for example, if 'shared decision-making' and 'patient choice' are equated). Even where more clearly defined and differentiated goals are specified, the problems of implementation are not primarily problems of will power but problems of putting practical resources in place. Amongst these resources are professional skills. But the skills which are needed are not narrow technical competences – for

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10 *Although it is worth noting that the arguments presented here for 'tailoring' involvement could equally plausibly be presented, using a more contentious language, as arguments for 'restricting' involvement, depending upon cases and purposes.*

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example, an understanding of the principles of involvement plus generic communication skills – they are some of the most demanding kinds of practical wisdom that make up professionalism in its fullest sense (discussed further in the next section).

The risks of counter-productive policy

Before finishing this section it may be worth stressing that focusing on these ethical challenges is not merely of abstract or philosophical importance. Unless we are clear about the various 'goods' and 'bads' at stake, there is always a risk that well-intentioned policies or practices may have negative side effects, and may even, as far as respect for patients is concerned, be counter-productive.

Whilst striving to enhance the levels of involvement afforded to patients we need to keep a clear-sighted view both of the 'real world' circumstances we are working in and of the range of 'goods' that matter. Recent reports from the Ombudsman (Parliamentary and Health Service Ombudsman, 2011) and Care Quality Commission (2011) as well as recent publications by The Patients Association (2010) shows how there are instances within the NHS where the basic levels of respect and dignity that should be afforded to individuals are simply not delivered. Correcting this is unquestionably an ethical imperative. Obviously this depends upon the standards of individual healthcare workers and their personal and professional values. However, these need to be underpinned by attention to the structures and cultures within which people work. No one could deny that basic respect and dignity is of central importance but, even here or especially here, we cannot simply rely on the assertion of these values; rather we need to take steps to embed them in practical settings. Exactly the same is the case for the more subtle, and more interactive, forms of respect reflected in models of involvement.

The apparently extreme example of undignified treatment is relevant for another reason. Whilst we cannot afford to postpone strategies for greater patient involvement until we have guaranteed basic dignity for all, we need to be careful that within specific services and settings we are not attempting to run before we can walk.[11]

For example, Mol (2008: 84) argues:

> When in interviews - or elsewhere - patients complain about bad health care, they may mention that they were not given a choice, but more often they talk about neglect. They describe how their particular stories or personal experiences were not attended to. They would have appreciated more action and more support … The point is not that people boss you about, but that nobody cares.

Mol uses this kind of observation as part of a broader critique of what she calls the 'logic of choice' as opposed to the 'logic of care'. Whether or not someone wishes to endorse her general critique of choice policies[12], everyone ought to be sensitive to the insights that: (i) 'choices' offered to patients are unlikely to be meaningful ones unless the basic foundations of respect and care are in place; and (ii) there may be occasions – as the above summary of ethical dilemmas indicates – where there are significant tensions between engaging people in choices, on the one hand, and respecting their wishes and caring for them, on the other.

As the five 'ethical obstacles' just reviewed all demonstrate, professionals frequently have to balance together the 'minimum' they owe to patients in relation to involvement and the 'maximum' kinds and levels of involvement that are possible in principle but do not always seem relevant or practicable. In all cases professionals should be treating patients with respect and, in relation to treatment choice, ensuring informed consent. Other, richer and more open-ended, forms of involvement may also be possible and desirable but nothing done in their name should threaten the foundation of basic respectful relationships.

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11 *This was a theme that also arose in the fieldwork which fed into Appendix 1 (and other elements of this discussion paper) and was repeated by several key informants.*

12 *Although this discussion paper is not the place for an ideological analysis of involvement policies it may be worth noting in passing that the different 'versions' of involvement, person-centredness or shared decision-making (alluded to in this and the next section) have partial affinities with different ideologies of healthcare organisation, and thus ethical debates about involvement cannot be neatly disentangled from political debates. At the same time it should be stressed that (a) connections between 'involvement models' and political ideologies are not at all straightforward , and (b) both 'consumer/choice' and 'collective/democratic' policy tendencies co-exist in mainstream UK health policy, with the rhetorical balance between them varying in constituent countries.*

3. CLOSING THE POLICY-PRACTICE GAP

Two broad lessons emerge from the analysis of the policy-practice gap in the previous section. First, the analysis suggests that more work needs to be done at both ends of the policy-practice divide. Policy ideals need to be further specified and supplemented by richer conceptions of the nature of health professionalism and by a range of more differentiated models of patient involvement that reflect the diversity of practice. At the same time, it is necessary to identify a number of feasible 'stepping stones' to help translate these ideals into diverse practical contexts; steps that can be developed and implemented in existing healthcare settings without waiting for wholesale transformations. It is also important to explore more transformative notions, of course, providing the challenges of making such transformations are acknowledged. In short, policy development and practice development need to be better connected. Second, and this is arguably the central lesson, there is a severe limit to how far the changes sought can be achieved by using standardised recommendations or purely 'technical' strategies. Both the ethical and the other practical challenges of implementing higher levels of patient involvement call for context-specific, flexible and imaginative professional judgment or what philosophers, following Aristotle, often call 'practical wisdom'[13]. There is certainly an important role for guidelines and other tools and practical resources but the value of these things *depends upon and cannot replace* healthcare professionalism. The remainder of this section will expand on these lessons, reflecting upon the challenges of renewing professionalism, developing practice and, in particular, of closing the gap between guidelines and practice in the area of medicines prescribing and adherence.

Renewing and strengthening professionalism

The policy orthodoxy surrounding patient involvement contains more or less explicit models of what is often labelled as 'new professionalism'. Whereas 'old professionalism' is represented as paternalistic (and generally 'top-down'), new professionalism is based on partnership and is 'patient-centred' or 'person-centred'. In some respects, the shift to new professionalism is portrayed as something that is well underway as a product of broader historical and cultural change, as new generations of 'providers' and 'users' take their places in evolving public and health services. In other respects, this shift is seen as something which needs to be further developed, steered and underpinned by policy initiatives, models and guidelines on good practice, and new educational approaches, all designed to remedy the deficit of the old professionalism.

In this context of helping to create, guide and support new forms of professionalism, policy ideals and models such as 'patient involvement', 'shared decision-making' or 'patient-centred' care make sense and are valuable. They help to articulate and disseminate visions of reformed practice. Their limitation is that they are typically expressed in generalised ways. As a result, they are more helpful in identifying what might count as bad practice than they are at specifying good practice. Take the notion of 'patient-centredness', for example.

Patient-centredness is an extremely elastic notion that seems to be able to accommodate all but the most unresponsive, uncaring or solipsistic forms of professional behaviour. It accommodates a range of things which, whilst

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13 *It is impossible to give a full account of practical wisdom here but, in summary, it is that form of practical knowledge which is concerned with the quality of activity itself and not only the quality of the products of activity. We are used to the idea of distinguishing between 'good work', in the instrumental sense of work that produces good products or results, and 'good work' in the broader sense of ethical or 'virtuous' work. Obviously both 'good results' and 'good actions' are important if we are to judge a health professional to be good overall but we can make sense of the distinction being made here. The former requires technical knowledge and the latter requires something more - practical wisdom. In the case of practical wisdom the means-end rationality associated with technical knowledge directed at achieving certain results is insufficient. Rather than being determined by the specification of any instrumental object or end, what matters and what is being pursued in practical wisdom includes the right kind of conduct. In trying to act with practical wisdom we must be ready to deliberate about both the means by which the ends of an activity are achieved and the ends themselves, and this requires the capacity to make discriminations not only about instrumental claims but also about what is most valuable case by case - and on that basis, to make judgements about the best (most virtuous) forms of conduct and ways to act in each set of circumstances (see, for example, Hursthouse, 1999).*

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important in their own right, can be in tension with one another, for example: (a) a concern with respecting and protecting patient dignity;[14] (b) a concern with responding to the particularities of the individual patient (i.e. properly utilising biological, psychological and/or social facts about the individual);[15] (c) a concern with fully taking note of and taking into account patients' subjectivities or life-worlds and in particular patients' preferences of various kinds; (d) a concern with some degree of shared decision-making (or shared control/power/responsibility etc.) between professionals and patients; (e) a concern with fostering quasi-consumerism where the goal is to offer a range of service choices and to develop services and systems that are more responsive to patients' demands. These items are not necessarily incompatible with one another. But these dimensions of patient-centredness *can* be incompatible with one another and, exactly as was illustrated through the discussion of dilemmas in the previous section, 'good practice' is crucially dependent on an understanding of the tensions between these things and of how tensions might be managed from circumstance to circumstance, and case to case.

It is clear that a professional who had little regard for a patient's dignity, was inattentive to the distinctive biological or social needs of this particular patient, took no interest in the patient's concerns and preferences and excluded the patient from key decisions would be a very bad professional! But it is far from clear what an 'ideal professional' would do if he or she, as they undoubtedly would, cared about all of these things. This is because there is very extensive scope for both contestability and variability with regard to these matters. That is to say, there is: (i) room for disagreement about how each of these considerations should be interpreted and how these (and other) considerations should be balanced

where they pull in different directions; and, in addition, (ii) a need for a range of different emphases both to reflect diverse clinical contexts and to reflect the different 'personal styles' and orientations of professionals and patients. This complexity echoes the complications rehearsed in the previous section about the problems of translating policy ideals into practices suited to specific settings and cases – a translation that involves addressing intertwined practical (i.e. organisational and ethical) challenges.

Given this complexity, tightly defined and prescriptive methods of professional regulation (for example, performance management approaches or 'tick box' protocols) are of limited value because, beyond a point, they are positively corrosive of the qualities needed to deliver patient involvement in two respects: (i) for the reasons given above, case-by-case professional judgement is an ineliminable element of skilful and successful patient involvement practices; guidelines have a place here but only so long as they do not become too narrowly defined or implemented; and (ii) in some instances patient involvement involves a 'human' (and voluntary) engagement between professional and patient that can be quite demanding of the personhood and emotional resources of professionals. In these instances 'authentic motivation' is a necessary ingredient of good practice and of what is valued by patients. There is a deep tension between this kind of 'genuineness' and the kind of motivation generated by compliance with governance regimes. This is not to say that there is no place for the use of incentives to drive change but rather that incentives cannot solve every problem, should always be accompanied by a health warning about side effects, and should – where possible – be used as (at most) one element of a broader professional development process rather than instead of one.

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14 *The King's Fund Point of Care programme reports an emblematic example of the 'failure to see the person in the patient': Significantly, the ambulance crew were the only people in the entire seven weeks who formally introduced themselves and asked what she would like to be called. Thereafter, for the first six weeks of her admission, she was called Elizabeth, which is her first name, which she has never been called in her life, ever. She's only ever been called by her middle name. But the NHS IT system records your name. All her labels were wrong. In spite of the fact that on a daily basis all of us told the people caring for her that her name is Margaret, and that is what she likes to be called if they want to call her by her first name, all of them called her Elizabeth. And that became very significant when she became confused. (Goodrich, & Cornwell, 2008: 9).*

15 *Many of the uses of 'personalised medicine' fall into this category – what these uses refer to is an extension of biomedical science to properly reflect individual variation rather than a concern with patient agency and preferences. See, for example, Personalised medicine: hopes and realities. (2005). The Royal Society, London.*

The key point to underline here is that just as specific approaches to involvement run the risk - in the 'wrong circumstances' – of being counter-productive, so too do some of the mechanisms that have been designed to 'steer' professionals away from 'old-fashioned', disrespectful or ineffective models of working. This is because they easily slide into mechanisms that undermine professionalism itself. This fundamental danger is increasingly recognised and articulated not only by professionals on the ground but by thoughtful analysts and commentators (e.g. Green, 2010; Iles, 2011). In UK healthcare this danger is particularly acute because powerful converging currents in clinical governance (linked with evidence-based healthcare) and in public service reform (linked with managerialism) both have strong 'technicist' dimensions and thus, particularly in combination, have the potential to be counter-productive in this way. Through attempting to specify what counts as 'appropriate care', 'good practice' or 'quality' and through attempts to guarantee the 'delivery' of these specified services, these currents (unless they are very carefully circumscribed) risk seriously undercutting the agency, humanity and discretion of professionals – the core qualities that make appropriate and good quality healthcare possible. These potentially counter-productive currents are also manifest in, and reinforced through, narrow and impaired discourses of, and conceptions of, practical knowledge and education, that tend to equate professionalism with the exercise of 'competences' or 'skills'. [16]

In a climate where healthcare is strongly managed and one in which the language of involvement exerts a powerful rhetorical force, there is a danger – discussed extensively in academic fields like sociology – that policies and practices are 'sold' as forms of patient involvement but are really no more than alternative forms of steering patients (as well as professionals). That is, there is a risk that patient involvement comes to be used as a more subtle and benign-seeming means of 'managing' patients. These are murky waters and there are no easy ways of capturing the distinction between 'inviting patients to help make decisions' and 'steering' them; [17] but everyone can recognise this possible hazard from examples of supposed 'shared decision-making' in their own personal lives. However, it is characteristic of rich and reflective forms of professionalism that professionals are at least aware of these dangers and are sceptical about 'public relations' uses of involvement to describe practices which are not essentially different from so-called 'old professionalism'. More widely, a number of people have voiced concerns about the risks of policy drivers, whilst being aimed in some sense at the overall good, creating or exacerbating tensions between the interests and perspectives of individual professionals and patients. This has been discussed, for example, in relation to the prescribing of statins, specifically in relation to the difficulty of achieving a balance between population-oriented and patient-oriented practices (Sculpher, Watt, & Gafni, 1999; Peckham & Wallace, 2010; Hann & Peckham, 2010).

