



White Paper

The medical knowledge crisis and its
solution through knowledge management

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Summary

1. It is now humanly impossible for unaided healthcare professionals to possess all the knowledge needed to deliver medical care with the efficacy and safety made possible by current scientific knowledge.
2. This can only get worse in the post-genomic era.
3. A potential solution to the knowledge crisis is the adoption of rigorous methods and technologies for knowledge management.
4. Awareness and understanding of these methods is not widespread and many of the technologies that currently exist are not designed to be compatible with others or interoperable
5. OpenClinical is an association of individuals, organisations and commercial companies who believe in the importance of improving knowledge management in medicine and who believe this can be best achieved through cooperation and consensus.
6. It has been set up to provide a range of services to members and partners, through one or more open-access web-sites. Among the services to be supported are
 - a. A single portal for information about developments in the field of medical knowledge management
 - b. Access to demonstrations of knowledge management technologies and their applications
 - c. Papers and other information on standards, including current needs, issues and proposals, for open discussion.
 - d. Open source knowledge content, including knowledge bases and reusable components
 - e. A directory of projects, technologies and services
7. OpenClinical has a particular concern with the primacy of *quality, safety and ethics* in the development and use of clinical knowledge systems.
8. It is against the development of proprietary standards that could in any way restrict access to medical knowledge.
9. OpenClinical is a non-profit organisation, funded primarily through grants, sponsorship and the goodwill of its members.

1. Motivation for OpenClinical: the medical knowledge crisis

Those of us who live in wealthy countries with well-developed medical services generally assume that when we have medical problems they will be dealt with promptly and as effectively as the medical art will allow. Until recently, most of us were looking forward to continuing improvements in this art as scientific understanding of diseases and their management continued to grow rapidly, and expected this to get a further stimulus with the explosion of new knowledge in the post-genomic era.

Unfortunately, the provision of top quality care is not uniform, even in wealthy societies, and the unprecedented growth in our understanding of diseases and their management is not matched by equivalent abilities to apply that knowledge in practice.

The principle reasons for these problems are lack of uniform access to new knowledge, and insufficient resources to deliver its benefits to all.

Socio-economic and organizational factors are a primary cause of unequal access to the best medical care. Health services are also under strain from the increasing medical needs of an aging population, the demand to provide a wider range of services with a constant or even reduced budget, and the rising costs of medical research feeding into increased costs of treatments and services.

In addition, there is a new difficulty that is almost certainly becoming a permanent feature of the medical landscape. The available information about new drugs, new clinical procedures and biomedical techniques, and even new diseases forms an unending avalanche of information for healthcare professionals. It has long been impossible for individual doctors and nurses to know everything there is to know about general medicine, it is now often impossible for them to keep abreast of developments in their individual specialties.

This problem is partly caused by our ways of publishing and distributing information - as documents which are slow to prepare and difficult to distribute - but a far more important factor is our finite capacity as human beings to absorb and correctly apply the new knowledge in those documents; all of us, however talented, have only so much time and energy. There are also limits to our ability to remember and recall information.

In *To Err is Human: building a safer healthcare system* [note ¹], the US Institute of Medicine reports that medical error annually results in between 44 and 98 thousand unnecessary deaths in the US and wastes up to \$29Bn per annum. "Even using the

¹ Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors; Committee on Quality of Health Care in America, Institute of Medicine.
(<http://www4.nationalacademies.org/news.nsf/isbn/0309068371?OpenDocument>)

lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS." Operational errors are not the only cause of avoidable adverse events but another important source is lack of knowledge of current best practice. In the area of cancer alone "perhaps 16,000 lives could be saved (p.a. in the UK) if all current knowledge of cancer were properly applied" [note ²]. In *An Organisation with a Memory* [note ³] a UK National Health Service panel chaired by the Chief Medical Officer reported that in acute hospitals alone 10% of admissions result in adverse events which lead to actual patient harm (about 850,000 annually), including deaths. The report continued: "Just as none of these statistics can be attributed wholly to service failures, research in this country and abroad suggests that they give no indication of the potential true scale of the problem".

In short, even the most professional and committed professionals cannot avoid gaps in their knowledge, or always apply that knowledge in the right way, at the right time. This has massive consequences in terms of avoidable mortality, morbidity and the use of resources.

