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A double-edged sword? Health research and research governance in UK primary care

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ABSTRACT

Contemporary health research is becoming increasingly formalised, regulated and institutionalised. In the UK, this has manifested itself in the development of a framework for 'governing' health research. The framework is often presented as a neutral decision-making tool guiding elements of research (such as ethical and peer review) through formal governance processes and approval procedures. We locate the framework as emerging in the wider context of the growth of 'guidelines' in healthcare that raises questions about the extent to which formal rationality has taken hold on knowledge production and what this means for health research. We therefore explore if and how the framework prioritises particular approaches to the production of knowledge and the tensions that emerge between managerial requirements and the work of researchers. We employed qualitative telephone interviews to access the accounts of both researchers and administrators across a range of primary healthcare settings in England and to capture a range of experiences and levels of involvement in research and governance. Our analysis revealed the double-edged nature of research governance: on the one hand, the framework provided a valuable aid to decision-making and the formalisation of tacit knowledge about 'good research practice'; on the other, consequent managerial processes engaged researchers in a series of low-level activities and privileged particular ways of viewing the world. Our findings add to existing knowledge by moving beyond documenting concerns over research governance and show how the reduction of research governance according to a 'common' set of principles and procedures facilitates the production (and managerial oversight) of quantitative and clinical, over qualitative and experiential, knowledge.

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Introduction

Accounts of knowledge production have revealed different systems of thought that shape what we know and how we know it (Berg, Horstman, Plass, & van Heusden, 2000; Cozzens & Woodhouse, 1995; May, Rapley, Moreira, Finch, & Heaven, 2006; Shapin & Schaffer, 1985). These range from systems concerned with rational and objective observation of scientific facts, through to those exploring how social facts are constructed, with the former dominating both the scientific and political landscape (Porter, 1995; Shaw, 2007). There are tensions between the theoretical and methodological approaches that these different systems give rise to (i.e. between quantitative approaches that seek scientific legitimacy and generalization from large samples and qualitative approaches that seek to uncover the ways in which individuals and

groups participate in the creation of their perceived social reality). These tensions are particularly evident in the field of health where research encompasses diverse approaches and studies (for instance, from intervention studies of new clinical therapies through to exploration of misunderstandings in consultations), but tends to privilege processes and outcomes associated with formal, standardised quantitative methods (May, 2006; Tanenbaum, 1994).

In recent years, health research has shifted from being a largely unregulated endeavour undertaken mainly by individual enthusiasts working independently of external controls, to one that is highly formalised, regulated and institutionalised. In the UK, this culminated in the recent publication of a framework for 'governing' health research, which aspires to enhance ethical and scientific quality, promote good practice and reduce adverse incidents. The Research Governance Framework for Health and Social Care (DH, 2001) (referred to from hereon simply as the 'framework') brings together diverse requirements and guidance relevant to research undertaken under the auspices of the NHS and has been advocated



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as a means of ensuring accountability and transparency of decisionmaking that allows for clear and simple statements to be made about the apparent acceptability of research studies. Ethical and peer review, scientific quality, public and patient involvement, financial auditing and health and safety issues are now all formally subject to governance (see Box 1).

Consideration of research governance has been limited to date, focusing predominantly on the expansion and operationalisation of the research governance environment in health research (Appleton, Caan, Cowley, & Kendall, 2007; Meerabeau, Ruston, & Clayton, 2003; Shaw, Macfarlane, Greaves, & Carter, 2004; Warlow, 2005); and the impact of governance on the initiation, conduct and outcomes of such research (Al-Shahi Salman et al., 2007; Jamrozik, 2004; Parker, Ashcroft, Wilkie, & Kent, 2004; Ward et al., 2004). Whilst this has been valuable in documenting processes, issues and concerns (such as the number of days taken to gain approval for new studies); the framework itself (insofar as it has received any attention at all) has largely been treated as a neutral decisionmaking tool.