This worry about the corrosive (and counter-productive)[18] effects of 'pushing' involvement agendas though managerialist means is not a trivial one. As Green (2010), Iles (2011), and others, have argued there is the growing potential for a profound malaise in healthcare and public service professionalism. The only way to respond to the threat of this malaise is to ensure that strong and 'deep' approaches to professional leadership and professional education assert and reassert the crucial role of 'practical wisdom' as intrinsic to professionalism. This means a renewed investment in both collegial and democratic currents of professionalism as checks and balances against managerial currents.[19]

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16 *It is arguable that these limited conceptions of the nature of practical knowledge play an especially corrosive role in this area. The risk is that education for patient involvement is reduced to training in communication 'behaviours', when practical wisdom (based on a broader understanding of involvement ideals and challenges) should be centre stage. For very good analyses of the philosophical shortcomings of narrow conceptions of practical knowledge, written from contrasting philosophical perspectives, see Lum (2009) and Winch (2010).*

17 *Some of the respondents in the empirical study that informed Appendix 1 volunteered this concern and 'admitted' to the sometimes thin line between 'involving' and 'managing' patients. This possibility has been reported elsewhere (e.g. Jones et al., 2004; DoH & Farrell, 2004).*

18 *Counter-productive in the sense discussed at the end of the previous section, i.e. policies that are supposed to produce more respectful relationships with patients having the practical effect of undermining respect.*

19 *Strikingly similar points have been made in recent major contributions to the study of 'performance regimes' in the UK public sector (e.g. Walshe, Harvey, & Jas, 2010; Talbot, 2010). For example, Colin Talbot (in Walshe, Harvey, & Jas, 2010, p283) notes how despite the official commitment of contemporary UK governments to a 'balanced approach' to better public services which recognises the importance of building capacity and capability (including professional leadership and development) and of users shaping services, 'in practice for most of the past twenty years central governments of both main parties have adopted very clear priorities in performance interventions: first, top-down managerial interventions; second, systemic-competitive interventions (league tables, internal markets, etc.); and only a poor joint third a focus on capacity and genuinely empowering users (as opposed to rhetoric about the idea)'.*

Overall we need to move beyond the simple 'old' versus 'new' models of professionalism debate towards richer conceptions of professionalism which are not about picking the one right model or approach but about having the experience and wisdom to pick models and approaches according to the circumstances and cases at issue (Cribb, Donetto, & Gewirtz, 2009).

Developing practice

This paper is largely focused on the broad policy challenge of patient involvement in relation to medicines choices rather than on the 'nuts and bolts' of bringing about change on the ground. Nonetheless, these 'nuts and bolts' matters are crucially important if policy rhetoric is to be something more than rhetoric. For the reasons set out above, the most important platform for practice development in this area is the collegial and educational cultivation, and institutional facilitation, of rich forms of professionalism embodying practical wisdom. However, providing this platform is put in place, attention also needs to be paid to putting in place concrete 'stepping stones' towards more meaningful and effective patient involvement practices.

Exactly what suitable stepping stones will look like – given the importance of context sensitivity and practical wisdom – will depend very much on the circumstances and what are judged to be both helpful and practicable steps (and in turn, of course, this depends upon the specific purposes of different involvement practices). But those who are committed to practice development do not have to start from a blank sheet of paper: there are important and carefully trialled examples of successful initiatives to draw and build upon. In the remainder of this section the importance of two broad styles of work in this area of practice development will be briefly summarised and contrasted. The hope is not only to provide some quick indication of useful directions but also to indicate some of the underlying contrasts between approaches and the broader policy choices that need to be made.

All relevant work on practice development will, of course, emphasise similar themes, most notably the importance of effective professional-patient communication and hence communication skills, and the potential for developing and using information and communication aids or tools (whether paper- or web-based) to support communication and decision-making. However, they will vary in the emphases they place upon the broader purposes of, or 'visions of', patient involvement practices. As with the 'old' versus 'new' professionalism debate, discussed above, the task of the reflective professional is not necessarily to identify the single right answer here but to understand the possibilities and their relevance for their own contexts of practice.

Probably the most developed body of practice here is that originally associated with the Foundation for Informed Medical Decision-Making (FIMDM) (see http://www. informedmedicaldecisions.org/). FIMDM has made a major contribution to the understanding of, and research and policy on, shared decision–making. This contribution is not purely theoretical but includes demonstration sites and the 'rolling out' of practice. The driving rationale of the approaches they have developed is the improvement of the quality of medical decision-making by attempting to ensure that relevant patient perspectives are incorporated in the process of decision-making; hence the label 'informed medical decision-making'. This approach includes the development of 'patient decision aids' – tools which provide patients with the evidence-based information they need to understand the clinical choices they are facing and which can also help them clarify and articulate their own values and preferences regarding possible treatments (including no treatment).[20] These decision aids can also be used in conjunction with various forms of intervention from others to help enable, encourage or support patient involvement in decisions. In short, this might be thought of as a 'decision improvement' approach to involvement – it improves clinical decision-making both by 'informing' the patient about the things they need to consider and by 'informing' the clinician about what matters to the patient. This approach to practice development also has included

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20 *For related research see, for example, Légaré et al. (2003), O'Connor et al. (2003) and Elwyn et al. (2006). A fuller explanation of patient decision aids, and an A to Z searchable inventory of decision aids, can be found on the Ottawa Health Research Institute website (see http:// decisionaid.ohri.ca/).*

attention to quality standards for decision aids and the potential use of policy incentives (including financial incentives) and legislation to underpin the delivery of the improved decision quality.[21] Although this tradition of work owes much to North American colleagues, researchers in the UK have also had a longstanding interest in this area and made substantial, critically reflexive and internationally influential contributions to its development and dissemination (for example, see Coulter, 1997, Elwyn et al., 2003 and Edwards et al., 2006). Similarly, there are an increasing number of directly related practice development initiatives in the UK.[22]

There is a strong research base showing the potential for this kind of approach although – for the reasons summarised above – we should of course be wary of seeing any approach as in itself a 'magic bullet'. There is plenty of evidence of important benefits from the use of decision aids, for example, but there are some questions remaining about whether the evidence accumulated so far is as strong on some indicators as it is on others.[23] There are also some significant theoretical critiques of decision aids – for example, questioning the extent to which they can construct the nature of decisions in either realistic or neutral ways (Nelson, Han, Fagerlin, Stefanek & Ubel, 2007; Stiggelbout et al., 2004; Stiggelbout et al., 2008). However assuming that they are implemented in a flexible and self critical way and with thought given both to how they might be suitably adapted to, or developed for, specific functions and contexts and to the appropriate kind of support

(where necessary) needed to enable their effective use, then such criticisms lose much of their force.[24]

Of course there is no intention here - as part of such a broad-brush summary – to offer an overall evaluation of this or any approach. All that it is important for current purposes is to underline the point that this approach is designed to serve a fundamentally important function. It is a response to the fact that, at least on many occasions, both knowing what counts as a good quality clinical decision (even on quite a narrow conception of clinical goals) and being able to make such a decision *depends upon* knowing what matters to the patient. When different clusters of potential benefits, challenges, side-effects and risks have to be weighed together the way in which the clinician involved – if they were the patient - would weigh these together is not the main issue. By contrast the preferences of the actual patient with regard to these things is of central importance.[25]

This approach to shared decision-making – leaving aside whether and how decision aids or other specific tools and techniques are used in it – therefore attends to the question of how key clinical decisions can be properly responsive to patients' concerns and preferences. But, as was discussed in section 1, involving patients in clinical decisions in this way (although of fundamental importance) can be seen as relating mainly to 'one direction' of involvement. There is also the overlapping question of how clinicians and clinical work might more

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21 *A very good recent overview of this approach and these issues is offered in Moulton & King (2010).*

22 *For example, quite recently the first few patient decision aids have been trialled on the NHS Direct website, and Health Dialog and other agencies are working in the UK to disseminate the model of decision improvement tools and practices.*

23 *The review of systematic reviews by Coulter & Ellins (2007) of 'strategies for informing, educating and involving patients' (in their care generally – not just in relation to prescribing and medicines use) shows a mixed evidence base. Good evidence exists for the benefits of patient decision aids and for the provision of coaching and question prompts to enhance the capabilities and confidence of patients in relation to participation. However, most of the demonstrated benefits of these interventions relate to comparatively 'soft' (although nonetheless important) outcomes. For example, communication and coaching interventions can improve participation in decision-making, and patient decision aids have been shown to improve patients' knowledge and understanding and 'to improve agreement between patients' preferences and subsequent treatment decisions' (p26). There is much less clear evidence of similar impacts from these efforts (to improve clinical decision-making through patient involvement) on subsequent health behaviours and health status (p25).*

24 *But it should be noted that, the more these conditions apply, the more resource intensive these tools become, with regular work having to be invested into adapting them according to circumstances.*

25 *Of course, there are cases where understanding the preferences of the patient may play a reduced role in determining the quality of clinical decisions – for example, where there is no significant choice, or where the cost-benefit differences between available options are dramatically large and there is thus no real diversity in different patients' preferences. But this still leaves other reasons for engaging with patient preferences which might feature in broader conceptions of 'quality'.*

INVOLVEMENT, SHARED DECISION-MAKING AND MEDICINES

broadly support patients' health-related practices, i.e. how health professionals can, through 'involving themselves' in understanding the experiences and concerns of patients, ensure that health services are suitably supportive of patients' broader lives and health related practices.

The tradition of practice development that best represents this broader interpretation of involvement and which focuses on practices that extend well beyond clinical arenas is work on 'supported self-management'. The fundamental insight that lies behind self-management approaches is the recognition that even those patients who happily rely upon clinical interventions and professional support will, nonetheless, have to spend the overwhelming majority of the time managing their health for themselves, possibly with the help of other lay carers. In addition, of course, many people deal with both short and long-term health-related concerns without seeking any help from professionals. Self-help groups and related community organisations and social movements have long recognised this fact and helped to give visibility to this kind of 'lay' expertise and work. If we start from this insight, the question then becomes, how can health service institutions and professionals operate in ways that recognise, 'work with' and actively support self-management (rather than unwittingly undermining it).

In the UK much pioneering work has been done to develop and trial patient self-management, and related educational and professional processes of patient support, by specialist agencies such as Diabetes UK. But the idea of self management itself does not entail a disease-oriented focus and is used as an organising idea for thinking about long-term illness agendas by agencies with a more open-ended remit, perhaps most notably the 'Expert Patient Programme' which offers training and other services in different aspects of self management for both patients and professionals. One such agency that has made a very substantial contribution to conceptualising and trialling 'supported self-management' and which aims to integrate the lessons of self-management into health services contexts, at scale, is the Health Foundation (http://www.health.org.uk/), especially through 'Co-Creating Health' and related service improvement programmes.

Co-Creating Health, which builds upon international experience and research, is an exciting and crucially important initiative for patient involvement practice development in the UK NHS. This is because, through adopting a 'whole systems' approach and by seeking to embed the principles of self-management (and partnership working more generally) into a range of NHS contexts, it pays attention to the 'nuts and bolts' of improvement and seeks to bridge the gap between clinical and lay perspectives and roles by creating shared frameworks for collaborative working. Since 2007 Co-Creating Health has worked with eight NHS sites (in the areas of Diabetes, Depression, COPD and Musculoskeletal Pain) and helped to develop and implement tools and cultures that enable professionals and patients to work collaboratively on the agenda-setting, goal-setting and goal follow-up stages of supported self-management. This explicitly 'holistic' approach to practice development has meant working on three interconnected fronts at once: working with patients on self-management knowledge and skills, working with clinicians on developing advanced practice skills encompassing attitudes, knowledge and skills of collaborative working and, not least, working on service re-design to enable collaborative or 'co-productive' healthcare relationships. Some of the lessons of the programme, including some of the health-related benefits for participants have already been collated by the Health Foundation (see e.g. http://www.health.org.uk/publications/snapshot-co-creating-health/) but the programme is on-going and broader evaluations, including an external evaluation (see Jones, 2010, Chapter 14) are in process. The obvious challenge to this kind of approach arises directly from its principal strength, i.e. because it takes a holistic 'system change' approach it needs considerable broadly diffused effort and commitment to realise, and, for related reasons, is thus not easily susceptible to 'gold standard' evidence claims.

