

THE ECONOMICS OF KNOWLEDGE AND THE PUBLIC DIMENSIONS OF THE KNOWLEDGE ECONOMY

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Patients, Patient Organisations, and the Production of Medical Science and Technology

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1. Medicine, science, and innovation in historical perspective

At the beginning of the 20th century relations between medical practice, science, and technology lacked the intimacy that now seems so self-evident. Despite the growth of basic research in human biology through the 19th century clinical research, ‘research at the bedside’, which was later to become central to their integration, scarcely existed outside the major medical centres of Germany and the United States. In Britain, for example, there were few outstanding clinical investigators before World War I¹. The medical profession was sceptical regarding the benefits of science-based technologies such as x-ray and the ECG². The evidence shows that, even though lots of research with the new technologies was published, there was little effect on the treatment of patients³. Routine medical practice changed only very slowly. Here, as in so much of European life, World War I shattered many old certainties. Industrial growth, and economic and social transformation more generally, were posing new questions of the medical profession. Such questions concerned less the precise interpretation of perceptible symptoms than the health assessment of individuals showing no signs of apparent ill-health. How fitted for work, or for military service, was a given category of men? Who would be offered health insurance, and at what price? A new realm of medical practice was opening, and it implied a need for large scale, and supposedly objective, methods of determining the health status of populations. Just as was happening with the automation of production, so here too new technology promised means of diagnosing on a larger scale. As markets became ever larger, and as medical practice became ever more specialized, the manufacture of medical technologies changed too. More subtly, clinical experience now became a formative influence upon the process of technological innovation itself.

The inter-war years were a time of consolidation. Radiological devices were gradually adapted to the specific needs of specialist practice and gradually became a routine feature of hospital medicine. They also became familiar in the community, as mass x-ray was widely used in tracing tuberculosis⁴. Specialization – an important stimulus to innovation in medical technology – was proceeding apace, though more rapidly in some countries than others. Increasingly, innovation came to be shaped by structures linking medical specialities and the firms supplying them with instrumentation, and based on a complementarity of need.

In the 1950s, inspired by the technological successes of the Second World, visions of a healthier future became increasingly technological. At a time of shortage and of reconstruction, of war-weary populations, and of the beginnings of the cold-war, technology seemed to promise so much. Not least for health. David Sarnoff, chairman of Radio Corporation of America (RCA) pictured a future in which "miniaturized electronic substitutes will be developed to serve as long-term replacements for organs that have become defective through injury or age ... It is not too far-fetched to imagine a man leading a normal life with one or more vital organs replaced by the refined substitutes of the future"⁵.

Many elements combined to reshape the relations between medicine, science and technology. Visions such as Sarnoff's were one. The search for new uses for skills and knowledge acquired during the war was another. Governments' determination to extend access to high quality health care was a third. High quality health care was to be made available to millions who, before the war, would not have had access to it. In Britain, establishment of the National Health Service also included provision for the expansion of clinical research, and arrangements for collaboration in this area between the Medical Research Council (established in 1913) and the government Departments of Health were made⁶. Moreover, where neither the provider of care nor the recipient had to worry about the costs (increasingly covered by the health service or insurer) ready recourse to the most sophisticated treatments seemed unproblematic. Driven both by idealism and by the search for profits, entrepreneurial activity was increasingly addressed to the health care system. We can distinguish two very different trajectories, concerning devices on the one hand and drugs on the other.

In the devices area much that occurred in the 1950s can be viewed as the systematic attempt to re-deploy skills, technologies, and knowledge developed in the war into medicine. Through the 1940s, '50s and '60s the medical technology industry had not only grown but also changed dramatically in its structure. The manufacture of x-ray imaging equipment, by now the most important market segment, had become highly concentrated by the 1950s, as small producers had merged or been taken over. Growth and concentration continued.

Innovation in the pharmaceutical industry was a different matter. Since its origins in the nineteenth century, the modern pharmaceutical industry had worked closely with university-based scientists⁷. The (perhaps chance) discovery that a chemical compound was biologically active could start off a line of investigation. Early on, it was often a matter of investigating the active principles of naturally occurring substances with traditional medicinal uses. So for example salicylic acid was identified in the bark of the willow tree. Thereafter chemists produced a derivative substance (acetyl salicylic acid) which seemed to cause less stomach irritation. This is the familiar story of the invention of aspirin. In the first decades of the twentieth century much of the inventive activity of drug companies consisted in screening families of compounds for possible therapeutic action. Only gradually did drug companies begin to direct their attention more strategically. For example, the potential value of the market in a particular therapeutic area could be a factor influencing their behaviour; the availability of competing drugs another, the expertise and traditions of the company yet another⁸. Penicillin is exemplary. When its therapeutic properties became known during World War II concentrated efforts were made in both Britain and the United States to establish large-scale production facilities⁹. It was needed to treat soldiers. But British companies did not

find it easy to pool their efforts, and their scientific expertise was limited. That, as a result, this British discovery was more effectively commercialised in the United States is well known. In the second half of the 20th century a further shift was the attempt rationally to develop a drug that would have a specific action (e.g. to block a particular receptor). Despite the rational strategies followed, chance ('serendipity') remained important. Drugs often prove to have therapeutic effects quite different from those initially sought.