In this paper we argue that the framework is not simply a 'technically neutral tool' but prioritises particular approaches to the production of knowledge and wider debates over the kind of experiences and knowledge that researchers can bring to healthcare settings. Whilst not arguing for or against the formal bureaucratic governance of health research, we are concerned to reveal if and how such frameworks might function to privilege particular

Box 1. Overview of research governance.

What is the research governance framework?

- The framework outlines broad principles of good practice for health and social care research, setting out responsibilities of the key organisations and individuals involved (including funders, researchers, organisations employing researchers and healthcare organisations).
- The framework is not law: it formalises processes and procedures. For researchers, cutting corners constitutes professional fraud or misconduct.

What areas of research does the framework cover?

- Standards for research are set out under five domains: ethics, science, information, health, safety and employment, and finance and intellectual property. Standards combine information from relevant UK and international regulations and legislations (e.g. the Data Protection Act). A second edition was published in 2005 accounting for changes in clinical trials' regulations.
- The framework covers the full range of contexts, methods and types of clinical and non-clinical research in health and social care.

What do researchers need to do to meet the requirements of the framework?

- Researchers are required to gain both *ethical* and management approval for each research project. This involves submission of pre-prepared information for consideration by (a) appointed NHS Research Ethics Committees (consisting of multidisciplinary and lay members) and (b) NHS Research Governance Committees (aligned with healthcare organisations). The National Research Ethics Service (formerly the Central Office for Research Ethics Committees) offers a common entry point.
- Whilst the system for ethical review developed in the early 1990s, the system for management approval emerged following the publication of the framework in 2001.

approaches to research and encourage researchers to reproduce such approaches. We do so by exploring: how 'research governance' is currently being understood in the context of contemporary health research, how research and researchers are constituted by research governance processes and procedures, and the tensions that emerge between managerial requirements and the work of researchers.

We focus deliberately on one healthcare setting, that of primary care. This is because primary care has a number of distinguishing features including its inherent multidisciplinarity and interprofessional nature and the breadth of work undertaken across the primary care team (Charles-Jones, Latimer, & May, 2003). This leads to the emergence of a broad range of research questions in primary care, as well as their operationalisation by transdisciplinary research teams employing diverse methodological approaches. It renders primary care a pertinent area for study as it is a site where different methodologies co-exist and are potentially incongruous with narrowly conceived governance processes.

Our paper is divided into four parts. First we describe the environment in which research governance and primary care research have developed in the UK. We then detail the context and method of our research before exploring the impact of the framework. Finally we draw out the implications of our findings.

Primary care research and research governance in the UK

There is a long history of government intervention in the conduct of science in Western societies (Cozzens & Woodhouse, 1995). Commonly the response has entailed a sequence of interventions starting with voluntary arrangements for ethical review (usually concentrating on experimental research) and working towards creating formal legislative and regulatory institutions and processes (Barrett & Coleman, 2005), and has been mirrored by concerns with medical ethics (Zussman, 1997) and issues of confidentiality, privacy and informed consent in 'human subject research' (Barrett & Coleman, 2005). The most recent stage has seen countries such as the US, Canada, Australia and the UK develop 'new' systems for governing health research, by integrating diverse regulations and guidance within a single framework.

In the UK, this process has culminated in the publication of the Research Governance Framework for Health and Social Care (DH, 2001, 2004). The framework is often presented as a response to a series of revelations of research misconduct (see, for instance, a description of events following the removal of human tissue at the Royal Liverpool Children's Hospital (Bennett, 2001)). However, it can also be located in the context of broader social and political concerns and, in particular, the historical drive towards experimentation and standardisation, with quantitative approaches developing as the dominant mode of framing knowledge about social phenomena and use of 'objective' language legitimating such research (May, 2006; Porter, 1995; Shapin & Schaffer, 1985). Since the 1980s this drive has been accompanied by a transition from traditional hierarchical government to governance via markets and networks (Harrison, 1996). These processes are not new however, in the UK, New Labour clearly expanded and accelerated them with governance now one of the means by which new public management and ideas about quality are operationalised (Daly, 2003). Allied developments include increased regulation on the part of relatively autonomous agencies acting on behalf of the state (Harrison, 1996) and the shift from professional autonomy and variability to a more rules-based, audited practice (Power, 1997).

