Centre for Health Planning and Management, Keele University

Royal Society Working Group on the Impact of ICT Developments on Health and Healthcare

Submission by Professor Michael Rigby

Professor of Health Information Strategy

Introduction

The initiative by the Royal Society is welcome and timely, and this submission seeks to follow the format of the specified questions of the invitation. However, whilst boundaries to inquiries are inevitable, at the same time health information and health IT systems should only be seen as support to an integrated health and healthcare system, and this evidence will conclude with some thoughts on the wider picture.

Identifying Relevant Future Technological Developments

1. What relevant technology trends are likely to impact on health and healthcare in the next ten to fifteen years?

The objectives of the Working Party well illustrate the range of potential technological developments, though no list can be considered definitively inclusive to the fifteen year time-span. Essentially, the key technological drivers will be: miniaturisation; new generations of sensors; remote and high volume data capture including digitisation; new paradigms of information processing and data communication; and artificial intelligence. The application fields where most impact is likely to be felt are: exponential increase of diagnostic opportunities and expectations; a wide range of continuous monitoring, particularly *in vivo* monitoring and intelligent home monitoring; generation and communication of multi-factorial and personalised alerts from both clinical and residential monitoring; citizen self-diagnostic kits for personal health screening or condition-specific testing, with integrated analytical and knowledge-bearing technologies; and personalisation of pharmaceutical prescription linked to genetic, physiological, and diagnostic factors and adjusted for personal dose response.

Assessing the Potential Positive and Negative Impacts of Relevant Future Technological Developments

2. What areas in the provision of health and healthcare could be positively or negatively affected by these developments?

The impact will be positive, negative, and perverse in each of many domain areas:

- As diagnostic opportunities are facilitated (by new techniques, and miniaturisation and diffusion of existing science in new paradigms), so diagnostic departments will need to re engineer whilst their workloads are likely to increase, also creating adverse pressures on senior professionals.
- Many services including mental health, care of the elderly, and cardiology will be expected to discharge patients earlier or maintain them in their own homes for much longer periods. Some of these, and others such as aspects of metabolic medicine and general medicine, will be expected to adopt new standards of regular monitoring through the new opportunities presented. This may in the short term reduce bed occupancy and other sheltered living demand, but will place new expectations on quick-response services (both domiciliary and admission), as there will be no point in implementing continuous monitoring if there is no rapid response facility.
- The pharmaceutical sector will have to adjust processes to accommodate a much higher use of personally tailored drugs; other health professionals to their prescription and administration.
- Primary and secondary care can expect a rise in patients who have 'self-diagnosed' with retail devices; such patients will expect rapid professional confirmation or otherwise of their provisional diagnosis.
- There will be sporadic peaks of demand on IT departments, and on suppliers, through demand for rapid adoption of proven new technologies, followed by a maintenance phase, followed by pressures for upgrading and replacement as technologies improve, yet such departments are already over-stretched and there is a shortage of adequately trained health informatics professionals.

- The capital and revenue economic pressures will be considerable; as usual the arguments for adoption will be on quality and economic savings grounds, but new revenue costs will be created of probably an equal or greater amount in a different format.

3. What action should be undertaken now to maximise positive impact, or to prevent or minimise adverse effects?

It is always difficult to adopt a rational approach, as combination of pressures from innovators and vendors of new technologies, consumer pressure groups, and the more populist press will all push for early adoption. Those who counsel a more rational approach, both on economic grounds and to seek first to identify the long term complex and perverse effects, will be strongly criticised as being negative.

The biggest single action which would be highly valuable would be to establish ground rules for piloting and assessing the overall effects, thus creating a holistic analysis of likely benefits and disadvantages. However, it would be unrealistic to think that a comprehensive pilot of any new specific IT application could operate for say five years before general adoption, so any piloting will inevitably be constrained and in scientific terms contaminated. Given this challenge, the devising and publication of a rule set for analysis and evaluation, akin to the principles for assessment of screening techniques, would be an invaluable contribution given the standing and impartiality of the Royal Society.

Evaluating the Wider Implications of Relevant Future Technological Developments

4. Do you have any concerns associated with the generation, release and subsequent use of personal data?

I believe that the questions of the new data sets created have received scant attention, and there are some potential time bombs.

