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Computers in general practice: Clinical governance, data quality and adoption

2011 Travelling Fellowship report

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Computers are now a significant part of the health landscape. Across the globe computers are increasingly a part of the interactions in both primary care and secondary care. The distribution of computers however is variable across each jurisdiction, with differing rates across primary and secondary care (1). Computers are now involved in all parts of the clinical interaction. At the consultation level, significant clinician time is now spent interacting with the computer - 16% in Australian general practice (2) and 25% in emergency departments (3). These figures represent a significant time impost on clinicians, but for what benefit.

In Australian general practice the most common activity is prescribing (4). Computing started out as providing 'electronic prescription pads' for electronic prescribing (albeit to still produce a paper artifact) is the most common activity, closely followed by recalls, referral letter generation, and progress notes. The pace of change is such that as these are 2007 figures, the current state will be much higher.

The impact on the clinical interaction is now quite profound. The presence of a computer changes the way in which doctors interact with patients (5), and there is a growing body of literature that describes the interaction as a triadic relationship (6-8). The computer as an actor in the consultation has many consequences. Information is flowing into the consultation in ways it has not in the past, allowing instant reference to national and local sources, from government and others (9). Information is a source of power and authority, and the computers ability to bring information into the interaction in new ways is changing the power balance.

At the same time, the presence of the information in the system itself is being recognised as an important resource, for a variety of uses: research, clinical governance, population health (10). Using data from computer systems for these purposes requires the data to be of high quality, and in a form that can be manipulated by computers.

The final element of this equation is to understand the issues behind the adoption of computers into clinical workspaces, the better to inform the future developments of computerisation, particularly when developing policy in this area. Adoption of computers has been quite variable across the globe. In developed countries for instance, some countries (Denmark, Belgium, Israel) have high penetration across the sector. Others (US, Canada) have high uptake in hospitals but not primary care or in primary care but not hospitals (Australia, UK) (1). Given that the most benefits of eHealth are to be found when the entire system is computerised, understanding the process of adoption is crucial (11).

The fellowship

This travelling fellowship allowed for me to expand the international exposure and collaboration involved in work at the local level, and international. Locally, this involves two main activities. Firstly, as Director of Research at the Inner Eastern Melbourne Medicare Local (IEMML) I have been involved in the setting up over 5 years of a data collection and management program, involving the practice of the division. Using the PDSA cycle, over the time we have been taking practice through now multiple iterative cycles of data collection, analysis and feedback. Whilst primarily for improved care within the practice, the outcomes from IEMML perspective have been firstly improved data quality, and secondly the practices have allowed IEMML to collect and pool the data for knowledge creation purposes. We now have over a hundred practices and data on over half a million patients.

The second element of my work is as the principal clinical lead for the national program, the Personally Controlled Electronic Health Record. This is a policy/implementation position, where I am involved in the design and development of the program, aimed at making an electronic record available to every Australian.

The fellowship involved a visit to Israel, where I presented my PhD work to a national audience (including the deputy director of the health ministry for Israel), and exposure to their simulation work on computers in the consultation. In Belgium I was exposed to the national program they are developing. In the UK I was a visiting research fellow at the University of Surrey, with Professor Simon de Lusignan. It was there that the principle work of clinical governance and data quality was

done. Finally I attended the Medical Informatics Europe international conference in Oslo, participating in a workshop with Professor de Lusignan on study protocols.

Data governance and provenance

THE MANY FACES OF DATA

Crucial to improving the quality is understanding the interaction of data (a discrete element) and the information expressed in the consultation (often called narrative) The flow of information has now been commoditised between the patient, the doctor and the computer, and it is the doctor that is primarily responsible for translating the patients expressions into a machine readable code. The following example shows the progression from patient to code:

Patient speech: ‘..and I have these feelings, see, these feelings all the time, like, like I just want to not be here’.

‘So you want to be dead’

‘no, no, its not like that. its just a darkness. I’d never kill myself, not with the kids. But I just, I just can’t lift the fog, it seems to just overwhelm me’

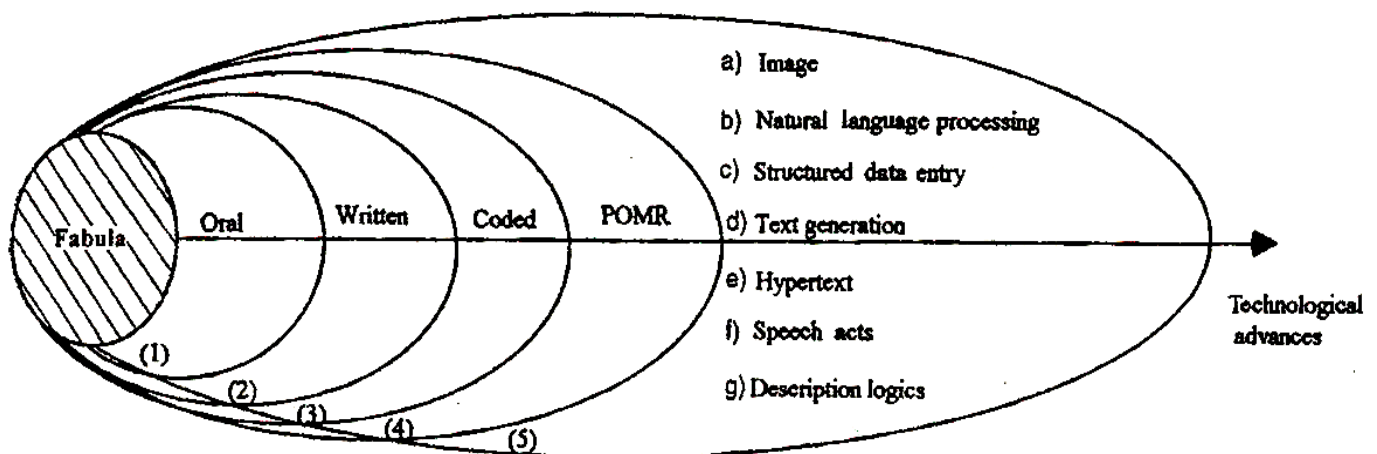
Narrative record: feels constantly down, not suicidal

Structured diagnosis: Depression

Code: 310496002, the SNOMED-CT code for Moderate Depression.

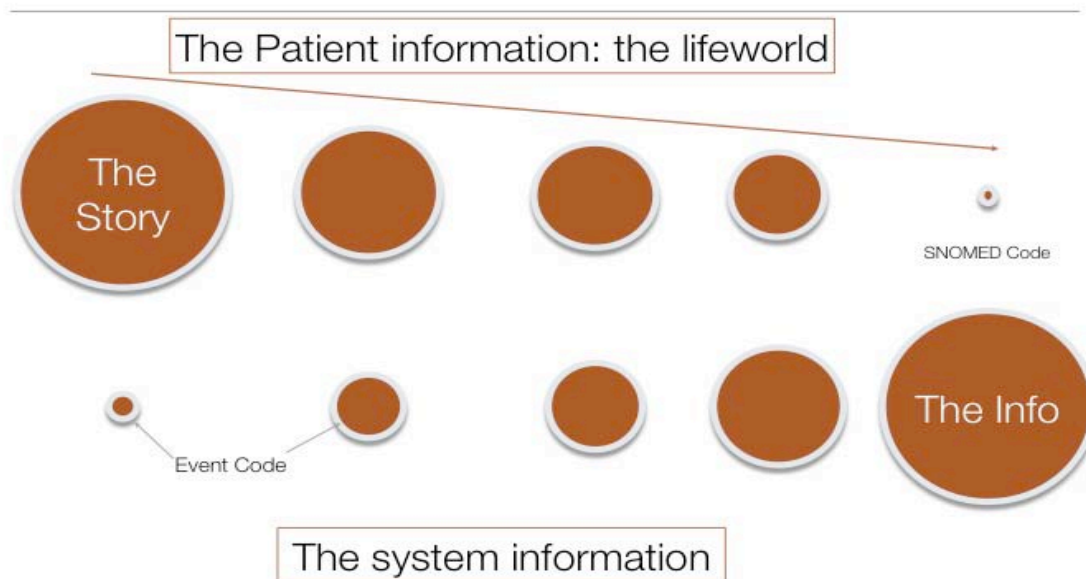
According to Purves (7), we have the concept of the ever reducing amount of information present in the consultation. From the ‘fabula’ we have a progressive diminution of ‘information’. a reduction from the fabula through what is verbally (and otherwise, let us not forget non-verbal communication) in the consultation, though that which is recorded in the medical record (and in what form) down to the individual, machine readable code.

