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Exploratory Workshop**

9-11 May 2004

THE PRACTICAL, LEGAL AND ETHICAL ISSUES OF EXTENDED NETWORKING IN E-HEALTH SOLUTIONS

Workshop Report

Compiled by

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Workshop Convener

Final Draft – v3

Centre for Health Planning and Management, Keele University, United Kingdom

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<u>Issue Setting Session</u>

The workshop programme is shown as Appendix 1.   The event opened with introductions by delegates (see Appendix 2), and an appreciation of the role of the European Science Foundation (presented by Michael Rigby in the enforced absence of Dr Marianne Minkowski).   There were then five scene-setting papers, defining the subject to be studied.   Papers supplied in advance were available to members as a set; the contents is shown as Appendix 3.

Introductory Paper – Michael Rigby (Keele, UK)

This paper introduced the fact that whilst the introduction of modern information technologies to health enables a whole range of new opportunities in information to practitioners, information to patients and citizens, and analyses of diagnostic and patient history data, the inter linkage with modern Communications Technologies brings new paradigms linked to new risks which were neither adequately studied nor controlled.

Networked e-health could be split into four categories – **networked records** which supported the local physician through access to records beyond his/her organisation; **telemedicine** which enabled diagnosis or treatment remotely in real time or through store and forward technology; **Internet sites** which supplied information to citizens, and also to health professionals; and **purchased software and services (including decision support)** where the actual provision may or may not be networked but the software had originated in another country.   In many cases the remote country is not identified.

In nearly all countries healthcare policy is a national competence, but in many federal countries (e.g. Germany, Spain, UK, Canada, USA) health policy and delivery are primarily the responsibility of the devolved provincial government level. In other words healthcare was a very local service. However, communications technologies enabled rapid international communication, and created a virtual therapeutic environment which transcended national boundaries, and thereby circumvented the controls for which each country had built up sophisticated systems over a considerable period of time.

From the citizen's point of view, the Modern Patient could have a totally international dynamic to their care even though they would consider that with the exception of holiday medicine it was totally local and integrated. Using examples of services currently provided internationally, a patient in the UK for instance could receive treatment for a skin condition based on teledermatology diagnostic advice received from an overseas expert on a store and forward basis; treatment for abdominal pain in their local hospital using decision support software which had been created overseas (included the embedded reference data); there could be genetic reference data added to their record by obtaining genetic information about a relative living overseas; and they could contract an illness and receive treatment whilst on holiday. Thus in this example, with the patient travelling only once there nevertheless could be diagnostic or treatment data from five overseas countries as well as their country of residence. There was little understanding of who could provide what care, with what responsibilities, under such circumstances. Though there were developments in data standards, there were few international agreements on treatment or terminology. Put another way, there were four unanswered questions relating to this type of patient's treatment:

1. Who is in charge?
2. Who sees the full picture?
3. What record(s) exist?
4. Who is liable?

This did not map well to current health organisational structures, which was based on organisational controls, mutual understanding and agreement in contiguous organisations forming a health community; and overall managerial controls. In some situations there was then a federal government level and/or a super-national body such as the European Commission with specific (normally limited) powers.

The justifications for utilising modern information and communications technologies beyond the organisational boundaries, and internationally, were in principle sound enough – to gain the best expertise, and to avoid delivery bottlenecks. What was lacking was the research into the new issues and effects, and resultant evidence-based systems and controls.

Vision Discussion Papers

Following this Introduction, the workshop then received four Discussion Papers, addressing different aspects of the issue of extended networking in e-health solutions.

Professor **Keith Bennett** of Durham University, UK, gave the **Computer Science** vision. He outlined his own interest in software 'maintenance' which because of the exponentially growing task was not referred to as 'evolution', showing that effective software was no longer static. The manifestation of an application seen by the user was

merely the tip of the iceberg – the hidden code and processes were much more extensive and complex, giving challenges when changes were attempted. With the growth of computer system sophistication and range of components, large enterprise systems which attempted to be totally comprehensive in one application were increasingly seen as potentially unstable. Professor Bennett was part of a grouping of university computer science departments known as the Pennine Group, which was developing more flexible solutions focused on autonomy of organisations and inter-operational definitions, rather than large enterprise systems.

In strategic terms the new issue was whether large 'systems' should be centralised, top-down, and imposed, or should be devolved, distributed, and with autonomous components. However, in health this latter approach raised specific challenges, particularly confidentiality, security, and continuity of value and meaning. This therefore gave a new range of issues to be addressed in the context of extended networking.

Second, Professor **Reinhold Haux** of UMIT, Austria, gave the **Health Informatics** vision. He emphasised seven points:

(1) The increase in computer-based data storage is created more by an overall increase in data volume than by a transfer from paper-based and film-based recording;
(2) The shift from departmental systems through institutional systems to regional or national record systems;
(3) The involvement of patients as users, and citizens, in healthcare data systems;
(4) The use of health records information not solely for direct patient care, but for health planning, epidemiology, and research;
(5) The important recognition that implementation of health informatics systems involves not only technical problem solving but also change management and strategic information management techniques;
(6) The shift from mainly alpha-numeric coded data to images and now also molecular-level data;
(7) The steady increase in the number and range of new technologies involved.

