A.M. Grant

Centre for Research and Evaluation in Diagnostics (CRED)
Centre hospitalier universitaire de Sherbrooke - Hôpital Fleurimont
Sherbrooke, Québec, Canada

Research and Education

Research and Education at the Centre for Research and Evaluation in Diagnostics (CRED), University of Sherbrooke

Introduction

The Centre for Research and Evaluation in Diagnostics came into being in 1994 as a response to the increasing awareness of the requirement for specific technology evaluation studies to improve how technologies, in this case diagnostic tests, could find their place in clinical practice in the most effective and efficient manner possible.

The aim has been from the outset to consider both practice change and innovation within the same philosophical framework. It was also clear at the beginning that there is a need for interaction of several organisations in the process of technology transfer from conceptualisation through to clinical use, including academic research, industry, government regulators, standards organisations, professional users (e.g. laboratory professionals, physicians, administrators) and the patient.

An operational consideration of this process from concept to clinical use, given in figure (1), opens up many challenges for the medical informatics components of our activities. Firstly the rapid focus of development in the biotechnology sector in bioinformatics has meant that we must consider head-on the impact of bioinformatics with medical informatics and indeed telemedicine and other similar variants. This subject has recently warranted much correspondence in the medical informatics literature including an editorial in the Journal of the American Medical Informatics Association entitled 'Bioinformatics and Clinical Informatics: the Imperative to Collaborate' [1].

Secondly, two parts of the process are increasingly recognised as informatics 'entities' namely the informatics associated with clinical trials [2] and the informatics associated with practice change most notably the role of clinical guidelines and the connection to evidence-based medicine [3]. The former corresponds to the pre-clinical (or pre-market) component of figure (1) and the latter to the clinical use (or post-market surveillance) component which is in fact a continuum of discovery and feedback as indicated in this figure. The challenge here is to understand and articulate the conceptual overlap between on the one hand a well-managed on-line clinical trial based on a pre-formulated protocol, and on the other hand the application in clinical practice of a given procedure, suggested process or technology.

The third area of challenge is in education both from the perspective of creating new skills as well as providing continuous learning. We have graduate students with biotechnological, informatics and business administration background creating an interesting applied multi-disciplinary mix. They receive an education situated within the University of Sherbrooke Clinical Sciences programme which gives a basic formation in epidemiology, patient studies and statistics and with additional collaboration with other programmes of the faculties of Administration or Information Science according to individual need. The graduates, which to date are primarily at the masters level, have a combined knowledge of the key elements of the process of technology transfer and also an in-depth view of the informatics components that support this process. Depending on personal interest this programme provides an increasingly satisfactory link between a basic sciences course and a career in industry. A diploma course in Biomedical Informatics and Evaluation Research is currently being developed.

Figure (1) is also a basis for considering the process of continuous learning and knowledge management. The exchange of ideas not only between developers or practitioners at a given stage of the concept to clinical practice process needs also to be considered for feed-forward and feedback consequence. Much of current redundancy and loss of energy takes place as a