The Purves Model



However, what is the purpose of the code - but to give meaning to the information, and indeed to in some way remain faithful to the fabula, to the patient, as a representative of a population, who came seeking care and information. The dichotomy here is that the point of least information from a lifeworld point of view, the code, gives the most amount of information from a systems point of view. Habermas (12, 13) would describe this as the tension between the lifeworld, the human day to day action, and the System.

The model



6

The dichotomy therefore arises because the system requires a singular element, the code, to make most benefit. In the above diagram, the top line represents the Purves model, where in fact narrative information is lost at each point, from patient speech to finally the code. From a system perspective however, the loss of information goes in the reverse direction. The coded diagnosis is of most use, and the patient narrative is of least use.

The next section discusses the significance of the clinical software, the computational engine that sits in the middle of the interaction, mediating the lifeworld/system interface.

CLINICAL SOFTWARE IN CLINICAL GOVERNANCE

Introduction

Computerised medical records (CMR) provide a viable mechanism for implementing clinical governance (14). Computers are involved in all aspects of the clinical interaction - from consulting room to system-level use of large systems that might control entitlement to treatment, screening, recall, and on-line booking of services. Typically around 20% of the consultation is spent interacting with the computer (15).

It is important to understand the context within which records are created (16). Simply having a CMR does not guarantee the creation of a complete record usable for clinical governance purposes; the interaction with the computer in the consultation is complex and evolving (17, 18). Using a CMR is not a neutral act (18). There are barriers to using the computer and coding systems (19) and interfacing with them constrains what is recorded (20, 21). However, the CMR does enable decision support programs to run that can reduce errors, (22) and the CMR can improve quality through audit/feedback cycles (23). There are issues about the governance of these records and the repositories derived from these data; and formal governance structures are often lacking(24).

Box 1: Scope and role of an information system to support clinical governance

- > Definition: A process for maintenance, improvement, monitoring and accountability for driving quality of care.
- > Computerised information systems can use routine data, and specially captured additional data (e.g. patient questionnaires) to audit quality.
- > Clinical governance makes demands of managers, clinicians and information systems:
- > Chief executives: Responsible and accountable for clinical standards within their organisation; including mechanism for measuring them.
- > Doctors: Challenges: Loss of “clinical freedom,” Clinicians are now expected to deliver best practice as defined in evidence-based guidelines; and participate in clinical audit.
- > Patients’ views of the service and their “experience” of healthcare are an important measure of quality.

Methods

BACKGROUND

The CMR had the allure of being an unrealised tool to support clinical governance; measuring quality, conducting clinical audit, and for ensuring safety. We therefore undertook an analysis of CMR systems used in Australia exploring the extent to which the CMR supported clinical governance, including to what extent this reflects contextual factors that may be unique to the Australian context.

REALIST EVALUATION

We carried out a review from a realist perspective. A realist perspective is useful in assessing complex interventions as it aims to develop explanatory analyses of why and how these interventions may work in particular settings and contexts. The realists mantra is: “Context (C)” plus causal link with an appropriate “Mechanism (M)” results in an “Outcome (O)” – (C+M=O).” Part of the realist perspective is that effects are reported according to the three Ws: “What Works, for Whom in What circumstances.”

In realist evaluations there can sometimes be difficulty in distinguishing context and mechanism. In this analysis we see the CMR system, used at the point of care, as the mechanism (M) and the health system – in this case Australian primary care - as the context (C) within which this is being deployed. Our outcome measure (O) was the capability to produce clinical governance outputs - evidenced by the ability to monitor the quality of care against given criteria and standards. This combination describes how in the Australian context (C), the CMR might contribute as a mechanism (M) to deliver the outcome measure (O), clinical governance (C+M=O) (Figure 1).

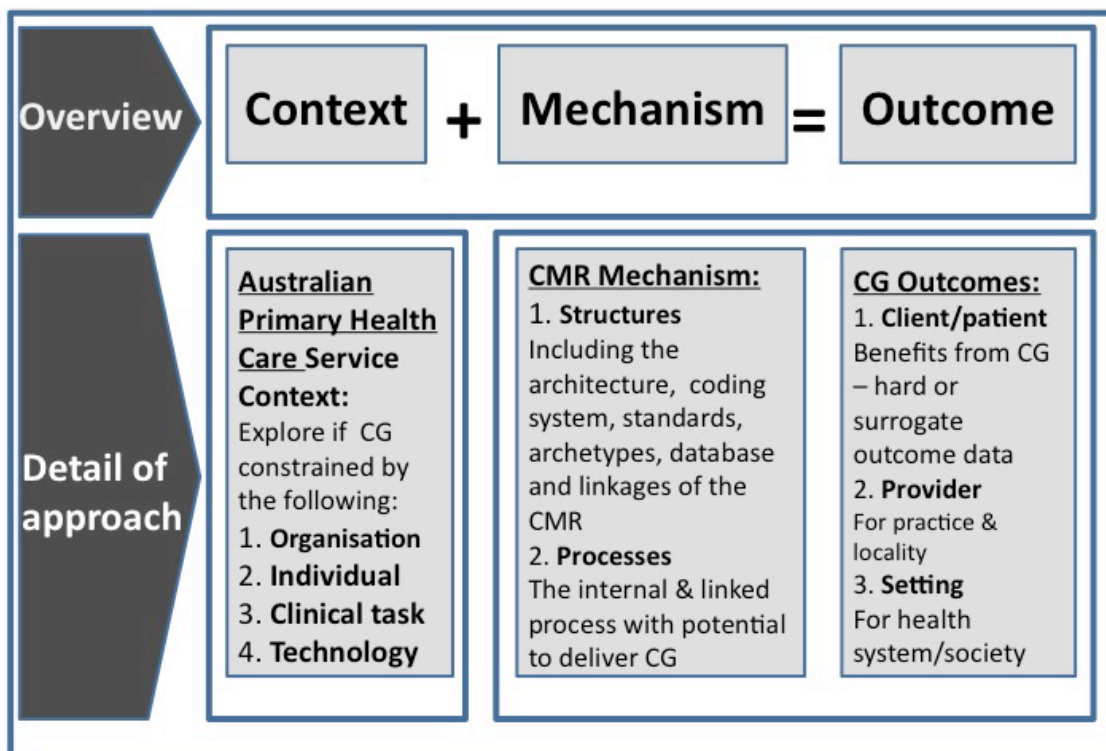


Figure 1: Overview model of the method to appraise whether in the context of Australian primary care the CMR provided a mechanism for driving clinical governance (CG) Context.

We mapped the primary care context using Lusignan's 4 level classification (18):

- > **Organisation:** Practice, Locality, Region, and National drivers/priorities
- > **Individual clinician:** Their knowledge of, skill in operation and attitudes towards CMR use for governance.
- > **Clinical task:** Usually the one-to-one clinical consultation that may well involve the CMR system, creating a triadic clinical relationship.
- > **Technology:** Features of the technology, which are unique to the particular context.