The pharmaceutical industry operated in a much tougher regulatory climate than the devices industry, even in the 1950s and 1960s. Drugs may have unexpected uses, they could sometimes also have devastating side effects¹⁰. The range of animal tests that had to be done to establish the safety of a drug was extended. Clinical trials involving human subjects became more and more carefully controlled. The time taken to bring a new drug to the market grew and grew, and development costs rose concomitantly.¹¹

More visibly, the costs of health care were rising dramatically. From the 1970s, health economists were starting to argue that new technology was responsible for a good deal of the cost inflation. If this were so, and if new devices were really being accepted and introduced for reasons which had more to do with technological enthusiasm than proven benefit, there seemed to be scope for rationalization. These considerations, sparked in particular by the rapid diffusion of expensive CT scanners, provided one stimulus to government rethinking¹². A second, more political, was public controversy over the possible danger of devices which had already entered widespread use. Politicians are particularly sensitive to possible risks to healthy populations of biological and pharmaceutical products. The 1970s had seen rapid expansion in the market for 'home-use' technologies, such as pregnancy tests and new contraceptive devices. It was one of these latter, the Dalkon Shield, which provoked particular controversy when its dangers became apparent. Politicians felt that action was required, and the United States Congress moved to extend the regulatory powers of the FDA from drugs to medical devices. The Medical Device Amendments of 1976 gave the FDA responsibility for evaluating new devices during all phases of development, testing and use. For one of the three classes of devices defined by law reviews similar to those traditionally applied to drugs would be obligatory: manufacturers would have to supply comprehensive information regarding the safety and efficacy of the new device at substantial cost in terms of time and money¹³.

In addition, governments sought means of rationalizing the distribution and use of expensive medical technologies. In a State health system such as in Britain's this was done by restricting the resources available for investment in new equipment. Other countries introduced other kinds of controls. In the United States from the early 1970s, individual States were required to introduce 'Certificate of Need' (CoN) laws in order to be eligible for certain Federal subsidies. In the Netherlands, legislation was also introduced in the early 1970s, obliging hospitals to seek permission from the Minister of Health if they planned to provide any one of a published list of expensive technologies (including CT scanners and dialysis machines). In France a still more complex and comprehensive set of controls were introduced in 1970, with national 'maps' showing the planned regional distribution of each of a list of expensive technologies.

Government policies of the late 1970s and early 1980s had begun to problematize medicine's reliance on new technologies and (less explicitly) the nature of those

technologies. At the same time a different and more radical questioning of medicine's attachment to technology was emerging. Mounted both from within the medical profession itself (largely from the non-clinical fields of social medicine and public health) as well as by critical observers, this radical discourse drew on a variety of scholarly and social resources. New theoretical perspectives on the 'social construction' of technology, showing the resources, interests and power involved in their making, played a part. A growing concern with the rights of patients added another dimension. So too did critical assessments from the standpoint of traditionally major consumers of medical care: women, the elderly, people with disabilities... From this perspective, technology became an instrument of professional control: a means of deauthenticating the normal lived experience of giving birth or growing old, or a barrier to the acceptance of physical difference.

Out of all of this emerged a new kind of health-research, which sought to provide health policy makers with the tools of rational decision-making. Health economics, largely making use of established techniques of cost-benefit analysis (and more commonly, given the difficulties in attaching monetary values to health gains, cost effectiveness analysis) to assess investment alternatives in health care, was one aspect¹⁴. Medical Technology Assessment (later the term Health Technology Assessment or HTA was preferred), that promised to provide means of assessing the manifold clinical, economic and socio-cultural effects of new technologies, was another¹⁵. And further, rooted in a critical interpretation of medical practice and epistemology, we see the rise of fields like medical sociology¹⁶ and (in the UK and the USA) of disability studies.

The result of these changes is a new complexity in the social structures within which biomedical knowledge is generated and innovations take shape. Thirty years ago it was possible to conceive of much biomedical innovation-oriented R&D as in effect shaped by an 'interorganisational field' linking a medical speciality with the industry supplying it with its instruments. Government, as source of support for R&D and of health care, as regulator, reflecting the dominant sentiments of the time, was a supportive but passive observer¹⁷. Today that has changed. Concerned by the consequences of technological change for the organisation and costs of health care, and armed with the analytic instruments developed over the past twenty years, governments are now seeking more active influence over the rate and direction of inventive activity, and over the diffusion of its products. But what of society: of health care-consumers?