During the same period, primary care has made considerable headway in building a research base and embracing a broad range of methods and disciplines. This followed a commitment to developing a primary care-led NHS in the early 1990s and government recognition of the need for an evidence base to support development in the field (Shaw & Greenhalgh, 2008). By the time the framework was published in 2001, research was concentrated in 31 UK academic departments of general practice and primary care, but also included diverse primary care research networks and practices (SAPC, 2002).

Theoretical framework

Theoretically, our paper draws on the sociology of knowledge and studies of science and technology with particular relevance to the analysis of the contemporary growth of 'guidelines' and 'protocols' in healthcare (Berg, 1997). This process is paralleled in health research where professional bodies, government agencies and patient representatives have sought to develop a range of tools to enhance the quality and standing of health research. Such guidelines and frameworks might encourage critical self-scrutiny that could confer benefits (such as improved patient safety), but they also raise concerns over a 'cookbook' approach to decisionmaking that might reduce integrity and '*represent a flagrant invasion of bureaucracy into the heart of the professional's jurisdiction*' (Berg et al., 2000: p. 766).

In a similar vein, commenting on the use of clinical decisionmaking tools in the primary care consultation, May et al. (2006) have observed that their use 'interposes an external epistemological authority into the consultation: the values and choices involved have been constructed elsewhere, in relation to an ideal-type patient, and ideal-type evidence' (p. 1026). What occurs is an homogenising process in which difference and context are de-emphasised in favour of uniformity and standardisation.

Berg et al.'s work focuses specifically on how governance of medical-legal examination results in selecting people that can legitimately claim a financial compensation for long-term disability. The background and stakes differ from health research however, there are important messages: the extension of decisionmaking tools into the field of health research suggests that researchers are similarly compelled to follow a pre-specified route through 'the ideal-type research process.' In so doing, expertise, experience and authority may become externalised, and particular types of knowledge either promoted and embraced or else devalued and discarded.

It is not our intention to provide a detailed account of the rise in ethical decision-making (see, for instance, Barrett & Coleman, 2005; Evans, 2000 or Zussman, 1997). However, the rise to dominance of a particular approach to ethical decision-making is pertinent: 'principalism' (Beauchamp & Childress, 2001) offers to reduce complex clinical ethical decisions to the operation of four principles, namely, beneficence, non-maleficence, autonomy and justice. Principalism was developed by two of the ethicists who advised the 1979 US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research and its practical impact has been such that research ethics is now conceived virtually exclusively in terms of the protection of human research subjects and their rights to informed consent, voluntary participation and freedom to withdraw, confidentiality and the like (Macfarlane, 2006). Beauchamp and Childress's set of four principles pares down the amount of information that might inform decision-making and provides a commensurable unit allowing for much simpler decisions. Such principles do not become dominant because they might be intrinsically 'the best' but because 'the social conditions are right for those promoting the system to defeat the champions of competing ideas' (Evans, 2000: p. 31), with an historical drive towards rationalisation, standardisation and quantification (see above) facilitating such dominance.

Principalism can be thought of as a form of 'commensuration', a social process that provides a method for discarding information in order to simplify decision-making (Espeland & Stevens, 1998). It promises neutral and technical processes that demonstrate objectively transparent decision-making processes to the public (Evans, 2000). Essentially decisions become decontextualised, information about deeper epistemological or theoretical commitments discarded, and relationships more abstractedly represented by numbers.

