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In the sociomedical laboratory of citizen health: exploring science, technology, governance and engagement in prostate cancer detection in the UK

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This Working Paper is presented primarily for discussion purposes. Please address your comments to: FaulknerAC@cf.ac.uk

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ABSTRACT

Evidential science and governance are closely linked in contemporary societies, nowhere more than in the domain of health policy. Healthcare technology is everywhere scrutinised and innovating, raising questions of the relationship between the modernising state and citizens' engagement in healthcare knowledge and practice. Prostate cancer is acknowledged as a major public health problem internationally, and has been widely represented in the mass media. Unusually, it is a high-profile disease affecting only men. International, national and local policies for the appropriate healthcare response vary and are contested. This paper presents a preliminary consideration of the role of an evolving healthcare technology, the prostate-specific antigen (PSA) blood test in the construction of this 'public health' problem; it identifies controversy between clinical practice and policy discourse on the disease – influenced by the methodologies of healthcare science; and it considers the part played by the science of prostate cancer detection in the shaping of the healthcare sciences. The significance of the engagement of men in sociomedical spaces of scientific uncertainty and healthcare risk is discussed.

The paper draws upon science and technology studies (STS) approaches and concepts of public policy analysis. Materials used include medical and epidemiological research and commentary; surveys of the use and interpretation of the PSA test and treatment options by doctors; materials emerging from healthcare science (the health technology assessment and 'health service research' movements); and healthcare policy documents. This exploratory paper discusses what was formerly regarded as 'early-stage' prostate cancer in the sense of localised disease confined to the prostate, and also is focused on the 'early' phase of healthcare science and governance engagement with this issue, which continues to evolve.

Keywords: healthcare science; governance; policy; citizen engagement; patient participation; risk; prostate cancer; PSA test; science & technology studies (STS); discussion paper.

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Introduction

This discussion paper begins by outlining recent conceptualisations of significant trends in the configuring of relations between healthcare science, medical techno-practice, civil society and the state. This focuses upon the healthcare sciences as state-orchestrated regulatory science; the methodologies and social modes of the knowledge practices of healthcare science; the boundary organisations in which 'evidence' is produced and negotiated; and the shaping of 'risk'. The paper then goes on to link and develop the application of these concepts in the case of one important contemporary sociomedical experience, namely testing for and detection of early-stage prostate cancer in men.

Healthcare is a social arena of continual, confusing, complex innovation in contemporary societies. 'Evidence' and governance are closely linked, nowhere more than in the domain of health policy (Davis & Nutley, 1999). Everywhere healthcare is under scrutiny by 'science', and biomedical science marches on, avowedly in pursuit of new knowledge and better healthcare. At the same time patients and publics are being accorded and gaining a more central position in neo-liberal agendas of healthcare policymaking and some patients may act as co-experts or alternative experts in more or less participative decision-making in the consulting room and other sociomedical spaces. Pressures abound for adoption and proliferation of new medical technologies, often allied with modernisation policies. Healthicisation movements mean that society is permeated with alleged risks to health, but the healthcare system itself is also a source of some well-publicised risks, and uncertainty about 'the evidence base' in many instances confronts those engaged in medicine, whether as professionals, citizens, strategy-makers, or scientific investigators. It has been argued that developments such as these, which are associated with the development of knowledge economies and 'network' forms of governance in medicine and other socio-scientific arenas, is leading to a form of 'reflexive policymaking' which 'embraces' uncertainty and risk, rather than attempting to eradicate those demons in a modernist, rationalist, and technocratic mission (Webster, 2004). Thus scientific evidence and the social forms of its production, become a central consideration

in understanding the positions that citizens might occupy in relation to medicine and the state, and the positions that medical or healthcare science might take in relation to the state and citizens. These conceptualisations of novel trends and configurations of participation in healthcare should not be taken for granted, however, and require testing against analysis of specific case studies of science-medicine-society relations where significant discontinuities and re-configuring appear to be present.

In framing this task, it should be noted that there have been growing signs of *rapprochements* between medical sociology, the sociology of scientific knowledge (SSK), and science and technology studies (STS) over the last ten years, which might suggest that useful approaches are being developed. Examples of this are the analysis of healthcare evaluation as a novel form of knowledge production (e.g. Faulkner, 1997); illustration of the role of patients and supporters as active agents in medical science (Epstein, 1996; Novas, 2004); examination of the active knowledge contributions of parents of children with possible genetic abnormality in genetic counselling healthcare settings (Latimer, 2006); health social movement/lay advocacy groups' influence in cancer-related research fields (Hess, 2004); the dilemmas of citizen participation in their own therapeutic encounters (Bloor, 2001); organised user resistance to 'curative' technologies (Blume, 1997); understandings of the societal challenges constituted by new medical technologies (Brown & Webster, 2004); study of the movement to standardise healthcare procedure (Timmermans & Berg, 2003); and the identification of medical technoscience as an increasingly significant multidimensional social force (Clarke et al, 2002). Most of the developments analysed in these contributions take uncertainty of healthcare knowledge, its contestable nature, and the possibly changing roles of citizens as crucial components.