The 'decision improvement' approach and the 'self-management support' approach to practice development are broadly complementary. Whereas the former aims to strengthen clinical decision-making the latter seeks to broaden conceptions of clinical work – to extend, and where necessary to erode, narrowly biomedical versions of health professionalism. Whereas the former zooms in on key clinical encounters in which important decisions have to be made, the latter zooms out to ask about care pathways and the broader systems and cultures of care and asks how these can be enhanced to support patients' ongoing lives. Proponents of the two approaches also respond in different, but again complementary, ways to

the worries rehearsed in the previous section about 'full blown' versions of shared decision-making not necessarily being appropriate in, or practicable for, every context and case. Those in the former tradition strive to identify, and target effort towards, the most crucial decision junctures (where 'preference-sensitive' and 'fateful' decisions need to be made i.e. those which depend the most upon, and have the biggest impact upon, patient's own values and biographies); whilst those in the latter tradition look to foster a variety of less structured models and styles of responsive and collaborative working for individuals, groups and communities.

Both of these contributions are vital to practice development in the area of medicines and patient involvement because, as discussed above, this is an area at the intersection of clinical and health-related practices. The focus both on prescribing decisions and on 'adherence decisions', and the close links between these things, mean that both 'decision improvement' and 'self-management support' are important. Indeed the area of medicines shows the need to combine the approaches very clearly: prescribing is itself often a process with an ongoing feedback loop between the patient and the professional. It is not just that a 'correct' prescribing decision needs to reflect the preferences and motivations of patients but also that prescribing may involve an extended process of decision-making, the 'correctness' of which will, in part, be informed by the compatibility of treatment regimes with patients' preferences and lives.

It is encouraging that there are influential traditions of practice development that provide conceptual and practical resources for, and real world examples of 'stepping stones' to, improved healthcare services and professionalism. But the underlying point of this section merits repetition: these different traditions of work may be broadly complementary but there are important differences in emphasis between them and anyone who has a commitment to reform in this area should be wary of fudging different examples

together as if they all merely represent different means to a common end. Different models of practice development embody different visions of the purposes of healthcare services and different conceptions of the optimum roles and relations of professionals and patients. Both policy development and practice development depend upon a willingness for professionals and others to be able to openly and clearly reflect on, and debate, these different visions and conceptions. For example, this means a readiness to recognise and discuss the fact that 'shared decision-making' (much like 'involvement' itself, or 'patient-centredness' – discussed in the previous section) does not have a single meaning but has a range of interpretations.

There are a large number of versions of shared decision-making – including narrower and broader versions - depending on a range of variables, in particular: (i) the kind of relationship that is envisaged between professional and patient (for example, how far should the professional see their role as about protecting the independence of the patient from professional judgement and values, or as about supporting co-deliberation about values as well as evidence? (discussed further in Cribb and Entwistle, 2011);[26] and (ii) about *which* 'decisions' fall within the scope of shared decision-making, for example, whether the focus is essentially on key clinical decisions (the typical focus of the 'decision improvement' tradition) or extends to 'systems re-thinking' (one of the foci of the 'supported self management' tradition). As was said in the previous section in relation to the 'tailoring' of involvement, the important question is not whether something like shared decision-making is a good thing – in some sense partnership models or collaborative ways of working will invariably be good things. The important question is about what versions of shared decision-making might be appropriate to (i.e. practicable in, and fulfilling the right purposes for) different circumstances and cases.

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26 *There are other ways of conceptualising the potential tensions inherent in models of shared decision-making. Finding the appropriate combination of, and balance between, 'choice' and 'care' in different cases (as discussed at the end of the previous section) is another way of formulating such tensions. Much depends upon exactly which rationale for shared decision-making is stressed. This has also been explored empirically in a number of studies; for example, Mendick et al. (2010) suggest that in some cases what ultimately matters to patients is whether they are sufficiently involved to feel that they 'co-own' the decision rather than that they are necessarily responsible for 'co-making' the decision (for a related discussion also see Edwards & Elwyn, 2006 and Entwistle and Watt, 2006).*

Improving involvement in prescribing and supporting adherence: from guidelines to practice

As explained in section 1, there is also a strong tradition of work on patient involvement specifically in relation to medicines, especially the work on 'Concordance' (one version of shared decision-making) originally fostered by the Royal Pharmaceutical Society. This work has included a substantial body of research and policy development and has resulted, for example, in the recent NICE guidelines on patient involvement in prescribing decisions and medicines adherence.[27] These NICE guidelines (along with accompanying and associated developments; for example, the NPC Plus competency framework (Clyne, Granby & Picton, 2007) provide a very substantial, and well-supported, platform for practice development in the area. They authoritatively summarise the broad rationale, principles and characteristics of good practice. Nonetheless, for all the reasons discussed above, there remain challenging questions about how best to translate these guidelines into actual practice so as to ensure that they have the level of impact that they deserve. This section will briefly rehearse some of these questions and offer some beginnings of a response to them. The core issues have all been fully discussed above and will only be briefly alluded to here. They concern the challenge of translating between general guidance and very particular circumstances and cases (and the possibilities afforded by specific contexts); the need for practical wisdom in recognising and managing the contestability of ideals and purposes; and the need to address 'nuts and bolts' factors, i.e. finding real world 'stepping stones' to improvement, without which guidelines inevitably remain detached from practice.

Given all the complexities of healthcare change, broad guidelines, such as the NICE guidelines, can help steer and support practice development. It is impossible to do justice to these guidelines here, not least because the full version runs to 364 pages (see http://guidance.nice.org.uk/CG76). They draw upon considerable research evidence to generate guidance for prescribers. In essence, they offer advice on how to manage both intentional non-adherence (patients choosing not to take their medicines) and unintentional non-adherence (patients not taking medicines because of other factors). In addition to sections on medicines reviews and professional-to-professional communication (see below) the advice focuses on enhanced communication between clinicians and patients, and puts particular emphasis on the greater involvement of patients in medicines decision-making. It includes what might be seen as a checklist of communication 'tips' and techniques (for example, inviting questions from patients and asking them open-ended questions). However, alongside and, as it were, 'beneath' this attention to communication skills narrowly construed, is a clear concern with fostering a set of attitudes and values among prescribers.

Prescribers are not only reminded that 'patients have a right to decide not to take a medicine' (assuming they have 'capacity') but are encouraged, more generally, to accept 'that patients may have different views from healthcare professionals about risks, benefits and side effects' (NICE, 2009, p8-12).[28] 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. In short, although it is not signposted in these terms, what is being advocated is not merely more technically effective means of transferring or transacting information about medicines, but forms of relationship that are more open, richer and more respectful towards patients.

The NICE guidelines, and the body of work that supports them, attend both to involvement in prescribing and support for adherence and, therefore, they reflect many elements of the two approaches to practice development and shared decision-making just discussed – an approach centred on enhancing the quality of key clinical decisions and an approach centred on strengthening and broadening services for patient support. However, here as elsewhere, it

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27 *It is noteworthy that right until the final draft these guidelines were labelled as 'concordance' rather than 'adherence' guidelines, and they very much embody the philosophy of the concordance work that informed them.*

28 *More generally, those people who have researched intentional non-adherence typically wish to help prescribers understand that it is often quite rational. See, for example, DeMarco & Stewart (2010).*

is important to acknowledge that there are important issues of interpretation and relative emphasis that arise when aiming to apply the guidelines. These issues of interpretation can be briefly illustrated here. For example, and sticking to a very general level, the guidelines embody two broad purposes: (a) improving adherence; and (b) increasing partnership working in prescribing decisions. They are based on the (largely) plausible premise that (a) and (b) are compatible and indeed that (b) supports (a). However in practice there will sometimes be tensions between the practical strategies one would emphasise if prioritising (a) (roughly involvement components 2 to 4 inclusive, listed above in section 1) or (b) (roughly components 4 to 6) inclusive (see section 1)), that is, situations where one has 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.

This one example is enough to indicate that there is a limit as to how far even these very important and helpful guidelines can define and determine good practice in specific cases. Guidelines can help inform but they cannot replace context-responsive professional judgement. Nor can guidelines completely circumvent wider debates about which policy ideals and purposes we should, in various contexts, be aiming to enact. Indeed it is arguable that the body of work that informs the NICE guidelines more fully reflects the 'decision improvement' tradition of practice development than the 'service re-thinking' tradition – especially as manifest in something like the Co-Creating Health approach with its stress on broadening the orientation of health services and actively fostering collaborative working through system and cultural change. These more holistic and 'radical' themes are relatively neglected in the academic and policy literatures on medicines adherence and thus have the potential to significantly enhance the available repertoire for improving patient involvement in the area of medicines choices.

When it comes to finding and putting in place appropriate 'stepping stones' to translate guidelines into practice comparatively little can be settled at a general level. Suitable

strategies will depend upon a conception of ideals and purposes and this, in turn, will partly depend upon what is appropriate (and practicable) in relation to different settings, treatments and conditions and in relation to different professional and patient groups. Given the pervasive ethical and practical complications rehearsed in the previous section it is simply a mistake to assume that any such guidelines could be directly and straightforwardly implemented anywhere and everywhere. Nonetheless, it is possible to summarise a few broad areas of improvement that need to be addressed, many of which are explicitly or implicitly signalled in the NICE guidelines themselves.[29] They relate to what might be thought of as the essential preconditions of patient involvement in relation to medicines, without which none of the more specific stepping stones to change can be put in place.

1. RECORDING AND PROFESSIONAL COMMUNICATION

Effective systems for recording and communicating medicines regimes are essential because patients typically travel with their medicines within and across different institutions and sectors and see a range of health professionals. It is important that the many professionals who may be called upon to discuss medicines have access to good medicines information including recorded reasons for specific prescribing decisions. Unless we can achieve high levels of successful professional-to-professional communication in this area, it is unrealistic to push for higher levels of patient involvement because patient involvement models rest on the assumption of informed professionals.

2. MEDICINES REVIEWING

NICE, and others, have stressed the fundamental importance of regular opportunities for medicines regimes to be reviewed. Routine medicines review systems are crucial for following up on the use of prescribed medicines and provide opportunities not only to support adherence but to revisit prescribing decisions, in some cases to enable more shared decision-making and more broadly to provide patient education and enhance the patient experience.[30]

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29 *The points summarised here also owe much to the many professionals who generously shared their experiences and expertise in recent fieldwork, some of which informed the examples offered in Appendix 1.*

30 *Medication review can be implemented in a range of settings and by a range of professionals and the development and evaluation of new initiatives in this area is crucial. The introduction of the 'New Medicine Service' alongside 'Medicine Use Reviews' into the NHS community pharmacy contract is a potentially important development for supporting patient education and adherence agendas as well as consolidating and extending the role of community pharmacists in this area.*

For medicines review to be effective and meaningful to patients it needs to be led by responsive professionals (ready to move outside of protocols) and ideally be given enough time and space rather than simply slotted into other busy practice activities and schedules. In the medium to long term, the goal should be to gradually build institutional climates where (a) patients are increasingly used to the idea of and comfortable with discussing their medicines with professionals, and (b) some professionals who have the resources (knowledge and skills) to do so are available for such conversations even outside of scheduled review events.[31] Once again, richer and more complex forms of patient involvement can only really be built on the foundation of suitably willing and prepared patients and professionals.

3. CREATING AND EXTENDING COMMUNICATION SPACES AND PROFESSIONAL 'SCRIPTS'

Arguably the most crucial building block for strengthening patient involvement in practice is the creation of conditions for genuine professional-patient communication. This is not an easy matter[32] and often involves carving out new or special spaces and times for communication either by changing the 'scripts' of consultations or by creating new kinds of appointments. These extended, and ideally more collaborative, kinds of clinical encounters can be usefully complemented by looking for broader possibilities for interactions between professionals and patients. These include non-clinical (and therefore sometimes more 'natural' and equal) encounters through social events, patient organised groups and/or professionally organised seminars and workshops that involve patients. Unless time and effort goes into establishing the possibilities for these new styles of communication – whether these just amount to a small extension to practice or to something more radical - nothing can fundamentally change.

4. BUILDING LOCAL TOOLS AND TACTICS

In some cases there may be 'off the peg' solutions to involvement challenges but more often than not these challenges can only be met by imaginatively tailoring (developing or adapting) tools and professional tactics to specific needs and purposes. In the area of patient involvement, especially in shared-decision making or concordance work, there has been a tendency to focus on specific kinds of 'tools', and especially upon 'decision aids'. These can be useful but they do have some potential limitations – they take a good deal of time to develop and trial and are not always easy to apply in specific circumstances. Nonetheless when 'owned by'/ 'adopted by' services they can support involvement as can a range of other patient support tools – for example, suitably targeted information sheets or web resources, agenda-setting tools, planning and agreement tools, record cards. There are also other more low-key practical devices which can be very important to get conversations going – for example, pictures of tablets, or the actual use of tablets in consultations so that medicines taking can be discussed in very concrete terms.

There is substantial expertise, amongst pharmacists and amongst others who use medicines in specific, often specialised, contexts, about how various medicines do and do not 'fit into' different patients' lives. And there is a wealth of good practice available about technical matters - such as dosing regimens, routes of administration, packaging and access to medicines and repeat prescriptions – that can significantly enhance the quality of prescribing and rates of informed adherence. However there is room for considerable improvement in ensuring that institutions identify effective procedures for spreading and embedding this expertise in routine practice.