Methods

We set out to explore primary care researchers' understanding and experience of research governance in a variety of organisational and managerial contexts. As the setting for our study we chose four Primary Care Trusts in England – the organisations responsible for managing primary healthcare services. Three were selected as being 'leading edge' sites in that they had previously engaged in an evaluation of governance arrangements for which they had received pump-priming funds and therefore potentially represented more highly developed systems. The fourth was selected as a comparison in that it had little experience of governance arrangements.

To identify potential interviewees in each of the selected organisations we enlisted the help of three national organisations, each with a defined membership of primary care researchers. We worked with these to identify 35 potential participants across the four sites who were invited to talk to the research team, reflecting a range of research skills and experience, as well as professional and organisational contexts.

We aimed to understand events through the accounts of researchers and hence employed a semi-structured guide (exploring interviewees' research roles and experiences, their experience and understanding of research governance, and issues pertaining to research governance processes), and allowing for exploration of the research and managerial contexts in which interviewees were situated.

We undertook 19 telephone interviews between October 2004 and February 2005, each lasting between 40 and 75 min. The remaining 16 invited to participate either did not reply or declined our request (due to relevance to individuals' work and/or time available to contribute to something that was already perceived as time consuming).

Because our focus was the experience of researchers, we did not systematically set out to include managers involved in developing research governance in each of the organisations. Nevertheless, as we anticipated, many of the researchers whom we interviewed had also been actively involved in developing and/or implementing research governance arrangements (see Table 1). Several interviewees were in senior research posts that entailed managerial responsibilities and/or had past or current membership of a Research Ethics Committee. They were thus able to comment from the standpoint of the regulators as well as regulated. We also ensured a fair spread across medical and non-medical roles as well as methodological expertise. Descriptions of interviewees are provided alongside illustrative quotes but remain necessarily broad to protect confidentiality and convey the multiple roles and positions that many occupied.

All interviews were audio-taped with consent and transcribed (except in one instance where the tape recorder failed to work). Our approach was one of thematic analysis (Miles & Huberman, 1994); with research questions, wider literature, and early familiarisation with interview data all informing the development of a coding framework that was refined and applied to transcripts. In the process of analysis and interpretation we were concerned to situate

Table 1	
Overview of interviewees	

	Research governance involvement		Methodological expertise			Research experience/seniority			Total
	Yes	No	Quant.	Qual.	Both/mixed	Beginner	Inter-mediate	Advanced	
Medical researcher	3	5	3	2	3		2	6	8
Clinical researcher	1	2		3			2	1	3
Non-clinical researcher	1	4	1	2	2	2	1	2	5
Administrator undertaking research	3	0		1	2	1	1	1	3
Total	8	11	4	8	7	3	6	10	19

interviewees' accounts within wider contexts (organisational, epistemological and so on) and attend to the specific context in which interviewees were situated (such as the interface between research and management). All authors participated in all stages of the research from development of the interview schedule through interviewing to initial identification of themes and their subsequent refinement.

We were aware from the outset that our own status and experiences as health researchers might predispose respondents towards unreflecting criticism of the framework. Following Mays and Pope (1991), the final stages of analysis therefore entailed consideration of how well our explanations cohered with what is already known about contemporary governance and health research. We were also concerned that interviewee accounts might overemphasise the burdensome nature of the research governance process, hence we are careful not only to avoid simple reporting of complaints, but also to offer some theorisation of what is happening.

Our study received approval from the relevant NHS committees.

Findings

Perceptions of the research governance framework

The researchers we interviewed were positive about the potential benefits of an overarching and guiding framework. Thus they reported, for instance, that they believed in 'research governance as a concept' and acknowledged the need 'to practice safe research, we owe it to our patients to do that'.

However, our analysis also picked up more negative concerns with researchers tending to view the processes and procedures associated with formal governance as potential barriers to research – 'in terms of slowing down research and preventing projects from going ahead' – and expressing some confusion about legal and bureaucratic requirements. We were therefore interested to explore why so few researchers spoke of the possible tensions between the development of such frameworks and the realities of their everyday research work, as well as the dangers of standardisation that potentially accompany such frameworks. Reasons for this appeared to be threefold.