The *healthcare sciences* have developed in methodology and expertise, and been institutionalised in various forms, internationally, since the 1980s. Much of this development of 'evidentiality' may be attributed to the response to rising costs in the healthcare systems of the advanced industrial societies, and increasing awareness of apparently non-rational variations in healthcare within comparable healthcare systems (famously, in the world of healthcare science: Wennberg et al, 1987), leading to

apprehension of a major deficit of scientific evidence to 'support' existing medical practices. The multidisciplinary work commonly known as 'health services research' (HSR) and health technology assessment (HTA) as it evolved during the 1990s typically focused upon research agendas of effectiveness and cost-effectiveness of public healthcare. Their approach brings together in varying combinations the disciplines, sub-disciplines and practices of clinical epidemiology; public health medicine; health economics; medical statistics; psychology; organisational analysis; medical/healthcare sociology; 'qualitative research'; general practice and the many specialties of medicine and clinical science.

HSR and HTA have become fields of knowledge production marked by uneasy and often unclearly-defined partnerships between these disparate disciplines. Although accounts of the disciplinary make-up of HSR/HTA vary, as does the practice, HTA in particular can be characterised as having a rather stable core methodological programme (Faulkner, 1997; Woolf & Henshall, 2000). HSR/HTA is a good example of a problem-driven area of multidisciplinary research expertise, and can be appropriately be seen as exhibiting some elements of the knowledge practices described in well known formulations as 'Mode 2 Knowledge Production' (Gibbons et al 1992), and 'post-normal science' (Funtowicz and Ravetz, 1992). Thus enrolment of citizens in various parts of the research process, other than as patients, accords (in principle at least) with the post-modernist model for 'socially robust' science, and this has been a process growing, albeit slowly, in the field of healthcare science. Nevertheless, the new healthcare science can also be characterised as espousing a neo-modernist (Faulkner, 1997) and perhaps also positivist (Harrison, 1998) mission. HTA/HSR is enrolled into a state-orchestrated policy which aims, essentially, to standardise healthcare practice in the face of its many vagaries (Timmermans & Berg, 2003).

The new evidentiality is closely linked to evolving governance formations in public services. The rise of the 'regulatory state' (Moran, 2001) and the movement from government to governance in which networks and enrolment between state and experts are key features (Rhodes, 1997) characterise significant developments in the relations of

science, civil society and politics. In this environment the credibility of knowledge, or evidence, becomes paramount. Information as a form of evidential guidance and even regulation gains increased meaning (Majone, 1997). The growth of evidentiality in and around the new healthcare sciences provides articulation points with the social legitimisation of healthcare policy and governance of contemporary public healthcare systems. HTA/HSR can be properly regarded as activities of 'regulatory science' (Lehoux & Blume, 2000; Irwin et al,1997). 'Evidence-based healthcare' should thus be conceptualised as a regulatory and credentialist phenomenon as well as a scientific movement.

Interaction between science and policy has been conceptualised in terms of 'boundary organisations' (Guston, 1999) which have been interpreted as stabilising the boundaries at the interface between the two spheres of activity. Analysis of the structure of interactions between evidence-producing institutions and healthcare policy communities in the UK suggests that they have such an intermediary role (though this author has some reservations, not explored here, about the degree of their stabilising function). These new intermediary knowledge institutions produce and give weight to evidence produced according to ever more codified standards. In the UK they have proliferated in institutions whose names convey their symbolic centrality: NHS Centre for Reviews and Dissemination, the Cochrane Collaboration, the National Co-ordinating Centre for Health Technology Assessment, and the National Institute for Health and Clinical Excellence (NICE). These newly-designed institutions can usefully be seen as boundary organisations acting to promote the generation and processing of healthcare science in the service of policy but at the same time acting as buffers between the evidence-producers (including ourselves, as patients, and a wide array of academic, clinical and commercial research organisations), and the evidence-consumers. In this buffer zone other stakeholders may secure engagement – industry, patient advocacy groups, clinical experts, publics. Thus these organisational sites of evidentiality allow for 'the politics' of healthcare innovation to be constituted.

These introductory considerations would be incomplete without a discussion of 'risk'. Contemporary societies have been diagnosed as undergoing an institutionalisation of risk (Giddens, 1991). Health hazards and the societal apprehension of risk have assumed an extraordinarily large place in analysis of contemporary societies and healthcare systems (e.g. Lupton, 1995; Petersen 1996; Howson 1998; Robertson 2000). Hazards and the social distribution of risk may also be associated with healthcare itself, sometimes termed iatrogenic risk and given its most extreme formulation, perhaps, in the radical early work of Ivan Illich (1975).