MECHANISM

We used the Donabedian (25) classification of structure and process elements to describe three types of mechanism by which CMRs may enable the delivery of improved clinical governance: structures, processes of care and review, and processes that impact on outcome. "Structures" included: the physical structures and design features (including conventions for room layout, record architecture and linkages). Processes of care and review included software capabilities such as the issuing of prescriptions. Processes that may impact upon on patient outcomes include elements such as the ability of the CMR system to detect and block all serious drug interactions.) We further divided the Donabedian categories: each of these sections section had further subheadings to produce the detailed tool across the categories, (see table 1). The CMR structure was divided using the OpenEHR model of the four separate components of a CMR system: interface, clinical archetypes, coding system and database <www.openehr.org>.

Outcome

We used Holzemer's classification to look at outcomes (26). We looked at outcomes for the client (or patient), for the healthcare provider (which we took at the locality level) and interpreted setting as impact at the population or health system level.

Assessment tool

We created a new assessment tool (Appendix 1), a bi-axial tool that used our adaptation of Donabedian's taxonomy (Table 1) to look at mechanism, and de Lusignan's to explore context. The cells of the grid are populated with outcomes related to clinical governance for patients/clients, the provider, and the broader population level. In this study the software settings were considered to be process elements. For example, a key enabler of clinical governance - such as the presence of a unique patient identifier within the system, essential for data aggregation – would be listed as a key component of the mechanism provided by the CMR.

Table 1: Donabedian based assessment of CMR as a mechanism to support clinical governance

Structures	
System Architecture (OpenEPR model)	Interface, Clinical archetypes Database type Coding systems
Information & Decision Support	Drug databases, interactions, clinical calculators
System Linkages	Patient registrations, laboratory links, Email
Search Function	Across populations, practices, Export functions
Patient access/Control	Access to information through web portals, etc. Attribution
Processes – care and review	
Quality Markers	Data quality, information quality, system accreditation
Billing/Pay for Performance	Routine data use Parallel billing system
Supports population level data outputs	Small area Sentinel networks Epidemiology,
Outcomes (Demonstrated within the system)	
	Critical incidents / Near misses / Confidential reporting Surrogate markers of quality and outcomes/Clinical audit True outcome measures

ASSESSING THE TOP SIX BRANDS AND ONE EXAMPLE OF A CMR SYSTEM WITH A LOW USER BASE

The top six CMR systems measured in terms of user base (27), were evaluated using this tool. We also examined a CMR system with a small installation base (and therefore less organizational resources within the company) for comparison. For each system we used either software in demonstration mode, or installed software in training mode. The testing was done with simulated patient data, and independently of the software providers, to explore how the system might retain clinical data and enable clinical governance activities.

Box 2: Software packages reviewed

- > Medical Director 2 (Health Communication Network, Sydney, NSW)
- > Best Practice (Best Practice Software, Bundaberg, Queensland)
- > Genie (Genie solutions, Brisbane, Queensland)
- > Medtech32 (Medtech Global, Melbourne, Victoria)

Maturity framework

We developed a CMR maturity model, again using the Donabedian classification into structures (including IT architecture issues), process and outcomes, using existing consensus about CMR maturity (28-30). At the structural level we looked at the number of vendors and their market share, use of standards and interoperability, and the use of unique patients identifiers and clinical coding (e.g. single national coding system). The processes were graded from passive reporting through to active decision support – again looking at individual patient, practice or locality and population levels. Outcomes data were expressed in terms of feedback about quality (Figure 2).

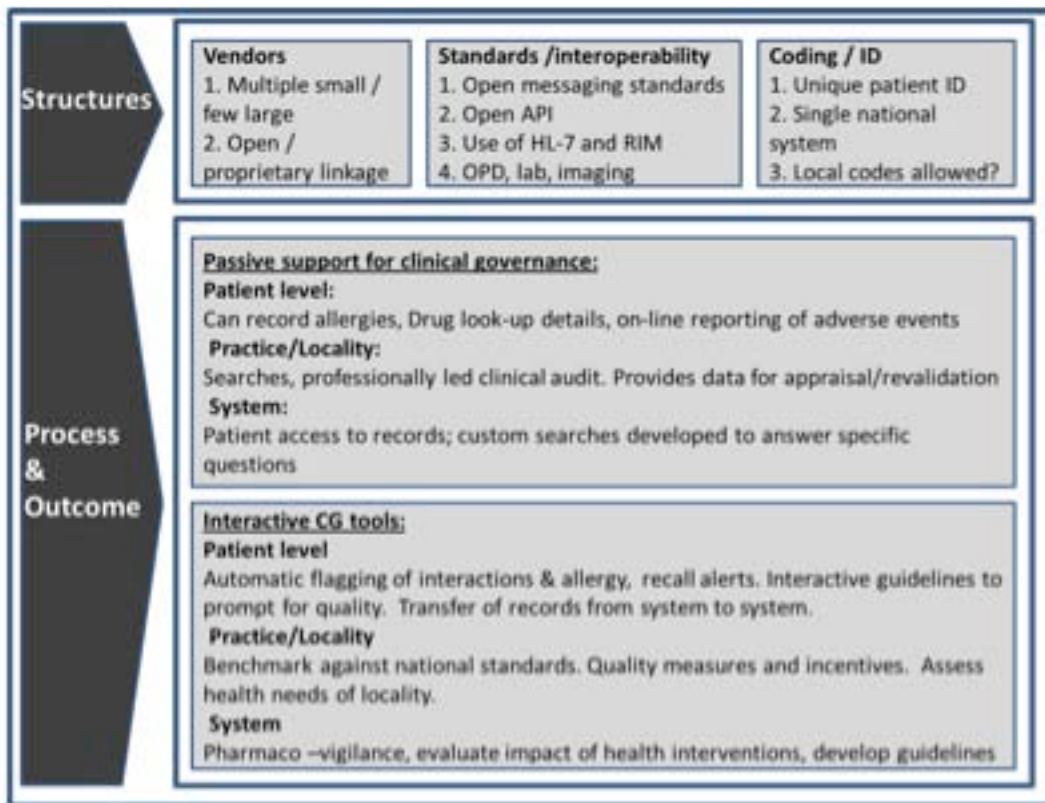


Figure 2: Schema of the maturity framework

The process and potential of the CMR to influence clinical governance outcomes were graded into a four-level model (Table 2). This grading is multi-dimensional:

- (1) Does the CMR play a passive or dependent role, compared to an active or autonomous role in delivering clinical governance;
- (2) The level of complexity of the transaction and whether or not it is adaptive;
- (3) The degree of integration with other information systems;
- (4) The physical integration and linkage processes underpinning it.

Table 2:CMR and CG maturity model

Level 1	Level 2	Level 3	Level 4
Passive process > Interactive > Autonomous			
Simple		Complex	Adaptive systems
External Adverse Event Reporting (no use of system)	Reporting involving information from CMR	Reporting using the CMR as vehicle	Interactive reporting where CMR both sends information and receives information, informing user of risks
Simple Prescribing	Prescribing with limited functions (interaction checking)	“Intelligent” prescribing where CMR uses local information such as guidelines to inform prescribing decisions	‘Autonomous’ prescribing where system integrates internal and external information to determine optimal management
Simple Audit Feedback loops	Audit data compared with external data to assess performance	Audit data pooled and used to develop local benchmarks as well as population health activities	Real-time data aggregation and assessment to allow ‘just in time’ monitoring of population, during pandemics, for example
Largely External to CMR	Integrated in CMR	CMR linked to other information sources	Integrated into health system
	Distributed database		Interoperable data
Isolated Integration	Linkage		

Results

CONTEXT

Organisational

In Australia primary care is delivered via general practice through around 7000 discrete practices. Patients are free to visit any GP of their choice and GPs act as gatekeepers to secondary care. Funding is largely fee-for-service underpinned by a national insurance scheme, but there are many accessory payments, (31) and other programs (32). Standards for clinical governance have been introduced by the Royal Australian College of General Practitioners (33).