Professor Haux pointed out that the consequences of this for the future were significant, including the need for trans-institutional health informatics system architectural styles, and the need for a mixed broader base of education in managing and using such systems. At the same time, societal needs including the issues of healthcare in an aging society meant that the information handling capability of health informatics was vitally important. No longer were automated record systems based in departments and relating to a subset of data items and a small population of patients, but the parallel paradigm shifts raised major new issues which require research in their own right.

Thirdly, Dr **Fabrizio Consorti** from University la Sapienza, Rome, addressed the **Clinical** viewpoint. He noted the support of the Health Ministers' declaration of May 2003 in favour of health informatics as a means of reducing unnecessary duplicate clinical activities whilst supporting continuity of care and communication between agencies. He identified five key words in the declaration – 1. Management, 2. Continuity, 3. Communication, 4. Realms of Information, and 5. Roles. He felt that this move towards deeper use of health informatics would cause a number of changes. Control of care would pass at least in part from professionals to the patient, whilst the relationship between professionals would be better defined through mandates, but there would be

new issues of trust between different third parties. Healthcare processes would change as a result of inter linkage between past health and lifestyle activities enabling more proactive health maintenance activities, and better continuity of care. Increasing access to evidence based medicine sources would shift patterns of practice from autonomous decision making to selection of evidence-based paradigms. A "consumer good" attitude to healthcare would put further tensions on clinicians. Consequently, he felt that the principal research areas were firstly on Relationships, particularly with regards to networking and with regard to the balance between the citizen's and the professional's control roles; secondly on Processes and the implications both of the move towards evidence based medicine and also increased management control over systems and processes; thirdly Change Management; and finally Education.

Fourthly, Dr **Persephone Doupi** of STAKES, Finland, spoke on the **Patients' Interests**. She pointed out that individuals in the community had multiple roles – patients, citizens, carers, consumers and clients. Not only did they have personalised needs, but also values and expectations. Their understanding of the scientific and technical issues was also personal. New health informatics based tools brought the potential for new types of service, whilst there was also a paradigm change in expectation to focus on prevention, wellness and health maintenance. The impact of e-health solutions would create new ways of the consumer interacting with services, as well as new perceptions and an interaction with new health-related habits. Studies had looked at the empowerment and autonomy of the "Patient Citizen", but there were significant limits to current understanding. These included unknowns about e-health-related behaviour; the impact of informatics on the patient-professional relationship; matching visions and expectations; ensuring representation of citizen beliefs and views in new policy and practice development; and the difference in expectations between normal healthy living and times when in need of healthcare. Dr Doupi pointed out the ethical issues of the new paradigms, including new manifestations of autonomy versus the power of the knowledge holders; new issues in privacy and confidentiality; the meaning of informed consent; and the balance between individual and public interests. Legal issues included data protection, safety and reliability, and liability. From these issues it was clear that there was the need for a significant future research agenda to identify the visions and values of citizens and ensure that these influenced technical and policy development.

The Issues Raised

The workshop then held a general discussion on the issues raised by the four introductory papers. Important points to emerge from this were:

- **Micro-macro balance.** Treatment occurs at the micro level, where many problems exist such as patient choice. Extending the virtual organisation and the boundary to almost limitless horizons gives a new paradigm of problems both for the patient in making decisions, and for professionals in knowing the opportunities and issues.

- **Scaling.** Extending networking in healthcare information systems has huge issues of scale – the development of the lifelong record, the composite health delivery system, and distant and international contributions to treatment create an ultra-large global organisation.

- **Data overload.** This is a future likelihood when treating the individual patient. The "cradle to grave" record, or more recently with genetic and outcomes studies respectively, the "sperm to worm" record, appeared a major step forward, but the individual user is likely to be swamped by large volumes of material extraneous to the specific consultation. However, automatically excluding aspects of data could lead to liability issues in the event of an alleged adverse outcome.

- **Differentiated histories.** Patients may intentionally give different emphasis or contents in histories presented to different health professionals for different conditions – they may actively not wish the whole of their history to be available on every occasion. Yet extended networking makes such differentiation more difficult, and raises autonomy and confidentiality risks

- **Uncaptured data.** These are a separate concern. Patients may concurrently seek alternative medicines and alternative therapies (up to 40% of patients was the suggested figure in some countries), whilst most patients will also apply "over the counter" (OTC) remedies. Thus the extended network record, by appearing fully comprehensive, may give an implication that it contains all data when this is not the case.

- **Issues of control**. Extended networking gives an "out of control" feeling, as it is difficult to know whether the patient, the individual treating doctor, the computer record, the network, or wider external policy factors are controlling the treatment of the individual, and the dynamics over the overall health system.