Firstly, although administrative processes were reported to have altered substantially, in reality research practices were reported to have changed little, if at all, with researchers describing 'a formalisation of what we were doing', and not discerning 'any notable change' to their research.

Secondly, those interviewed felt that the attention received following a series of high profile 'research scandals' necessitated some kind of response. The framework was described as filling this gap, preventing bad research and 'making sure the research is of higher quality and has considered some very important aspects that may have been missed before the process to do with risk, health and safety, quality, consideration of the patients involved, that type of thing' (Administrator/researcher: mixed methods, involved in research governance). Thirdly researchers distinguished between the potential benefits of the framework and the problematic nature of implementation and management across the four sites:

'It's not so much the Framework itself...it's the bureaucratisation of the Framework...and it's how it's been put into practice' (Medical researcher: mixed methods, involved in research governance).

Hence it appeared that health researchers thought of the framework and administration as somewhat separate endeavours: whereas they did not report feeling explicitly controlled by the former, they appeared to feel constrained with the development of bureaucratic governance processes.

Demonstrating 'good practice'

The researchers we interviewed described a shift away from simply understanding and employing 'good practice', towards clearly demonstrating this. This was achieved through more explicit processes and procedures, demonstrable accountabilities, greater emphasis on assessing and managing risks and creating an auditable paper trail:

"...for me research governance is about having explicit systems in place that can be checked on and can be audited so it's possible for you to come into my office and say "can I look at the ethics approval, can I look at the consent forms...can you show me that you are recruiting patients in the way you say you are recruiting them?" And all that has to be documented.' (Medical researcher: mixed methods, involved in research governance)

Linked to this, the framework appeared to provide a means of legitimating and making transparent decision-making. Requirements such as scientific peer review contributed to facilitating good or stopping bad research, and also provided a tangible basis for decisions. For instance, one senior medical researcher (mixed methods, involved in research governance) reported that he could now '...say to that consultant who's come along with that idea, there's a reason you've been stopped, it's because it's bad science, and here's the evidence'.

This impacted on *all* research and represented a substantial shift for researchers away from informal processes, tacit knowledge and professional regulation and autonomy to the incorporation of specialised and demonstrable bureaucratic processes across projects. Interviewees reported putting dedicated systems in place and being '*expected to be very transparent in the way they...provide detailed information*'.

This led to a tendency on the part of most participants to focus on 'managing' research, suggesting the reduction of research governance to 'tick-box' processes rather than facilitating knowledge of broad principles and their application to research practice. This process of 'managing' research involved ethical and managerial review and '...*if* [researchers] passed all of those they get...ticks in the appropriate boxes and they're told they can go ahead' (Administrator/researcher, qualitative, involved in research governance).

Most participants (and particularly those predominantly interested in quantitative approaches) found it difficult to articulate broad ideas about good governance, falling back on descriptions relating to processes and procedures in the context of their own work. For instance, although not explicitly asked to do so, many participants referred to new contractual relationships characteristic of research governance. These included the transparent allocation of responsibilities for commercial research in general practice, establishment of contracts for peer review of research protocols, and the requirement for formal insurance cover for independent contractors in primary care. However, as in the case of the latter, precise individual and organisational accountabilities remained obscure:

'I'm still slightly hazy...but personally I've made sure I'm covered through my own – certainly for any negligence – my own insurance company' (Medical researcher: qualitative, involved in research governance).

The emphasis on managerial and contractual dimensions appeared to have changed research relationships. The overwhelming emphasis was on ad hoc, external support from varied sources with participants reporting stronger relationships between academic and non-academic contexts and the forging of new relationships with research offices and managers. Many advocated sustained dialogue as a means of developing shared understanding (as opposed to 'policing' research).