- Citizens will increasingly expect diagnosis, prognosis, and prescribing to be adjusted for their genetic profiles. At present practical restrictions (particularly in handling of the data volumes of genetic profiles) limit genetic analysis to selected cases, but ICT development will reduce this practical barrier. A core problem is that in addition to some persons who were adopted as children but whose adoptive parents have never released this fact, informal estimates from different sources indicate that up to 10% of persons (and 25% in specific localities) have biological parents different from the "mother and father" who brought them up – the discrepancy almost always being that of biological father. When the physical availability of genetic code becomes much more practical, and therefore considered a diagnostic norm, huge ethical dilemmas will be created when release of genetic information would reveal these family secrets.
- Many aspects of continuous pervasive monitoring, whilst initially being liberating by enabling the patient to live at home without health professional supervision, will on deeper consideration be highly invasive to private lives. For instance, visits to a public house, or consumption of certain types of foods against professional advice, may create a feeling of surveillance and restriction similar to that of monitoring offenders. Personal knowledge indicates that persons up to their 80's may have sexual liaisons, and they are entitled to as much privacy as any other consenting adult. Some forms of monitoring may include location monitoring as well as activity monitoring, and this too may seem psychologically invasive as well as lifestyle enabling.

5. What medical, legal and ethical issues merit consideration when introducing new technologies, such as the responsibilities, processes and liabilities for decision making?

This is a key issue, seldom adequately considered:

- Once an "at risk" patient is put on to a form of monitoring to enable domestic living, there will be a justified expectation that a response system is available and effective. This will require establishment of lines of responsibility, provision and funding of adequate services, and good education and communication between the response team and the lead responsible health or social care professional.
- There will be an expectation of equipment reliability, with implications also for product liability and professional negligence claims (justified or otherwise).
- There may be strong pressures for provision of such services for individuals, and this may include pressures by families and informal carers for self-motivated reasons even if the patient is not suitable.

- As new multi-factorial alerting mechanisms, and personalised pharmaceutical prescribing, become feasible they will be rapidly be demanded as a norm – the continuation of the familiar tale with regard to new and expensive drugs.
- Above all, if monitoring or other ICT enabled facilities are provided in a health care context, the data must be considered part of the medical record as by definition they are an integral part of the person's health care support. The physical organisation and practical impact of this upon electronic record systems, and also upon the availability and understanding of interrogation of large volume data by the full health care team as necessary, need to be appreciated and considered (and if compacting or filtering software is used, whilst this can have a beneficial effect it also raises liability issues).

6. What regulations or other mechanisms (including standards) would facilitate the responsible development of relevant technologies?

These do need to be developed, application by application, particularly with regard to data standards, recording protocols, and the like. The experience of the DICOM standards with regard to digital X-ray handling might give some pointers on how to develop systematic approaches.

7. What infrastructure would be required to allow any new technologies to be used effectively?

Both the availability of new services, and the exponential growth of data volumes, will provide major challenges to the comprehension by health practitioners of the data available, and to the physical handling and storage of the data. Development programmes for Electronic Health Records generally have failed to address this challenge, and a broker solution (1,2) might be appropriate.

8. What are the most likely promoters and barriers to the take up of new ICT devices and systems?

The most likely promoters are innovators, vendors, special interest groups, and the public and politicians fuelled by the press. Financial managers and economists postulating short term savings may also be advocates. The barriers will be capital, followed by bottleneck pressures on providers. IT capacity, professional education, and organisational and process re-engineering needs are practical constraints, but are likely to be ignored until crises arise.

9. What education and training would need to accompany the introduction of technologies, and who would need to be informed?

The answer is manifold. Application-specific education as well as training would be needed, and this would include those who received an indirect effect (such as housing staff, and ambulance crews who might be called to respond to monitoring alerts). General practitioners and many hospital doctors would need educating in the general principles of the new techniques and data sets, including how to access them and how to obtain guidelines and reference data. Aspects of pharmacology would need re-engineering, including education and training. Finally, ICT support staff will need education and training to enable them to implement and support the new technologies.