2. Sources of public involvement

In many countries, the rights of patients to be (at least) consulted regarding their treatments have been increasingly acknowledged over the past decade. This has not been a simple process. It has taken different forms: the result either of changing perceptions of minority rights, ethics or politics, or of the rise of 'consumerism' more generally. Consumer organisations have often supported patient groups in demanding greater responsiveness to their needs on the part of health service providers. The 'consumer of a service' seems a more 'empowered' individual than a patient. So the patient becomes the consumer, critically assessing the availability and quality of care offered by competing institutions. This has long been the case in market-dominated

health care systems such as in the USA, and in systems of socialised medicine, to a more limited extent, at the edges of health care: in the private nursing home sector, for example, or health resorts and clinics whose customers are happy to pay to have their bodies look good. But now the notion of the health care consumer has wider application. In the United Kingdom it has become dominant. There, “the term ‘consumer’ refers to people whose primary interest in health-care is their own health or that of their family, as past, current and potential patients, users of services or carers, and people representing any of these groups through community organizations, networks, or campaigning and self-help groups”¹⁸. Whilst the consumer concept is all-inclusive (who is not a potential user of health services?) and hints at consumer rights, there is also criticism of this reconfiguration of the patient as consumer. It seems to legitimate the encroachment of market forces into a domain once hallowed by a morality of care, rights, obligations: the domain of citizenship. Is access to health care to reflect the morality of the community or that of the market? Recognising the duality that has emerged, we either use the term ‘patient/consumer’ or we mutter about the lack of a proper term. Patients and consumers are terms with different associations and resonances. In this report we will use the terms ‘patient’ and ‘patient perspective’ whilst recognizing that there are valid objections to the terminology¹⁹.

Patient/consumers can demand good quality care, accessible care, and redress when things go wrong. They can demand the information necessary to enable them to exercise their rights in an informed manner. Public reference to the rights and the preferences of the patient/consumer is a political marker: an indication that the experiences, concerns and priorities of patients/consumers are being taken seriously. That is why not only health service providers but sponsors of health service research and research institutes too want to identify with these issues. It is partly a question of showing oneself to be responsive to the changes taking place in society.

One overview of the rise of health-consumer groups distinguishes 6 broad rationales underlying their emergence: first, population groups with a shared identity (e.g. indigenous peoples, disability groups) around which groups have coalesced: second, local geographical interests (eg the threatened closure of a local hospital); third, self-help and single condition groups (organised around diseases such as HIV/AIDS, cancer, or genetic diseases); fourth, groups of people harmed by or advocating specific health care products or practices (eg thalidomide or breast-implant victims, or women advocating natural childbirth); fifth, protest groups having an ideological basis (eg anti-vaccination groups); and finally generic groups formed to advocate on behalf of the whole population²⁰. Fundamental to all of this, writes Bastian, is

people’s increasing interest in health information. Increasing exposure to information can further fuel the trend: seeing the extent of disagreement among experts and the depth of scientific controversies can be a radicalising experience. Consumer advocates are particularly exposed to this as they prepare information for other consumers and become members of decision-making bodies. Sometimes issues that do not attract much comment or controversy within the health care profession arouse shock and anger when they become public ...Health issues are also being drawn into the public domain by professionals themselves, who may want to inform or influence the public, gain greater recognition or funding of their work...

For present purposes we need only distinguish two broad underlying motivations or forces. ‘Consumerist’ – inspired initiatives aimed at involving the public in R&D-related activities (referred to above as ‘generic groups’) have gone particularly far in the United Kingdom. The beginnings of these initiatives can be dated to the early 1990s²¹: in particular to the British government’s 1991 “Research for Health Strategy”, which included a commitment to involving consumers at all stages of the research process. Between 1991 and 1994, however, little happened: perhaps a result of lack of commitment, lack of understanding about what this might mean in practice; and the re-organisation of health services then taking place. In late 1994 the Central Research and Development Committee of the NHS decided to establish a consumer group which would advise it. Finally, in 1996 a “Standing Advisory Group on Consumer Involvement in the NHS R&D Programme” was established. Its Chair was the Director of the National Consumer Council and its Vice-Chair was the Director of the UK Cochrane Centre²². The Committee was to advise on how consumer involvement could be enhanced, and on its consequences.

Elsewhere, patient groups have gained influence over R&D priority setting and research funding by more ‘adversarial’ strategies, often inspired by prior social movements with overlapping membership. These include, notably, the HIV/AIDS groups drawing on experience in the gay liberation movement and cancer activists, inspired both by the women’s movement and the AIDS groups. Thus breast cancer activism, according to one study, traces its origins to the women’s health movement of the 1970s and the work and writings of a number of women suffering from the disease²³. By the late 1990s, with more than 300 breast cancer organizations in the USA, a degree of political influence had certainly been won (see below), but there was also considerable fragmentation. Whilst the organizations largely agreed on the need for more research on breast cancer, they did not agree as to what sort of research that should be. Mainstream groups seek to represent the interests of women as cancer patients and consumers of health care to decision-makers at various levels, whilst more radical groups “seek direct representation of their memberships in decision-making about cancer research and health policy, and point to the need for unconventional cancer therapies as well as state-of-the-art biomedical treatments, call attention to the political and economic contexts of women’s cancers, and critique what they refer to as the “cancer industry” for its profiteering”(loc cit p 1406).