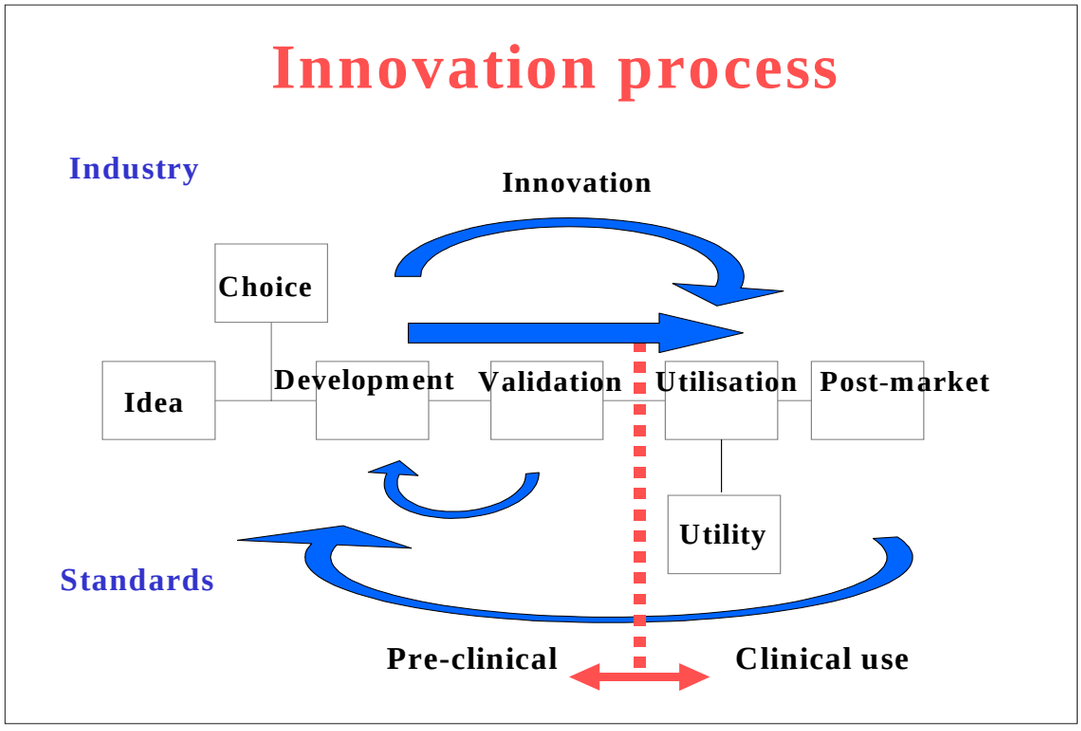

Fig. 1. Process of technology development and transfer from concept to clinical application

technology moves from experimental into actual use. This is seen for example in the length of time to devise, plan, execute and conclude a multi-site clinical trial, the low recruitment rates versus available clinical trials, or the length of time for the satisfactory uptake of a new technology or therapy into clinical practice. One high level reason for this is the need for the different stake-holders to inter-sect, namely industry, government, academia and practitioners. By providing representatives to the Canadian In Vitro Diagnostics and also Health Informatics standards committees we have gained some insight into elements of this process. We are undertaking research into on-line methodologies for linking the different stake-holders with respect to optimising both the pre-marketing and post-marketing stages of technology transfer and technology assessment.

The operational improvement of each of the steps of the practice change/innovation process seems to provide an interesting paradigm for innovations in biomedical informatics as it asks the question how can information be effectively transferred along the process of technology development and application as required by the different stake-holders, requiring at each step evidence of the quality of the information. It is also increasingly demanding a focus on methodologies for data abstraction and analysis and modelling and simulation, common methodologies being probably relevant both at the bio- and medical- ends of the biomedical informatics spectrum.

The Informatics of Practice Change

The Autocontrol project was started in 1995 its aim being to provide to physicians a complete information of practice as a basis not only for quality control but also as the mechanism for practice improvement. The starting point was a recognition based on an extensive questionnaire survey of the willingness of physicians not to be involved in wasting money if their professional judgement should not be threatened. It was also evident that there exists minimum mechanisms of feed-back that enable continuous evaluation of practice (4, 5). These studies have received main financial support from the HEALNet (Health Evidence Application and Linkage Network) research network. HEALNet is a member of the Canadian Networks of Centres Excellence program.

The model of Autocontrol has evolved and its current form is resumed in figure (2). The four components reflect different aspects of information processing and two of these, information and critique are the main subjects of current research. The model also forms a basis of the TEAM (Total

Evaluation and Acceptance Methodology) information system evaluation methodology (6). There are currently three application areas.

Clinical Unit

The data of the university hospital electronic patient record is transferred to a relational database enabling after quality validation different analytical procedures using tools of the OLAP – on line analytical processing type for sub-population analysis and also graphical and analytical tools for assessing trends. The first step is to undertake an agreement with the head of the clinical unit to be able to work with the entire clinical team preferably a member of the team for example a resident to be a member of the research team. Analyses of different aspects of test use have been undertaken interfacing with a series of meetings with the clinical team identifying causes and solutions for improving test use. We have experimented with using on-line access to information in this setting however the face to face interaction at the time of the regular scientific meeting of the clinical team remains the most productive. This has lead to changes in the hospital information system which oblige additional justification at the time of test requesting and a tracking system of practice change required by the medical council executive.

Continuity of care

It became of interest to extend the work within a clinical unit to understanding how information is exchanged between clinical units and at the same time to understand the use of information in managerial decision making in the context of the complex process of continuous care. Whereas this was a logical step for developing the practice change informatics methodologies it was also a logical step for understanding technology transfer which must make the argument of how a technology can influence the continuum of care and understand the relationship between for example in investing in a diagnostic technology and the outcome this may have in improving the allocation of resources for patient care.