- **IT provider role.** This role is unclear as on the one hand the IT provider is a technical supplier of a platform, but on the other hand not only do they have responsibility to hold and maintain stored data, but their design decisions influence the practicalities of practice. At the same time, the IT provider is a new type of player in the health sector who has their own needs, but may underestimate their wider responsibilities. Moreover, this is a young and dynamic commercial sector with a degree of instability in the constituent organisations.

- **Definition of truth.** The extended network database has to be taken on trust. What is the "truth", not least with regard to correct understand and recording of situations and circumstances? Additionally, both the patient and individual practitioners may have motivations to give a particular emphasis which is not totally objective. In some situations the patient may have a motivation, or a psychological tendency, to give incorrect information, but this is difficult to deduce when the data are accessed remotely. Similarly, though the vast majority both of practitioners and suppliers have high integrity, there are exceptional cases where the truth, or the complete picture, are not truly represented in the professional record, but the remote reader of such data may have no option but to take the presented data as true at face value.

- **Ownership.** This is a further challenge. There is no single owner of the extended network, and indeed components may be changed over time unbeknown to an individual user. Similarly, ownership of data raises issues, not least the balance between patient ownership, clinician ownership in that the clinician generated the data through their clinical skills and knowledge and it also represents his/her activity

and results, and organisation and commercial ownership of aspects of the health delivery processes.

- **Liability.** This was seen as a major issue. On the one hand liability for software and networks is unclear, particularly when they cross organisational or national boundaries. The extended network is a sum of the parts, but liability for each individual component is difficult enough to hold to account, whilst no one had liability for the composite network. Secondly, when contributions to treatment (including databases and treatment guidelines) come from outside the organisation, liability for any adverse outcomes of the resultant treatment is difficult to establish.

- **E-health integrity and liability.** The patient as citizen has the right to consult remote providers by email or Internet site, but there is currently little protection for the consumer as to the integrity and true identity of such providers. Conversely, the remote provider is dependent upon the truth of the patient's presented scenario when giving their advice. Further, the availability of remote e-health services may result in some patients delaying presentation to a traditional treatment provider.

- **Patient (and professional) education.** Citizens need to learn how to look critically at remotely provided data (and treatment), and critically evaluate it. What is appropriate and available in one locality may not be appropriate in another, or the solution may not be available. Citizens and professionals need educating in critical appraisal, including legitimacy, appropriateness, and local availability.

- **Trust.** Whilst extended networking in e-health can bring remote expertise instantly, it does not enable the building up of a traditional trusting relationship. Similarly professionals need to address this same from the professional point of view. The availability of external expertise can appear to bring scientific enlightenment but it may not in fact be trustworthy. Patients and practitioners need to be able to understand how to establish trust in the remote source.

- **Philosophical and role changes.** Networking brings changes in perceptions of personal roles. Patients may feel less involved in their own treatment if part is provided remotely (not least the evidence), whilst conversely they may feel more empowered if they can access information with which to hold a dialogue with a professional.

In summing up the discussion, Michael Rigby indicated that there needed to be a paradigm shift to enable global research on global issues, which was currently not being enabled. In particularly, there is a need to develop new models of trust to accommodate networking in e-health, in the way that has occurred over several decades for both civil aviation (ranging from pilot training and navigation technologies to airport codes and markings) and food labelling (including content and storage conditions, and in the management of which process the WHO was an equal partner).

Group Discussions – Opportunities, Issues, and Unknowns

The workshop then broke into groups, to examine the top-level conclusions from the discussion and plenary analysis of the scene-setting papers, and to identify those issues requiring further consideration. Key outputs are reported below.

Organisational, Social, Legal and Ethical Issues

First, the group identified that the extended network approach in health led to new concepts of organisation, and of organisational definition. The health care delivery organisation was no longer a single entity, was not under single ownership, and did not have a cohesive managerial or accountability structure. Further, traditional concepts of the learning process within organisations did not apply. This phenomena had a potential impact on quality, whilst the impacts of new sources of knowledge on the local context were as yet unknown.

Secondly, models of care would be different from location to location, and may affect types of treatment delivered, potential professional accountability, teamwork, (for instance radiologists working remotely from clinical colleagues), and the means of reimbursement of the organisation or the individual. This pattern of working could be stressful, and also raised quality and accountability issues.

The overall uncertain effects of the health virtual organisation model were also discussed. On the one hand networking could support remote practitioners in isolated localities, and thus enable better, more equitable primary and local secondary care. On the other hand, the major secondary care locality, with its interaction of sharing and learning functions, could be undermined if the physical team was diffused, with some expertise and services being provided remotely. The chance for physical observation and learning was undermined, and thus overall traditional proven models of training and development compromised.