Where the British ‘consumerist’ approach had to contend with initial apathy, or lack of commitment, on the part of the scientific and medical communities, the more confrontational groups, such as breast cancer activists, often faced downright opposition. Anglin notes

A Time Magazine article criticised patient activism in general and breast cancer activism as one of its significant variants, for forcing the development of “junk science” in response to lobbying efforts and “Congressional whims”. Junk science, the article argued, “interferes with real sciences and threatens to disrupt progress towards actual cures”...Members of the scientific community have likewise been critical of breast cancer activism and the positive response activists have received from Congress, the national Cancer Institute, and specific research institutions”

Though the political contexts out of which they have emerged differ substantially, as do the mechanisms for involvement generated, those working in both the 'consumerist' and 'adversarial' modes agree that involvement of those most affected, patients, in the research process should have many benefits for research and development.

It doesn't do to exaggerate the distinction between these two modes of involvement, which may in any case be becoming less clear-cut. Positioned in a sense between them are numerous instances where grass-roots organisations of patients and care-givers have formed coalitions with medical practitioners specialised in their specific form of treatment to formulate common political demands. Such demands can range from additional resources for treatment (for example, extended provision of kidney dialysis)²⁴ to acknowledgement of a new area for research meriting earmarked funding (eg Alzheimer's disease)²⁵. Today too, some of the demands previously formulated from an adversarial perspective are now finding political support. For example, a recent study supported by the Commission of the European Communities in the area of Telematics for the Elderly and Disabled, recognizing the value but also the difficulties of 'user participation' in R&D, argued that participants should not be volunteers selected by the researchers, but should be nominated by the relevant consumer-associations²⁶.

The nature of patient/consumer involvement in research

How do patients/consumers engage with the research/innovation process? Roughly speaking we can say that, corresponding to the two sources of patient involvement distinguished above, two distinctive modes of engagement in research have evolved.

The 'consumerist' approach, typically steered from above, seeks to involve individuals usually chosen by policymakers or researchers as in some way representative of the group to be served. In a 'consumerist' mode, practice is likely to involve inviting consumers to participate in, or advise, committees whose responsibilities, ways of working and agendas have already been defined by professional participants. An example is provided by the Health Technology Assessment programme of the UK National Health Service, where a study was conducted of what 'involving consumers' entailed²⁷. Whilst consequences are felt to be generally positive, it becomes clear that learning, adaptation and support are required for consumer-involvement to be felt to be working. Consumers are likely to have an effect in proportion to their ability to "engage professionals in discussion in their own language and [to] make use of electronic communication..." and in "framing research questions important to them in terms that would also allow them to be addressed by the ... programme". The authors of this study conclude with the following observation

Advancing consumer involvement raises two complimentary questions: how can we meet the moral and political imperative of consumer involvement, and what is the impact? This paper has addressed the first question... To answer the second we would like to know whether consumer involvement alters the range of research topics, or the framing of research questions, or the teams commissioned to undertake the research"

We will turn to the second of these questions below.

Another recent British study surveyed centres co-ordinating clinical trials, and asked about the extent and nature of consumer involvement in the trials for which they had been responsible.²⁸ It found that nearly two thirds of centres responding had experience of involving consumers: in designing trial protocols, in drafting information for patients, and in participating in steering committees. Nevertheless, the authors conclude that “involvement of consumers is still relatively uncommon”. On many occasions it had not been thought of, on other occasions there had been doubts as to how to do it.

The ‘adversarial’ approach shows patients winning a collective ‘voice’ in priority-setting, decision-making and the conduct of research through their political activism. This approach is likely to involve more radical questioning of ways of working, agendas and agenda-setting, the weight of different forms of expertise, etc

Rabeharisoa and Callon have provided a valuable analysis of activism in the French context²⁹. The AFM (*Association Française contre les Myopathies*) is an association of people suffering from neuro-muscular disorders (myopathies) and their families and carers. It is also a major source of financial support for research. Thanks to the huge amounts of money which the *Téléthon*³⁰ has put at its disposal the AFM can exercise substantial influence on research. In its support for research (it has many other supportive activities, including a periodical, *Vaincre les Myopathies*) the AFM has devoted itself principally to biomedical (including genetic and ‘post gene’) research. It has a scientific advisory committee with an eminent membership. Rabeharisoa and Callon show how, for the scientists, the AFM was in essence a fund in aid of research: like INSERM or most funds for medical research. The scientists, through the scientific advisory committee, thought themselves best placed to decide which lines of research should be supported. The organisation’s leadership, however, didn’t see it as a fund in aid of research, but as an organisation devoted to beating the diseases. What this study shows is a process by which the AFM leadership took authority back, turning the scientific advisory committee into precisely an advisory committee, and negotiating a ‘partnership’ with the State. This shift in power, corresponding to a re-negotiation of the goals of the organisation would necessarily have major implications for priorities in research. The transformation was only possible thanks to a leadership willing to face conflict both with eminent scientists and with politicians. It also involved a number of steps. We can think of them as ‘blurring of boundaries’ and the ‘replacement of familiar distinctions by new ones’. The boundaries between ‘science’ – the realm in which scientists claimed authority – and ‘non-science’ were blurred. The AFM hired scientific experts who would not be doing research but who could engage with the scientists as peers. They multiplied the forums at which ideas and experiences were exchanged (eg through colloquia, visits to leading laboratories around the world). Myriam Winance, in a doctoral dissertation, has followed the AFM’s ‘discourse’ through the pages of its review, *Vaincre les Myopathies*. She found that whereas the journal had previously been organised into a ‘scientific’ part (‘cure’) a ‘medical’ part (‘compensating’), and a ‘social’ part (‘participating’), that structure gradually gave way. The journal, and the discourse, came to replace these categories by new ones ‘daily living’ and ‘neuromuscular diseases’. The language, the demarcations, no longer reflect and support existing realms of expertise³¹.