Diagnostic and screening 'techno-practices' (Faulkner, 2004) can be considered to play a part in the shaping and experience of health risks, and it is at this point that the question of detection of asymptomatic diseases slips into the frame. In sociologically-informed theoretical work on 'the new public health', Lupton has suggested that diagnostic testing is seen as offering people control in the face of the disorder represented by possible disease (1995:78). The knowledge provided by diagnostic testing in principle enables protective action to be planned. Thus the apprehension of risk and individual testing of asymptomatic people to determine if a disease is present are part of a process in which both are mutually supportive, constituting a process of knowledge generation, personal and collective. In a context of socially amplified risk and uncertainty, it is understandable that screening and early detection technologies are becoming not only an increasingly important part of modern healthcare services, but also a growing source of ethical and social concerns from public health perspectives (Stewart-Brown, 1997). Howson (1998) has analysed cervical cancer screening as a healthcare site where the practices associated with risk and with population surveillance are brought together. Thus organised forms of screening for disease may increase the collective stock of knowledge of health and health behaviour held by health services and authorities, at the same time promoting concerns about health risks in certain population groups. Howson has described the understanding of the 'relationships between the subjective articulation of risk and *the processes shaping those articulations*' (my emphasis - 1998:210) as an essential task of the social scientific study of public health and disease prevention.

Cancer-related trials may pose direct risks of safety and efficacy for participating patients (Keating & Cambrosio, 2006), and also constitute environments in which awareness of risks may be promoted. Thus in the case to be discussed here, the production of scientific knowledge about prostate cancer detection is taken to be part of a process in which men's apprehension of risk is shaped. The production of this knowledge requires the engagement of men with a scrutinised healthcare system. The paper discusses the emergence and uptake of testing technology for prostate cancer, its routinisation as a more or less stable, collective, but variably patterned medical techno-practice, and the production of evidence about prostate cancer detection by the healthcare sciences employing various research methodologies and patient recruitment techniques. These features of healthcare and healthcare knowledges, should be seen as part of a societal process in which the contours are being constructed within which men's personal appraisal of risk of prostate cancer is delineated through their engagement with activity that is a hybrid of healthcare and science. At the same time, this societal process is one that is intimately linked to matters of governance, the societal management and distribution of risk, and the construction of innovative forms of healthcare science itself.

This working paper is a preliminary conceptual analysis of the story of the first stages of the science in and of the detection and treatment of early prostate cancer in the UK. A fuller analysis which will bring the details more 'up-to-date' and extend the theoretical discussion, will be the subject of a subsequent publication.

Detecting prostate cancer; the science and technology of societal screening

Prostate cancer is a significant health problem with significant mortality rates. The epidemiology of the disease itself is not detailed here, but it is worth noting one recurrent comment amongst healthcare and clinical scientists who study this disease – that most men die *with* it rather than *from* it. Thus we note some advisory precaution in interpreting the true 'size of the problem' for society in the context of its high public profile. On the other hand, prostate cancer *detection* has been constructed in healthcare policy communities as a very major healthcare policy problem for over a decade in the UK, as

elsewhere. Testing and screening for disease are undoubtedly popular in contemporary society. In the case of life-threatening illnesses the popular image is that diseases apprehended early have a better chance of being cured or ameliorated. However, it is also the case for many that the offer of testing by healthcare practitioners, in the absence of symptoms, does not evoke a positive response. The major question for policymakers has been: should a mass screening programme, akin to that available for women in the case of breast and cervical cancer, be introduced? And the answer to this question in the UK, officially, and with the claimed support of extraordinarily detailed 'evidence', is – and remains – a very firm 'not yet'. The production and negotiation of this 'not yet', its meaning and its consequences, are the subject of the rest of this paper, placed in the context of the conceptual framing introduced above.

Rates of mortality from prostate cancer, and the incidence of its detection, were rising dramatically during the 1980s and early 1990s internationally. However, it was clear that part of this trend could be attributed to increased rates of detection of the disease. In the early to mid-1990s in the UK, prostate cancer was the subject of mass media and public attention, and controversy, as the issue of screening for the disease became prominent. Media headlines such as "Rising fear of prostate cancer 'could cost the NHS £400m'" (The Guardian, 31.10.95) were frequently to be seen. It was common to hear about public figures who had contracted the disease, such as General Norman Schwarzkopf and the musician Frank Zappa. Such personalised references undoubtedly contributed to raising the public profile of the disease and to increasing the public perception of risks associated with it. The fact that prostate cancer is a disease affecting men is also significant in its rise as a topic of healthcare science and policy. The absence of national screening programmes for men, compared to breast cancer and cervical screening for women in the UK was noted in public debate at the time. The perception of this gender disadvantage (whether it *is* a disadvantage to health in this instance is open to doubt) was reflected also by some academic work (Cameron & Bernardes, 1998).