New concepts of record system architecture were needed to structure the available data to prevent overload and data redundancy, and at the same time to provide safety and backup. The dynamics for patients could also be different, with a difficult choice between locally available care and alternative patterns available at a distance. Patient care in the virtual organisational setting had yet to be studied beyond atypical pilot projects. Issues of responsibility for care, the impact of ageing, and demands on delivery systems needed to be considered. There were also issues of semantics and linguistics when networking extended widely. Cultural difference might produce a "flattening" of care patterns, rather than accommodation of personal preferences according to local culture.

Privacy and Liability

Regarding privacy, extending networking raised ethical issues of who is the owner of the data, who is the owner of the data repository, and what is the life of the data (its utility for the author may be much less than its contribution to the summation of the patient's life history). Centralisation of data would remove it from the author, and would lead to extensive data banks. Different countries had different positions.

Access needed to be audited, but access rules would vary between countries. The professional author of patient-related data would not know which new owners and users were holding and reading it.

In a conventional setting weight is attributed to authorship based on local knowledge of the source. However, with remotely networked data attribution of appropriate weight to authorship is compromised, because the experience and credibility (and possibly the identity) of the author may be unknown.

Liability now became shared, but in a virtual way, between a number of contributory authors. It would be difficult to impose liability for a component when material was used by a subsequent actor.

Relationships

Whilst the knowledge and skills which could be acquired remotely could add to the quality of health care, it was equally important to ensure that face-to-face skills and competencies were not lost, and the amount of face-to-face contact not significantly reduced, otherwise greater technical competence of one type would be more than offset by loss of interaction and skills of another type.

The Public Health function, and also Outcomes studies, could be compromised by networking. It was difficult to capture data about populations and their treatment when care was given remotely. Conversely, Outcomes data were difficult to capture when the patients treated were distributed widely.

Finally, the group emphasised the importance of improving the e-skills of healthcare workers. Without proper skills in using, and interpreting, electronically distributed data practitioners would be disadvantaged and patients put at risk.

Future Research Challenges

The workshop then moved on to translate the issues into Research Challenges. Extended networking in e-health solutions is an issue that challenges existing research paradigms: it crosses national, research domain, and intellectual discipline boundaries, and consequently there is no readily identifiable vehicle for addressing the key issues comprehensively. Whilst health care systems and delivery are normally national responsibilities, by definition extended networking crosses delivery system and jurisdictional boundaries. The issues do not fall within conventional medical research as there are no therapeutic techniques being researched; they do fit in within computing and communications technology research as the core technologies are already proven; and though there are studies into impact and organisational effects these are primarily focussed on behavioural responses to the new technological paradigms within local settings.

As a consequence of the wide geographic and domain spread of the issues of extended networking in e-health, definition of the catchments and thus control of research environments difficult. The Workshop identified that the research issues are disparate, large, but nonetheless vitally important. The following were identified as the current key unmet research issues:

1.   The changing face-to-face encounter

The face-to-face encounter is a core activity of healthcare delivery. E-health provision changes this radically. It may bring external support and expertise, either directly to the patient without mediation, or through support to a local health professional. Remote

sites and sources will not share the nuances provided by the face-to-face encounter. Individual local practitioners may be reinforced by externally supplied knowledge, but there may be questions about its accuracy and relevance. The local practitioner and the patient may encounter conflicts between local and external sources. Some aspects of expertise may be lost at the local level as specific functions increasingly are delivered remotely, thus downgrading the local face-to-face option. With networked records exponentially increasing the volume of data available from the past record at the consultation, the effect may either aid local diagnosis and treatment by giving a more comprehensive picture, or may jeopardise it by data swamping or overload. The patient may not be comfortable with a current health professional seeing the totality of their previous history. Research is needed on these issues, the triggers, and the potential controls, particularly with a view to developing models and paradigms which can guide the development of effective e-health practice.

2.   Trust

How can appropriately based trust be built up in extended e-health? The citizen or patient may be inappropriately drawn to exciting promises and possibilities of treatments which may not be accurate, relevant, available or affordable. Some sources are known to offer poor advice, be malicious, or be financial scams. On the other hand, the impartiality of an expert neutral source can be advantageous, ranging from giving details and seeking advice for very confidential or sensitive conditions, through to establishment of a support modality from a source which shows sound understanding of the patient's problems and preferences. Clinicians need to be able to place trust in remote systems, whether expert knowledge bases, operational software, or treatment advice, as the user clinician carries the prime liability for the results of their use whilst having little knowledge of the origins or architecture.

3.   Healthcare Delivery Support

Extended e-health can have many different effects upon healthcare delivery systems, whose existence is essential to the equitable availability of quality health. Treatment recommendations may be generated from external evidence regardless of the cultural evidence or economic impact. Remote practitioners in isolated rural areas may feel supported and empowered, making recruitment easier and reducing practitioner stress levels. Specialist centres may be able to develop advanced teams who can make their expertise available much more evenly and widely through distributed methods. Female practitioners and others with dependents or practical limitations to their practice may be able to practice more easily by remote means, ensuring equity for practitioners and increasing the available workforce. But conversely, local district sources of expertise may be bypassed and thus atrophy, or be streamlined out of existence in an e-enabled business plan, thus removing both the local face-to-face option and informal education opportunities for local clinical staff.