Once more, between these two extremes we can find examples of radical innovation, of the kind typically demanded by activists, but now with the support of some 'central authority'. It is worth considering one such example in some detail.

Founded in 1979, the British Alzheimer's Society is both a national membership organisation (with some 22,000 members) and a charity supporting medical and scientific research using funds raised from the public. The research programme had been started about 10 years ago. Three or four years ago the director was asked to develop proposals for a radical restructuring of the research programme. Involving consumers was a big part of what he wanted to accomplish, and for two reasons. On the one hand, the moral argument for involving them is particularly strong in the case of charities like this: "it's people suffering from dementia and their families who provide the resources that we're giving out". In addition he was, and is, convinced that involving consumers would lead to better research being done. Proposals involved reducing the status of the scientific advisory committee from a decision-making to an advisory body. Here too, this provoked a sceptical response from the scientific community, but the Society's Board of Management decided to push ahead regardless.

A part-time Director of Research was appointed, and the QRD programme ('Quality Research in Dementia') was launched in 1999. £1 million was committed for the first year. Consumer involvement really goes to the heart of it. The procedure involves a large *Consumer Advisory Network*. When it is time for grant applications to be made, this is widely publicised. Potential applicants submit summaries. These are posted in an Intranet (restricted access), and any member of the consumer network can comment on any proposal. The comments also go on the intranet. The scientists can respond if they want to. A scientific advisory panel assesses scientific merit and the consumer network ascribes consumer merit. The Director of Research then assigns all the proposals an aggregate score. Only projects with a high aggregate score go forwards to the next round, where full applications are invited. These are peer reviewed, both by scientists and by consumers...again via internet. Evaluations are posted and the applicants are now invited to respond to the comments. Sometimes proposals are changed at this stage. New scores and rankings are given. In the third stage short-listed scientists are invited for interview. The grant awards panel consists of three 'experts' and three 'consumer representatives', with each member having one vote.

In addition, three volunteers from the consumer network are assigned to each research project that is funded. These volunteers keep in touch with the project and go to visit the research team. Again the scientists were initially sceptical but that has changed. Accepting these visits from consumer representatives (as well as writing 6 monthly progress reports) is now a condition of being awarded a research grant. There is no shortage of volunteers for this: in fact more people volunteer to do this than they need. In the view of the Director of Research both the number and the quality of the grant applications continue to rise...

These examples provide instances of patient/consumer representatives achieving growing influence over the funding and performance of biomedical research. Other examples, perhaps less striking, would show patient representatives slowly achieving

some voice in decision-making by a wide range of other funding bodies, both governmental and charitable. It has to be recognised, however, that this is a phenomenon that is almost certainly occurring more commonly in some countries than in others. It must also be acknowledged that the presence of patients in committees concerned with priority-setting, or funding decisions or evaluations does not in itself attest to significant influence. There are equally many stories – though little systematic evidence – attesting to nothing more than ‘politically correct’ tokenism. In the examples quoted above, and in the studies conducted in the UK, there was clearly some initial opposition (or at least scepticism) from the scientific community regarding the value of any contribution from the side of patients. The mere presence of patient representatives in decision-making bodies does not in itself lead to changes in the research supported: let alone in the performance of research. Indeed, a recent study in the Netherlands found considerable discontent among patient associations regarding both their influence on research and the relevance for their work of the research that was conducted. That study went on to argue the need for more systematised research from a patient perspective, by analogy with the value that health economics and other ‘regulatory science’ had had in strengthening the hand of government³².

The influence of ICT

There is little doubt that the huge amounts of medical information now available on internet is leading – or can lead - to patients/consumers being informed in ways that are wholly new. Given the influence that this information source is thought to have on patients, it is hardly surprising that a number of studies have been conducted of the accuracy and the quality of the information contained in popular web-sites. A number of these studies are highly critical, whilst others try to establish criteria of quality for web-sites.³³ One recent study of 121 websites providing information on five common health topics found only a weak correlation between the credibility of a site and the accuracy of the information it contained³⁴. Another survey of 200 popular breast cancer sites found that more and less popular sites contained different kinds of information³⁵. Internet-based discussion groups that permit patients to exchange experiences have also grown rapidly in number and these too can be an important resource for patients, and for patient associations. Individual patients, and patient groups, are now in a position to inform themselves not only about treatments available elsewhere to which they might not have access, but also about treatments still regarded as unproven.