Practices in Australia have a variety of ownership structures including corporate owners, partners, associates and sessional GPs. Some CMR's enabled varying degrees of control according to status within the practice – owner, employee, etc. Programs also allowed for different role-based access for nurses and receptionists.

The individual clinician

GPs in Australia are trained in the Australian General Practice Training Program (www.agpt.com.au). The curriculum for training includes a specific section on E-Health focussed on the practical use of computers, but not their applications for CG.

98% of GPs have a computer on their desk and use them for clinical purposes. Most GPs use their CMR for recall, maintenance of immunization registers, monitoring of population health, making clinical notes and/or recording diagnoses using a clinical coding system (4). There are some 22+ clinical packages on the market. Over 40% of GPs are involved in some sort of audit/quality assurance cycle associated with using their computer data, usually mediated by the local Division of General Practice (9). These activities require good data and appropriate extraction techniques.

Technology

Although doctors use many sources of information in the consultation (34), it is the clinical packages that can have the largest impact on the clinical outcomes. In general practice, the government has encouraged good data recording through its Practice Incentive Program. Practices have received a payment for recording of allergies and the creation of summary data in their CMR's

We identified four technological issues that compromise clinical governance activities:

- > Different (and local) coding systems make national and international comparison of quality more challenging;
- > The absence of standards meant CMR vendors might develop and implement their own messaging 'standard' for use between variants of their program including use of varying flavours of Health level-7 (HL7), with much less scope for quality control and the risk of inbuilt errors.
- > Patient access to the record was absent. Such facilities are not part of the Australian landscape yet.
- > Backup facilities were not inbuilt functions of the software, but were integrated into general system backups according to accepted guidelines.

Clinical task

The assessment tool divided each of the identified activities according to the actor. The individual clinician had little influence on the software processes. In comparison with paper

records, we felt the CMR disempowered the clinicians – in effect ceding many areas of control to the organisation or the technology. Customisation options were minimal. Some programs did not allow individual doctors to change their passwords without going through an administrator. Access controls for all staff were either set by the program or customisable by a designated administrator.

A significant amount of data required to perform key clinical tasks is now provided by third parties, who have to be trusted to have proper governance systems. The responsibility, governance and overall control of these sits outside the CMR. For example, drug information was derived from either government sources or from the industry. Until 2009, the most popular general practice software incorporated screen drug advertising. An audit of these advertisements found that 95% were non-compliant with the Medicines Australia Code of Conduct, though there was a little evidence that this impacted upon prescribing practice (27). Most programs sourced travel medicine advice from a variety of sources. Immunisation schedule data was the one area that used a common, validated source (the federal government).

There are significant gaps and variability between Australian CMR systems in their drug interaction checking, though these issues are international (35). Whilst there are standards about CMR functionality they largely fail to include how applications should perform in clinical environments especially as the CMR becomes more 'active' in the patient space (36).

Some areas were easy to ascribe to an actor, but others were quite complex. Drug Interactions, for instance, required taking an externally provided database, integrating it into the program, and then allowing GPs to potentially customise the level of alert setting, and then integrate all of that into the consultation. Others such as practice audit required a reliable software process that was then dependent on a practice system to make best use of the information.

MECHANISM – THE CMR

Mechanism structures

All systems generated a unique identifier for each patient, and all recorded the Medicare number (a non-unique number used for the federal insurance scheme). All CMR systems utilized a graphical user interface (GUI) and all had standard clinical archetypes such as history, examination, past history, social history. All were able to provide a summary view although differences in those views were apparent (37). All were able to code diagnosis and problem list data, although three different coding systems were used: International Classification of Primary Care (ICPC), International Classification of Disease version 10 (ICD-10) and Doctor Command Language (DOCLE). None used the Systematised Nomenclature of Medicine – Clinical Terms (SNOMED-CT), the official Australian standard and none required data to be entered in a coded fashion. All the CMR systems allowed attribution of data according to login, or according to source. Some incoming data (such as specialist letters) required manual attribution, whilst for data such as pathology the attribution was automatic.

Every CMR system was able to accept pathology and radiology as atomized data (either HL7 or Pathology Interchange Format). All programs allowed linking of requests with received reports. Four packages allowed both generation of electronic documents and receipt. All used proprietary systems to do this, with little ability to work cross platform.

The CMR systems (in keeping with the genesis of software systems as electronic prescribing packages) had comprehensive drug databases. Most used the database from MIMS Australia, otherwise using information from a variety of sources. Data regarding Australia's Pharmaceutical Benefits Scheme (PBS), which detailed government subsidies for most drugs, was sourced from the PBS itself. All had ability to generate drug interactions,

although users were able to set the level of drug interaction alerts and in several systems turn them off altogether. Use and availability of drug calculators (weight/dose calculators or warfarin calculators) was extremely variable. All packages had a variety of other external information sources available from within the system.

All CMR systems had immunisation information, many had travel information, and one had an extensive library of text based health information resources within the program.

All programs have search functions built into the system. Most have some inbuilt searches (patients over 65, eligible patients without a cervical smear in the last five years) that relate to funding initiatives or chronic disease management. The ability to do other searches was quite variable and often required significant computer/database knowledge.

Mechanism process

Only four of the CMR systems were able to participate in regional data quality activities. These activities revolve around the Australian Primary Care Collaboratives program, The Practice Health Atlas, and division's use of the PEN Clinical Audit tool. All these activities require the use of an external tool to interrogate the program's database and generate pooled data. One other package had its own tool to perform similar functions. All programs were able to generate pay-for performance lists, according to the particular funding initiative. No system had inbuilt data quality checks (prescribing insulin without a diagnosis of diabetes for example). One system had an 'in-house' sentinel/research network ability, no other program had such a designated function.

Outcomes

Demonstrated outcomes for the patient:

Most medical records are computerised and widely used for clinical governance activities, but these approaches are fragmented (38). No package dealt effectively with the health outcomes, in the sense that they were able to adequately demonstrate improved care from within their own processes. Assessing health outcomes required an interpretive process by accessing and comparing external data. The tool asked for 'surrogate markers of quality' and 'outcome measures', neither of which was particularly well or sufficiently defined to be assessed. However, in the future these features will become of prime importance.

Outcomes at population level:

None of the CMR's was able to deal directly with these issues. However, the ability of the systems to provide data to inform activities at this level is increasingly crucial. Divisions of general practice are able to use the data for informing practice at a local level (39) but the ability for this data source to influence national activities is currently poor.

Maturity framework

At the structural level Australian CMR is well developed but there is scope for further progress against our maturity framework. There are probably too many vendors, a lack of open standards, as yet no implementation of a standard coding system.

Australian primary care is largely at level 2, with some systems only supporting level 1 and with some systems offering level 3 models. There was no evidence of level 4 systems. Some CMR systems had features which from the international perspective must be a developmental blind alley. The DOCLE coding systems is one of these, it is unlikely to ever become part of an interoperable health system.

Discussion

PRINCIPAL FINDINGS

In the Australian context, at practice and locality level the CMR works well, and is being used to facilitate clinical governance activities. Nearly all practices have systems with search functionality that enable participation in clinical audit. However, whilst practices and localities are widely engaged in clinical governance processes, this is being done in an uncritical way. In particular there is little attention given to data quality, and no obligation to code clinical conditions.

The record structures are often proprietary and there is a dearth of open architectural models; with many mission critical functions happening within a black box.

Implications of the findings

Benchmarking standards at a national or international level will be challenging if poor data quality and the disparate nature of record systems and system architecture continues. It is not possible to have lossless conversion of data held in one coding system to another. Whilst statistical techniques can be used to compensate for missing data, complete data this is never the same as having complete data. Disease registers are much more challenging to set up when there is incomplete coded data, and patients with a condition not on a disease register are not going to benefit from computerised prompts or recall. Their standard of care may also be lower. This data quality and use issue will become a major problem as more information is shared.