The PSA test, a blood test for aiding in the detection of early prostate cancer, played a large part in the increased rates of detection of the disease. It became an iconic technology

in the development of healthcare governance and the enrolment of the new healthcare sciences in state-orchestrated policy legitimisation in the 1990s. The technology and its role in therapeutic services have been beset by evidential uncertainties, and the question of its role in possible mass screening programmes has attracted huge amounts of healthcare science research in many of the advanced healthcare systems. Technologically, the problem with the PSA test is that it does not have a good predictive value – thus a ‘positive’ test does not necessarily indicate a cancer which will go on to become symptomatic, nor does a ‘negative’ result necessarily rule out the presence of cancer. Raised PSA levels highlight uncertainty about whether further clinical investigation is to be recommended (making variable interpretation of the test by different practitioners extremely important – see below). This situation is compounded by the fact that in spite of there being three major modes of treatment for the localised disease, i.e. confined to the prostate (surgery, radiotherapy, ‘wait-and-see’/monitoring), in terms of survival the one to prefer in general or in individual cases is also unknown. These fundamental observations, apart from motivating a large amount of R&D to find better tests and to design research that will reduce the uncertainty, makes for an experience of extreme uncertainty about the risk of the disease and indeed the risks of being tested for it, for men of a certain age. Under these conditions it would be difficult for policymakers to justify introduction of mass screening using the techniques available. It should be noted, however, that the scientific justification for the cervical and breast cancer screening programmes, in terms of decreasing mortality from the disease through therapy, also have been severely doubted in healthcare science communities.

Growing ethical and social concerns about the risk of screening were signalled in the United Kingdom by the formation in 1996 of a national advisory group, the National Screening Committee, charged with responsibility for advising government on all existing and new screening technologies and programmes. This immediately identified screening for prostate cancer as a priority topic for review. Healthcare science in the form of Health Technology Assessment was enrolled into the process of policy development in the field, with the avowed aim of providing a solid basis for policy decisions (Sherriff et al, 1998). In other words, policy looked to science for legitimisation. The issue of screening for prostate

cancer was also identified as one of the highest priorities in the first research agenda produced in the early deliberations of the UK national Health Technology Assessment programme. In the mid-1990s the UK's national HTA programme commissioned *two* 'systematic reviews' – exhaustive evaluative studies of existing research – on the same topic of the effectiveness of testing and possible cost-effectiveness of screening programmes (Chamberlain et al, 1997; Selley et al, 1997). The odd decision to undertake two systematic reviews reflects the novelty and uncertainty of HTA methodology at the time. These concluded inevitably that there was inadequate evidence to support the introduction of mass screening using the PSA test and also that the comparative effectiveness of alternative treatments for early prostate cancer was unknown. These conclusions, it was stated by the UK government, were subsequently supported by HTA reports from several other countries and awareness of the conclusions 'helped to contain the uncontrolled dissemination of PSA testing' (<http://www.dh.gov.uk>, 09/2003) – a statement whose fragility is demonstrated below.

Collective detection and therapeutic practices: shaping risk experience

The policy response to the screening question also required knowledge of how the medical profession was using the PSA test in clinical practice. Apart from the doubt about introducing a formal population screening programme, the other danger perceived by policymakers and professional activists was a threat of possible uncontrolled diffusion of testing in spite of official policy, carrying with it a risk of creating needless anxiety or over-treatment for large numbers of men. It was important, therefore, to know the extent of variation in then current clinical practice in using the PSA test because this would have direct implications for the pattern and volume of different types of further diagnostic activity and of treatment undertaken. It would also be crucial in its effect of building the social and clinical contexts in which asymptomatic men would appraise their wish to be tested for prostate cancer - in other words, to shape the context for men's subjective articulation of risk - and their subsequent experiences of testing and treatment processes. To address this question, it was necessary to ascertain the state of collective beliefs and techno-practice amongst clinical specialists, in this case primarily urologists. This required

a combination of clinical science (urological) knowledge of patient profiles and the testing technology, together with identification of social and organisational 'variables' relevant to clinical practice in the field. Also helpful would be an understanding of the importance to the construction of men's risk experience of interpretive practices in professional work. This multi-disciplinary work was undertaken in one of the new sites of evidentiality, a health services research centre conducting HSR/HTA located in a University in the UK. The study surveyed all urologists in the UK and concluded that it is highly likely that aspects of the organisation of urological services, which vary between geographical areas and health care centres, and the socialisation of urologists, will lead to an unequal social patterning of detection of the disease amongst men in the UK. Centres where there was a urologist specialising in prostate cancer were more likely to use lower cut-off points in interpreting PSA levels, thus making it more likely that further action would follow in these centres (Faulkner et al, 2000). Similarly, a parallel survey of oncologists had shown that they would generally treat with radiotherapy rather than surgery, thus favouring the more conservative approach (Savage et al, 1997).

This variation was paralleled in research which revealed variations in type and approach to *treatment* of early-stage prostate cancer. In particular in the USA a much more interventionist approach was evident compared to the policy most prevalent in the UK namely 'watchful waiting', in other words active monitoring to detect signs of progression of the disease. However, in spite of this relative surgical conservatism, there were rapid increases in the use of surgery – 'radical prostatectomy' - in England during the 1990s, both in urologists' reported preferences for treatment options, especially for men under the age of 70 (Donovan et al, 1999), confirmed by NHS data which also showed marked regional variations in the upward trend, possibly related to access to PSA testing and the location of surgeons able to carry out radical surgery (Oliver et al, 2003).