Worthy of note in this context is a recent British initiative (of which Dutch and Spanish versions are currently in course of preparation), Project DIPEX, DIPEX is an internet-based information-medium that aims to provide insight into other people’s experiences of specific conditions. Started in 2000, DIPEX (Database of Patients’ Experience) consciously reflected both the importance of the ‘informed patient’ and the possibilities of ICT in this regard³⁶. Announcing the launching of the project, its authors wrote

A well-informed patient is likely to be less anxious and better prepared for consultation...and those patients who do not want to take such an active role will still benefit from good information. An understanding

of treatment choices can improve psychological status and outcome...Many people with a new diagnosis seek information from a mix of formal and informal sources [including]self help groups and internet..

Patients are typically seeking both information on available treatments and information regarding the implications of their illness for their lives. The stories of other sufferers from the same disease can be particularly valuable. But how can a patient, finding such a story, know anything of its representativeness? DIPEX would “combine systematic collection and analysis of interviews with people about their experience of illness with evidence of the effects of treatments”. The initial response to the plans, from General Practitioners, consumers, academics, and support groups were all positive, and the project has gradually moved forward. Anyone visiting its website today (www.dipex.org) will gain access to patient experience in the form of videoclips on each of the conditions that have been studied so far (hypertension, breast cancer, prostate cancer). DIPEX is currently involved in a self-evaluation, with preliminary results showing that both content and format are highly valued.

Closer to research is the Cochrane Collaboration, “ an international non-profit organisation that aims to help people make informed decisions about health care, by reviewing and promoting the best available evidence on the effects of interventions and treatments. It is a charity registered in the United Kingdom. Its governing body is the Steering Group with a secretariat based in Oxford in the United Kingdom”. The collaboration is dedicated to reviewing, sifting, and evaluating data available from clinical trials conducted around the world. To quote its website:

“Some health care treatments can make you better but some are fairly useless. Sometimes the treatment can be worse than the disease. At other times it can look as though a drug or other treatment did the trick, while really the benefit came from something else that happened at the same time (like having a couple of days in bed). Or, the disease just ran its course and you would have got better anyway. If you want to know if something is really worth trying, you need good evidence about the treatment’s effects – ideally from high quality trials”.

There is also a Consumer network, with its own website and newsletter. As of 2001 there were more than 500 members of this network, 60% of them in Australia/New Zealand and in the United Kingdom (with significantly smaller numbers in the USA, in Western Europe, and in the developing world). The Cochrane Consumer Network website explains its role and ways of working

The Consumer Network is a consumer organisation within the Collaboration, including individuals and community organisations from around the world. The Network supports and develops consumer participation in the Collaboration, and helps make the information available to consumers. People get involved by helping identify important questions from the point of view of people who have to deal with the health problem. They help hunt out trials, and some get involved in commenting on drafts of Cochrane reviews, or spreading the results of Cochrane reviews in their communities.

The Consumer Network's activities include:

- Keeping people in touch with what's happening with a newsletter
- Offering training workshops and developing training materials
- Preparing material on how to make sense of health care research and Cochrane reviews
- Publishing a "digest" for consumers on what's new each time *The Cochrane Library* comes out
- Running a website that includes all these resources, and a consumer health information system

Other websites also provide patients with the possibility of informing themselves about clinical trials currently in progress, and about trials enrolling patients in which they might, if they wish, enrol. For example www.clinicaltrials.gov which is run by the (US) Food and Drug Administration, offers people the opportunity of locating all current clinical trials either by condition or by area³⁷

In its use of ICT as a means of organising a patient-input into the assessment and prioritisation of proposed research, the Alzheimer's Society in Britain has developed a potentially highly promising approach. So far as this author is aware this initiative has not as yet been copied by other research-funding bodies.

It seems reasonable to conclude that the growth of internet-based information sources is providing patients, individually and collectively, with far more information on new developments in treatments, and on on-going clinical research. Potentially at least, patients are thus better equipped to share in decision making both regarding their own treatment and regarding the direction of R&D. In this paper we are not concerned with the consequences of access to information for patients' individual behaviour or their ability to articulate their individual treatment-preferences, whatever effect this may be having on traditional doctor-patient relations. These information resources, in themselves, are just that: resources. Combined with the training offered by the Cochrane Collaboration, by the Alzheimer's society, by the Consumers in NHS R&D Support group, they can potentially equip patient representatives to make a more significant and informed contribution to decision-making. But for this actually to occur, with observable changes in the performance of research and in the innovation process requires more than that. It requires on the one hand the renegotiation of structural relationships (eg between the scientific community, the medical profession, government, industry), making space for an independent input from patient associations; and on the other hand the further development of research from a patient perspective, which would enhance their influence, just as health services research previously enhanced the influence of government.

These changes, fundamental to any true reconfiguration of health-related research and innovation, are proceeding only slowly, and in many countries not at all. Token patient representatives in committees often have little influence. Moreover, recognising their growing political visibility, and common enthusiasm for new diagnostic and therapeutic modalities, patient associations are increasingly supported

by (and rendered dependent upon) private industry. When this is known to be happening their independence and legitimacy may come to be questioned.