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31 *The recent Royal College of Physicians report (N=1, Why people matter in medicines, 2011) stresses the need for doctors and others with responsibility for communicating about medicines (in reviews and elsewhere) both to work in partnership with pharmacists and also to be supported to develop their own pharmacological education – stating that, for example, '[e]very GP practice in the country should have access to a local pharmacist adviser, to whom they can refer patients with medication problems, and who can be used as a source of advice for both patients and GPs on medication related issues' (p8); and that 'pharmacists have a very good pharmacological education ….We need to make sure that all future prescribers – including doctors and nurses – have this knowledge in order to deliver better patient care. Only in this way will prescribers have the ability to communicate information about medicines. … [T]his ability is fundamental, and underpins not only safe practice but also adequacy in partnering patients and the public in understanding the part that medicines can play in their lives' (p7). Certainly, thought needs to be given to the best balance between drawing upon specialist medicines knowledge (irrespective of profession) and spreading knowledge more widely, but both are clearly important.*

32 *Please see Appendix 1 for a much fuller discussion of this theme.*

What these practical tools and tactics, and other good practice methods, have in common is that they provide manifest evidence of professionals taking an active interest in the patient's point of view on what is being discussed and decided. Just as tools need to be developed and adapted for the immediate job at hand, so the related communication strategies and relationship styles employed will only fully work if they organically arise from, and appropriately reflect, local circumstances.

5. INSTITUTIONAL AND COLLEGIAL LEADERSHIP

The kinds of change that are demanded by the new policy orthodoxy of involvement, and endorsed in this paper, depend upon strong professional leadership at both national and institutional levels. Such leadership can help to provide clarity about basic principles and standards but also link this with the encouragement of debates about competing visions and purposes and about practice dilemmas. The resulting educational and collegial initiatives need to encompass, but go well beyond, an understanding of models and techniques and foster a lively interest in, and a sense of responsibility for, context-responsive practical wisdom. They should also help to establish some 'bottom up' mechanisms for identifying, monitoring and sharing good practice (including conversations about when, where and how it can be adapted for other settings and services) and encourage the trialling of new approaches. Institutional and professional leadership is also essential in fostering, and responding to, broader forms of collective involvement in healthcare planning. The interest in the individual patient's voice has often been advanced by broader social movements and organisations, and wider attempts at developing forms of civic engagement in healthcare or the 'co-production' of services can help to substantially enrich models of professionalism.[33]

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33 *This commitment to broader and deeper levels of collective involvement, and to related but wider notions of democratic accountability, also help to answer the legitimate worries of critics who view scepticism about managerial forms of accountability purely as a form of professional self-protection. Also see, for example, Doherty & Mendenhall (2006).*

4. CONCLUDING DISCUSSION

There is certainly an 'ethical imperative' to involve patients in treatment decisions. At the same time there are enough ethical complications to mean that 'practical wisdom' needs to be employed in the tailoring of involvement to circumstances and cases. The 'quality imperative' is equally undeniable – unless 'compatibility with patients preferences' is included in our notions of decision quality then we operate with limited, misguided, and in most cases simply indefensible notions of quality. Nonetheless, our conceptions of 'quality' also include other dimensions of concern that may sometimes limit the scope for individual patient involvement, including, for example, patient protection concerns, or public health concerns. Finally, as signalled in the opening section, the arguments for an 'economic imperative' also have relevance but are more obviously contestable. Following the discussion above, the reasons for this contestability should be clearer. Whilst there is a good case for arguing that patient involvement is cost-effective because patients' informed choices will generally lead to fewer 'unwanted' interventions and higher levels of adherence with 'wanted' interventions; this case needs to be qualified in two key respects. First, it is obviously important that any cost savings are treated as a side-effect of better involvement policies rather than a direct driver in specific contexts – because the latter risks distorting the proper processes of delivering carefully tailored involvement practices. Second, the overall cost-related benefits may be limited because: (a) after a period of improved involvement, and the 'involvement cost-effectiveness premium' derived from it, there is no reason to imagine further levels of involvement would yield still further cost containment; and (b) perhaps even more significant – the provision of carefully tailored involvement practices itself has significant cost implications and it would be wise to re-invest some of the potential savings from revised treatment choices into the broader development and dissemination of good practice in this area.

Overall the arguments for patient involvement in treatment choices and for shared decision-making (in various versions) are certainly strong enough to justify the policy orthodoxy summarised at the start. The practical and ethical complexities rehearsed in this paper do not provide any grounds for dropping the accompanying sense of imperative or for lessening the enthusiasm or zeal of involvement proponents. However, they do provide grounds for caution about the generalised ways in which involvement is sometimes 'pushed' by, or interpreted in, policy interventions. Approaches to policy change in this area need themselves to reflect, protect and support the values that motivate the desired change.

Finally, there is no prospect of closing the gap between the policy orthodoxy and routine practice unless we learn from experience and expertise 'on the ground'. Both collegial leadership and educational change depend upon reducing the emphasis on abstract models and labels and increasing our attention to the practical and philosophical complications that have to be negotiated in day-to day clinical work. To help this process of reorientation, two appendices on these themes are offered to support the identification of, and education about, more 'realistic' approaches to policy change and practice development.

Appendix 1

LESSONS FROM PROFESSIONAL PRACTICE

This appendix explores and illustrates the translation of ideas about involvement into actual involvement practices by drawing on the insights of professionals with experience of patient involvement practices including more collaborative forms of working.[34] The value of looking at these examples is not only that they give a broadly optimistic message (i.e. by showing that, and how, involvement practices are possible) but also that they indicate the range of difficulties that have to be overcome to enact them. Talking about 'difficulties' is not intended to set a negative or pessimistic tone but rather a realistic one. It is important to have a realistic sense of the difficulties that have to be overcome if we want to change practice. Otherwise it is too easy to talk as if a simple, pain-free, cost-free change of model or mind-set can effect change. The difficulties here are largely practical ones - the professional, technical and organisational burdens of, and barriers to, change. But caught up in this mix are what might be thought of as ethical burdens and barriers. That is to say, changes in practice will rarely be non-contentious. There will almost inevitably be a range of considerations which point in different directions or which suggest different emphases according to what principles or values we foreground. Negotiating change thus requires some consideration of ethical balancing acts. These will not be considered in any depth in the account that follows, but some of them will be signalled in passing (they are summarised in Appendix 2 and discussed further in the main body of the paper and in work cited there).

The insights drawn upon here are based on informal conversations about involvement with about 75 interested professionals and on semi-structured qualitative interviews with 25 professionals who were closely involved in developing or enacting involvement practices, or at least work in areas where involvement practices had been 'normalised'. (The conversations and interviews took place between January 2009 and September 2010.)

What is presented here is not a conventional analysis of qualitative data. Rather it is an illustrative summary of some of the lessons from these conversations and interviews using the professionals' own words extensively. Although the ambition is to provide a relatively systematic and rigorous account and to reflect the data carefully, there is no explicit emphasis here on establishing validity, still less on representativeness; rather the core ambition is simply to illustrate possibilities, and prompt discussion and reflection, through the presentation of some examples. Where italics are used, the quotes are taken directly from the tape-recorded and transcribed qualitative interviews.

The overall analysis highlighted the number of different factors that need to be considered when enacting involvement practice. Here, for presentational purposes, discussion of these has been organised around the eight different components of patient involvement practices identified in the main report: (1) creating the conditions for communication; (2) informing and educating patients; (3) promoting self management; (4) being responsive to patient perspectives; (5) joint agenda-setting; (6) joint decision-making; (7) relationship building; and (8) re-working relationships and systems. The components cannot be separated out from one another in reality, but are being abstracted out here to help focus attention on some of the different strands of involvement work. All, or nearly all, of these components are present, albeit on some interpretation and to a greater or lesser degree, in each of the examples of patient involvement practices used here. However different examples will be used to focus in on each of these components and illustrate what they can involve in practice. The services referred to (and/or similar kinds of services) have been audited and evaluated extensively but that is not the focus of the current discussion. The purpose here is simply to illustrate and discuss the practices so as to help share a better understanding of the nature of patient involvement.

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34 *There is, of course (at least) as much to learn from the experiences and insights of patients who have engaged in collaborative working. It is simply that this study focused upon learning from the experience of professionals.*

It would be possible to illustrate all eight components in relation to some paradigm services. For example, diabetes care is an area where a lot of innovations in partnership working have arisen and been formalised. There are recognised programmes for encouraging shared care planning and decision-making and self-management and this has entailed new service models and philosophies and changes to the professional development and practices of individual practitioners and multi-disciplinary teams. For that reason, five professionals with considerable experience of these changes were interviewed. However, a range of examples are used here to illustrate the components of patient involvement and to reflect practices that are not necessarily as widely recognised, formalised and embedded across institutions as the diabetes practices and models, including some that have arisen from and are emerging from local teams and from the philosophies and practices of individual professionals. Here each component will be illustrated through one or two examples. As the account unfolds, some of the tensions, including the ethical tensions, between these components will be illustrated.

The use of examples gives rise to questions about if and why these cases are different from other cases, or from one another, and whether what might be relatively easy in one situation may be very difficult or near impossible in others. But respondents were often quite keen to assert that the broad principles underlying their work were of general relevance and so at the very least this suggests we should be ready to reflect on the key differences between cases and to ask whether our first thoughts about the appropriateness of the different components to different cases are really justified. There may well be sound reasons for our judgements that cases are different in important respects but, on other occasions, these judgements may simply reflect habitual thinking.

EXAMPLE 1

Example 1

SUPPORTING INFORMED ADHERENCE WITH BLOOD PRESSURE TREATMENT

In the service drawn upon here specialist nurses work with new patients and patients who have not achieved good outcomes with hypertension medication, often because of non-adherence or intermittent adherence. This involves listening to, and extended discussions with, the patients (and carers), prescribing medicines and making adjustments to medication regimes to achieve more 'informed adherence' or 'concordance' between prescribers and patients.

COMPONENT 1. CREATING THE CONDITIONS FOR COMMUNICATION

Communication does not come about effortlessly. It requires the right levels and kinds of time, space, skills, attitudes and trust, and all of these things require significant investment of thought and effort if not financial resources. The clinical nurse specialists who provide this service stressed the importance, and challenges, of creating a space of trust in which patients and professionals could exchange perspectives 'openly' with one another. Their accounts underline two of the fundamental factors that are essential to understanding the challenge of patient involvement: first, patients and professionals are not always on the 'same page' or on the 'same track'; second, it is not always easy, for a variety of reasons, for patients and professionals to talk to one another.

The nurses begin from the recognition that 'patient involvement' is not really 'an option' in relation to use of medicines, because it is a necessity:

The patient's in charge. That the patient, it's their condition, it's their tablets and you know, they choose, I can't make anybody do anything. So, you know, all you can do is explain and offer and suggest and […] give them the information so they can make an informed choice.

The patient [is] an integral part of the patient management in hypertension, because it's a chronic condition […] it's something that has just to be managed, so unless they are part of the planning and implementing, it tends not to work. We want them to take part, you know, it's not a question of saying, of advising – although we give advice – it's a question of actively involving them in planning their care.

However although the 'theory' (providing information and support to encourage patient involvement and decision-making) is relatively easy to summarise, the practice is very demanding indeed. This is not least because both parties are often used to different communication climates and norms in which patients can be more passive. And these norms also enable patients to keep things to themselves, which they might like to do:

They're quite often passive, used to being passive, they're used to being passive. And so, I'm trying to get to change that into... active […]. What I'm, sort of, desperate to get them to do is to take part.

They're not used to this sort of dialogue, the doctor's in charge or the nurse is in charge, they're the boss and the patient then does what they're, appears to do what they're told. So they like to please, they like to look as if they're doing, what they're doing and they'll go, you know, and not do it. It's a huge frustration!

In addition to other aspects of clinical expertise these nurses have had to develop hard won professional expertise in creating the conditions for, and practising, what they call 'an open communication dialogue'. Above all else this means creating an atmosphere and a kind of relationship in which the patient feels able to be honest:

I'm not, you know, I'm not a headmaster or anything like that, I want her to feel that she can actually tell me what's going on with her tablets and how she feels about them.

My role is to make life better for them when they, when they come to us, by letting them tell me what's been going on in their lives with their tablet-taking and let them get back in control in any way […] that I can.

I'm not here to judge you, I'm not the doctor and, you know, I'm not in authority, I don't wear a uniform so […] I'd like to think that I don't look a threatening person to them. And, so, I've said to her, 'look, go to all your cupboards and empty everything out that you've got and I'll have them all and I'll dispose of them and then we can just start again and start afresh.'