4. Organisational Behaviour and Control

Within any health system, but in different ways specific to the national health care model, organisations are essential as practical means of making health care available, managing

resources, and rewarding deliverers. Extended e-health by definition creates the virtual organisation, including services provided (by planned intent, or by stimulating demand) from outside the national jurisdiction. Knowledge of how to manage, control, and innovate virtual organisations is limited, especially trans-national ones, and particularly in health care. Yet increasingly the virtual organisation, or at least the physical organisation with outposted virtual components, will be the organisation of the future. Research needs to develop better understanding of the dynamics and the appropriate control mechanisms. But conversely, local district sources of expertise may be bypassed and thus atrophy, or be streamlined out of existence in an e-enabled business plan, thus removing both the local face-to-face option and informal education appropriate amongst clinical staff.

5. Patient Centeredness

Health care is about the health of individuals; moreover individuals should take responsibility for their own health, ranging from healthy lifestyles and behaviour to the appropriate seeking of preventive and therapeutic services. E-health is focused primarily upon the technology. Because of costs of infrastructure, and potential power and economies of scale of service provision, it has an innate tendency to be dominated by large organisations (whether commercial or traditional expert health providers). Whilst e-health can bring expertise to patients, it can also make the patient feel de-personalised and the recipient of impersonal advice from an anonymous external source. Research is needed to ensure optimum ways of continuing to ensure a citizen and patient focus exists in extended e-health – enabling equity of access regardless of any imbalance of connectivity; enabling informed choice; assisting with different degrees of familiarity with e-health and telehealth techniques particularly for older or less educated citizens; and ensuring that the delivery processes are totally patient-focused. Face-to-face and "screen-to-face" delivery techniques need developing to ensure that the patient, and not the screen, is the focus of attention. There may need to be a specific advocacy role developed to enable citizens to select, and to use, e-health appropriately.

6. Quality of E-health Care

By nature and definition, extended e-health provision is a collaborative form of care delivery. Because of the extended dimension, the contributors are likely to be distributed across different organisations and possibly different countries. The health care domain has spent decades steadily developing means of measuring and optimising quality of care in traditional settings, and indeed is only at the beginning of grappling with that situation – issues ranging from iatrogenic morbidity to incompetent clinicians still need to be further addressed. Yet e-health, for the reasons mentioned, crosses and evades such controls as are now in place in individual health sectors. Given the dependency of citizens, and the expert nature of health care delivery, it is not satisfactory or ethical to take a "user beware" attitude – the moreso as there is informal evidence that trans-national e-health is an attractive activity area for clinicians deprived of their practice opportunities in their home environments. Study needs to be applied urgently to issues of measuring and managing quality of extended e-health-based care.

7.   Outcome Measurement

Closely linked to Quality of care is the measurement and study of outcomes. On the one hand this is scientific study to track patients and ascertain the clinical and functional outcomes of different patterns of care. By definition, extended e-health imports different patterns of care (or from the delivery point of view expert treatments), so this important dimension of scientific study takes on a new challenging dimension which is not met. And on the other hand, outcomes measurement is the means of identifying poorly performing practitioners, both to restrict and dangerous practices, and to give consumers comparative data to enable an informed choice of provider. These studies too are challenging in extended e-health. Solutions, including protocols for studies, urgently need developing.

8. Public Health Outcomes

The public health function is important in any country. As well as basic epidemiological functions, it should enable study of treatment and disease trends, of efficacy and effectiveness, of issues such as changed iatrogenic problems, and above all the advent of new epidemics or diseases. Public health is, by definition, highly dependent upon the availability of data about the citizen group in question from the treatment sources which serve them. Extended networking in e-health results in loss of the identifiable catchment area or organisational groupings, rendering data collection and thus the public health function severely compromised. This is a major societal and indeed global challenge. Research, possibly leading to recommendations for international agreement on data collection and sharing, is needed as a priority.

9. Appropriateness of Telehealth

Different means of telehealth care delivery have different strengths and weaknesses; similarly different paradigms of health care and delivery have different attributes and advocates. Telehealth and e-health open up possibilities for less conventional treatments, which may give benefits to some but put at risk the health of others, particularly if it results in patient delay in seeking formalised treatment for serious conditions. There needs to be applied research into the appropriateness of telehealth, possibly leading to a rule set to enable both the citizen user and the health professional user to identify the appropriateness of particular sources and solutions under different circumstances.