Comparison with the literature

The complexity of the clinician-patient-computer interaction is reflected elsewhere in the literature. Patient centred care and relationship centred care have taken hold and been shown to affect outcomes. Computerisation is changing the balance of power in the interaction.

There is no requirement to provide any specific functionality at all, no set of criteria over information use, and no standards over usability or even formally recommended testing protocols. The 'Swiss cheese' model of error (40), highlights how gaps in complex systems can result in errors. Drug interaction checking is an example of this, with interaction resources needing to be integrated into the prescribing package and then used by the clinician.

Patient access to their records has become the norm elsewhere (41) and increased openness may help ensure good governance. Australia has aspirations to provide patient access through the National "Personally Controlled Electronic Health Record" program¹.

A comparison with the UK system of CMR driven pay-for-performance suggests there may be quality gaps that computer mediated incentives might help close (42, 43).

CONCLUSION

We have developed a framework for evaluating how CMR systems support clinical governance in a particular context; and if those involved in it to achieve their goals. By applying the tool to several Australian CMRs we have highlighted the issues that exist today, but importantly shown a graded way forward, using a simple model and maturity framework.

The limitations of the process relate to the heterogeneity of the data and their sources and the continuing change over time. CMR system implementation in Australia has enabled better clinical governance. Improving systems technical capability and rigorous

¹ <http://www.nehta.gov.au/ehealth-implementation/what-is-a-pcehr>

standardisation is likely to be associated with more comprehensive assessment of quality and outcomes for patients.

Appendix 1: Redesigning descriptions of work, protocols, and clinical trials documentation for quality improvement and research

This next section describes the work done on developing a structured approach to designing and reporting studies involving data extraction from computerised systems to ensure a repeatable view of quality is developed.

INTRODUCTION

Current descriptions of work (DoW) for clinical audit and protocols for research studies have changed very little since the 1990s; and rarely systematically appraise the quality of any computerised data they include. The CONSORT (CONsolidated Standards of Reporting Trials) statement sets out clear guidance and led to the development of checklists for the reporting of trials (44). This statement has not only influenced the reporting of trial but also led to the development of more systematic schema planning and reporting of other kinds of studies. However, CONSORT contains little about computerised data quality. Audit and service evaluation conducted taking data at face value without an understanding the human element of clinical coding or research studies not taking into how and where data might be recorded in computerised medical records (CMR) risk error.

Health services have increasingly become computerised and modelling is an important aspect in system development. Generally the computerisation of primary health care has led computerisation of secondary care. Primary care data provides opportunities for clinical audit, service evaluation and ensuring that clinical governance standards are achieved, and for research (23). Modelling provides a mechanism for representing actors involved in a process; how they interact and how data flows. Reference models are generic models that apply to range of different circumstances. Whilst much of the early development of primary care computer systems was organic, developed by small groups of practitioners with technical support; newer more complex systems are developed as a result of a more formal process.

GENERIC MODELS FOR RESEARCH AND RESEARCH NETWORKS

Modelling wider influences on an investigation: We propose modelling the broader influences which might be enabler or form barriers to participation in a study using the Business Process Modelling Language (BPMN). We introduced BPML to define business requirements, as processes requirements are important as to whether individual practitioners or organisations might participate in a study. For linked research required the same individuals to be represented in both linked databases we need to model “geographical requirements”

Research study modelling: Clinical audit and research studies can be represented by high level unified modelling language (UML) diagrams. Data flow models: Data flow diagrams illustrate data flows associated with a process. We present high level data flow diagrams for research studies.

Reference models for using routine data to inform about clinical governance

Paradigm of clinical governance: Clinicians have a duty to provide a good standard of care, following models of good practice based on evidence-based principles (38)

Reference models for clinical governance – enabled by routinely collected primary care data and wider information sources:

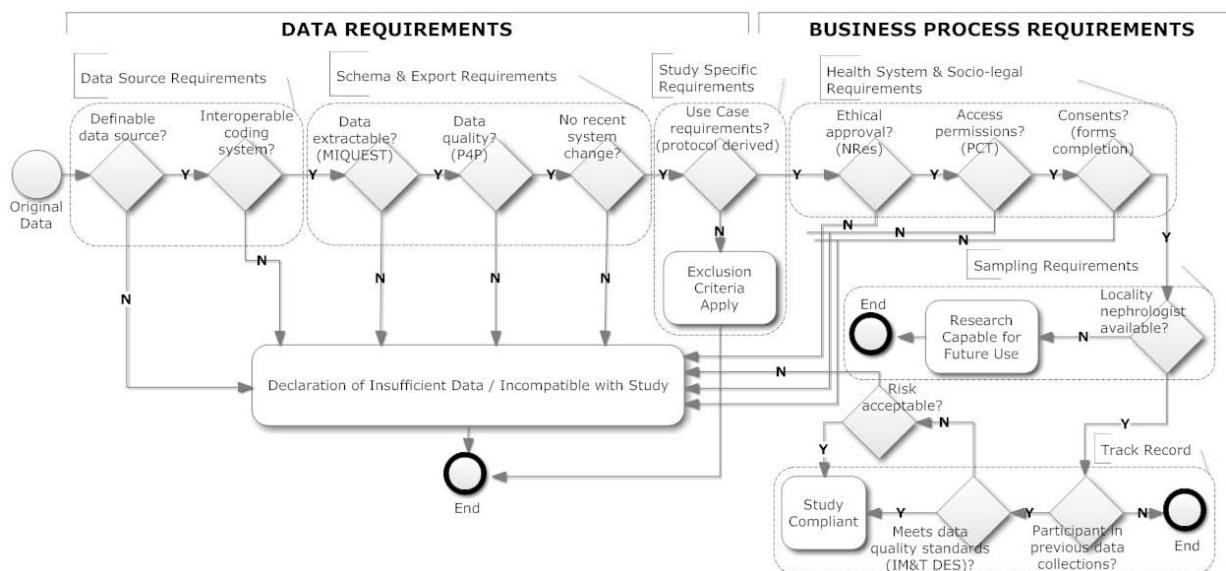
- > Specifying and modelling data collection from clinical trials

The randomised controlled trial (RCT) is the gold standard investigation: RCTs are the gold standard clinical trial for collecting evidence about the effectiveness of an intervention and whilst not immune to criticism have stood the test of time. The clinical report form (CRT) is a core component of a clinical trial as it forms a complete record of the study variables.