'I think there's probably...potential for a lot of these organisations to work much more closely together because there's certain knowledge and understanding in the universities for example that isn't out in the PCTs yet, and vice versa...' (Administrator / researcher: mixed methods, involved in researcher governance)

Our participants also emphasised how research and management had become increasingly co-dependent. Individual researchers' decisions were not sufficient in and of themselves but required formal managerial support or approval to be legitimised. This was particularly evident where the boundaries between research and other activities (such as audit or evaluation) were blurred. Whilst 'research' requires approval from ethics and governance committees before it can proceed (see Box 1), activities such as 'audit' do not. However, governance systems appeared to encourage those involved to seek additional guidance on what, if any, governance requirements need to be fulfilled. Take the following extract describing just such a situation:

'...if something really ought to be called research, is to say it is my view that this is a piece of review although you've called it an audit, but by all means write to the chairman of the [Research Ethics Committee] and he will give a view on it...Quite often he'll agree with the researcher and say no need for ethics approval here. Once the researcher's got that letter then they're covered and the chairman will say this is not a research project this is audit, and they're covered as well.' (Administrator/researcher: qualitative, involved in research governance)

Here the decision rests with the Chair of the Research Ethics Committee who is responsible for categorising health research and the researcher is provided with an 'objective' statement, legitimising their work and allowing them to proceed with the appropriate 'cover' in place. Such examples suggested a more protectionist approach to research with decision-making reinforced through managerial processes. Several instances were described where permissions or advice was sought in order to '...[not] *be caught out later*' or '[to] *just to be on the safe side*'.

The assumption that all health research could be easily accommodated within 'new' governance procedures was problematic. Bureaucratic practices were reported as detracting from actual research time. Take the example of piloting new studies: the following researcher describes how governance procedures were at odds with the evolution of a large research project:

"...research needs to be piloted and adjusted, learning in the early stages that these things occur, and the procedures don't seem to allow for that. And so there's the chicken and the egg thing...' (Medical researcher: mixed methods, involved in research governance)

Piloting and changes are a prerequisite for many health research studies. However, it appeared that, at the outset, researchers were compelled to engage with procedures that potentially negated the realities of such work.

Standardisation and the use of new technologies

Our analysis has begun to unpick how the introduction of management processes and procedures has guided health research/ers towards prioritising particular activities over others. An important driver of this process was the introduction of 'structured forms' (guiding applications and thus structuring researchers' approach to governance and ethics), with a standardised national electronic form for seeking research ethics approval introduced prior to our fieldwork, alongside a range of forms for seeking management approval (see http://www.nres. npsa.nhs.uk for current examples). Whilst the former was the culmination of a process that had been under way since the establishment of the ethical review system in the 1990s, the latter were relatively new.

Our interviewees clearly identified potential benefits of such forms in terms of focusing their attention on certain areas or issues, but also acknowledged drawbacks such as the tendency to reduce 'good governance' to simplistic, process-oriented terms and thereby to undermine potential for more coherent or sophisticated theoretical or moral basis for decision-making.

This double-edged nature of forms was typically summed up in the words of one administrator/researcher (qualitative, involved in research governance). On the one hand, they viewed forms as a good thing in that 'although apparently bureaucratic...it does force people to construct a proper question and think about their methods and say where their patients are coming from, how they're going to be recruited, how they're going to be consented...and so on.' On the other hand, they referred to the ability to 'cut and paste' information across forms as placing less significance on the need to think through the context of requirements and how their research might fit with this. Whilst this same interviewee viewed the ability to 'cut and paste' and 'transfer terminology' as a potential benefit, they also recognised that this structured approach was not relevant to all research and particularly for 'some qualitative studies where a lot of the form's irrelevant'.