And it's done in a smile, yeah, it's done in a sort of a half-smile, you know, we, you sort of have a bit of a laugh about it…

This approach takes time, with consultations routinely lasting 30 to 45 minutes and sometimes more. It is clear from this alone that it is an approach that relies on transactions which are 'different in kind' to many professional-patient transactions such that the approach could not be straightforwardly translated into them. However, even with this amount of time and the self consciously friendly and non-judgemental approach, some patients will not 'open up':

This is where we're at, what's gone on before, you know, whatever the reasons, but, if I've said something that makes you change your mind, and you will start taking your tablets, that's fine. But, you know, I […] should think the greatest psychotherapist can't get really to the bottom [of it].

Sometimes you'll never get them to, you know, they're so intransigent that they won't open up.

If you don't want to take your tablets don't take them! Just tell us! I mean, I don't, you know, I really don't care! Just don't let's give you any more tablets.

Through the palpable sense of frustration contained in parts of these accounts the 'gap' between the clinical world and the patient world is made manifest. Patient involvement practices are about the process of closing this gap in a variety of ways.

When dialogue can be established, a whole range of things become possible. Professionals can learn about the patient's life, perspectives and values and there is also an opportunity for providing information to, or educating, patients. Next the focus will be upon the second of these but, of course, the 'two directions' of communication cannot be separated out in practice.

COMPONENT 2. INFORMING AND EDUCATING PATIENTS

Patient education about medicines starts from a detailed engagement with what individual patients already do, and understand, in relation to their medicines:

We ask the patients to bring all their tablets with them and we go through the tablets with them.

Anything on their prescription sheet can be inaccurate and so the only treatment the patient is having is what they put in their mouth that morning. […] So, it may say, 'take 2 a day' on the box but in fact the patient is only taking one a day. So, that's not, it's not wrong, it's just what's the patient's doing.

Eliciting information about medicines use from patients is sometimes very difficult but the emphasis on creating a non-judgemental and open encounter means that it is often possible to get a clearer picture of the way patients think about and use their medicines, including why they sometimes don't like their medicines or use them. This means that the nurses have to be sensitive to a range of biographical and cultural factors that might influence a patient's beliefs and practices. On some occasions this will include addressing misconceptions about, or a simple lack of understanding of, conditions and treatments. In many cases patients will have inherently complex and confusing medicines regimes which need to be looked at in the round and, perhaps, consolidated. The opportunity to get an overview from patients does not just facilitate education about medicines but is set in the context of a broader health promotion and lifestyle approach:

So then I started from the beginning, to explain to her what her blood pressure was, why we treat it, what the problems are, what are the dangers of high blood pressure and how we treat it and how the tablets work. And that's just very simply describing it as, that you take the tablets, and they only last for 24 hours and then they're washed out of your system and your blood pressure goes back up. And so I spend quite a long time explaining that this doesn't treat the blood pressure it just bring it down and protects the organs of the body. And, that that's why a tablet is required each day. And I put it similar to the oral contraceptive pill, if you don't take a pill every day then you might get pregnant.

A lot of our patients are, may be diabetic, or they've got arthritis, or they've go[t], you know, lots of other things wrong with them and they're on maybe ten drugs? Ten-twelve drugs, maybe more. And so, that is a good time to go through their

EXAMPLE 1

EXAMPLE 1

tablets and, say, if they're diabetic, you know, explain why those are so important to take, you know, at certain times of the day or not, and then... Some tablets are perhaps less important, you know, they're, I think, you'll find that an awful lot of people are overwhelmed by the number of drugs that they're on. And that's a real big cause of not taking them. Because they don't know what makes them feel rotten, so if they don't take them, then, you know, that's their answer to it, and I'm there to provide ways of cutting them down perhaps, or putting them on slow release. […] So, there's lots of ways that you can show them that you are on their side and you want, whatever they're taking, to be taken accurately.

And part of that package is taking the medicines or losing the weight or doing more exercise, it's a sort of triangle of things that are in their […] control. And how we can find a modus operandi that's going to work for them. […] So it's not just the hypertension, […] it's the whole person.

This kind of responsive and broad-ranging approach to patient education is not only time-demanding but also demands the development of considerable professional skills, amongst which 'listening skills' were most strongly emphasised along with a readiness to cope with being 'challenged' by patients:

People who feel they've been listened to, it's the most fundamental thing, actually, if I'm going to say anything, […] and reflect back on what the person has said, so you've understood […] what's going on here. And you give the information in terms that they can understand, and… personal. You know, not just, 'here's a leaflet'. A leaflet can add to that. And in the dialogue of listening and giving them information, being open to the questioning during the time, and at the end of the consultation, you know, making sure that there are no further questions they want to ask.

When you're starting off that's quite nerve-wracking, but, there's noth[ing], you know, you can challenge me on anything now... […] That's quite hard for health professionals to take, you know, take the challenges, because [you] can't possibly know everything. […] But yes, it doesn't bother me now, but it was difficult in the beginning, which is, you know, why perhaps these dialogues are difficult for other people to do.

But if patients are encouraged to be more open and 'active', this does entail different approaches and skills for health professionals who not only have to be able to listen but also have to be able to deal constructively with challenges. The attitudes and skills that relate to one person 'acting upon' another are different from the attitudes and skills that are appropriate when two people are properly 'inter-acting'.

It is not just a question of simply 'closing the gap', as referred to above; professionals have to be ready to acknowledge that there is a gap, or even a clash, between the two points of view, but still find ways forward that aspire to something like 'partnership working' without denying the reality of any such gap or clash. This shift towards a 'dual agency' assumption connects to a pervasive tension between the different aims of the educational components of interventions (indeed of all aspects of interventions) – tensions between the 'empowerment' and 'prevention' goals of health education; or, in more general terms, between handing over control and trying to steer people in the direction of looking after their health. These different aims are encapsulated in these two comments from the same respondent:

My role is to make life better for them […] when they come to us, by letting them tell me what's been going on in their lives with their tablet-taking and let them get back in control in any way […] that I can.

What am I trying to do here? I'm trying to prevent heart attacks, strokes, kidney disease, vascular disease, dementia, and eye damage.

Example 2

SUPPORTING PATIENT MANAGEMENT OF DIABETES

EXAMPLE 2

As noted above, diabetes care is one of the areas that has led the way in terms of patient involvement practices. There has been a widespread recognition – supported by the work of Diabetes UK – that the effective management of diabetes depends upon fostering new healthcare 'scripts'. In a nutshell, this entails patients not only taking an active part in, and responsibility for, the day-to-day monitoring and treatment of their condition but for them also being enabled and encouraged to take a more active and central part in consultations, care planning and teamwork. In turn, this requires new 'professional scripts' as professionals need to learn how to respond to, and put in place, systems to support patient agency and perspectives. This section draws on conversations and interviews with nurse specialists and General Practitioners with a particular interest in these shifts.

COMPONENT 3. PROMOTING SELF-MANAGEMENT

A move towards more widespread and more effective self-management involves work on every facet of the healthcare system and a reorientation in the health service:

> to support people in their wellness not their illness. Or both I suppose in an acute situation.

This means putting in place educational opportunities for patients and professionals, developing shared models of working across sectors and settings, changing the culture of teams and developing practices of, and tools to support, patient agenda-setting and decision-making. In this context, patient education becomes a very significant dimension of healthcare and much more than a strand in professional consultations. This allows not only for a shift in scale but also for more breadth of educational approaches, philosophies and aims which can, for example, include structured courses and peer-led group work designed to support 'ownership' of the issues:

> I think it's about a six-week course so it's really just giving them the skills to be able to start self-managing. And also to be able to come to consultations, and it not being on our terms. So our part of that would be, you know, when people come, […] to give them the opportunity to think about their agenda before they actually come.

> Because we know what's important to us, but unless it's important to them, then it's really of no value. Because in diabetes care, you know, it is all about self-management. It's about them managing their disease for three hundred and fifty odd days a year. And us just tinkering now and again when they come in and saying, 'what have you thought about this or that?' So, it's very important that they […] identify what is important to them.

> It's encouraging the patients to go on courses to help them how [sic] to manage the situation better, helping them to self-manage it, looking at professionals going on another course to help us to... change the way that we've always worked, or possibly have always worked, in a very medical management of diabetes. And encouraging patients to be more involved in their care.

The corresponding role of the health professional then needs to become less prescriptive and to find ways of engaging with, responding to and enabling patient self-management:

> And that's very much changes in diabetes management. Because, whereas before we would have been quite prescriptive about what to eat and when to eat it and how much to eat, I think there's a realisation that really wasn't working. You know, people were saying, 'yes, yes, yes', walking out of the door, and do completely what they'd already been doing for fifty-sixty years! So… we've got a dietician attached to the team and she will see, you know, them. And obv[iously], if they are eating something that is very high in sugar, then she will actually provide alternatives as opposed to say, 'don't do that.' You know, so she will say, 'a better choice would be...'.

> So they say, 'well, ok, from everything that I've heard, you know, I'm going to try to do something.' And we then, we don't tell them what it is in any way but we […] go through how they would actually really bring that action plan right the way down. So rather than saying, 'ok, so I'm gonna lose weight,' well, it's about, 'so, you really want to lose weight but how are you going to do [it] and what exactly are you going to do every day? And when you reach a barrier on that, how are you gonna address it?'

EXAMPLE 2

Professionals stressed the importance of, and the difficulty of establishing, a common commitment to self-management across teams and sectors so that pathways can be planned with some consistency of approach as well as some continuity in relationships. Effective team working was seen as essential not only for reasons of consistency and continuity but to fully realise the respective contributions of different specialisms:

So that it's important that we use the same sort of skills and processes to discuss with a patient, because if we don't, the patient thinks two different things are happening [...] and, you know, it's disconnected. 'Ah, but the hospital told me this and the GP is sort of doing this!' [...] And if you don't have the same message in the same way, it's very hard for people to understand what decision they want to make.

Because we all bring something very different to the table. And, as a nurse, you know, I may be looking at the practical issues. You know, we may say, some people with diabetes, well yes they should be on a certain insulin regime, but I may then say, 'but, actually, they haven't got the dexterity and so we would need to use a certain type of pen.' Whereas the dietician may say, 'yeah, but if they act slightly differently then they may not need that sort of insulin', and the consultant may say, 'well, why don't we take them off insulin completely?' So, we just all bring different, because we're all coming from a different starting place. We have different knowledge bases and I think that's why, you know, we all bring something different.

This emphasis on the importance, and challenge, of reshaping the whole system and professional environment that patients encounter extends, for example, to the crucial role of administrators and receptionists and their skills and attitudes:

I think the first thing that... the first contact they're going to have is with the receptionist, and that needs to be a good contact to set the scene.

We have a lot of receptionists that are now involved in diabetes care. And there are whole systems in practice around encouraging people to come to their appointment. If a patient gets tons of letters saying, 'look, you haven't come to your appointments, your eyes are gonna fall out, or, you know, your foot is gonna drop off', they're not gonna come! So it's about saying to a receptionist, you know, when you're encouraging people to turn up for their appointment, you

know, have something that will help them to engage and help them to turn up. Because if they think they're gonna come and they're gonna be told off, they won't come!!

One important aspect of self-management is an increased role for the patient within the consultation not only in agenda-setting but also in decision-making (discussed further in the next example). A constantly repeated message from all the professionals consulted was that not all patients seek or accept the responsibility for making decisions or 'choices'. It was also pointed out quite often that there are not always meaningful clinical choices available. But when there are such choices these can be shared with the patient who will then at least have the option of contributing to and owning the decision that they are going to have to enact and live with. And where the possibility of this kind of involvement exists, then, in the experience of these professionals, there is a much greater likelihood of decisions being actually followed through and reviewed effectively:

Then I might say, 'look, here are the options, so you could try insulin therapy, we could try adding in a third tablet or we could try keeping things as they are.' And you will say the benefits and the drawbacks to all of them. So with insulin it is about blood glucose monitoring and injecting. With the tablet it may well be you're adding in another tablet so you're now on thirteen tablets a day and you have to remember to take the tablet. And not doing anything, in actual fact, they do maintain, they are, they may well be increasing the risk of developing complications. So it's about saying, 'well look, this is where your diabetes is at the moment, this is where ideally your diabetes needs to be to help to reduce that risk, these are the options that you can have, what do you want to do?' There are sometimes groups that will just say, I don't know. Tell me, and I'll do whatever you say.' There are some people that will choose to not do any intervention, but to actually take their chances and they will say to you 'I'll take my chance. You know, if I have a heart attack, I have a heart attack.' And then there are some people who will say, 'well, what would you recommend?' So, if you do give them all three choices, [...] quite often people will decide themselves. And that's fine. You know. And sometimes, you know, they get to the target, other times they don't. If, for example, somebody chose, so if in actual fact you really know that their diabetes would be ideally managed with insulin, but they make any of their other two choices, what you need to do then is ensure that you're following them up at regular intervals. So that if

their diabetes control deteriorates further, you know, you are able to step in and say, 'well, should we review your plan?' and go from there really.

It was an example of giving someone some options which, in a sense, were difficult to make, I think. […] And my perception with this particular patient, but equally with other patients in a similar situation, is that they can move on when they reflect on the fact that, at the end of the day, it's their condition and they're in the most powerful position to change things.