Changes in the production of knowledge and of technology

Through a variety of processes, which can be roughly categorized as the result of either 'consumerism' or of political activism, representatives of the public (patients, consumers) are increasingly to be found in advisory roles, or in decision-making committees, of bodies supporting and evaluating medical research and new medical technology. At least in some countries: this is far from being a universal phenomenon even in the OECD area. Moreover, thanks to the rapid expansion of new sources of information, notably on the internet, these representatives of the public are increasingly well-informed. But what effect is all this having on the conduct of research and on the process of innovation? No simple answer to this question can as yet be given, partly because the phenomenon is still relatively recent, and partly because of great variation both between countries and between fields (reflecting differences in the extent of patient-organisation and mobilization). But also because, in the absence of systematic inquiry, it is very difficult to sort out mere 'token presence' from true influence. What we can do, however, is try to map out a *hierarchy of forms of influence* that we might expect to find.

At the bottom of such a hierarchy we would focus on the extent to which patients are allowed to share in decisions regarding which areas of biomedical research should be favoured with financial support, or which technologies should be provided or reimbursed. This is probably the most common development now taking place. So far as research is concerned, choices here are typically between areas defined by, or projects submitted by, existing research communities. Clearly, where this practice is adopted the implications for the overall research effort will depend upon the role of the funding-institution in question within its particular field. The greater its role and its status (provoking possible emulation by others), the greater the consequences.

Taking a step beyond this is the British Alzheimer's Society. In their research funding practice, as we have seen, researchers are expected actually to modify their proposals in the light of patient comment.

Comparable are those approaches that allow for patients' participation in the design of the clinical trials by which the value of new diagnostic and therapeutic modalities are established. Consider some of the decisions that have to be made in establishing a trial. How should trial populations be constituted? In the United States HIV/AIDS organisations argued that where potential AIDS drugs were being tested trial populations should be drawn from each of the distinctive groups that stood to profit from the drug (women, ethnic minorities, sex-workers, drug-users, and so on). Each group had a right to know what the drug in question might mean for its members. Against this, and reflecting conventional trial-methodology, researchers typically preferred to recruit exclusively from easy to reach and retain groups (middle-class white male homosexuals). HIV/AIDS advocates' argument that there should be a right to participate (or be represented) in trial populations was not easily accepted by medical researchers³⁸. How should the end-points of trials be defined? There is growing evidence that trial end points taken as defining the potential 'value' of the therapy being tested may not correspond to what prospective users themselves most

value. In Britain the Alzheimer's Society has argued to the National Institute of Clinical Excellence (NICE, which advises the NHS on new technologies) that patient views should play a role in their assessments.

At the summit of the hierarchy of influence would be practices, the most controversial of all, which entail renegotiation of 'what counts as valid knowledge' and 'by what means such knowledge can legitimately be produced'. A good introduction to what is involved here is provided by Steven Epstein's description of the emergence of 'community-based research' of AIDS drugs in the USA³⁹. In the mid 1980s, Epstein explains, primary care physicians and people with AIDS (PWA), disenchanted by 'official' modes of research favoured by the National Institutes of Health, set about designing their own clinical trials. Thus in 1985 a coalition of practitioners in the San Francisco area with AIDS practices (called CCC) was established, and in 1987 in New York an organisation called the Community Research Initiative (CRI). Each set about organising trials in which data would be collected from the normal practices of practitioners treating large numbers of PWA. Despite the scepticism of established researchers, this mode of knowledge production proved itself shortly thereafter. A trial of the drug pentamidine, organised by these organisations despite being refused funding by the NIH, led to the drug being approved by the FDA "the first time in its history that the agency approved a drug based solely on data from community-based research".

Patients 'know' their illness or disability in a way that practitioners, and still more laboratory researchers, do not. They know what it is to live with that illness, to adapt their lives to the limitations it imposes: limitations that certainly depend upon social and economic specificities. They know their own responses to specific medications and how to use those medications in ways compatible with how they choose to live their lives. It is well known that patients suffering from hemophilia, for example, dependent on (self-administration of) one of other form of anti-coagulant (Factor VIII) have to 'educate' physicians new to their case. What is the relationship between this kind of 'experiential knowledge' and the knowledge we call 'scientific'? Issues such as this are central to today's 'politics of knowledge production' in the biomedical area. What the implications might be for innovation is a question that it is only now becoming possible to address.

Notes and References

¹ See eg C. Booth "Clinical research" in J. Austoker and L Bryder *Historical Perspectives on the role of the MRC* (OUP 1989) p 205

² This section is largely based on Stuart S.Blume "Medicine, technology, industry" in Roger Cooter and John Pickstone (eds) *Medicine in the 20th century* Harwood Academic Publishers, 2000, pp and "Structures of innovation and their historic roots: the case of medicine" in L. Guzzetti *Science and Power*

³ Joel Howell *Technology in the Hospital*

⁴ See e.g. A de Knecht-van Eekelen, J F M Panhuysen and G rosenbusch *Door het Menselijke Vlees Heen. 100 jaar radiodiagnostiek in Nederland, 1895-1995* Rotterdam; Erasmus Publishing 1995

⁵ Quoted in K.Jeffrey 'Pacing the heart: Growth and redefinition of a medical technology, 1952-1975' *Technology and Culture* (1995) 595

⁶ Christopher Booth, loc cit, p 233.