Governance of PSA test diffusion: constructing a sociomedical scientific space

The policy on PSA testing in Britain has nevertheless been relatively conservative, as noted above, in an attempt to control diffusion of the practice to large sectors of the male

population. Subsequent to the early UK HSR/HTA work on prostate cancer which was used to support the state's negative position on mass screening, national healthcare science in the form of the HTA Programme in the UK has devoted further large amounts of resources (some £13 million, raised to £20 million) to research with the aim of producing evidence on which to secure NHS policy, including both the screening question and the 'therapeutic limbo' (Brown & Webster, 2004: 51) of uncertain treatments for asymptomatic men.

Research was deemed to be needed to tackle the problem of low recruitment rates to clinical trials (this was a problem in several important cancer trials at the time) if the HTA approach was to produce the knowledge about treatment comparisons that was seen as necessary. This dilemma in research policy led to innovations in HTA methodology: 'New methodological approaches are required urgently to investigate this issue and to bridge the gap between clinical practice and the need to acquire evidence. Such approaches need to retain the essential principle of randomisation while incorporating more fully patients' perspectives and preferences' (Donovan et al, 1999). And in the meantime '...until more evidence accumulates, patients and urologists should use the information available from recent systematic reviews to reach shared decisions about treating localised prostate cancer and provide information that highlights uncertainties about the potential effects of such treatments on survival and quality of life' (Donovan et al, 1999). This early mention of 'shared decisions' is notable, presaging subsequent developments in the methodology of producing knowledge in this field, and, it is argued here, sharing the health and healthcare risks in the process. Also notable is the presumed enrolment of men into a sociomedical space where they are exposed to the uncertainties of healthcare science in relation to this disease, a space which while engaging men's participation also maintains the experimental scientific paradigm of the controlled trial.

Thus an innovative feasibility study was mounted to try to assess how to improve recruitment to a future full scale randomised trial of alternative treatments (given the earlier failure of a Medical Research Council trial). At the same time, the National Screening Committee set up a UK Prostate Cancer Risk Management Programme to

provide information for clinicians and potential patients, drawing upon evidence and advising on policy (this has resulted in more recent changes to the policy on risk communication and test diffusion which are not discussed here). The state-endorsed feasibility study used 'qualitative methods' to assess men's reasons for participation or non-participation, and it aimed to allow for and take account of men's own preference, if any, for one or other form of treatment if prostate cancer was found.¹ The design of this study necessitated offering the PSA test to several thousand men in order to identify a small number with the disease who might be randomised to one or other treatment. The design of the study focused particularly on the initial offer of the PSA test. There was an ethical concern that men offered the test should be fully informed about the test and possible treatment side-effects, the favoured approach being that this should be in the context of professional face-to-face consultation, rather than the conventional information sheet and consent form. The feasibility phase thus examined the feasibility and social acceptability of 'case-finding' amongst a population of men otherwise unaffected by urological healthcare, the conduct and performance of PSA testing in a screening context, men's attitudes to screening, preferences for treatment of early-stage prostate cancer, and men's willingness to accept randomisation to one or other form of treatment. Overall, the 'most efficient and effective' design for a trial of alternate treatments was to be determined (the above comments draw upon the present author's involvement in the planning of this study).

This development, interpretable as being toward a 'counselling' and risk-sharing model of men's decision-making about consent to participate in a randomised control trial, the prime method of knowledge production in the healthcare sciences, is clearly consistent with the direction of both the NHS Centre for Reviews and Dissemination (NHS CRD, 1997) and British Association of Urological Surgeons' recommendations to constrain use of the PSA test, though perhaps elevating the degree of information provision and magnifying the health service incursion into asymptomatic men's appraisal of personal risk and healthcare decisions. This can be contrasted with the prevailing approach in the USA, expressed here by David Kessler, Commissioner of the regulatory body for new medical devices, the Food and Drug Administration (FDA) at the time the PSA test was

approved for use in early detection. At this time screening programmes were already widely diffused in the USA, bolstered by public health campaigns such as 'Prostate Cancer Awareness' weeks: 'This test - used with other procedures - can help detect those men at risk for prostate cancer early on when more treatment options are available..But for the test to help, men must be aware of the importance of early checkups and get them on a regular basis' (FDA, 1994).

The feasibility study mentioned above led to UK government support of a very large empirical research project starting in 2001 in the UK, a randomised control trial to compare treatment strategies for localised early prostate cancer (radical prostatectomy, radical conformal radiotherapy or active monitoring). This is known as the ProtecT study, which is taking place in nine clinical centres in the UK. The trial involves counselling and PSA blood tests for 120,000 men aged 50-69, with the expectation that 2,000 would be detected as having signs of early prostate cancer. It is still under way (to 2008) and the surveillance of participating men will continue for 10 to 15 years after the start. It is notable in the context of this discussion on the evolving methodology of the healthcare sciences, that this study is stated to combine 'the qualitative traditions of sociology and anthropology, epidemiological and statistical disciplines informing randomised trial design, and academic urology and nursing', and the study 'contravened conventional approaches by being driven not by the randomised trial design but by the qualitative research' (Donovan et al, 2002a). Regardless of the interpretation that we might give to this allusion to possible power-shifts in the inter-disciplinary and inter-methodological relationships of stakeholders in healthcare science, one outcome of the methodological innovations claimed here has been to increase recruitment rates to the large-scale trial of alternate treatments for localised prostate cancer from an estimated 30-40%, to 70% (Donovan et al, 2002a).