1.1. Some possible remedies

The figures quoted above really only quantify a problem that has been increasingly recognised for some time - that our clinical services are not delivering the quality and efficacy of care that the science base makes possible. For some years a movement towards "evidence-based medicine" (EBM) has been arguing this view and has been gaining ground all over the world. The aim of the movement is to encourage clinicians to make decisions that are fully informed by available scientific knowledge and not just based on individual experience and opinion. The main methodology of EBM is to carry out rigorous and comprehensive reviews of international clinical research, and to publish the results of those reviews in the form of documents setting out recommended clinical practice together with the justification for those recommendations.

EBM represents a vital contribution to improving the consistency and quality of care, notably the work of the international Cochrane Collaboration, providing a rational foundation for all clinical practice which can be translated into guidelines for best clinical practice. However, EBM also has a problem. Since it depends upon traditional methods of disseminating medical knowledge - by means of paper guidelines, research papers, books and so on - it risks simply adding to the already intolerable burden of information on doctors and other healthcare professionals.

Despite all the efforts in reviewing and publishing the evidence for and against, the objectives of EBM are under threat if we depend solely on traditional methods of disseminating medical knowledge (whether on paper or, as is now becoming normal, via the internet). The reality is that few busy doctors have the time to do the reading that is necessary and, even if they are assiduous in their reading, the imperfect human

² ICRF Vision for Cancer, 1995

³ <http://www.doh.gov.uk/orgmemreport/orgmemexecsum.htm>

capacity to remember and apply knowledge in the right way at the right time and under all circumstances is clearly a critical limitation.

Healthcare agencies traditionally respond to these problems by extending professional training and providing in-service "refresher" courses. But these are palliatives at best: training is time-consuming and expensive, and medical knowledge is increasing at a rate many times faster than formal courses can disseminate it.

An alternative to more training is to encourage greater specialization by individuals and healthcare organizations. The pressures towards specialization are strong. Unfortunately, the result can only be that clinicians know more and more about less and less - and it becomes difficult for them to manage the many patients whose conditions require skills that cross traditional specialty boundaries. Patients in this category include those with multiple conditions, a common feature in the elderly, perhaps the fastest growing patient category.

More radical solutions are sometimes suggested, such as attempting to reduce the incidence of disease through improved public health policy or public education. Even when they are successful such processes are painfully slow (and often controversial). In any case they cannot keep pace with the increasing demand for healthcare that comes, for example, from people's constantly growing expectations and demands.

The response of the media, politicians etc is commonly to demand greater "efficiency" of healthcare professionals, to insist upon improved performance and better management (often without increasing resources). But improving the performance of skilled but busy people is not generally achieved by merely exhorting them to work better, faster, or more cheaply. As human beings, healthcare professionals probably make decisions, plan their time and remember what they need to remember as well as they can. Blaming the individuals or organizations that provide our services (and punishing them through professional sanctions or the courts when they fail) is no solution. If services are to improve significantly, they are likely to require new ways of working or improved tools.

Another political response is to propose reorganization of the delivery of healthcare - to concentrate resources and expertise for example. In the USA a major shake-up of healthcare services is under way with the creation of large managed care organizations. These offer standardized "packages of care" for specific conditions - often embodied in carefully prepared "disease management protocols" - whose aim is to provide a consistent level of clinical effectiveness at a given cost. Similar trends are spreading to many other countries, such as the UK and elsewhere in Europe (though they take on different forms according to whether the emphasis is on public or private healthcare).

These changes have their critics. On the face of it, standardization of care should produce more uniform quality, but many clinicians are anxious that the only uniformity will be of the cash-limited kind, that is, uniformly poorer quality. Another fear is that the imposition of standardized treatment protocols will undermine the clinician's skill, encouraging a narrow approach to treatment and discouraging him or her from seeing the patient as a unique person with particular problems and clinical needs.

As the results of the human genome project become translated into further revolutionary advances in clinical practice the knowledge crisis can only get worse. If we cannot disseminate biomedical knowledge well enough now, how can we hope to manage a knowledge base that is much larger and more complex? Many people now believe that the only practical hope of overcoming, or even containing, the knowledge crisis is to introduce new technologies and new kinds of help in delivering safe, high-quality care. Among the most promising are *knowledge management technologies*, which can assist clinicians in their decision-making and in the organization and management of their routine work.

2. Knowledge management in medicine

The paraphernalia of the information revolution - computers, communications networks, compact disks, imaging systems and so on - are now widely expected to make a vital contribution to helping doctors and other medical professionals do their work better. New information technologies include:

- Electronic patient records, which are more up to date, easier to access, and more complete than paper ones;
- Standardized medical terminologies and languages, both within and across natural language communities;
- Methods and tools to support faster dissemination via the internet of new scientific understanding of diseases and their treatment;
- More timely and reliable methods and tools to support communication and coordination among members of care teams.