⁷ J. Liebenau 'Innovation in pharmaceuticals: industrial R&D in the early 20th century' *Research Policy* 1985 14, 179-187

⁸ Bert Spilker *Multinational Drug Companies: Issues in drug discovery and development* Raven Press 1989

⁹ J. Liebenau 'British success with penicillin' *Social Studies of Science* 17 (1987) 69-86

¹⁰ H. Sjöström and R Nilsson *Thalidomide and the Power of the Drug Companies* Penguin Books 1972

¹¹ A.C. Gelijns and E A Halm (eds) *The Changing Economics of Medical Technology* vol 2 of 'Medical Innovation at the Crossroads'. Washington DC NAS Press 1991

¹² See Stuart S Blume *Insight and Industry* Cambridge. MIT Press, 1992

¹³ The general opinion, both among industrialists and policy analysts, is that this legislation did not greatly affect either the market or the innovation process. Indeed, since considerable data were needed in order to make a convincing case to the FDA, manufacturers were obliged to cooperate, perhaps still more urgently than before, with clinicians who could gather the data from patients. It has been suggested that this need to collaborate, and the incentives offered by manufacturers, might even have enhanced diffusion.

¹⁴ See eg Ashmore Mulkay and Pinch *Health and Efficiency*

¹⁵ Pasclae Lehoux and Stuart Blume ...

¹⁶ Wright and Treacher *The Problem of Medical Knowledge* (Edinburgh 1982)

¹⁷ This generalisation neglects the very different circumstances obtaining in the areas of preventive health care (eg vaccines R&D, where the public sector traditionally had an important role which has, however, declined over the past two decades), and rehabilitation medicine governed by more restrictive social welfare regimes.

¹⁸ M.Blaxter 'Consumers and research in the NHS' in *Consumers in the NHS: an R and D contribution to Consumer Involvement in the NHS*. London, Department of Health,1995. Quoted by Oliver et al. See f.n. 39

¹⁹ We recognise that for many groups, people with disabilities for example, or others demanding the right to choose, the term is an unhappy or unacceptable one. If I happen to be deaf, or use a wheel chair, or have trouble learning, but scarcely ever go to the doctor, how can I be called a patient?

²⁰ Hilda Bastian "Speaking up for ourselves: the evolution of consumer advocacy in health care" *International J. Tech. Assessment in Health Care* 14 (1998) 3-23

²¹ See M Blaxter *NHS Executive Consumers and Research in the NHS* (NHS Executive 1995); *Research: What's in it for consumers?* First Report of the Standing Advisory Group on Consumer Involvement in the NHS R&D Programme (NHS Executive 1998)

²² On the 'Cochrane Collaboration', see below

²³ Mary K Anglin : Working from the inside out: implications of breast cancer activism for biomedical policies and practices" *Social Science & Medicine*44 (1997) 1403-15

²⁴ David Rothman

²⁵ Patrick Fox

²⁶ C. Bühler (ed) *Empowered Participation of Users with Disabilities in Projects: a summary with the main result of the FORTUNE project* (EU 2000)

²⁷ S Oliver et al "Involving consumers in a needs-led research programme: A pilot study" *Health Expectations*4 (2001) 18-28

²⁸ B. Hanley, A Truesdale, A King, D Elbourne and I Chalmers "Involving consumers in designing, conducting and interpreting randomised controlled trials: questionnaire survey" *British Medical Journal* 322 (2001) 519-23

²⁹ V. Rabeharisoa and M.Callon *Le Pouvoir des Malades* pp 105-110

³⁰ A 'Telethon' is a television programme, usually of 'marathon' length (for example, a whole evening) in which viewers are encouraged to telephone in with donations to the cause in question. The audience is kept abreast of the volume of funds pledged throughout the evening.

³¹ M. Winance Doctoral thesis *Thèse et Prothèse. Le cas de L'Association Française contre les Myopathies*, CSI, Paris.

³² Stuart Blume and Geerke CatshoekPatientenPraktijk

³³ For example, see W M Silberg et al "Assessing, controlling and assuring the quality of medical information on the internet" *Journal of the American Medical Association* 277 (1997) 124-5, J M Roberts and K L Copeland "Clinical websites are currently dangerous to health" *Int J Med Inf.*62 (2001) 181-7, K M Griffiths, H Christensen "Quality of web-based information on treatment of depression: cross sectional survey" *BMJ* 321 (2000) 1511-15

³⁴ H. Kunst et al "Accuracy of information on apparently credible websites: survey of five common health topics" *BMJ* 324 (2002) 581-2

³⁵ F. Meric et al “Breast cancer on the world wide web: cross sectional survey of quality of information and popularity of websites” *BMJ* 324 (2002) 577-81

³⁶ A. Herxheimer, A. McPherson et al “Database of patients’ experiences (DIPEX): a multi-media approach to sharing experiences and information” *Lancet* 355 (2000) 1540

³⁷ For example, entering the term multiple sclerosis produces (at this moment) a list of 22 trials. Clicking on any one of these produces a short description of the trial: its purpose, eligibility, what is required of participants, and contact information.

³⁸ See Steve Epstein *Impure Science* California University Press 1996, esp Chapter 7

³⁹ Epsein, loc cit pp 216-9