10. Liability

In a conventional health system the liability for both the appropriateness and delivery of treatment and for integrity of equipment and support services is usually clear. Moreover, as treatment is given within one jurisdiction so this liability, and any related issues such as eligibility for compensation, lie within a known legal system.   Extended e-health undermines this in two respects. Firstly, there is the differential involvement of different experts, and of remote software and evidence sources, each of which is difficult to assess empirically before or after their involvement in treatment, and which by definition are all contributors of different significance to the overall diagnostic and treatment pattern of the individual. Secondly, these contributors may operate in different jurisdictions, with

different legal systems, and with no ease of accountability to the user. Research is needed both into the best means of handling this new paradigm of international consumer liability, but also into means of developing appropriate levels of control and (when necessary and appropriate) compensation and retribution.

11. New Paradigms of Information Architecture

With regard to information and communication technology to support health care delivery, traditionally the pattern of architecture of record systems, of expert decision support systems, and of other support technologies has been clear. Extended networking linked to modern communications and software technologies undermines this in two respects. First, because the network is extended and virtual, the end user may not know the details of the design and logic of components of the virtual network; indeed, they may be difficult to identify, if for instance an external expert consults a remote knowledge base and simply passes over the advice received as a result. Secondly, with the rapid evolution of web-based software services, there may be no permanent architecture. Data may be amassed, and expert guidance or calculations sought, according to real time calculations as to the quickest available provider. It is quite possible to envisage remote reading of diagnostic images or traces in future being passed automatically to the external source which at any moment can provide the quickest service based on current workload and real time communications availability, as with current telecommunications routing.

12. Responsibility and Mandates

In conventional health care, a health professional consulted by a patient knows their responsibility. If they refer the patient onwards it is normally clear the degree to which they have transferred responsibility as well, and following discharge back there is normally a clear understanding as to the degree to which responsibility for ongoing support has been returned to the original referral source, and the degree to which it remains with the specialist provider. With the advent of shared electronic records, and the potential for collaborative and virtual team working, there has been some development both of shared operational guidelines, and also of the structured representation of mandates for action. However, with a wider networked virtual delivery pattern, and with the ability of citizens to choose their sources of treatment, new paradigms of treatment responsibility, particularly in the case of concurrent treatments for different conditions, are raised. The providers may be in different healthcare systems, with different patterns of service availability and inter-clinician responsibility. Means are needed of identification, and of representation, of clinical responsibility and of signalling the need for concurrent distributed care providers to collaborate.

13. Data

Data form the very heart of health care delivery – empirical data, biophysical data, scans and images, patient narrative, and clinician narrative. When captured within one health care organisation, or indeed within one health care system, it is increasingly common for the combination of educational and health informatics processes to be moving towards common terms and definitions. Extended networking, however, raises new issues.

Firstly, data do not have stand alone intrinsic value, but are heavily qualified by their context – for instance, by whom and under what circumstances observations were recorded or concurrent treatment at the time when physiological measurements were taken. With extended networking, and the dependence of one clinician upon the sharing of data recorded by another unknown one, it is essential that adequate details of context and authorship are transmitted along with the data sets forwarded. Means of identifying attribution raise new challenges, as names, and indeed the boundaries of professional responsibilities, will not have meaning without other explanation or standardisation. Other challenges are the meaning of narrative phrases, particularly those which are vernacular descriptions by either patients or practitioners, while clinical terminologies may vary between health systems as well as between natural languages. The standardisation of data, data representation, and transmission of data enter into new paradigms beyond those of the health messaging conventions currently being addressed.

14. Data Storage and Maintenance

When health care is provided from one organisation, it is assumed that this organisation will be responsible for the storage, maintenance, and subsequent later availability of clinical data. With the advent of modern communications linked to electronic records, this is no longer necessarily the situation, though prime organisational responsibility for individual components likely to endure (though this may be compromised by organisational mergers or changes). However, when health care is provided by dispersed means, or individual clinicians expect to be able to draw data from previous care contributors in remote sites, it becomes even more important that these data are available, stored in ways which protect their integrity and identity, and can be made readily available by successor bodies. Thus new paradigms of data storage and data maintenance apply. Access rules, commitment to storage for a defined reasonable period, and in future the conventions for enabling data brokerage, all require to be addressed.

15. Describing the Domain

Finally (or first), is the issue of defining the e-health domain. One aspect is the clear range of technologies and techniques, the use of which needs on the one hand technical specialists and on the other hand the informed enablement of clinical end users and patients. But definition of e-health as a technical domain totally overlooks the fundamental role it has on the basic essentials of health care delivery and the participant professionals and organisations, and on the expectations and behavioural effects of citizens. This has led to the development of topics such as health informatics and the academic promotion of an e-health domain of study. On the other hand, there are those who argue that such terms are diversionary, and health practitioners and citizens should know how to use modern technologies and related opportunities in their daily practice in the same way that they use the telephone in new ways, or in the way in which 24 hour banking has enabled better use of financial services without it becoming become a protected ring-fenced domain. Extended networking in e-health can, in theory, bring any health practitioner or any treatment, or more fundamentally the expectation of that treatment, to any citizen.