The parallel aim is to be useful with the progressive implementation of networking between regional institutions and the implementation of the regional patient record. Whereas the paradigm is multidisciplinary care the design has been to study the critiquing of information within focus groups formed of representatives of a

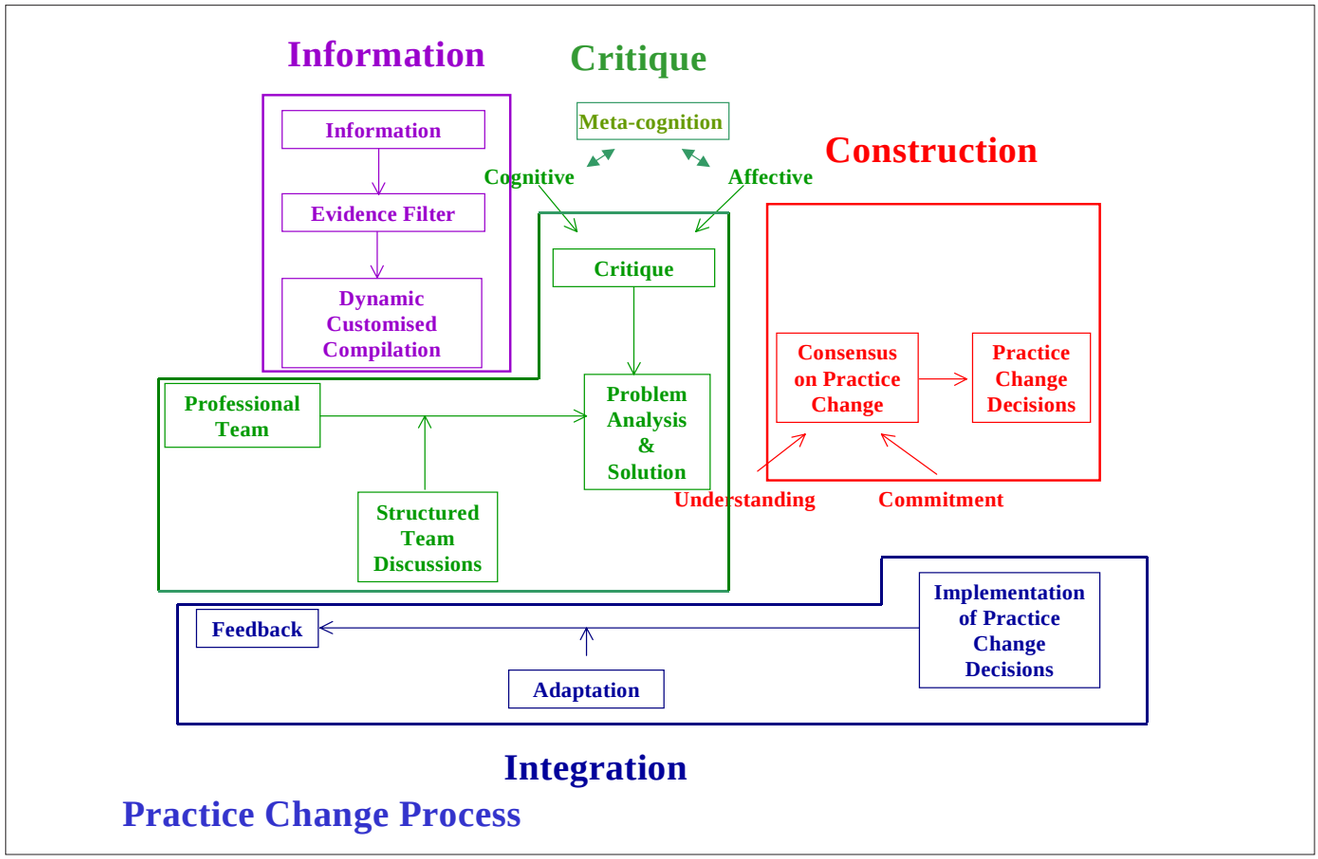

Fig. 2. Model of Autocontrol

given professional category namely physicians, nurses, community support representatives, services and administrators derived from the regional speciality and primary care organisations. This approach may be invaluable to understand ways of improving the cognitive acceptance processes associated with practice change. In a subsequent step a multidisciplinary model will be formulated. A primary salutary finding already evident is that the policy of communication of information whether or not by electronic means should be more in evidence as a framework to associate the progressive regional informatisation as it receives funding over the next years.

Intra-professional communication

The formulation of clinical guidelines tends to be a prerogative of professional associations who participate in ensuring continuing high professional standards of their members. It is well recognised that there can be a resistance to guideline acceptance at the local level (2); furthermore there can be redundancy as professionals at each institution provide parallel clinical guidelines and protocols for local use. The aim therefore is to put professionals in contact from different institutions in the province of Quebec so that information about guidelines and protocols can be shared and also critiqued to collectively understand resistant factors and to provide a process to enable common protocols across the institutions. A web-site for Quebec laboratory professionals in medical biochemistry has been developed for the systematic critiquing of guideline components and the identification of different classes of factor that inhibit or promote guideline introduction and compliance. Although we have experienced a lag time for technology introduction we have found a progressive acceptance of the use of on-line technology for this purpose and an enhanced communication and critique about the factors that cause probable unnecessary variation in practice. A notable finding is that sharing information about 'local' factors is very useful as part of the practice change process.