This last point appeared particularly pertinent as structured forms were identified as expressing epistemological assumptions, prioritising particular forms of knowledge and/or approaches to research:

'if you look at...the generations of standard forms... they have been weighted very heavily towards trials, and that can mean if you're a qualitative researcher that there are boxes you don't tick, and...there are lots of issues that you don't name...there are partly ethical/partly governance issues related to qualitative work which just haven't had a place in the documentation and the procedures...' (Non-clinical researcher: qualitative, not involved in research governance) Thus, those employing participatory and qualitative approaches regarded such governance technologies as privileging clinical trials and hospital- or laboratory-based studies, commercial and pharmaceutical research, and quantitative approaches (including a particular concern with randomised controlled trials). They were described as inhibiting participatory and qualitative research, forcing researchers to pre-empt things that they would prefer to keep more open-ended, and challenging the foundations of their research:

'So it's contrary to the nature of participatory research, you're having to do things that aren't participatory before you can get the approval to go ahead and do participatory research...' (Clinical researcher: qualitative, not involved in research governance)

A clear-cut division of the research universe into researchers and research subjects was a given within the dominant research paradigm. However, this division was problematic for methodologies which saw research subjects as participants in the research process:

"So one of the questions on the...form is how many potential research participants have you recruited? Well some of the participants are my research partners, you've had to have done that before you've actually got as far as filling the...form in. So the language makes it very difficult to answer on a standard form" (Clinical researcher: qualitative, not involved in research governance).

In addition, an emphasis on numbers transformed disparate information (e.g. regarding recruitment to studies) and appeared problematic for qualitative and non-clinical research. For instance, drug intervention studies were seen to 'fit' with current risk assessment systems in terms of calculating '*tangible physical risks*', whereas the non-clinical research presented a different set of problems:

"...there are other wider debates to do with the whole notion of informed consent and the experience of participants in research, and where the balance lies in terms of being transparent and accessible and in dialogue with people about what you're doing, and at the end of the day...not taking away from their responsibility to make their own decisions. Those are the kind of things that are live issues in non-clinical research...[its] a whole different ballgame..." (Non-clinical researcher: qualitative, not involved in research governance)

The overall approach to governing health research was perceived as offering some appeal in that it offered a unitary framework of principles within which any value or preference could be made commensurate with any other. However, it also aroused disquiet in that disparate values could be expressed in standardised ways that then detracted from the context and meaning behind decision-making processes. These later concerns were felt to raise particular problems for primary care research: participants pointed to the tension between the breadth of approaches to health and research incorporated within primary care and the protocols into which it was required to 'fit' that stripped away these very qualities.

Discussion

Our study has focused specifically on the UK research governance framework and its application to primary care research, problematising the nature of research governance in order to investigate how research governance is understood by researchers and the impact this has on their work. It is hardly surprising that the main issue specific to primary care was the potentially negative impact of a narrowly conceived, quantitatively-oriented framework on such a diverse field.

Our findings show that researchers are positive about the potential of such a framework to legitimate existing practices. In many cases 'new' governance requirements simply formalised the working patterns of researchers prior to publication of the framework and findings suggest a welcome formalisation of existing knowledge and processes, making explicit what had previously gone unsaid (or at the very least unmonitored), and formally recording different aspects of research that might previously have continued unchecked. However, in line with existing analyses of the implementation of the framework (Al-Shahi Salman et al., 2007; Appleton et al., 2007; Parker et al., 2004; Ward et al., 2004) and professional guidelines (Berg et al., 2000), findings suggest a real concern over increased bureaucracy, increased susceptibility of health research to interference, and enhanced surveillance of researchers. This resonates with Berg et al.'s (2000) suggestion that not only do such instruments 'make the profession's decision-making processes more transparent' but that they also 'make that process more vulnerable to 'meddling' by outsiders' (p. 766).