> Modelling the research network

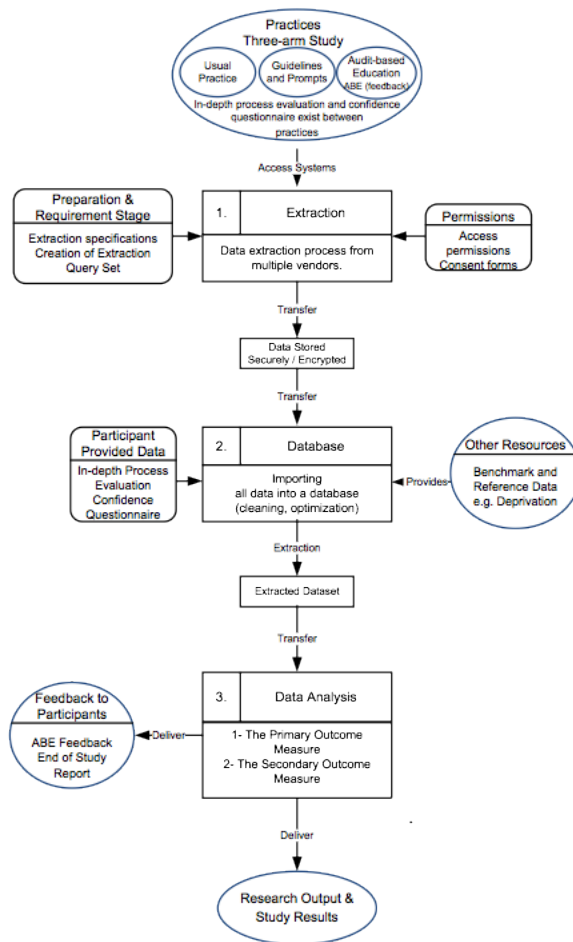
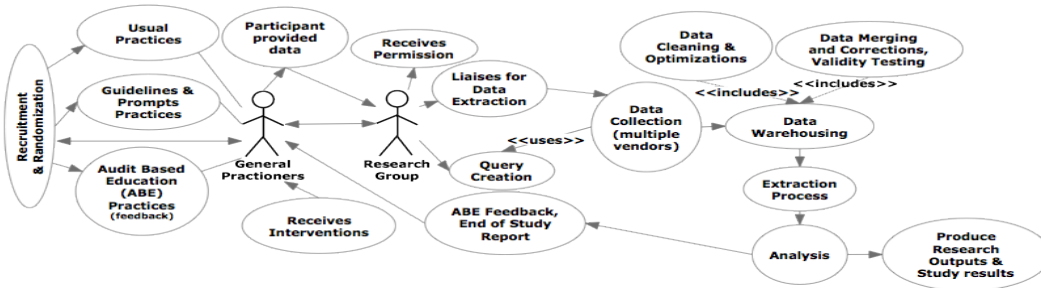
Research networks as enablers of research: Networks have been developed within primary care, at regional and national level to supporting the research process. The primary care networks exist to improve the capability and capacity for research in primary care and to recruit to trials and other studies (45). They can also be part of national or regional sentinel networks; or part of single vendor linked data collection schemes. The health service in England has developed networks further through the creation of comprehensive research network infrastructure.

The business processes and teams needed to enable research: We primarily model the function of the research or quality improvement network using BPML. The primary functions of the network of are to facilitate data oriented quality improvement activities and research. Our model of an effective network is one with a library or UML and DFD templates that can be deployed to support a range of activities. Using a three arm study involving the influence of either usual practice, guidelines and computerised prompts, or education sessions on the performance of recording of chronic kidney disease (CKD), the design process of the study therefore involves us of the business process model given in figure x below. The business process model serves to present a complete frame of the working model of the study and is the basis to then move to the next two diagrams, UML and DFD.



UML essentially describes the information processing from the researcher perspective in terms of information flow, whilst the DFD concentrates on the actual flow of data. UML therefore has a focus on elements such as consent, actions taken by the researchers in certain circumstances. DFD's focus on the technical aspects of elements such as data warehousing and storage and extraction processes.

UML USE CASE QICKD



Data flow diagram

Often the modeling in a research study is either absent, or only one element will be identified. The intention is that by using all three models, the studies will be better designed to prevent data and study problems becoming apparent only when data collection is complete and analysis has begun.

Appendix 2: A comparative analysis of Adoption between Israel and Australia

This article serves to compare the health systems of two countries, Australia and Israel, with the object of determining what each can learn from the other, particularly in the context of the computerisation of the health care sector, a change that has the potential to be as revolutionary as the introduction of the scientific method in the 1700's. We start from a description of each system, and then move to a discussion of the comparative impacts.

INTRODUCTION

Article 25 of the United Nations Universal Declaration of Human Rights states:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including ... medical care and necessary social services.

Indeed, the provision of health services is a basic function of any society, whether it is provided by the state, or citizens by other means. All societies, from the most primitive to the current day have all provided some form of healthcare. The existence of doctor, medicine man or healer/'shaman' predates probably even the other 'oldest profession'. Up until the last century, individuals arranged their own healthcare. Now, however, the state takes varied but ever increasing roles. How that intervention occurs is the subject of much debate and many and varied models, from the 'all in ' model such as the UK's National Health Service to more laissez faire models exemplified by the United States.

The effects of this are that the state now plays a significant role in the administration and innovation of healthcare. The twin arms available to any government: regulation and funding are deployed in varying degrees. The challenge to governments now is the most efficient way of funding the delivery of healthcare, in the context of the greatest change to healthcare since the introduction of the scientific method, the computerization of the healthcare space. Computers first appeared in health in two well recognized areas. Their use in the wider world for administration was mirrored in their adoption for patient administration systems. Secondly, the increase in computer power and speed meant that techniques such as CT scanning became possible.

Now, however, the computer (and the internet) is an essential and increasing part of the healthcare system (1, 46). Whilst the analysis of the costs involved are difficult (47) the impacts can be significant (48). Technology affects costs, care and is a 'disruptive' influence (49).

Social theory

Social theory provides a frame to consider the dilemmas inherent in the state involvement of healthcare. This dilemma exists in the conflict between treating health as a large scale, policy 'black box' when in fact it is, even in this technological age, an intensely personal activity based on thousands of human to human interactions every day. We cannot separate the patient from the context in which they exist, a context includes relationships at work, in the family, and in the wider community.

The writings of Jurgen Habermas give us a framework in which understand the mechanism of the interaction of the state with healthcare, using the concepts of System and Lifeworld. Lifeworld is a term first used in a phenomenological description of human society(50). Lifeworld is the stock of skills, competencies and knowledge that ordinary members of society use in order to negotiate their way through every day life, to interact with other people and ultimately to create and maintain social relationships (12). Lifeworld contrasts

with the system, which Habermas describes as a rules-governed element, usually representing either the economy or the state (13). It is in the many healthcare interactions, the consultations that the system interacts with the patient's lifeworld. In the lifeworld, actions are mediated by communicative action. Similarly in system activity, actions are mediated by strategic action.

Habermas describes the tension between communicative action and strategic action. Communicative action refers to interactions that are mediated through talk and oriented to an agreement that will provide a basis for consensual co-ordination of individually planned actions. Strategic action occurs when at least one party aims to produce an effect on others. Strategic action is related to success, rather than to understanding, and occurs when one of the parties treats the others as though they are an object. Strategic action is action oriented towards success (51). This tension is often manifest in the health professional, who must engage with the patients lifeworld and the system in order to mediate the outcome. A consultation about certification for work purposes, or government funded initiatives (immunization, for example) are classic examples of this tension.

Patients do not interact with the system, they interact with humans (52). Increasingly though, the system is manifest not only through the health professional, but through the computer (53). The challenge is to understand how best to use computers as purveyors of strategic action, without disrupting the lifeworld, in which they also participate.

CONTEXT OF HEALTH CARE IN AUSTRALIA

The Australian Health Care system, like any health system, is a complex interaction of many moving parts. But also like any other system, the basic unit of health care consists of the many, many interactions between providers and patients. Its uniqueness lies in the blending of public and private care, and in the varied funding streams. The summary that follows is a very brief simplification that includes only the large scale programs.

Australia spends 9.4% of its GDP on health, 35% of which goes to public hospitals, and 18% on private medical services. The federal government funds the majority of health care through taxation. Each taxpayer pays a Medicare levy (currently 1.5% of taxable income) that in part goes to fund the outlays for health. Any shortfall is taken up by general taxation revenue. From that the federal government funds the state governments to run public hospitals in their areas. For primary care there is a national insurance scheme (called Medicare), which provides rebates for fee for service care outside the public hospital system. Outside this system, patients can take out insurance to pay for private care in a parallel private hospital system.

From the patient's perspective, they can see any general practitioner (gp) they choose. Once there the GP is free to charge whatever fee they choose, and the patient can claim a rebate from the government. The GP can also choose to not charge the patient, but 'direct bill' the government. For the patient, this is effectively free care. For secondary care, the patient (and their gp) have a choice. Patients can be referred to a specialist (and again, any specialist) for which the same rules apply (but only if a referral from general practice has occurred). Patients with private insurance can then be sent to a private hospital for care. Alternatively, any patient can be sent to a public hospital, where all care is free. Virtually all tertiary hospitals in Australia are public hospitals.