Policy-practice tensions, uncertainty, and *sharing* risk

The nation-wide ProtecT study forms part of a wider NHS Prostate Cancer Programme as part of the broad policy initiative known as the NHS Plan launched by the Department of

Health in September 2000 (NHS Executive, 2000). This takes the form especially of a risk management programme aimed at providing asymptomatic men with information about testing in order for us to make 'informed choices' about proceeding with the test; and upon speeding up access to diagnosis and treatment. The Programme also included provision to increase the number of urologists in the NHS by nearly 100 by 2005.

In the context of a policy NOT to introduce a public screening programme, it is clear that at the beginning of the 21st century there is considerable ambiguity in the existing policies and practices, and confusion amongst both the medical profession and men concerned about the disease. Men with urinary problems in the UK are likely to be PSA-tested either by general practitioners or by NHS urologists, and may be tested by insurance-funded private medical companies without their knowledge. Self-testing kits are available commercially. Unsurprisingly perhaps, men with suspected or confirmed prostate cancer appear generally in favour of testing and a policy of screening for the early-stage disease (Chapple et al, 2002). Thus as Donovan *et al* note, screening may be creeping in through the back door (Donovan et al, 2001) – exactly what policymakers have been seeking to avoid. One implication of this is that more men than is justified by the existing science will be exposed to further investigation and to radical treatment, in other words surgery or radiotherapy with their associated side-effects, which include relatively high proportions of incontinence and impotence. As Faulkner *et al* (2000) showed, it is highly likely that this trend to increased testing is associated with urologists at a relatively early stage in their careers and with clinical centres where there is sub-specialisation in prostate cancer. This suggests that increased clinical specialisation in the disease by younger urologists at an early stage in their careers is likely to promote pressure for men firstly to undergo the test in the absence of symptoms, and secondly to undergo radical treatment in conditions of uncertainty about disease progression, with a relatively high likelihood of the possibly nasty side-effects mentioned above (though the arrival of Viagra might be seen to mitigate the effects of impotence). Thus this case study contributes to describing professional risk-shaping dynamics which are deeply embedded in contemporary social processes of medical professional education, controversy within the frame of evidentiality, and the collective organisation of care in healthcare settings.

Discussion: sociomedical spaces and the methodological project of healthcare science

The case of early detection of prostate cancer shares common threads with other arenas of medical techno-practice. There is evidence of variability in patterns of outcomes of healthcare delivery, with clear implications for inequalities in the delivery of care to different populations and patient groups, and thus concomitant effects on the social distribution of healthcare risks. Men exposed to the British National Health Service have unequal chances of detailed investigative testing for the presence of early prostate cancer. Specialist urologists display collective patterns of clinical knowledge and beliefs which are expressed in their clinical decision-making and are associated with features of the professional organisation of care and local institutional patterns. Such patterns are also implied in a relatively higher rate of PSA testing amongst less socio-economically deprived populations, and lower rates amongst minority ethnic groups such as black and Asians (Melia *et al*, 2003). These institutionalised practices contribute to shaping the context in which risk of prostate cancer may be appraised by men differentially exposed to the healthcare system.

Regulatory policy - resistance to mass screening programmes - in this field shows signs of underlying ambivalence related to tensions between a search for robust evidence about the comparative effectiveness of different treatment approaches for the localised disease, and the attitudes of men and the medical profession toward the relative benefits and harms of early detection.

The progress of evidentiality in this area has involved a careful re-negotiation and reconstruction of the experience of men within health care science research, in the sociomedical laboratory of the healthcare system (Faulkner, 1997). Prostate cancer has become a 'politicised' socio-medical issue in particular ways. The powerful stakeholders in the development of PSA use have been practising clinicians and their professional representative bodies, and healthcare scientists and their government-related sponsors, and to some extent, but with ambiguous roles, ourselves: men who may or may not be at

risk of developing symptomatic prostate cancer and experiencing anxiety about whether to enter the world of testing, for what might be innocuous signs of the disease. This world of testing may be constituted in the course of 'normal' health-related encounters with the healthcare system or via 'enrolment' (in the clinical/healthcare science research sense, and in the STS/actor-network theory sense) into the scientific knowledge-generating, uncertainty-containing, risk-sharing, laboratory of healthcare.