Even robust health care organisations can be significantly be distracted, indeed destabilised, if external evidence suggests essential changes to service availability or treatment patterns. The unmet research needs presented above identify the range of issues raised, which fall across many disciplines and potentially affect all citizens and health professionals, though to different degrees. There is thus a need for a basic epistemological description of the e-health domain, moving well beyond the technologies to the concepts, the skills, the interactions, the ethical issues, the organisational impact, legal and liability frameworks, and the societal effects. This should be with a view to enabling e-health development and developers to be more responsible for identifying and understanding the bigger impact as well as the immediate local effects, and at the same time permitting linkage with other domains ranging from basic clinical education through to health policy, enabling appropriate aspects of e-health to be integrated operationally.

Conclusion

In conclusion, and taking cognisance of the range of research issues raised and reported above, the workshop considered what was needed to progress these. These were seen as follows.

1. **Raised profile**

   Members of the Workshop recognised that better understanding of the issues could only be achieved by continued and enhanced publication, addressing the different issues and promoting them in a range of different publications.

2. **Networking**

   Members felt clearly the value of this ESF-funded event, enabling open and frank discussion. This was a unique and very welcome opportunity. The benefits of continuing such networking, but in a structured way so as to maintain a focus, where recognised, though the means was less evident

3. **Research Funding and Support**

   As already iterated, the research issues cross domain and organisational boundaries. Whilst research into individual issues in single domains is occurring, the bigger picture integrated research is hampered by lack of adequate funding sources which are not restricted to a single domain or a single jurisdiction.

4. **Extended Research Hypotheses**

   Much of the existing research in the domain is based either on testing the utility of a particular technology, or on addressing a very specific research question. Better understanding of the wider issues would be enabled by the appropriate development of extended research hypotheses, which were cast wider and looked at a greater range of dimensions over a longer period.

5. Improved Educational Paradigms

Existing training and education in e-health, and on its impact on practice, are somewhat limited, and restricted to the more technical dimensions. These have a role, but the wider messages could be much more effectively imparted by the development of richer case studies, virtual reality, or other more "populist" but scientifically underpinned educational tools which raised – separately for public and the health domain – the opportunities and issues of this new paradigm in health and its delivery.

6. E-health Observatory

Whilst there are a number of initiatives or networks to catalogue particular e-health technologies and applications, these are mainly of a simple descriptive or promotional nature. In other aspects of health, particularly more recently in European public health and in health reform, the value of the Observatory approach has been proven. The Observatory enables passive observation and monitoring of effects, causes, changes to behaviour and to values, and other consequences of planned or unplanned change. In e-health within Europe, Denmark has applied this approach with regard to Electronic Health Records. The workshop membership felt that there would be considerable value in funding an effective Observatory for networked e-health, with appropriate staffing, funding, and objective terms of reference.

7. Regulatory Agency

E-health and its extended networking is basically to be seen as an opportunity. However, with any opportunity there are the possibilities of malicious practice, and of serious unplanned adverse effects. These may be rare, but they can be serious, and they can seriously undermine and jeopardise the greater good. Because by definition extended e-health networking crosses national boundaries, it seems urgent for there to be a mechanism for limited but essential international regulation – for instance, seeking to address false claims of professional qualification, or ensuring basic standards of liability and consumer redress, as well as ensuring adherence to international standards. Such a model should be very firmly based upon research evidence, to provide control against misadventure of maliciousness. It would an appropriate balance for the outcome of an innovative workshop to lead concurrently to the development of scientific application to improve the common good, with scientifically determined controls to prevent accidental or deliberate misuse and avoidable adverse effects.

8. Synergy with HIS-EVAL Activities

Members saw a potential synergy between the activities of this workshop, and the HIS-EVAL network which has emerged informally out of the Exploratory Workshop funded by the ESF into the Evaluation of Health Informatics Systems. The area of common interest concerns methodologies and techniques for cross-disciplinary study of the impact of health informatics systems and e-health. It would be appropriate if follow-on activities from this workshop were to have cross linkage with those activities, though recognising at the present time

HIS-EVAL is currently an informal voluntary network as it has not found sustaining funding.

9. Potential Future Vehicles of Action

The Workshop sought to identify ways in which it could promote the issues identified. The purpose of the workshop was to identify the nature and specific attributes of issues which it was felt were not being understood or addressed with regard to extended networking of e-health solutions. Whilst on the one hand the meeting felt that it had been particularly successful in identifying the range of issues, their nature, their complexity, and their potential risks as well as values to society and health systems, there was a consensus that at the same time the workshop was ahead of general understanding of the issues. More significantly, it was ahead of there being adequate international mechanisms to facilitate study, ongoing research, or necessary evidence-based regulation. This was exacerbated not only by the cross-disciplinary nature of the issues, but by the fact that health delivery in general was a nationally focused issue, whilst the very nature of extended networking focused on cross-boundary impacts. The subject also crossed the boundaries of technological science, behavioural science, policy, and regulation.