By themselves, however, these information technologies do not address the knowledge crisis. They provide important tools for the professional clinician, but they do not help directly in the retrieval and application of the right knowledge at the right time with the right result. For this we are now beginning to see new knowledge management technologies becoming available, and clear evidence that they can have a positive effect on patient outcomes. Some of these technologies are designed to help the individual healthcare professional, at the point of care, others aim to support more effective operation of clinical organisations.

At the individual level, computers can be used to make use of electronic patient records to prompt and remind clinic staff of tasks that need to be carried out [1] and to suggest the most appropriate decisions or procedures for each individual patient. A new generation of decision support systems is beginning to appear that can help the community physician with, for example, advice about the use of medications [2] and the assessment and management of genetic and other risks [3]. The evidence is now strong that point of care systems to assist healthcare professionals can have real benefit, in terms of improved clinical outcome for the patient and savings in the cost of delivery of care [4, 5].

In modern, science-based medicine, the traditional process of care - one clinician looking after one patient - is being replaced by one in which the patient is managed by a *multidisciplinary team* of health care professionals, such as oncologists and cardiologists working with general practitioners and home-care nurses. The effectiveness of such shared care depends critically on the ability to share patient-specific information and medical knowledge easily among care providers. Indeed it is widely recognized that the inability to coordinate information and services across organizations represents one of the major impediments to quality care and that we need to take a more process-oriented view of health care delivery with appropriate organizational and information infrastructures.

A clinical guideline is in effect a *knowledge model* of the preferred process of care. Such models can be combined with an organizational model of the healthcare system, and take advantage of the workflow technologies that are widely used in industry today, to provide a *careflow* infrastructure for dissemination and application of medical knowledge and support communication and coordination of the healthcare team.

In contrast with most industrial and office processes, however, clinical processes are often highly unpredictable - and safety-critical – so they must provide sufficient flexibility to permit healthcare professionals, and patients, to override routine rules and methods where that is desirable. Current tools provide some capabilities for permitting flexible use in patient care, and ensuring that the healthcare professional retains the final decision, but guaranteeing responsible, safe and ethical use remains the area of greatest challenge for knowledge management technology.

3. Knowledge management and OpenClinical

Medical informatics has long been established as the research area concerned with clinical information technology (in such areas as electronic medical records, messaging systems, decision analysis, imaging, telemedicine and the internet). Medical informatics is now being augmented with a range of new knowledge technologies, many arising from the field of artificial intelligence, which are contributing new languages and tools for modelling medical knowledge. There is now a considerable body of technical expertise and research results in the field of knowledge management, in medicine and in other fields. The main knowledge management tools that are currently being developed and applied in medicine are summarised below:

Models and formats	Software
Terminology & language models	Terminology servers
Ontology models & standards	Ontology authoring tools
Clinical task models	Enactment engines
Guideline and protocol formats	Authoring tools
Careflow models	Careflow management systems
Messaging models	Communication engines
Medical devices	Middleware

Despite the diversity and sophistication of many of these developments, and clear evidence of clinical value, take-up is still limited. Among the reasons for relatively slow adoption - by industry, by clinicians and by medical researchers - are a lack of awareness of what medical knowledge management is and what it can do, inadequate access to tools and services, and incompatibilities between them, limiting their effectiveness and creating potential for misuse.

OpenClinical's short-term aims are to help raise awareness of the range of knowledge management technologies that are available, their uses and benefits, and to promote standards to improve compatibility between products and systems. It will do this by providing a number of services including:

- Introductory articles and technical briefings on medical knowledge management methods, technologies and products.
- Demonstrations of technologies and applications which can be run on or accessed through the site
- Presentations of clinical knowledge-management projects, discussion papers etc.
- Links to sites maintained by OpenClinical partners and sponsors.
- Access to knowledge management software, which can be downloaded from the OpenClinical site or from partner sites.

These services will be made available on the OpenClinical website at www.openclinical.org (see Appendix 1 for more information). The site has been developed collaboratively by a number of distinguished researchers in the knowledge management field and with the support of several medical organisations and sponsors.

The OpenClinical team aims to provide a comprehensive and up to date source of information on technologies, methodologies and experience. The medium-term aim is to provide an informal "portal", a single point of access for comprehensive information throughout the general field of medical knowledge management.

