INNOVATIVE HEALTH TECHNOLOGIES

Distributed Innovation Processes and the Uneven Growth Of Medical Knowledge

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RESEARCH FINDINGS

KEY FINDINGS

The principal aim of this project was to understand the nature of the apparently uneven growth of innovation and practice in medicine by comparing and contrasting developments in two areas (cardiology and ophthalmology) and across two medical systems (the UK and US). We hoped to increase understanding of the innovation process in this part of the service economy, to research into the interdependence between the growth of knowledge and the emergence of innovation systems, and to provide an empirical assessment of recent developments in innovation research, particularly in relation to co-evolutionary approaches to the development of knowledge and institutions.

- Our research has led us to a radical reformulation of the notion of an innovation system and to distinguish the innovation ecology from the related innovation systems and the innovation system from the invention and diffusion systems.

- We uncovered rich innovation ecologies but these ecologies comprising hospitals, firms, research laboratories and regulators do not of themselves constitute an innovation system. The system arises from connections that are made for a purpose, namely to solve problems.

- The systems investigated were enormously complex and defy any simple description. They were found to be highly experimental with research efforts widely diffused. Firm strategies varied considerably with small firms opting for buyout/exit options while large firms innovated by acquisition.

- The emergent nature of medical innovations, their novelty and unpredictability, and their transnational character suggested that we were dealing with complex systems to develop medical experiments and it would be unlikely ex ante to pick winners. Long sequences of problem solving are involved and this implies associated dangers of premature choice across rival alternatives of unknown potential. The transient nature of the solutions suggests that the issues at stake are not only matters of efficiency but of creativity, and creativity is an individual and a system property that requires time to realise its potential.

- Major consequences follow for innovation policy in relation to medicine in particular the relative importance of processes bridging between the medical supply industry and the communities of medical practitioners in hospitals and medical research centres, and the constraints set on the diffusion processes by the complementarities between the innovations and the organisational changes needed to integrate them into medical practice.

RESEARCH TEAM

Professor J S Metcalfe, University of Manchester
Mr Andrew James, University of Manchester
Dr Andrew McMeekin, University of Manchester

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On the Nature of Medical Innovation

Innovation in medicine is a complex process that unfolds unevenly in time and space. It is characterised by radical uncertainty and emerges from innovation systems that can hardly be comprehended within geographical, technological or institutional boundaries. These systems are instead highly distributed across countries, competences and organisations. In this study, we develop a model of the growth of medical knowledge that emphasises shifting problem sequences, the transient and provisional nature of proposed solutions, new knowledge bases for the solution of problems, cumulativeness and the crucial role of practice as the locus of experimentation and testing of new procedures.

We test our model on the growth of medical knowledge and practice in two areas: cardiovascular disease and ophthalmology. The particular cases analysed were percutaneous transluminal coronary angioplasty (angioplasty for short) and diagnostic devices in glaucoma. These are important areas of innovation that speak to the complicated interaction between medical service systems and the medical supply industry in delivering new medical services.

Medical Innovation Systems and Problem Sequences

We started with the view that medical innovation involves the interplay between social technologies as well as physical technologies of product and medical practice. Central to this is the idea that not only innovation processes are systemic but that they apply only in local domains of knowledge and that they evolve over time. What is to be explained is how these systems emerge, grow, stabilize and sometimes decline. To explore this we developed the following hypothesis: 'distributed innovation processes are constructed around *innovation problems*'. But it soon became clear that it is an *extended problem sequence* that better describes the underlying dynamic and that to understand the development of the procedure in terms of invention, innovation and diffusion we would have to identify and track the respective problem sequences over the extended histories of each technology at a markedly international level.

Coronary Angioplasty

Angioplasty represents an almost 'complete' solution to the problem of advanced coronary artery disease. Within a few decades it has become the most frequently performed interventional procedure in the Western world and has proven in many cases to be a viable alternative to bypass heart surgery. Like many major innovations it demonstrates cumulative building on past practice, the horizontal transfer of ideas from other areas of vascular surgery, and the role of previously developed diagnostic procedures (angiography) in generating pictures of constrictions in the arterial system.

Its development followed a clear problem sequence. Andreas Gruentzig, a radiologist in Zurich, conceived and developed to a production version, a new type of balloon catheter, which when inserted into the constricted coronary arteries and expanded, increased blood flow. His relocation to the US provided him with development resources and stimulated a growing but controlled band of cardiologists applying the new method. Experience gathered served to shift the problem sequence as an unanticipated problem, restenosis emerged; to which the solution adopted has been the innovation of the stent. This solution led to the identification of further, unanticipated problems which are now understood in terms of wound healing processes with the current proposed solution being the drug eluting stent. Each major shift in the problem sequence depended on the accumulation of experience and has brought new actors into the innovation process reflecting different kinds of knowledge required to solve the new problems, much of it located in pharmacology and materials science. Much of the innovation post Gruentzig (he died in 1985) has been located within the diffusion process. It is not that practice makes perfect, rather practice serves to identify the appropriate problem set within this particular design space.

Glaucoma

In contrast to angioplasty, glaucoma remains a relatively unsolved problem with a limited range of relieving procedures. Advances have occurred but have been primarily in diagnosis rather than treatment. There, innovations in measurement of the defects of the interior of the Eye are widely used in clinics and by

Optometrists and the chief advance has been in carefully qualifying the notion that glaucoma is the correlate of enhanced intra ocular pressure (IOP).