Pharmaceuticals

Two pieces of detail to funding are relevant to the next discussion. In the first instance the Australian PBS. Pharmaceuticals in Australia must first go through a regulatory hurdle of the Therapeutic Goods Administration, before being made available. Once listed, a drug can then be subsidised through the PBS. For most drugs this means pensioners pay the full cost of a drug up to a maximum of \$6.40, and the general public the cost up to a maximum of \$29.90. The government then pays for any difference. There are two further categories to

this – drugs that must only be prescribed for a specified purpose (SP), and drugs for which an authority must be obtained for prescribing. In all cases the government is able to describe the pack sizes and repeats.

So, for example, a drug such as Diclofenac (voltaren) has over thirty listings including 50mg pack of 20, 50mg pack of 60 (with 5 repeats) SP for the management of osteoarthritis, and other classifications requiring authority. The listing is updated quarterly with any changes (new drugs, new indications and changes to pack sizes, etc).

General practice funding

GPs are the cornerstone of medical practice in Australia. GPs represent half of medical practitioners and are the enforced gateway to virtually all secondary care. 85% of the Australian populace see a GP each year. In addition to the fee-for service (FFS) funding described earlier, there are several ways in which the federal government provides funding for general practice, in order to make up for the deficiencies of FFS. This is through Service Incentive Payments (SIP: specific item payments for PAP smears, immunizations etc) and Practice Incentive Payments (PIP). The latter are not based on episodes of care, but on the provision of service, such as practice nurses. There has always been a specific PIP for the provision of information technology. A PIP is payable on a calculation of practice size, paid to the practice (not the individual doctor) and requires the practice to meet certain criteria. For Information technology this has been for: having a computer system capable of generating a prescription, then for the recording of allergies in the CIS, and now is based on the availability of electronic resources and provision of secure messaging.

The final piece of the puzzle is the divisions of general practice network. Currently under revision, for the past 15 years there have been around 115 organisations spread across the country expressly to support general practice in its activities. In the late 1990's divisions were funded to provide support officers to enable the computerization of general practice, and currently the network has a much smaller number of "e-health support officers" to improve data management in general practice.

Use of computers

Adoption

Unlike many other jurisdictions, the adoption of computers in Australia has been largely organic. The first clinical use of computers was to utilize administration systems for patient recalls. General Practice computerized rapidly in the 1990's, driven by the increasing complexity of the PBS. Grappling with regulations that had tripled in number, the structured, regulated nature of the PBS lent itself to computer support. Early programs were described as 'electronic prescription pads'. When about 50% of practices were computerized the government introduced both the PIP for ehealth and funded the division support officers. This increased the numbers to where they now stand, at over 90%.

Lacking the obvious driver of a local need, computerization of the hospital sector remained low. Multiple attempts to computerize the clinical space failed, and computerized hospitals (in terms of widespread use in clinical settings) is less than 10%, but most states are in the midst of significant upgrade programs.

Use

Consultations in Australia are about 12 to 14 minutes long, with 10% of the time actively interacting with the computer (by use of keyboard). 7% of consultations are initially driven by the computer (15). Not surprisingly, prescribing is the most common use of the computer, followed by receiving of test results. There is no facility for e-prescribing nor e-ordering at this stage. In fact, because general practice computerized in isolation from the other sectors, all communications (including certificates, referrals, etc) are still done by paper. After

prescribing and lab results, generating referral letters, updating progress notes, recalls and audits are the most used (>50%) functions (4).

Sharing

Electronic information about patients is largely kept in silos of electronic repositories that in effect mirror the paper equivalents; information cannot leave the electronic walls of the institution concerned. The largest collection of data about the Australian population resides on the disconnected servers in general practices across the country. In order to correct this deficit, the federal government is implementing the 'Personally Controlled Electronic Health Record' (PCEHR – for more details see www.yourhealth.gov.au). The PCEHR is an ambitious program to enable the sharing of information. General Practice and other providers will create a Shared Health Summary, and documents such as discharge summaries, specialist letters and prescribing will be available to both providers and consumers via the system. The PCEHR will not directly hold the information, it will be kept in either the source system or in a dedicated repository. Only copies will be displayed by the system. The PCEHR is due to be deployed on July 1, 2012.

CONTEXT OF HEALTH CARE IN ISRAEL

In Israel, since 1995, a national universal health care law ensures coverage for all. Income is subject to a health tax of 4.9% and all permanent residents have to be insured in one of four competing Health Funds. Care is provided by a combination of primary curative care via the health fund, primary preventive care through a mix of government services and the health funds, and secondary/tertiary care by a combination of sick fund, government, and NGO clinics and hospitals (54). Funding is provided mostly from the government, but the private participation healthcare expenditure is on the rise. All citizens are entitled to a Uniform Benefits Package, regardless of which organization they are a member of, and treatment under this package is funded for all citizens regardless of their financial means. Health care indices in Israel are similar to average European ones, with the exception of a higher fertility rate. Health care expenditure is 8 % of GNP in 2008 and has remained stable at this level for some years. Presently the major problems of the health care system are economic sustainability, an inadequate focus on primary care, and a recent physician strike that is still somewhat on-going, already claimed to be the longest labor dispute in Israeli history.

Coverage includes medical diagnosis and treatment, preventive medicine, hospitalization (general, maternity, psychiatric and chronic), surgery and transplants, preventive dental care for children, first aid and transportation to a hospital or clinic, medical services at the workplace, treatment for drug abuse and alcoholism, medical equipment and appliances, obstetrics and fertility treatment, medication, treatment of chronic diseases and paramedical services such as physiotherapy and occupational therapy. Primary Care (PC) is provided by the 4 sick funds (HMOs), through a system of community clinics or solo private practice (2,6,7). Over a 1000 Certified Family Physicians and about 2000 GPs are employed as Primary Care Physicians (PCPs). Licensed physicians can work privately, e.g. for private companies providing physicians for night and weekend calls. Licensed physicians can be employed by hospitals as non-qualified specialists. Most Israeli graduates seek specialty training with about 10% selecting Family Medicine. In Israel, a General Practitioner is a licensed physician who has no specialty qualification and is working in Primary Care. A vocationally-trained and Board-certified Family Physician (FP) is a licensed physician who went through 4 years of vocational training (VT) or residency in North American terms and passed the qualifying examinations MCQ at mid-VT and oral at the end. Some medical specialists provide primary care, privately or through HMOs (typically pediatricians, gynecologists and internists). General Practitioners - mainly IMGs and some local graduates without specialty training - make up the bulk of GPs in the community.

The four nationwide Sick Funds are: Clalit (the largest with about 54% of the population belonging to it), Maccabi, Kupat Holim Meuhedet and Leumit. In 2010, there were 25,542 doctors in Israel - 3.36 doctors for every 1,000 people. But the number of how many of them practice is unknown.

Pharmaceuticals

Use of Computers

All healthcare organizations in Israel and especially the Sick Funds heavily invest in IT. While computerised administrative systems appeared in the late 70s and early 80s, Ambulatory Computerized Patient Record (CPR) systems were first installed in 1991-3 in the two major Funds. Clalit's "Ofek" project was first in world to aggregate healthcare data across different providers (with about 4 million citizens, 55% of population covered). A national EHR project is in pilot phase.

Primary Care Physicians (PCP) are employees of the Health Funds. Hospital physicians are either employees of the hospital via the Ministry of Health, or Clalit Health services which is the only HMO to run its own hospitals. This dependency created a situation where it was easier for the providers to be more "persuasive" in the introduction and usage of technology. Caregiver natural resistance to the changes, was more easily swept aside with arguments for the good of the organization were put forward. There was almost no resistance to the deployment of the new technology. Presently 99.9% of PCPs enter medical data electronically, and similar figures exist for the rest of the healthcare system.