The central role of OpenClinical is to champion the use of knowledge management technologies in routine medicine, and support developments that will promote their adoption. A longer-term objective in this respect is to stimulate discussion and the development of ways of guaranteeing *quality and safety* in this new field, and the creation and adoption of standards that will support such guarantees. After all, medicine is a safety-critical field and knowledge management users and suppliers should expect that the best current technical practices are applied. These will include standard software safety techniques that are used in fields like aerospace and nuclear engineering, and also the best available methods for capturing and updating medical knowledge for its new role at the point of care.

OpenClinical's fundamental position is that knowledge management technologies are the same as any medical technology – the primary aim is efficacy, improving patient care, but this must be implemented within a quality and safety culture like that which is actively maintained in the pharmaceutical and other safety-critical industries.

3.1. Management of OpenClinical

The OpenClinical website is being established and, initially, hosted at the Imperial Cancer Research Fund's Laboratories in London, England, as a service to the medical community [note ⁴] but it is managed by an independent scientific committee.

As part of its function OpenClinical will provide access to information about commercial products and services, and indeed it will seek sponsorship and support from commercial and other organisations in order to offset the costs of running the service. However, it has been set up with the firm objective of being a non-profit and non-commercial service to its users, and its objectives and operations will remain independent of any commercial or other organisation.

4. References

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⁴ ICRF is a medical charity and has provided seed funding for OpenClinical, including two full-time staff for up to five years and a high performance Unix server (a 4 processor Sun Enterprise 450 with 1.8Gb of main memory) for running OpenClinical services.

Appendix 1: the OpenClinical Web Site

1.1 Briefings and technical reviews

The main purpose of these briefing documents will be (a) to review the current state of the art in the specific technical area and (b) to initiate discussion of standards related issues. Authors of these articles will retain copyright.

- Knowledge based patient records
- Knowledge representation and acquisition
- Ontology modelling
- Terminology and standard medical languages
- Decision support
- Clinical communication and coordination
- Quality and validation
- Protocols and guidelines
- Clinical genomics?
- Distributed processing and workflow
- Telemedicine and home care

1.2 Other publications

- Discussion papers (unmoderated)
- Project reports (refereed)
- Standards proposals (from technical groups)

1.2 Demonstrations

- Authoring tools
- Knowledge verification and testing
- Guideline and decision support tools
- Careflow modelling and careflow management systems
- Web tools

1.3 Medical knowledge content

- Data and knowledge-bases
- Component Libraries

Appendix 2: Participating in OpenClinical

The simplest way to participate in OpenClinical is to visit the web site and make use of its services. As described above these will include open technical briefings and discussion papers, access to demonstrations of knowledge management technologies and applications, and provision of software tools for downloading where the developers have given permission for this to be done.

We also expect to develop additional services, such as support for discussion and technical interest groups, publication of refereed papers on topics in medical knowledge management and so forth. No-one will be expected to join OpenClinical to take advantage of these services, and no information will be recorded about who has visited the site to access this information.

In addition anyone can become a *member* of OpenClinical, by which is meant that they can contribute to the creation of material for dissemination via the service and are entitled to use any information published by other members. An area of particular interest will be in the consensus development of technical standards by members in any area of medical knowledge management (see examples in the body of the paper). Services to *members* will include

- Automatic circulation of OpenClinical News, a brief regular notice of new information that has been published on the site.
- Creation of technical interest groups and support for discussing and proposing standards in these technical areas
- Publishing *open-source knowledge* (e.g. medical term sets, ontologies) that comply with the standards.
- Compiling and disseminating knowledge components that can be downloaded for use by OpenClinical members.

To be a member of OpenClinical the only requirement is that the individual or organisation registers with the service.

Friends of OpenClinical: for a modest payment (TBA) friends of OpenClinical can automatically subscribe to *OpenClinical Intelligence*, a series of technical briefing papers which will be commissioned exclusively for OpenClinical. *Friends* will also be entitled to have their name or logo listed on the List of Friends should they wish.

Sponsors of OpenClinical. Corporate sponsorships will be sought as a means of offsetting the costs of running the OpenClinical service. Sponsors will be automatically members and friends of OC, but the principal benefit will be that their corporate identity will be displayed prominently on the site.

Partners of OpenClinical. The OpenClinical management team is discussing various forms of partnership. Partnerships are intended primarily to provide a mechanism for collaborating with independent non-profit organisations to achieve the common aims of the partners.