The study has shown the challenge to the paradigm of IOP derived glaucoma occurred around fifty years ago. Now the disease is more widely understood as an optic neuropathy with multiple causes, including but not exclusively, IOP. The locus for further understanding the disease mechanisms appears to lie in the fields of molecular biology and genetics but this shift has had little impact on clinical practice and the technologies on which it rests. Eye drops and surgical procedures still dominate, albeit enhanced with the use of lasers in the case of the latter. In recent years neuroprotective agents that directly protect optic nerve cells are in trials and early experiments with gene therapy have been reported in the literature.

The research focused on the development of laser imaging modalities that visualize the optic nerve. This problem sequence was particularly clear from network analysis which hinted at an interesting interaction between new types of scientific instrumentation, their role in producing more detailed understanding of the nature of glaucomatous damage and their subsequent use, considerably modified, in clinical practice. Drawing on extensive desk research and interviews with major players, we charted the initial development of laser scanning ophthalmoscopes in German and US eye research laboratories, through to an extended innovation process involving large incumbent firms, new start-up firms, research hospitals and the wider clinical community. This showed an innovation system in constant flux, with a changing composition and fluctuating interdependencies. Of particular note, the study identified the important role played by research hospitals as a powerful orchestrating force, where new industrial imaging modalities could be tried in clinical practice, where new insights could be drawn in from biomedical science and also in their role as a vehicle for communicating the effectiveness of new technologies to the wider clinical community.

Conclusions

Our findings undermine any simple minded 'bench to bedside' model of medical innovation as well as narrowly defined 'national system' models of innovation and our results have implications for the appraisal of medical innovation and in particular for medical technology assessment. We have found rich innovation ecologies but these ecologies of hospitals, firms, research laboratories and regulators do not of themselves constitute an innovation system. The system arises from connections that are made for a purpose, namely to solve problems. The respective innovation systems are initiated locally and grow rapidly from small beginnings with participants changing as the problem sequences evolve.

The respective innovation systems are enormously complex, continually evolving and defy any simple description. Their development extends over many years and the relative contributions of hero surgeons and medical supply companies change, with the latter becoming the dominant source of technical developments once the technological trajectory and perception of the design space has stabilised. For angioplasty this took two decades but for glaucoma a clear resolution of the design space has yet to be achieved. Clearly, by the differential rates of success in tackling different disease, not all problems are equally capable of generating innovation solutions but all problems and their possible design spaces are more sharply delineated by better measurement technologies, moreover, all the problems co-evolve with the nature, scope and beliefs of the relevant community of practitioners.

The emergent nature of medical innovations, their novelty and unpredictability suggested that we were dealing with a system to develop medical experiments in which it would be unlikely ex ante to be able to pick winners. In all our cases long sequences of problem solving are involved. This implies that there are associated dangers of premature choice across rival alternatives of unknown potential. The transient nature of the solutions to particular problems implies strongly that the issues at stake are not only matters of efficiency but of creativity, and creativity is an individual and a system property that requires time to realise its potential.

About the Project

In developing a comprehensive appreciation of these issues we applied a combination of methods: desk research; structured interviews conducted with the major actors (both national and international) in the medical profession, the academic medical community, the medical supply industry, health care managers and policy makers; empirical network analysis and network visualisation techniques.

Our first task in each case was to construct a reasoned and as complete as possible history of the invention, innovation and diffusion sequences for the different procedures. For this we drew upon Manchester University's medical community to help inform the comparative histories from which we developed a time line analysis of the life cycle of the different technologies and the place within them of the different actors from hero surgeons to medical companies. We framed the process of epistemic and technical change as the exploration of an *evolving design space* with each innovation a component part of one of many possible trajectories of solution within that space.

To understand the structure and evolution of their epistemic foundations we conducted in-depth analysis of the growth of scientific papers and patents. We developed and used network based techniques rather than more conventional bibliometric methods. This proved to be a promising way to uncover the evolving problem sequences that would represent movement in the respective design spaces, capture the cumulativeness of knowledge growth and its branching character, and identify the underlying innovation systems across geographical and disciplinary boundaries.

In each case we worked with very large scale data sets (circa 12,000 primary bibliographic records, respective citations, institution affiliation and geographies associated with authors) to develop the metrics and the graphics to depict the distributed nature of innovation. When applied to patents, with a data set containing over 5,000 patents, we are able to track the complementary sequence of innovation devices used to deliver the new procedures. Patents and papers are generated by different incentive systems for different purposes and thereby throw different light on the evolution of the problem sequence and its connection with practice.

We believe that our methods helped identify many of the salient features of the trajectories of technology within shifting design spaces. We have also developed specific algorithms to extract the appropriate information and devise strategies for further validation of the results. The techniques of longitudinal network analysis used are, we believe, unique in their application to medical innovation research. The resulting maps, 'networks', 'trees' and 'branches' of papers and patents provide for a detailed tracking of the problem sequences in the epistemic and technological domains and demonstrate the pattern of evolution of the corresponding innovation systems.

While the notion of technological trajectories and paradigms is well established in the innovation literature, there has not been a similar approach previously to the mapping of trajectories using data on such a large scale. To complement this extended quantitative investigation, we have carried out interviews with practitioners in the field in the UK and the US, including a visit to the US and a number of telephone conferences with leading US practitioners. We believe that different techniques of investigation provides strong and independent tests of each other's veracity as well as being a methodological achievement in its own right.

For further information contact:
Professor Andrew Webster, IHT Programme Director
Department of Sociology, University of York, Heslington, York YO10 5DD
Tel: +44 1904 43 3064/4740 ◆ Fax: +44 1904 43 4702/3043 ◆ E-mail: iht@york.ac.uk
Web site: http://www.york.ac.uk/res/iht/