Men's participation in PSA decisions and in clinical trials of screening and treatment of prostate cancer, therefore, amount to a peculiar socio-medical formation in which evidentiality is to the fore, health stakes are high, uncertainty and risks from treatment and from society's offer of diagnostic profiling are high, and in which governance encounters extreme difficulty in containing clinical practice. Tension between governance control and the slippery slope of practice is high. Men's experience of risk of the disease is shaped especially by and through a heightened form of risk-sharing arising in the social space of consultations in which evidential uncertainty is paramount and where the progress of scientific study is a constituting factor. This socio-medical space is amplified, and indeed constructed as an object of investigation, within the parameters of research studies such as the large population-based case-finding and randomised trial study referred to in this discussion.

It is useful to consider in what ways this single, large scale, nationally-supported study might be one of an array of scientific projects constituting an innovative shift in the development of the healthcare sciences. In order to appreciate this it is necessary to recognise that the method of the randomised control trial typically engages members of society – patients - as the 'informed' and 'consenting' recipients of medical interventions and as the vehicles or vessels of measurement regimes devised by healthcare scientists and clinical practitioners (albeit in some cases drawing upon "patients' views" in the process). The innovation here is that the 'users have been involved in the design and conduct of an ongoing trial' (Donovan et al, 2002b), and a case has been made by healthcare scientists for the *primacy* of 'qualitative research' in this knowledge-generating project. Unusually, it is claimed that 'The findings from the qualitative research informed

the design of the main trial, including the definition of the monitoring treatment arm and the programme of recruitment by nurses' (Donovan et al., 2002a). These findings were also 'used to change the information given to participants so that it was more acceptable and understandable, avoided terms interpreted differently by patients and recruiters such as 'trial' and 'watchful waiting', and explained randomization and trial design more effectively'. Thus this seems to represent a significant departure from the 'normative' model of healthcare science represented by health technology assessment (Williams et al, 2003).

So why has this occurred in this particular study, or, what are the characteristics of this type of project that are conducive to this politico-methodological development? The large trial constructs a novel, worrying, risky, laboratorised evidential space which contains interaction between participating men and nurses and urologists. In these spaces, in 'information appointments', information about the uncertainties of PSA testing and prostate cancer treatment, and the meaning of aspects of healthcare science (such as 'randomisation') is conveyed to and discussed with men in a 'counselling' mode. This recalls, for example, interpretation of healthcare counselling practices in which distinctions between information and advice can be difficult to disentangle (Silverman, 1997). Investigators turned the data-gathering spotlight on to this interactive space. Insights developed from men's reactions and understandings of this communication have been used to re-design the 'recruitment' process. Thus the enrolment of members of the population into long-term knowledge-producing healthcare laboratories (men take the roles of 'users' as well as patients) is accomplished through methodologies which attend to the experience, anxiety, linguistic interpretations, and choice-making in these medico-scientific encounters. The scientific work is not only informed by qualitative methods but this is also framed as a participative methodology, in which 'users' may be seen as beneficiaries of the research process they themselves are contributing to.

'Qualitative research' struggled to attain a place at the healthcare science table during the 1990s, typically being promoted as a precursor, adjunct or 'extra' to the core experimental methodologies (Pope & Mays, 1995), useful for example in devising 'outcome measures'

of healthcare interventions. The deployment of 'qualitative research' described above certainly goes beyond these formulations to have a more fundamental role, and is innovative within the evolving annals of healthcare science. I suggest that there are several reasons why it has occurred in the case of detection and treatment of early-stage prostate cancer. It would be simple, and indeed somewhat tempting, to frame these reasons primarily in terms of an interest group analysis. Health policy communities wish to 'do something' and 'be seen to be doing something' about a serious healthcare problem with a high political profile; clinical and healthcare scientists wish to produce answers to scientific conundrums via defensible methodologies, and ultimately to provide robust guidance on which clinical policy may be based. However, such explanations, while doubtless carrying some weight, do not provide an account of the relationship between the specificity of the socio-medical phenomenon of detection of early-stage prostate cancer and the deployment of qualitative research alongside the methodology of the controlled experiment. Such an account must recognise the *extreme* evidential uncertainty at the heart of the prostate cancer issue, and the fact that both the possible detection of even microscopic evidence of the disease, and the therapeutic options under review, present men with very high levels of risk and likely anxiety. Equally there was intense scepticism that the ProtecT trial would be feasible in the face of alleged clinician opposition and patients' presumed refusal to permit themselves to be 'randomised'. Alongside this is the local response of medical practitioners motivated, especially, by high levels of concern about missing possible life-threatening diagnoses in clinical encounters. These parameters constitute a sociomedical space in which a methodology is required through which can be addressed both a need for high levels of men's participation in the healthcare laboratory, and attention to our potential anxiety about life-threatening illness and uncertain knowledge of it, and clinicians' acceptance of this uncertainty. Thus through this novel space healthcare science can be constituted as 'user-friendly', and healthcare governance can be constituted as managing policymakers' and individual risks and fears, and clinicians' scientific uncertainty. This hybrid space, therefore, constitutes a form of engagement between science and society that combines elements of both the scientific enterprise and pastoral care. It is worth recalling here that Foucault deemed pastoral care to be 'the premier technique of power in late modern societies' (Foucault,

1981, cited in Bloor, 2001). This negotiated form of engagement is legitimised by being designed into national, government-backed science and policy agendas and contained in the public-policy buffer zones of healthcare science.