10. How are professional roles and responsibilities likely to be affected by the increasing use of ICT?

The existing tension and dichotomy between personalised care by individual professionals, and 'cook book' medicine through the use of external guidelines and techniques will continue in increased form. Many health professionals, including the frontline staff responding to triggers and alerts from monitoring, will have to understand, and accept responsibility for, personalised decisions between complying with an alerting trigger and interpreting the event as within normal limits or potential for that individual.

11. How can the development of technologies that meet patients and informal carers needs and are practically useable be best facilitated?

The first step is R&D in alpha pilots and beta sites, but R&D is notoriously difficult to manage strategically. Beta sites – normal locations devoid of specific advocates or enablers – are particularly

important and undervalued. Secondly, a comprehensive investment strategy which includes investment in service re-engineering, in response teams, and in the new paradigms of service ranging from genetic counselling to personalised drug production and dispensing, must be managed in a co-ordinated way for any application. Thirdly, informed pressure groups, press and politicians should be fed a balanced scientific picture of the issues, risks, and perverse effects and not just the short term 'good news'.

12. What are the potential impacts of the costs of any of these new technologies?

Self evidently, each technology and its practical applications must be economically assessed individually (including on-costs and support costs). However, for reasons already stated it must be assumed that in every case the cost effect will be skewed upwards by increasing public demand and expectations.

13. What are the implications of the international use of future technological developments, global use of health data, availability of ICT enabled support, and interoperability?

This is so fundamental a question that it needs a more expansive answer.

First, whilst paper-based record and information systems produce their own practical (though unwelcome) constraints as to information availability and transmission, and in a similar fashion health organisations can manage their activities by controlling policies and guidelines, by self-evident definition modern ICT technologies, and the use of external evidence and reference data sets, explicitly break down all these controls and barriers. This means that modern ICTs challenge management principles and controls, including autonomy of treatment policies (3,4).

Secondly, an EU-funded study specifically looked at assuring quality in health telematic services, recognising the international dimension (5,6,7). This identified a number of major challenges, not least the lack of evidence of the context-specific knowledge, or indeed the legitimacy of qualifications, of remote healthcare providers (either persons or organisations). International action was called for, but has fallen upon deaf ears. The model of the Codex Alimentarius, jointly run between the World Health Organisation and Food and Agriculture Organisation, was cited (8).

Thirdly, the natural move towards use of best global experts, including provision of expert services, is likely to lead to a number of perverse and destructive effects. Principal of these are expert overload (9) and lack of knowledge of local factors including culture, climate, and service availability (8,9).

Fourthly, essential good practice, including audit and outcomes studies, has as yet no trans-national organisational structure (8,10).

In summary, the lack of a global means of controlling and regulating international e-health practice is very worrying. The nearest analogy is civil aviation, where over 100 countries now meet and mutually agree working practices which are taken back into the law of every participating country, those regulations been based on supporting scientific analysis and interpretation, leading to evidence-based guidelines. A similar system is urgently required in health (8), and Royal Society support for this would be a major beneficial outcome of this enquiry.

Overarching Comments

As mentioned in the introduction, whilst the focus on the availability and effects of innovative ICT technologies is important, it is also important to stand back and look beyond the boundaries. Four issues are particularly highlighted here:

i. It is important for any new technique or technology, including ICT-enabled advances, to be considered as part of a health system and for the effect upon the population and other aspects of health systems to be considered. It is recommended that any new technology should be required, as part of a culture of social responsibility in science, to seek a third party Health System Impact Analysis, not dissimilar to an environmental impact statement but related specifically to the likely effects on the health system and the population's interaction with the technology and services.

ii. The implementation of any new technology should be seen as wider than that technology itself. There are lessons to be learned from the implementation of minimally invasive surgery, ranging from the dangers of inadequate preparation and roll-out training beyond the pioneer sites, through to the tensions of rapid re-engineering of services, the psychological and indeed professional threat to many senior professionals, and perverse effects on other members of the healthcare economy such as community nursing and primary care. An approach broadly modelled on the best guidelines for appraisal of screening technologies, assessing the full range of supporting actions from public advice through to appropriate reinforcement of diagnostic and therapeutic techniques, should be advocated as normal practice and an ethical requirement.