The promotion of patient self-management thus entails a systematic re-thinking, and 're-tooling', of healthcare systems and relationships and this makes it a very substantial practical and organisational challenge. At its heart though is a change in the consciousness of both professionals and patients, and in their habitual scripts. And, even when this shift of orientation is successfully accomplished, the new scripts are far from problem free but include significant burdens and dilemmas for both patients and professionals.

COMPONENT 4. BEING RESPONSIVE TO PATIENT PERSPECTIVES

When professionals fully attend to the perspectives of patients they do not just encounter 'information' – accounts of patients beliefs or opinions about things – but the whole of the 'first person' experience and point of view; what is sometimes called the patient's 'lifeworld'. This means encountering and responding to the emotional dimension of patients' lives and the strong emotions that inevitably accompany many stages in the illness trajectory:

And people can get very, psychologically people can get, feel that they've failed. If you want to introduce a tablet into somebody's diabetes management, if you say that, they feel they failed. You know, […] and it can be quite devastating for them if they realise that they've got this condition where they need to take medication. So […] at the very beginning you need to explain to them that diabetes is mainly managed through diet and lifestyle where possible. But, because the condition changes over time, we will probably need to introduce some form of medication.

You've got, you know, the patient regret as well in it, 'if only I had done, if only my control had been better' you know, 'I've done this to myself'. You know, not everybody because some people still just say, 'oh well, you know, it isn't my

fault', you know, 'nobody told me about, the complications of diabetes.' But, for some people there is this awful guilt […] and fear, really, of what is happening and what will happen. Particularly in people in renal failure and, you know, and people whose eyesight is deteriorating, it can be very scary at that stage.

So of course then years down the line again, […] it may well be, because diabetes is a progressive condition and it's a chronic condition and they say that in type-2 diabetes sixty percent of people will need insulin, we are… you know, six years after diabetes, commonly recommending using an injection to manage diabetes and at that stage, that's the hardest part for somebody. That and the development of a complication is really very very hard and the biggest piece of my work is about supporting people make the decision to use insulin, that's the majority of the work that I do there. And that is because […] they feel they failed, which isn't true, and secondly they're really fearful of needles and there's huge myths around insulin, and, what […] can happen if you're taking insulin. And I think, because of the age group, a lot of people look to their parents and their parents used insulin basically just before they died, or just before they had their foot amputated. So they have all of those feelings that they come with.

It is evident that supporting self-management involves attending to the whole person and cannot be understood as simply a rational-technical process. The support that is offered may include information exchange and use decision tools etc. but it is also, at the same time, emotional support or care. Accompanying and helping someone on an illness journey calls for dispositions which reach into the core of carers and which, sometimes, for very good reasons, are not always available from professionals. Those professionals who are helping to foster and support self-management face a range of difficult balancing acts and dilemmas and one thread running through these is the need to balance the encouragement of independence with the need to be ready to offer emotional support when it is needed. Some of the balancing acts faced by professionals might be seen as largely pragmatic or 'tactical' questions – for example, when to support short-term decisions from patients, even where these might be seen as sub-optimal or are against guidelines, in order to build a longer-term relationship founded on the values of self-management:

That's when the dilemma comes in. Because if, you know, this guy may well now be heading to nine months, twelve

EXAMPLE 2

EXAMPLE 2

months from when he was first referred in. But the reason why we haven't stepped in quickly is because he's declined the treatment. He's declined whatever treatment we've got. And, you know, the guidelines will say to you, well, you need to do this, you need to do that, you need to do the other, and in theory, it shouldn't be twelve months down the line where we haven't optimised his control. But we are, because we've needed to go through that rapport with him and he needs to engage in that treatment before we can give it to him. So there's a dilemma there.

Well, it may be that you... the optimum insulin regimen to achieve the best glycaemic control just wouldn't be acceptable to a person. So you might suggest a certain insulin regimen, but actually the patient is not... is going to go away and only give […] one injection a day. So you might then have to decide with the patient, what is it they're willing to do! And then in some ways, that's the optimum for that moment and that time.

Other similar, but sometimes more fundamental, dilemmas reported by professionals include: the question of how far to try and change the scripts of interactions away from a traditional 'expert-led' model when the patient does not want this change to happen and where other aspects of the care environment are reinforcing the traditional model; and how far and when to try and persuade patients about the 'best option' or rather accept and welcome the patient's preferences:

A patient might come and they'll say, 'Well, look, I'm just here to do whatever you tell me!' and as far as I'm concerned, that's the patient's choice and I will give them the options and then they can maybe make a choice, but we might, you know? I mean, I might be that sort of patient. I just want to be told what to do, so I can do it and get on with my life – that sort of thing. You know, I can see how someone can make that choice, […] so I think that we have to be responsive to the different approaches that patients take.

I think you do try and put some gentle pressure, if you feel that there is a... a clinical danger for the patient, there's a danger for the patient. So, it may be around, you have somebody with, say, Type 1 diabetes, if they don't take their insulin at all, you know, the possible scenario is death! So, I mean, you want to ensure that the patient, you know, remains alive! So, the pressure might be, 'OK, this is how the insulin works, this is what each one does, this is the insulin that if you don't take you have a risk of being seriously unwell […] you know? So this is what I would say, I would

say to you, 'never... never miss this particular insulin.' So I would put that sort of pressure on somebody, yes, that sort of pressure saying, 'this is, this insulin keeps you alive. This other insulin is for your food, so if you miss a meal or if you don't give it, your blood sugars will go high, and you won't feel very well, but…'

Achieving the right balance here is difficult but particular concerns were expressed about any notion of 'choice' that simply transfers the traditional responsibility of the professional to the patient and fails to represent the need for, and importance of, the professional's contribution to, and accountability for, clinical decision-making:

So there's this shift around to how do we support the patient […] in this, so if you're looking at it from the best point of view, you would say, well, how do we support the patient in their self-management? And the worst point of view is well that's the patient's decision, and they decided not to do anything about that and they died! You know? So […] what I really would be careful with, is that by shifting responsibility - maybe that's not the right word! – but by collaborating, what you do then is blame the patient for not doing things.

The patients are making the decisions, because equally they're [the clinicians] making the decisions, you know, maybe even, maybe not equally, maybe it's something like eighty sort of twenty, and the clinician is twenty percent and the patient is eighty percent because, after all, they're the ones who are going to have to go away and decide to take the tablet, etc. So […] if the patient is making the decisions with the support of the clinician, then they're more likely to do it.

I think that's really important, that the clinician's agenda is equally important as the patient's agenda and vice versa. It's not just about one or the other.

It is evident that supporting self-management is no easy task. It necessarily entails working with very difficult emotions and, simultaneously, calls for considerable professional judgements in managing the inherent balancing acts and dilemmas. Although this can be very satisfying work it was also frequently referred to as 'exhausting'.

Example 3

SHARED DECISION-MAKING IN CARE PLANNING FOR MENTAL HEALTH CRISES

The work reflected on in this example is a structured approach to collaborative planning developed with adults who experience recurring psychotic episodes. This approach includes an exploratory agenda-setting discussion and a subsequent shared decision-making meeting which formalises agreed care plans for future episodes in writing. This approach has been tried and tested (albeit in a research context) and is currently being 'rolled out' to another group of patients with less severe conditions. This is a multi-professional approach and the discussion here draws upon conversations and interviews with medical consultants and other staff who have been closely involved with this work.

COMPONENT 5. JOINT AGENDA-SETTING

There is, of course, no sharp distinction between agenda-setting and decision-making. Constructing an agenda involves making a lot of 'decisions' and a critical issue for patient involvement policies and practices is at what stage, and how far, patients are involved in determining what happens and what gets considered in healthcare encounters long before any final treatment decisions are made. But there is a useful commonsense distinction between the processes of exploring and discussing the 'menu' of care and treatment possibilities and the processes of 'closing off' the options by coming to an agreement about what should happen. The development of a 'joint crisis plan' separates these two phases out by having two separate meetings. Crucially the first meeting is not run by, or inclusive of, the clinical team but supported by a trained facilitator, who is normally a mental health nurse but could potentially be a suitably experienced lay facilitator:

A facilitator, who's independent of the clinical team […] will meet with the patient when the patient has recovered from their previous episode, and discuss with them the kinds of things that could go on such a plan, so there is a menu of items. They would include things like, what their current treatment is, what their current medication is, who they're seeing, if they know the consultant, their care co-ordinator, or case manager. Then it might include things like, what are

the early signs, the first signs of relapse? What […] has been effective in the past in averting a full relapse during that sort of phase, what has been unhelpful? Might include medication, might include calling somebody to be with the patient, or somebody to talk to the patient.

A broad range of issues can be covered in the plan. These include issues that are both central, and less central, to the clinical agenda, but they will all be things that matter to the patient and for that reason are central to the provision of appropriate care and support:

It's up to the patient what goes in the crisis plan, it's not prescribed. The menu offers them the choices and the possibilities, they can put other things in that haven't occurred to us in the past.

Whether they'd want somebody contacted who would make sure that their flat was secure, say, or arrangements had been made for children or pets, or whatever, that kind of stuff.

When does the patient think an admission is appropriate? Admission to hospital for patients with a psychosis is a very fraught thing usually, because the patient often doesn't believe there's anything wrong and they don't believe they need to go into hospital. So, to be able to reflect on this and to think about it and plan when the patient is able to make a judgement about the appropriateness of hospitalisation is a very... well, it's ethically a useful approach and in practice we've got evidence that it does make a difference.

'What should we do when… you start to behave in a threatening way...?' I mean, because people have things that set them off or will help to calm them down, and those are very, very kind of individual.

There are significant challenges and obstacles to implementing this kind of structured agenda-setting exercise in this context, many of which have relevance for other services also. For example, it involves a readiness on the part of professionals to find the time and other resources needed to properly attend to the emerging patient agenda (because it would obviously be counter-productive to have agenda eliciting meetings which are

EXAMPLE 3

EXAMPLE 3

not followed up); in some instances professionals may be sceptical about the capacity of patients to contribute, and some patients may also be sceptical about the possibility and point of doing so:

> How are we going to find time to do all of this, to have a discussion with the patient, and then to have this joint crisis plan?! And that's complicated to get all of those people together, you know, at the one time, and for the patient to turn up as well.

> There may be some staff, clinical staff who are just very sceptical that such a thing would be meaningful […], that you should pay so much attention to what the patient says, you know, when they're clearly very psychotic and don't know what's in their best interests, that's going to be... it's not that common, but, you know, it sometimes arises…

> Basically patients with a history of mental illness are very ... are generally - especially those who have been admitted to hospital under section - a bit mistrustful of services. They see them as kind of authoritarian people who can make you do things that they won't want to do. […] So to persuade a patient that actually, look, this really is an opportunity for you to have some... a voice in your treatment, may be difficult for some. You know, some are so suspicious, so disbelieving that this could ever happen to them, that they're not prepared to engage.

Here, as in all the other cases, there are some patients who do not want to, or see it as their job, to take a share of the planning. But for some people, and in some respects, this reluctance can be seen as an understandable response to a lack of relevant experience. The strength of the contribution that patients can make is to some extent a product of the depth and breadth of their experience:

> It's difficult to get people […] to imagine risks, if they've had no experience of, […] or relatively little experience of being unwell, if you like.

> Once the patient has had a couple of years of treatment, and they've probably tried different things, they've got quite a lot of experience, as it were, of what works and doesn't work. And it's much easier for them to, for us to have a discussion, because if you're having a discussion early on, it's, 'what can I say?' They... the range of options may be just a little overwhelming and difficult to make sense of.

Nonetheless, although lack of relevant patient experience can circumscribe the scope of the contribution that

patients can make to agenda-setting, there are many aspects of agenda-setting (such as potential social support needs or the personal 'pet hates' about professional behaviour) which are less dependent on extended experience of conditions or treatment and which matter just as much if services are to be responsive to patients.

COMPONENT 6. JOINT DECISION-MAKING

Following the agenda-setting meeting there is a decision-making meeting – the joint crisis planning meeting. Here the goal is to bring together the patient (along with the independent facilitator and possibly an advocate/friend) and the clinical team and to come to an agreement about what should happen in the event of another episode needing care:

> The [...] patient is invited to bring a friend, relative or an advocate with them. And the care co-ordinator, and the clinical team, we want a senior psychiatrist there, the consultant preferably, or a senior psychiatrist – usually, the consultant. The care co-ordinator will be there, and we then have the facilitator, the independent facilitator, whose role it is to ensure that the patient's voice is heard; that the patient is happy with what is going to go in the plan. The patient has the last word about what goes in the plan. If the patient doesn't want something to go in the plan, it won't go in the plan.

> The aim of the meeting is to find a negotiated agreement about what should go in the plan. This may involve some compromise on the part of the clinical team, it may involve some compromise on the part of the patient. In the vast majority of cases, such an agreement can be reached. Patients in some way self-select themselves, as people who want to have a greater say in their treatment, who want to have the opportunity to influence the clinical team.