We have extended existing research documenting concerns with bureaucratic processes and procedures and revealed a more complex picture of how the organisational processes encompassed by the framework encourage research/ers to manage their work in particular ways and by particular means. Our findings indicate that a 'new' division of labour – between research and managerial practices – does not simply reflect neutral managerial processes and regulatory requirements but, instead, the routine work of health researchers to seek approval for their work engages them in a series of low-level activities that embody particular ways of viewing the world. Furthermore, the managerial process appears to decouple the researcher from the context of their research with the effect that some aspects of health research are highlighted (such as managerial labelling of research or audit) whilst others might be silenced (such as the iterative nature of much gualitative research). In effect the 'managerial decision' appears to mediate between the research and the researcher reconstructing the later as an administrative conduit and reframing researchers' concerns as a set of limited preferences that can be elicited and acted upon. This is evident in the use of structured forms: rather than functioning as innocent containers, forms appeared to operate as technologies for standardising practice (Berg, 1997), privileging quantitative approaches, representing values in 'objective' terms, and simplifying decision-making by assessing different types of research by a single common standard. This resonates with the wider literature exploring how decision-making tools highlight some aspects of experience but silence others (May, 2006; May et al., 2006; Pinder, Petchey, Shaw, & Carter, 2005) and how a set of principles can facilitate a pared down focus to simplify decision-making (Evans, 2000).

Health research and governance systems did not appear to be entirely incommensurable in that we have described instances where they work well together and appear founded on similar, mutually-enforcing principles. However, those operating outside or on the boundaries of dominant epistemological frameworks struggled with tensions between systems. This suggests that the places where health research and governance come together (such as research ethics committees) act as sites of struggle, where diverse values, approaches and behaviours come together and potentially conflict. Rather than operating as a neutral decisionmaking tool, the framework then facilitates the production of certain forms of conduct by health researchers. Governance processes aspired to a bureaucratic form of commensuration via the use of guidelines and standardised forms and the application of 'common' governance issues to all types of research. This might well propel decisions, but also emphasises the technical aspects of research and overlooks accepted differences between, for instance, qualitative and quantitative or participatory and subject-oriented research. This reflects tensions between experiential, qualitative knowledge and experimental, quantitative knowledge that have been previously reported (Espeland & Stevens, 1998; May, 2006; May et al., 2006; Shapin & Schaffer, 1985; Tanenbaum, 1994). Such tensions have a particular relevance for primary care research (given the breadth of research undertaken within this setting) but may not be so evident in other areas, such as hospital medicine.

Our study has limitations in terms of the number of people interviewed however, it has allowed us to show how the coupling of 'research' and 'governance' needs to be understood in relation to social and political developments. The creation of a managerial tier focused on governing research suggests a broad move towards an institutional managerial project, characteristic of New Labour, that is difficult to reverse. In reality it is hard to imagine going back to the package of approaches that comprised governance of health research before contemporary systems were introduced. However, it is clear that the contemporary systems emerging from the requirements of the framework incorporate wider political, social and epistemological agendas and do not reflect the full scope of health research.

We are somewhat cautious of the standard mantra that 'more research is needed'. However, given the scarcity of empirical work investigating research governance we do advocate further work. Future studies might examine the development of research governance technologies: the impact of processes and procedures on defined areas of research (e.g. sexual health) and vulnerable populations (e.g. those with mental illness); the policy drivers that shape government intervention in research; or how research governance language works to shape knowledge production. Such studies might be informed by, for instance, science and technology studies, medical sociology, discourse studies and political science. By undertaking such work those involved in health research stand to (a) obtain a better understanding of the social forces that have led us to a situation where such frameworks and processes have such a hold on us, (b) discern better ways in which we can make sound decisions relating to health research that combine both objective judgements and subjective elements, and (c) facilitate change by examining how the tensions and contradictions that are foregrounded in health research and governance are 'best' played out.

Since we collected our data, the Department of Health has acknowledged that, in relation to clinical research at least, administrative processes should be streamlined (DH, 2004) and introduced, for instance, new methodological filters within electronic forms for ethical review. Such changes are valuable in easing the administrative burden of healthcare research. However, they fail to address fundamental concerns regarding the focus on particular epistemological foundations and methods (to the marginalisation of others) and the assessment of all research according to a fixed set of principles. These must be addressed in order to fully capture the breadth of moral and ethical life of health research.

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