iii. New ICT technologies should not just be implemented piecemeal. Industry and retailing have shown ways forward, for instance new supply and logistics paradigms have been created driven by production line scheduling and electronic point of sale (EPOS) information systems (11). The former head of BT Research pointed out that a soft drink vending machine on a garage forecourt was equipped to dial its supplier to advise that restocking was required, but the heart monitor of a passing pedestrian would advise no-one that the wearer was in the early stages of a heart attack. There needs to be greater support for more innovative linking of different ICT technologies (such as linking portable monitor, telecommunications, and geographical positioning) whilst in the process also considering health system, economic, and societal effects.

iv. The significance of globalisation and international communication of data cannot be underplayed. This can clearly have major positive effects, and also major risks and dangers. The fact that many specialist services may be provided totally offshore must be recognised, with concomitant benefits (such as quality and efficiency), while also risks (lack of control and liability) must be considered, along with the collaborative regulatory and control mechanisms alluded to earlier for implementing services radically changed by new technology.

It is hoped that this inevitably space-constrained evidence is helpful, and the author would be happy to elaborate further on any specific points.

Michael Rigby

Professor of Health Information Strategy

Centre for Health Planning and Management
Darwin Building
Keele University
Keele
Staffordshire
ST5 5BG

m.j.rigby@hpm.keele.ac.uk

7th September 2005

References

1. Rigby M, Budgen D, Brereton P, Kennett K *et al.* The Data-Gathering Broker – A User-Based Approach to Viable EPR Systems; in Engelbrecht R, Geissbuhler A, Lovis C, Mihalas G. Connecting Medical Informatics and Bio-Informatics – Proceedings of MIE2005 – The XIXth. International Congress of the European Federation for Medical Informatics; IOS Press, Amsterdam, 2005.

2. Rigby MJ, Budgen D, Brereton OP, Bennett K, *et al.* A Dynamic Data-Gatherer as an Emergent Alternative to Supra-enterprise EPR Systems; in Bryant J (ed.). Current Perspectives in Healthcare Computing 2005, 169-178; BCS Health Informatics Committee, Swindon, 2005.

3. Rigby M. The Management and Policy Challenges of the Globalisation Effect of Informatics and Telemedicine; Health Policy, 46, 97-103, 1999.

4. Rigby M, Birch K, Roberts R. The need to ensure that the globalization of information and telematics does not destabilize health-care worldwide, Journal of Telemedicine and Telecare, 6 Suppl 1, S116-8, 2000.

5. Forsström J, Rigby M, Roberts R, Nilssen S-I, Wyatt J, Beier B, Delfosse I. Towards Evaluation and Certification of Telematics Services for Health (TEAC-Health) - Key Recommendations (Final Report of the EU Health Telematics Application Programme project HC 4101, Towards European Accreditation and Certification in Health (TEAC-Health)); University of Turku, Turku, 1999.

6. Forsström J, Rigby M. TEAC-Health – Research-based Recommendations for European Certification of Health Telematics Services; in Hasman A, Blobel B, Dudeck D, Engelbrecht R, Gell G, Prokosch H-U: Medical Infobahn for Europe: Proceedings of MIE2000 and GMDS2000, IOS Press, Amsterdam, 2000.

7. Rigby M, Forsström J, Roberts R, Wyatt J. Verifying Quality and Safety in Health Informatics Services; British Medical Journal, 323, 7312, 552-556, 2001.

8. Rigby M. And into the 21st. Century: Telecommunications and the Global Clinic; in Rigby M, Roberts R, Thick M (eds.): Taking Health Telematics into the 21st. Century; Radcliffe Medical Press, Abingdon, 2000, 187-206.

9. Rigby M. Globalisation or Localisation: Common Truths or Local Knowledge?; in Rigby M (ed.) Vision and Value in Health Information; Radcliffe Medical Press, Oxford, 2004, 149-158.

10. Rigby M, Birch K, Roberts R. Key Issues in Taking Health Telematics Safely and Ethically into the 21st. Century; in Rigby M, Roberts R, Thick M (eds.): Taking Health Telematics into the 21st. Century; Radcliffe Medical Press, Abingdon, 2000, 173-186.

11. Roberts R, Rigby M, Birch K. Telematics in Healthcare: New Paradigm, New Issues; in Rigby M, Roberts R, Thick M (eds.): Taking Health Telematics into the 21st. Century; Radcliffe Medical Press, Abingdon, 2000, 1-17.