The production of knowledge aimed at understanding and providing a healthcare response to prostate cancer continues. Further investigations have multiplied and cluster around it. Thus the societal apprehension of prostate cancer itself is being re-shaped through an expanding range of research conducted not only by the multiple disciplines of healthcare science, but further disciplines such as genetic science and genetic epidemiology. Ongoing studies at the time of writing include study of genetic aspects of the disease, and study of the effects on 'quality of life' of participation in the screening part of the large-scale population study itself. Thus participation in the sociomedical laboratory of prostate testing itself may have an impact on men's health, apprehended as 'quality of life'.

Participation in this social laboratory – where testing itself is tested - also 'configures' men as users (Woolgar, 1991) or potential users of the techno-practice of PSA testing and interpretation. It has been said that the state's role in the 'direct or indirect configuration of a technology's intended users has escaped attention' in science and technology studies (Rose & Blume, 2003). I hope that the case of prostate cancer detection discussed here shows that healthcare science acts as a mediator of relations between the state and citizens participating in particular sociomedical practices, which are simultaneously missions of healthcare science.

This paper has begun to analyse the configuring of contemporary science-medicine-state relations in the important case of the detection of prostate cancer. A number of further questions and lines of analysis remain to be further developed. Firstly, this paper has opened up the question of different varieties and 'depths' of uncertainty constituted in the sociomedical space of PSA testing, but the identification and characterising of these vectors of uncertainty require further exploration. A theoretical innovation would be to consider the *organisation of uncertainty* through and around these spaces. Secondly, there are some obvious but unclearly defined connections between the citizen evoked in this

discussion and the 'biological citizen' being conceptualised in relation to biotechnology and the enhanced social salience of the corporeality of the body (cf. Rose and Novas, 2004). There are also unexplored connections to the notion of the scientific citizen (Irwin, 1995; Bloor, 2001). Thus processes of citizens' (men and significant others) identity-formation, subjectivities, and collective beliefs, expertise and organisation related to the experience of belonging to a PSA-tested population cohort, and the like, are worthy of study. Thirdly and finally, this case study is one where high stakes and high uncertainty co-exist, and it is in this context that the role of qualitative methods which promote citizens' contribution to a project of healthcare science has emerged most emphatically. For example, the large study discussed here showed signs of 'action research' methodology (though whether the scientific actors involved will comfortably embrace this term is open to question). Thus it will also be profitable to extend study of the ways in which other sociomedical scientific practices with similar characteristics, and localised prostate cancer detection itself, might continue shaping the hybrid modernist-but-participative style of the healthcare science project.

Postscript

The science and governance, diffusion and regulation of the techno-practice of the early detection of prostate cancer remains highly controversial, as demonstrated by these concluding mass media reports, on which I make no further comment in this preliminary paper:

Having survived German bullets and the rigours of life in central Afghanistan, the Himalayas and upper Ganges, Alexander finally succumbed, like 10,000 other men every year, to cancer of the prostate (The Times 17.1.05).

Bayer has produced a new variant of PSA, the c-PSA (complex PSA)... So c-PSA levels increase if the prostate is malignant but not if it is enlarged by the benign hyperplasia occurring in older men. No allowance, therefore, has to be made for the size of the prostate or the age of the patients. Continuing studies overseas show encouraging results (The Times 17.1.05).

'Use of the PSA test is swamping urology and radiotherapy services, the Government's cancer tsar has admitted' a GP in Lancashire, and cancer lead for XXX Primary Care Trust, said it was 'obvious' reducing PSA testing would cut radiotherapy demand. He said: 'I don't think we have shown PSA testing in healthy people is the right thing to do. I have grave reservations. It's an emotive issue but the Government needs to take a strong lead to enable GPs to say "I will do an examination but asymptomatic men should not have this test".' (UK daily newspaper, January 2006).

The standard post-PSA test is the transrectal ultrasound and biopsy; the blame for its failure to detect cancer despite a raised PSA is attributed to an overreliance on the established practice of taking only six biopsies on one occasion. Even in the best hands, ultrasound misses many prostatic tumours, so biopsies are often done without seeing the tumour (The Times, 16.1.06).

The most widely-used test for prostate cancer may not reduce the risk of men dying from the disease, according to research published today (The Guardian, 10.1.06).

March 2006.

¹ "Patients' preferences", in the context of experimental research designs relying on randomisation, raise difficult issues for medical statisticians – leading in some instances to studies which attempt nevertheless to allocate some patients to their less preferred treatment and evaluate preference itself as a 'prognostic variable' (e.g. Torgerson et al, 1996). The 'Qualitative Methods' used included face-to-face interviews with men, and recording of consultations (which were transcribed) in which they were able to discuss information about the PSA test, its uncertain meaning and consequences. Furthermore men were asked to advise on their interpretation and understanding of the 'information' offered, leading to revisions to it.

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