In the immediate term it proved difficult to identify specific research proposals, or the means by which these might be undertaken as they would involve studies of planned and unplanned impacts of non-regulated activities, particularly those individually initiated by citizens or individual clinicians. It was understood that the ESF were terminating the Funded Networks vehicle, which could have provided an appropriate mechanism.

It was suggested that at the present time the issues could best be promoted and moved forward by:

- **Publications** – members were encouraged to develop and submit scientific publications on this theme, so as to raise awareness and coverage.
- **Book** – It might be desirable to seek to publish a book on the issues, though one of the current problems was the lack of structured evidence.
- **European Commission funding** – most European Commission funding was related to specific Calls for Proposals. The networking and membership of this Exploratory Workshop could provide a core grouping for responding to an appropriate Call which would enable issues such as patient safety to be progressed.
- **European Science Foundation** – the foresight of the ESF in funding this workshop was acknowledged and appreciated. It could be appropriate to seek further discussions as to the vehicle for continuing awareness raising and experience sharing discussions, as the essential first step to developing a sufficient body of research objectives and methods as to enable deeper research proposals to be prepared and submitted.

<u>Appendix 2</u>

European Science Foundation Workshop, 9-11 May 2004

<u>Programme</u>

Sunday 9 May 2004

19.30   Welcome drinks, Bar, Keele Management Centre
20.00   Dinner, Hawthorns Restaurant

Monday 10 May 2004

09.00   Plenary Welcome
        Agreement of Programme, Objectives and Working Arrangements
09.15   Presentation of the European Science Foundation - Representative of the
        Standing Committee for the European Medical Research Councils – Marianne
        Minkowski
09.25   Introductory Paper - Michael Rigby
09.40   Discussion Paper – <u>Computer Science Vision</u> - Keith Bennett
10.55   Discussion Paper – <u>Health Informatics Vision</u> – Reinhold Haux
10.10   Discussion Paper – <u>The Clinician's Vision</u> – Fabrizio Consorti
10.25   Discussion Paper – <u>The Patient's Interests</u> – Persephone Doupi
10.40   Plenary Discussion
11.00   COFFEE
11.20   Introduction to Group Work
11.30   Discussion Groups Considering <u>Opportunities, Issues, and Unknowns</u>
13.00   LUNCH
14.00   Plenary Report Back and Analysis
15.00   Discussion Groups Considering <u>Research Issues – Unknowns, Risks, Controls</u>
16.30   TEA
17.00   Plenary Report Back
18.00   Break
19.30   WORKSHOP DINNER – Old Library, Keele Hall

Tuesday 11 May 2004

09.00   Meet up, confirm Discussion Group tasks
09.15   Discussion Groups Considering <u>Enablement, Inclusion, and Special Issues</u>
10.45   COFFEE
11.15   Plenary Report Back
11.45   Resumé of Event's Conclusions so far; <u>Critical Review</u> - Don Detmer
12.30   Plenary Discussion - <u>Action Lines, Promotion, Publication</u>
13.00   LUNCH
14.00   Task Groups - <u>Action Lines, Promotion, Publication</u>
14.45   Plenary Report Back
15.30   Summing up and close
16.00   TEA, Depart

Appendix 2

European Science Foundation Workshop, 9-11 May 2004

Delegate List

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<u>Appendix 3</u>

European Science Foundation Workshop, 9-11 May 2004

<u>Key Prior Publications by Delegates and Invitees</u>

Aas, IHM. A qualitative study of the organizational consequences of telemedicine. Journal of Telemedicine and Telecare 2001;7: 18-26.   p1-10

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Brereton, P, Budgen, D, **Bennett, K**, Munro, M, Layzell, P, **Macauley, L**, Griffiths, D, Stannett, C. The Future of Software: Defining the Research Agenda.   p37-55

Beun, JG. Electronic healthcare record; a way to empower the patient. In International Journal of Medical Informatics 69 (2003) 191-196.   p56-61

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Detmer, DE, Singleton, PD, MacLeod, A, Wait, S, Taylor, M, Ridgwell, J. The Informed Patient: Study Report. Summary. University of Cambridge, Judge Institute of Management, Cambridge's Business School.   p62-74

Melzer, D, Raven, A, **Detmer, DE**, Ling, T, Zimmern, RL. My Very Own Medicine: What Must I Know? Information Policy for Pharmacogenetics.   P75-86

Doupi, P, van der Lei, J. Design Considerations for a Personalised Patient Education System.   p87-92

Doupi, P, Lampe, K, van den Hoven, J. Internet Health Resources: from Quality to Trust. Methods Inf Med 2/2003   p93-101

Johnsen, Jan-Are K, Steinsvik, OO, **Gammon, D**. Health-care professional's participation in an online discussion forum: The impact on structure, content and   To

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Hooghiemstra, T. Summary Study ICT in the care sector.

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Hooghiemstra, T. The Implementation of Directive 95/46/EC in the Netherlands, with Special Regard to Medical Data.

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