The agreement aims to cover all of the kinds of issues that have been raised in the agenda setting meeting - for example, how to interpret and respond to a relapse, preferred treatment options, treatment refusals, conditions for hospitalisation, who to inform and involve for personal and social support and what that includes. The clinical team may not find it possible to secure agreement to their own 'first choice' treatment but that is simply part of the compromise and agreement process. Sometimes, of course, full agreement will not be achieved, but the patient's preferences can still carry independent force:

The psychiatrist might think that a particular medication is the most appropriate, the most effective, or best. But the patient may have... may not be willing to have that medication, it may be they've had the medication in the past, they haven't found it particularly helpful or they don't like the side effects. And so [...] they'll say, 'Well, I don't want that medication, but, you know, what other medications might there be?' And so there might be an agreement on another medication, which may not be the first choice medication, but which is satisfactory from the point of view of the clinical team, and acceptable to the patient.

Occasionally, they cannot agree, in which case […] it's not a joint crisis plan, it's what we would call a crisis card. But any patient can state their written preferences. […] Refusals have to be taken into account now, they have legal force under the Mental Capacity Act.

The process described here thus refers to a structured and formalised application of a 'shared decision-making' approach (an idea which can sometimes be used in a more extended, diffused or even metaphorical sense). It 'operationalises' shared decision-making in the form of the two systematically organised meetings and in the form of the written 'plan' which records the agreed decisions and which is held by the patient and others:

Usually the clinical team, obviously, has a copy. The patient will usually choose to carry a copy on their person. Then they will decide whether they want the GP to have a copy and usually the GP has a copy. Usually a relative or friend will have a copy, and then it's up to them, you know, if they then have other people; like […] if they're living in some supported accommodation, then they'll want the manager of that place to have a copy. It's […] up to them. There's a whole range of possibilities.

The professionals involved in this work report (based on research evidence and first hand experience) substantial benefits in relation to major clinical indicators, and more subjective and qualitative factors. However the challenges and dilemmas should not be underestimated. As with the agenda-setting element, noted above, the first challenge is working out when this broad approach is suitable. It is not simply that some patients may express a preference for not wanting to engage but that there are circumstances where professionals have to make a judgement about whether this kind of partnership working is feasible or in the best interests of patients. Sometimes people are clearly too

unwell; on other occasions a more complex and balanced judgement may be called for:

Where somebody is acutely psychotic, particularly in the early stages, they might be generally very anxious and suspicious, and, don't understand that they're unwell.

It's quite a delicate, fragile situation in terms of trying to work with somebody who's acutely unwell like that. […] So it does feel more appropriate to just try and persuade them to take something that [...] will relieve the situation, and then talk about it at a later point in more detail.

Once you start discussing options, you start having... inevitably having to discuss levels of certainty about different things. And once you start raising the prospect of some uncertainty about this, 'well, this... this may help, or it may... or it may not', for instance! You know, 'or it may help two thirds of people... it might help you...', then some people do not respond to that so well. I find that quite anxiety provoking. I mean, I think the power of placebo sometimes is about being able to say to somebody, you know, 'this will help you.' And [...] some people do seem to be looking for that.

Properly executed, shared decision-making changes some of the default assumptions about healthcare relationships and responsibilities. For example, it means that the problem of 'adherence' becomes a problem for the professionals and the health system and is not just a problem about patient behaviours – will professionals 'follow through' on the agreed plans and what are the possible problems if they do not? It also raises potential problems for the accountability of professionals for risks and costs, when they are only one party to the decision and may have good reason to compromise to accommodate patient preferences. In other words, and once again, very significant practical, organisational and ethical challenges are inherent in shared decision-making approaches:

The more you allow patients to voice their preferences, the more you confront the question of: if the patient strongly prefers a treatment which you know is not very effective, and rejects a treatment which you know is very effective, and you go along with that, and something terrible happens – the patient commits suicide – how will your professional body, the General Medical Council, how will the coroner view your behaviour as a clinician in this respect? […] If we're serious about patient participation and this shared decision-making, we really need to look through the consequences [...] at the level of regulatory bodies and legal bodies.

EXAMPLE 3

EXAMPLE 3

In addition to the demonstrated clinical benefits, the professionals interviewed were very clear that the joint crisis planning work had broader benefits for patients and professionals and that the general approach had substantial relevance to all other aspects of their work (and healthcare generally). The benefits of starting from, and taking seriously, the values and preferences of patients can be derived even in cases were the conditions for full formal joint decision-making are not met (for example, because of lack of capacity, or inability to agree). Even within the context of compulsory treatment, there are still some meaningful and important choices that can be offered to patients (for example, about administration of medicines – such as depot injections versus supervised oral medication). More generally, being able to participate in one's own care decisions enhances the experience of care and the likelihood of it being effective:

The thing I heard very strongly from patients was that their biggest priority was just not wanting to be back in hospital. Which is where I now feel more confident about, trying to give people choices, but choices that will keep them out of hospital! [...] They know they don't want to be back in hospital, but they don't have the insight about the need for treatment, then we... within a legal framework, we give them options that will meet their primary desire, which is to stay out of hospital!

Inevitably, in having that discussion, you learn more about what […] the patient or the user wants. So, you have a better understanding of them. You're spending the time looking at the options with them, and I think that is often appreciated, and that helps your therapeutic alliance, your working relationship, and whatever you then come up with, you've got a situation where, if the patient has said, 'yes, I would prefer that one', […] then they're more motivated to stick with it.

You know, that we might think something is a good idea for them but, I mean you can offer people things until you're kind of blue in the face and if you haven't found out what's important to them or what the barriers are to their accepting it, you know, then you're always going to be, yeah, wasting your time really.

Analogous benefits can apply to professionals, including improved relationships, a greater sense of efficacy and, in some respects, a broader conception of potential roles and satisfactions in health care:

I should have said that one of the values of the joint crisis plan is not just the information that's there, which makes clear what should happen in a crisis, but the process of negotiating it changes the relationship between the patient and the clinician; that may be the most important thing, it's that change in the relationship, you know? It is a different kind of relationship and there's more trust on both sides.

I think it's largely to do with role models and the way in which different professional groups relate to patients, you know? One can learn a lot from watching experienced nurses, or experienced social workers dealing with patients. I've learnt a lot from non-medical staff about [...] how to deal with patients.

I mean, social workers are better at this really, in that they... they start where people are at. You know, they have this kind of adage, 'you start where people are at.'

Because it's... you know, this essentially makes working with people more interesting and more fun, I think, you know? If you're not just, kind of, asking the same kind of symptom questions all the time.

Example 4

EXTENDING AND ENRICHING RELATIONSHIPS IN HIV CARE

Healthcare for patients who are HIV positive is, like diabetes care, an area which is well known for developing and 'normalising' innovative approaches and practices. As with all the cases discussed here, the crux of developing patient involvement practices is re-conceiving and changing conventional patterns of relationships between professionals and patients. These processes of re-conception and reconfiguration are potentially very broad ranging and far reaching and relate both to care relationships with individual patients and to broader relationships within the social field of healthcare. The work cited here indicates some of these possibilities and draws upon interviews with medical consultants and conversations with other related professionals.

COMPONENT 7. RELATIONSHIP BUILDING

Building stronger and richer relationships is very demanding, because it entails taking on more open-ended commitments; it depends upon paying attention to, and being respectful about, relatively 'small matters' in clinical interactions and having the same regard for the 'large matters' that extend well beyond the clinical interaction in both time and scope. This is evident, for example, from the level of concern that can be attached to helping to negotiate a medicines regime that is suitable for individual adolescent patients and from the level of concern and understanding that the same team can show for why some of these patients do not take their medicines but still need the same quality of attention and care. This point will be retuned to shortly. First, there is some degree of choice about medicines and this has to be practically negotiated:

Your starting point has to be, you know, what do you think you can manage and what can I fit around that? So for most adolescents, a once daily regime is usually fairly high on their priorities, with a low number of pills and pills that are small. I mean, you can't always create the magic, but, if you don't start out with what they want and then what can I fit to it, there is no point.

We have a box with all the pills in, and I can take the pills out, different sizes, and say, 'well, if you take that... you have to take three different medicines to suppress your virus in

three different ways, otherwise you'll get resistance'. And some of those have been combined, so I can take them out and say, 'well, do you fancy the blue one, you know?' […] And then you line up the baby pills and say, 'well, you'd have to take four of those little ones, plus one of those. Or four of those. Or you could just take the two big ones.' And that's, you know, they can see them, they can feel them.

You have some choice in what you are going to be able to take. And particularly things like fitting it in around college […] Unless you're given that choice and that option, and you actually understand the lifestyle of the young person that you're dealing with, there is no point in prescribing things at 8 and 8, because they're not going to be out of bed! […] It's about knowing enough, or the team knowing enough about [a] young person's life to be able to fit the medicines within their lives.

These focussed exchanges about treatment choice are one manifestation of respect and mutuality, and a small part of the open-ended process of coming to know and forming a relationship with patients, which takes time and is an endless task:

It's about getting to know somebody, understanding them, making them feel comfortable in the setting which is strange. Hopefully winning their confidence, so that, you know, when you suggest something to them they trust that. And usually it's, you know, as I say, it's just a normal process. And because there are genuine options. I mean, […] it's not like we can say, you know, medical evidence is completely clear-cut, this is what you should do. We can actually say, 'well, you could [do] this you could do that, it's up… you know, it takes… you decide how you want to do it'.

But once they know the diagnosis, aged sort of around between 10 and 12, they know the name, they know it's HIV. And from that point on, we start to see them for a small time alone and then their mum or carer comes in to the appointment. So that you build a relationship with them. And then around 13, 14, when they're sort of phrase competent, I explain where my confidentiality is, you know, what they say doesn't necessarily go out the door unless, obviously, you know, it's something that I need to act upon because it's going to harm them or somebody else. I mean, we never

EXAMPLE 4

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know... we only know a tiny bit of what happens in patients' lives, but at least you get a bit more of a picture. And I think being able to have a one-to-one with an adolescent, you know, a one-to-one chat on a relatively regular basis does help build that picture up of what is going on in their lives, but it's only a tiny bit; you're forever surprised. You think you know somebody and then... oh, my goodness!

Of course patients may not want to engage with health professionals or to cooperate with health systems but that does not mean that professionals cannot be flexible and imaginative about maintaining some kind of relationship; nor, above all, does it mean that professionals cannot make an effort to understand patients' lives, including their social and psychological lives. And these exercises in imagination and empathy can extend into areas which – from a purely biomedical perspective – can be profoundly challenging and frustrating:

So some young people who are sick, you know, we'd see very frequently, every couple of weeks. But then some young people who are doing badly don't want to engage. So they won't come and then there'll be a crisis, and then they'll phone up. So that we do lots of sort of open access, so they have a way, you know, they can get hold of us. We do texts and everything, so people can just, you know, text you and tell you that they're in a crisis moment. [...] So there is no two-strikes, you know, if you don't turn up to two out-patient appointments. If you don't turn up to your out-patient appointment, you'll be phoned by me or by one of the nurses. You will then be texted, you will then be phoned again, texted again, and then, you know, as I say, I bug you enough and you turn up! And they laugh!

There's more to coming to hospital than taking your pills. You know, it's more about being able to have those conversations about how do you negotiate relationships, when you have HIV and you've never had sex? How do you... you know, how are you going to disclose to your best friend when you want to tell them? You know, [...] so it's more about... and when things go wrong, who are you going to turn to? And are you going to have a relationship within health care that means that you can come back and take at least your antibiotics and your anti-fungals. Or if you get pregnant...!

So we have a section of the population in clinic who have never taken... really taken their pills. But they need looking after, even if it is only establishing a relationship with them, so that when they do become sick, they have a relationship with someone who they will turn to when... you know, for palliative care, you know, sadly that is happening, that they have somebody who can help them through that as best as is possible.

[There are some patients who] despite everybody's best efforts, will never get on to medicines and they will die from their HIV [...] and it's utterly tragic and in some ways, very frustrating. I don't think we tend to get frustrated now because we've seen it enough to sort of understand the very complicated... well, not understand but live with the very complicated reasons they have for taking those decisions. Or not taking those decisions. Or the fact that HIV is such a big... it's such a big beast in the box, that sometimes just to, you know, denial [...] is a very protective mechanism, in some ways. It can be a very destroying mechanism, but you can absolutely understand where they come from, in just not wanting to open that box.

Building relationships thus involves an ability to see things from other (non-clinical) vantage points and against longer-term time-scales. If what matters is the long-term wellbeing of patients then health professionals have to try and find a balance between their provision of, and advocacy for, immediate treatment needs on the one hand and their longer-term and deeper 'availability' to patients. In an era where, for good reasons, cost-effectiveness is never far from consciousness and where measures of 'outputs' are often rather narrow, the widespread implementation of such open-ended conceptions of care is not easy:

I think that's the main thing, that it is very time consuming. And I dread somebody coming across and saying, 'well, you've put all this time and effort in and let's see what the results are!'