E-prescribing is still not possible, but pilot projects of digital signature of prescriptions are already deployed and going fully digital is pending. Funds members portals are available where physicians' appointments; lab and imaging results and some hospital and specialist physician reports are available. Call centres that cater to appointments, emergency advice exist, with IT based innovations such a video-consultation with a paediatrician becoming increasingly available. The IT staff of the largest Fund, Clalit is around 500, and IT budget - 1.55% of the organizational budget.

Business Intelligence programs allow for pro-active medicine such as the prevention campaign for colon cancer among the above 50s population. The 'Clicks' CPR system is well established in Clalit & Maccabi and is used by all primary care givers, nurses and most of the paramedical staff. While Maccabi use a centralized data warehouse approach, Clalit use a Hybrid model known as the Ofek Project. Ofek is a "Virtual clinical data repository", Clinicians can use Ofek to search all digital data on a patient,. The data is not moved from the original site, and is not saved in the clinician's application. Only the new record is saved. Response time is claimed to be <5sec avg. "faster than asking for the file", but in the author's personal experience it is largely dependent on bandwidth, and at times may take up to 20 sec. Use of the Ofek has been extended to non-Clalit hospitals, Sheba and Rambam. Through the Ofek Clalit has successfully created a Virtual Healthcare Record (VHR) which is reported to be to first of its kind in the world. Based on Microsoft technology, Ofek unites disparate data from around the Clalit system and provides a single view of all hospital, clinic, and lab data. As it is a VHR, many issues of security have been resolved as the data viewed is not stored or kept at the viewer. Access is severely controlled by a central system. 32 different roles have been defined by Clalit and each role has very specific rights and privileges. In hospitals for example, nurses can read/write to the data of their own ward, and not view data from another ward, while physicians can read/write to their own ward data, but only view data from another ward. Needless to say, a "write-once only" log is kept and any exceptions dealt with immediately at the highest levels of the Health Fund.

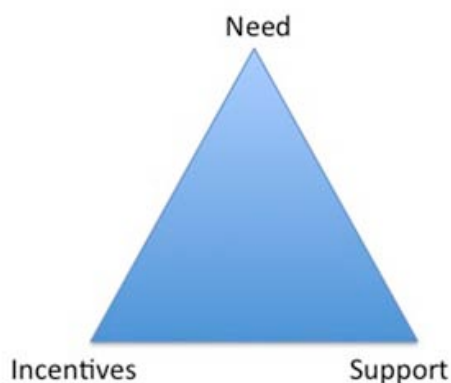
Implications

The challenge is enhancing the exploitation of the CPR capabilities while empowering the patient-doctor relationship. The presence of computers will transform medicine in unforeseen ways, presenting us with educational and moral challenges.

In summary, the two health systems differ little in the amount of funding, but have some significant differences in the mechanism of distributing that funding. Australia funds its public hospital system via direct method involving grants via the commonwealth, whilst Israel uses a purchaser/provider model. Israel extends that purchaser/provider model to community care, whilst Australia uses an open ended rebate scheme. Australia concentrates on medical care via doctors, whereas Israel includes dental, occupational therapy and physiotherapy.

In terms of computerization, Israel pursued a more centralized program, driven by the health funds, whereas Australia has pursued varied approach with a mixture of uptake driven by need and some centralized incentives. That they have arrived at very similar results is an interesting study, especially when looking at the variation at a more micro level.

If we assume that the adoption of computers is driven by a balance of three elements: need, Incentives and support, then a more detailed understanding of the significance is apparent. These three elements occupy three points of a triangle. All three interrelate. If the Need is strong, then the requirements of incentives and support are low (think adoption of mobile phones). If the need is not there, then more incentives and support are needed. The less support, the more incentives, and vice versa.



The adoption triangle 1

Although the endpoints are similar, the journeys taken to get there have been quite different. In primary care Australia has taken a more organic approach, driven by clinical need. In that sense the Australian system has responded better to the lifeworld environment of general practice. Where there have been gaps identified, the judicious use of incentives and support have removed obstructions and allowed adoption to take place. Thus incentives to buy computers, support through divisions to adopt them. Now there are incentives to use structured data for things such as allergies, in other words to get GPs to use computers in a way that benefits the system, not the lifeworld.

An examination of the differences is also illuminating. Australia, with its less centralised system, has allowed for segments of the healthcare system to remain computer naïve. Outside of large institutions, the decisions on computerisation are made by individual and

small groups of clinicians on a case by case basis. Specialists remain poorly computerised and therefore poorly integrated into the system. Israel by a centralized system has a more complete system, which allows for better transfer of data within the confines of a health program.

The comparison therefore takes us to the process of matching the strategic needs of the system with the communication activities at the human level. Central imposition will not work well unless it is matched in that way. Understanding the interplay of needs, incentives and support will allow policy makers to develop programs that benefit both the big and little picture.

Fellowship Impact

Since returning and continuing to work on the elements from the fellowship, there have been several impacts

PAPERS

Submitted

The computerised medical record as a tool for clinical governance in Australian primary care: Pearce C, de Lusignan S, Phillips C, Hall S, Trevaglia S. ; Submitted to International Journal of Medical Informatics.

In final draft

A Comparison of Health System and EMR Interactions between Israel and Australia: Pearce C, Reis S.

Conference Workshop

Redesigning descriptions of work, protocols, and clinical trials documentation for quality improvement and research. de Lusignan S, Andreasson A, Pearce C, Ntasioudis A, Jones S. Medical Informatics Europe, 13th International Conference, User Centred Health Care, Oslo, August 2011

PROJECT

Monash and Melbourne East General Practice Data NETWORK (MAGNET) – represents a research collaboration between IEMML and the Monash University Department of General Practice involving research uses of the IEMML data cube.

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Appendix 3: Full assessment tool

STRUCTURES	Individual clinician <i>Their knowledge of skill in operation & structure towards EPR use for governance</i>	Clinical tools <i>Usually one 1 to 3 clinical consultation – may involve implementing guidelines</i>	Technology <i>With no primary & secondary roles – computer available technology with EPR. Secondary roles may include pay for performance</i>	Organisation <i>Practice, Locality, Region, and National differences/variables</i>
System architecture	<ul style="list-style-type: none"> Interface (GUI, OHL etc.) Clinical interfaces Database (shared, relational, open API – Local/linked) Coding system ROCCs (interfaces) Shared record capability Audit trail Adaptation 			
Information support	<ul style="list-style-type: none"> Security, back-up, system recovery, vendor support Information-relevant system <ul style="list-style-type: none"> Drug information-databases Guidelines Clinical information Tools Source (internal/external) Clinical decision support <ul style="list-style-type: none"> Drug-drug interactions Drug-disease interactions Drug-allergy reactions Alerts/triggers Immunisation Clinical 			
System linkages (used if no national / international standards)				
Search function	<ul style="list-style-type: none"> Patients <ul style="list-style-type: none"> Registration database Index ID Laboratory <ul style="list-style-type: none"> Testing Class Dr-pathways Special & tests Referral Others Prescription <ul style="list-style-type: none"> Practice Linked data Export functionality – and common interface formats Others 			
Patient access / control	<ul style="list-style-type: none"> Access to record (Email only) Full or limited (portal) Ownership of record (control access) Access to posted quality data Others 			
INTEGRATION				
Quality markers	<ul style="list-style-type: none"> Demographic quality Data quality Clinical quality – participation in audit – practice / locality / national Process for practice – Appraisal / indicators Compliance Accreditation (of the system) Training (of the users and their supervisors – e.g. GPs/health guardians) 			
Billing and pay for performance	<ul style="list-style-type: none"> Routine data used for pay for performance Local National Separate billing process data Separate incentives 			
Epidemiology / Health needs assessment	<ul style="list-style-type: none"> Epidemiology / national networks Health service management / needs assessment Safety and surveillance 			
OUTCOMES				
1)	Navigate markers of quality			
2)	Critical Incident Reporting			
3)	Outcome markers			