The Informatics of Innovation

Multi-site collaborative biomedical research

The CRED has since 1994 assumed direction of the informatics axis of the Quebec Cardiology Network. It has three main roles, the enhancement of web-based services, to provide leadership in the development of informatics architectures that support multi-site research, and the organisation of an annual conference in informatics applied to biomedical research (7).

The cardiology network is one of 15 that have been established since 1994 by the Quebec medical funding organisation the FRSQ - Fonds de recherche en santé du Québec. The aims of these networks are to promote cooperation between scientific and clinical researchers and also between different research groups and institutions within major health themes. Funding promotes both infrastructure and opportunities that stimulate collaborative research. The networks which until recently were unique for the province of Quebec, are now being emulated at a federal level with the establishment of the Canadian Institutes of Health Research.

Many trends such as the provision of high speed networking and the development of bioinformatics as well as clinical informatics need to be taken into consideration in planning the informatics environment needs for such networks. Work in non-medical domains concerning the knowledge environment and organisational learning cannot be neglected.

With the sequencing of the human genome, the next ten years or longer will be concerned with identifying gene constellations linked to different disease presentations and different treatment responses. In the studies of genotype and gene expression , the importance of different disease related genotypes will require evaluation in human disease and control populations. Furthermore, as promising gene associations become described then the medical profession needs to understand these findings so that persons and families in higher risk groups can be counselled.

This situation emphasises the logical relationship of the steps from laboratory based research through to patient counselling. How the information is diffused affects the public reaction which in turn influences funding priorities and community research support. There is also an ethical dimension to knowledge sharing. The accuracy of this information depends on all the steps in the information chain and the process whereby data become knowledge.

The PIERCE program

The PIERCE program (Prototypage informatique en recherche clinique/ Prototyping informatics and evaluation for research in the clinical environment) promotes that informatics research and clinical research should be undertaken so that the objectives of one support the other, each being of equal importance. The aim is not only to support on-line clinical trials but also to support sharing information about disease diagnosis and management and hence the electronic medical record is at the heart of this development. Three principle areas are distinguished namely integration in practice, confidentiality and security of data sharing, and tools for management and analysis (8,9).

Clinical research units in lipid disorders from major sites in Quebec have participated in a preliminary

analysis to enable consensual data collection as well as a study of information flow in the different clinical research sites. Prototyping teams of research nurse and informatics personnel were formed at each site to develop and validate the content of the medical record and to train the participating health care professionals. The software Health One provided by Health Data Management Partners of Brussels which is based on the draft European standard ENV 13606 has been evaluated as part of this program (10). Denominalised encrypted data is distributed by internet protected by virtual private network technology. Different clinical trial management tools are in progressive implementation.

Education and Knowledge Management

Defining a curriculum

As part of preparing for developing a diploma in Biomedical Informatics and Evaluation Research we have investigated the current teaching of health and medical informatics in Canada (11) and are participating in an on-going exercise to define a curriculum in health informatics for Canadian use (12). We have also contributed to the recently published recommendations of the International Medical Informatics Association on education in health and medical informatics (13) and to a discussion of the curriculum for medical informatics and medical education in the 21st century (14).

Developing a knowledge management environment for technology transfer

In a cooperation with industry we are investigating the exploitation of a web-site to provide electronic communication between a company and its clients in such a way that the different major aspects, technology, organisational and health care can be addressed during the life-cycle of a given technology. The aim is to enable both a better presentation of the capability of the product to the customer and also to better implicate the customer in the refinement of the technology as well as speed up the process of trouble shooting.

The Future of Research in Health Informatics in Canada

There is much concern that the needs for health informatics research will be under-valued in the current Canadian reforms in the funding of health related research. This discussion is echoed in some of the observations noted above concerning the need for clarity in the relationship between bioinformatics and health informatics as well as the need to show that information system development and exploitation in the health system needs to be supported by a component of research and education. HEALNet has created an initiative to help the definition of the future needs for health informatics research (13). It would seem that similar discussions are underway in other countries. Hopefully this will lead to an international strengthening of the discipline of health informatics.

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Address of the author:
Andrew M. Grant MB ChB MRCP FRCPC DPhil
Professor and Executive Director
Centre for Research and Evaluation in Diagnostics (CRED),
Centre hospitalier universitaire de Sherbrooke –
Hôpital Fleurimont,
3001 12ième ave nord
Sherbrooke, Québec, Canada J1H 5N4.
Tel: +1 819 346 1110 x 14158;
Fax: +1 819 820 6853
http://www.crc.cuse.usherb.ca/cred