COMPONENT 8. RE-WORKING RELATIONSHIPS AND SYSTEMS

Once the potential open-endedness of professional-patient relationships is acknowledged and responded to through less restrictive professional 'scripts', then more fundamental kinds of relationship change become visible and possible. Healthcare relationships, and associated health systems can be, and are being, re-worked in a variety of ways. Some of these changes are already quite widely embedded across many areas of healthcare; others are still emerging. For example, the idea of multi-professional or inter-professional 'team-working' is widely accepted, as is, increasingly, the notion of somehow including patients and lay caregivers into constructions of 'the team'; i.e. there has been a shift away from thinking of healthcare as about the professional-patient dyad and towards the idea of putting in place and supporting networks of care relationships. But, as with the diabetes example, whilst it is easy to see the advantages of more holistic and multi-professional team-working, there are logistical challenges created in a context where many professionals work in different sectors and in 'shifts', especially when this complexity is contrasted with the importance of 'continuity of care' and relationship-building. For example:

If you have HIV, to have to go and tell your whole story again, it can be very complicated.

Sometimes you get a situation where it's almost like, overwhelming at the beginning because you, you're potentially talking about drug treatment for the mother for their own health, how to deliver the baby, what to feed the baby taking treatment. And so sometimes you just say, 'ok, forget, the baby is not even born yet, let's worry about that later on, let's just think about what you need and at the moment your health is such that we would advise you to start antiretroviral therapy and we'll worry about how you deliver later on, let's see what happens with that.'

In that clinic setting it's usually myself and a midwife, the same person, the same two people all the time. […] So yeah, they do get a continuity of care. Some of them have been pregnant before and are old friends, coming back.

There are also many circumstances where the focus of professionals has to extend beyond the individual patient. This is because, even in the immediate situation, there may be more than one person's health and wellbeing to

bear in mind (for example, because of pregnancy, or other dependents, or carers) and this can sometimes give rise to difficult tensions and dilemmas:

A mother might decide she doesn't want any treatment during her pregnancy, and we would say, 'well that's, may be ok in regards to your health but it's not good for your baby because it increases the risk of the baby becoming infected with HIV.' All we can do in that setting is try to explore why they have, that person has this belief or persuasion. […] You can't make them take a treatment they don't want. […] Now you can't dictate on how they deliver either. So, they have their choices right up to, you know, up to that point. But once the baby is born it's different, the baby has its own right.

Often they have their own, you know, HIV within the family, they have their own children, they have their own issues; they come from a sector where unemployment is very high […] and therefore there's a lot of other factors playing on the carer's ability. But a younger child is dependent on the carer giving him the medicines. So we work very... very closely with parents, carers, in a very supportive role. Although if carers won't engage, you know, we do occasionally have to get social services involved to try and sort out exactly what is going on.

You know, you have to get it right when you decide to start a child on medicines, and they... often with HIV, you see, they don't know why they're taking their medicines early on, so it's even more complicated, but you have to be very... you know, with their carer has to take that responsibility. I mean, we've always thought it was very important, but I think increasingly we see the late effects of, you know, teenagers and young adults who were born with HIV basically dying because they never got onto medicines properly through the whole of their childhood and adolescence, and with a treatable virus still.

It is notable that the professional who made this last remark reported becoming increasingly 'assertive' in their approach to carers in an effort to help secure the longer-term health and autonomy of the patients who were dependent upon them. Finding the right – ethical and practical - balance between assertiveness and responsiveness depends very much on the case in question and can also vary depending upon whether one is dealing with a patient or a carer. In addition to a family orientation, there is also, of course, a public health dimension that enters into the balancing acts that shape policy and day to day practice:

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And there's also the public health of preventing onward transmission, so that you need young people to stay engaged in services in some way, and if you just make it all about, 'do you take your medicine, or not,' they're not going to come.

Enriching relationships is not, therefore, all about finding fuller and deeper ways to relate to the health experiences and needs of individual patients but may also involve challenging patients and carers to be responsive to the needs and wants of others. According to these professionals, treating someone with respect can involve something more than, and different from, being simply responsive to them. One of the ways in which this can be accomplished is by giving patients roles as 'people', especially roles in which they are clearly not passive or subservient. For example: teaching medical students about what counts as being a good communicator and doctor:

One of my savvier older teenagers… […] I said, 'would you mind spending 15 or 20 minutes explaining to him [a medical student] what you think makes a good communicator in a doctor?'

It's good for them to have somebody listen to them and, you know, to feel that… I would say to him, 'you don't have to do it, but while you're waiting to get your pills, will you talk to the medical student? They're learning, this is our opportunity, you and I to teach them to be a better doctor'.

If you ask adolescents what they want, they want someone who knows their stuff. I mean, they know if somebody is lying and doesn't know the answer […] They want someone who's interested. They want someone who will maintain their confidentiality, and they want somebody who is interested in them as a person.

It's just better as an educational experience to hear it from a young person who is a patient, who has really been through the mill and can tell you really exactly what it's like to be not told about what's going on for days on end in hospital; to be ignored when they're in pain; for people to talk over the top of them; for people to be basically patronising, you know? You hear it from them, and they usually put it pretty straight!

Encounters such as this, i.e. non-clinical encounters in which professionals and patients meet as people, can help to dislodge habitual assumptions and scripts. This advantage also arises, for example, from experience of dealing with people in a range of other contexts, for example, in working with potential 'research subjects' where their status as independent and autonomous people is so much more clearly embedded in understandings:

So research is actually a very good place to start in terms of involving people in their care because it's a real, it's a real, it's a formal contract actually. […] This is what it will involve, maybe you're gonna take a new drug, or you'll take a drug in a different dose or whatever. And, this may be harmful, it may be beneficial, we don't know until we've tried it and it's your choice as to whether you take part or not […] and the bottom line is whatever you decide is right. I mean, if you decide you don't want to take part that's fine, we'll still look after you as well as we can, you know, and be very clear about that and meaning it.

Patients can also be active as people, and can be encouraged by systems to be so, in more strategic and collective ways by working both within and 'against' services – by helping to inform and devise guidelines, in setting up peer support systems, or more generally in being involved in the planning, evaluation and/or challenging of services:

There are networks, there are NGOs and so forth, there are communities, organisations for people with HIV including women's organisations, black, African organisations and so forth and we do… they're offered, patients when they first come will be told about these so they can link in with them. Then there's all the information so there are patient information sheets on all the drugs, there's booklets for pregnant women about, you know, the issues in pregnancies, […] which are available. […] They can be pointed to or they would get from other resources and stuff from the Internet as well.

HIV, it's always been a kind of an area where patients have been very proactive […] probably always but, you know, as therapy started to become available, it was very much a case of, you know, 'have you read this paper?' Organisations sort of set themselves up and, you know, they almost challenged patients to go into their doctor's and say, 'have you read the latest, report?'

HYPNET is the HIV Young Persons' Network, so it's a mixture of healthcare providers in the voluntary sector with this Youth Committee that's being set up. And we meet four times a year […] primarily to look at best practice in the transitional care of adolescents with HIV from paediatric to adult services.

The other guidance that we're writing is this adherence guidance. […] And it's basically asking young people at different ages of adolescence, what they thought was helpful, and what did they think wouldn't be helpful, in terms of helping them to take medication.

We've set up quite a lot of peer support. So the other idea with medicines and HIV is that if you had a peer mentor, or attended a... […] there are other agencies called things like Body and Soul, and Teen Spirit. So that if you attended a support group that might help you with your medication. Or if you hadn't tried... you know, you ought to try... we tried to set up a buddy system, so that if you're a younger teenager and you were buddied up with an older teenager, would that help you?

There are well know tensions around how far patient groups can work within professional service contexts or how far they should define themselves as being, in some respects, 'combative' with professionally organised services, but these two positions are not necessarily exclusive. Professionals emphasise how much there is to be gained from meeting 'service users' outside of normal clinical encounters and in spaces that are seen as more 'neutral' and 'equal', whether these are professionally organised fora or ones organised by service user movements and bodies. These broader social and professional encounters enable professionals to get a feel for patient perspectives in new ways and – most importantly – enable services to be shaped by those who are subject to them. For this reason the collective involvement of patients in their care is an important support and complement to individual patient involvement. Of course, there are also associated worries about 'representation' and the fact that some voices will get heard and not others, i.e. that variations in access or involvement, or wider health inequalities, will not be addressed, and may be reinforced, by these initiatives:

So you'd get one turning up and not the other one turning up, because their lives are very busy and there's a lot of other stuff going on. And we all went bowling as a clinic and we took them, you know, but of course the really organised girls turned up, you know? And that's the same... the same people turn up to the sort of voluntary sector and peer support, and the same people do... there was a chief of a youth committee where they will be able to influence policy, practice, commissioning... but it will be the same group.

This example, like the others, indicates the diverse and complex balancing acts and rich forms of engagement practised by professionals who care about, and seek to enact, patient involvement. The examples, taken together, and the discussion of the practical and ethical dilemmas embedded within (and across) the eight components discussed, hopefully provide a 'feel' for the challenge of strengthening involvement practices more widely. But they also provide a relatively concrete and vivid sense of the 'practical wisdom' needed by professionals, and exercised by these groups of professionals, and why this clearly transcends (although obviously encompasses) technical competence relating either to medicines knowledge or 'communication skills'.

EXAMPLE 4

Appendix 2

A BRIEF SUMMARY OF THE MAIN PHILOSOPHICAL AND ETHICAL ISSUES RAISED BY INDIVIDUAL PATIENT INVOLVEMENT IN DECISIONS ABOUT THEIR OWN CARE, OR 'SHARED DECISION-MAKING' IN HEALTHCARE.

This appendix identifies some legitimate concerns about aspects of patient involvement policies. It is not intended to undermine the importance of patient involvement nor the justification normally offered for it. The concerns are identified in a simplified summary form, but many of the issues raised are discussed in more detail in this discussion paper or in the other project papers that informed it (and the references these cite).

The standard justification for patient involvement in care decisions:

Paying attention to, and taking note of, patient perspectives (a) respects the autonomy of patients, (b) improves decision quality – because patient preferences are vital to determining what counts as the best treatment (including no treatment), and (c) enhances ongoing effectiveness – because it provides 'informed adherence' or 'concordance'. Shared decision-making thus allows clinical expertise and patient values and preferences to be optimally combined.

Some significant complications related to the standard justification of patient involvement:

- What counts as a suitably autonomous patient or, more specifically, as the relevant autonomous preferences of a patient are not always easy to determine.

- Eliciting the values and preferences of patients is not straightforward - for example, even when articulated, an individual's apparently autonomous values and preferences are not always internally coherent and sustained, therefore the problem of how to identify the relevant preferences remain.

- There is a dilemma about how best to handle an apparently autonomous preference not to be involved (in various respects) in treatment decisions.

- Involving patients in decisions and attempting to elicit patient preferences may be burdensome for the patient and may be judged by some, at least on occasions, to threaten other important dimensions of the professional-patient relationship – for example, trust in clinicians, and capacity for clinicians to offer emotional support and protection.

- Patient involvement in treatment decisions may have to be balanced against, or circumscribed by, other considerations. For example: (a) professionals will often want and need to retain a high level of accountability for the decisions that they are party to and this will limit the option sets and choices they are prepared to embrace; and (b) treatment choices do not solely effect the patient involved in them but have resource implications and may also have other impacts on the public sphere including public health; i.e. broader conceptions of decision quality and effectiveness may apply than those implicit in the standard justification.

Other significant complications associated with models of shared decision-making:

The various models of shared decision-making, both in the abstract and in their enactment, necessarily embody sets of assumptions that can be questioned; for example:

- It is by no means obvious that the perspectives of clinicians and patients can always be unproblematically combined – nor are the practical processes or 'choreography' of joint deliberation or negotiation easy to specify. And, related to these concerns, there are important debates to be had about what ultimately 'matters' in shared decision-making. For example, is what matters that decisions are 'co-made' or that they are 'co-owned'?

- The emphasis sometimes placed upon the 'neutral' presentation of options by professionals is open to critique; it is difficult to see how professionals can avoid their own values and preferences framing the presentation of option sets.

- More broadly, the emphasis sometimes placed upon the notion that professionals bring 'evidence-based knowledge' and that patients bring 'values and preferences' to the shared decision-making process can be questioned. Both parties are likely to bring both relevant knowledge and values. Nor is it clear that it is always, or necessarily, a bad thing for professionals to bring their own values and preferences into shared deliberation (and indeed some shared decision-making models embrace this).

- The expectations built into some practical approaches to shared decision-making may have important equity implications. For example, some patients, or groups of patients, may be alienated, or relatively disadvantaged, by specific models and styles of professional-patient communication aimed at involvement (or, for example, by the levels of literacy assumed by some decision aids).

- There will sometimes be tensions between shared decision-making at the individual level (the standard case of a professional and patient working together) and patient involvement at a collective level (for example, service users and providers working together to help define the purposes of services, pathways of care and suitable option sets). There are good reasons to suppose that, at least some of the time, the collective deliberated perspectives of the larger group of stakeholders could legitimately restrict the scope of choice of individual patients.

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