16 Information Technology Infrastructure, Management, and Implementation: The Rise of the Emergent Clinical Information System and the Chief Medical Information Officer

Jon David Patrick, Paul Barach, and Ali Besiso

"We are drowning in information, while starving for wisdom. The world henceforth will be run by synthesizers, people able to put together the right information at the right time, think critically about it, and make important choices wisely."

—Edward O. Wilson, *Consilience: The Unity of Knowledge*

Introduction

Over the past 30 years Health information technology (HIT) has been positioned as a battle between two classes of technology solutions, that is Clinical Enterprise Resource Planning (CERP aka EMR) versus best-of-breed systems. The CERP systems are provided by the largest vendors as whole of hospital or whole of organization solutions intended to satisfy all users in the organization. Experience shows that they fail to fulfil that promise. Best-of-breed solutions are tailored to suit a particular community of users to perform specialized tasks such as surgical scheduling, tracking, and clinical details. These systems get higher rankings from users for usability and efficiency but create problems for IT departments by requiring individual maintenance tasks for each installed system, and silo data which is needed for back office administration and analytics. In the last 10 years, the best-of-breed solution has been in retreat with the onslaught of CERP vendors holding sway over the decision makers with a promise of increased revenue for more detailed billing and common access to all data [1]. At the same time, the clinicians at the coalface of care are complaining bitterly about CERP systems, which have unsuitable interfaces [1], add more work, and fail to respond to change requests [2].

We argue there is a distortion in the nature of the IT processing requirements in this current juxtaposition, and a new paradigm of service description and function would significantly improve the performance of staff and the determination of the return on investment (ROI) in HIT investment and impact on patient outcomes, staff satisfaction, and revenue optimization.

Understanding the value of any IT investment requires identifying the usability criteria of the

J.D. Patrick, PhD, MSc, Dip LS, Dip BHPsch (✉) A. Besiso, MHI, BHSc
Innovative Clinical Information Management Systems (iCIMS) Pty Ltd., International Business Centre, 2 Cornwallis St, Suite 4, Sydney, NSW 2015, Australia
e-mail: Jon.Patrick@hla-global.com; ali@icims.com.au

P. Barach, BSc, MD, MPH
Clinical Professor, Children's Cardiomyopathy Foundation and Kyle John Rymiszewski Research Scholar, Children's Hospital of Michigan, Wayne State University School of Medicine, 5057 Woodward Avenue, Suite 13001, Detroit, MI 48202, USA
e-mail: Pbarach@gmail.com

J.A. Sanchez et al. (eds.), *Surgical Patient Care*, DOI 10.1007/978-3-319-44010-1_16

technology, how to evaluate the usability for the real staff users, and how to determine their improved productivity and subsequently the ROI [3]. In this context, we consider usability is a general term applicable to all aspects of the acquired HIT and not the narrower sense used in user interface studies [4].

The Three Level Hierarchy Paradigm for Healthcare HIT

We posit that there are three major levels of HIT services that are required in any extensive health system, and that they need to be served by different technologies having different end users working for the different outcomes. Each of these levels needs to justify their rationale for a particular type of HIT by defining their own usability requirements.

Level 1. Departmental HIT for coal face clinical work: this is the context of clinical care where the importance of usability lies in screen real estate, data flow, and workflow. The most important aspect of the HIT is to support staff caring for the patient. For the HIT to fulfil basic usability, it must support work in its most detailed way, that is, it must fit closely to the daily operations of the people using it, acting like a silent colleague, by never interrupting or dragging the staff away from their work, by being available to provide exactly what is needed easily and readily at the moments of highest crisis. In cognitive science terms, HIT needs to reduce the workload of data collection and analysis on providers so that they can apply their cognitive skills to clinical management and not to user interface navigation. Crucially just as clinical practice changes, so must this Clinical Information System (CIS) be nimble and change too; otherwise, over time it will regress away from fulfilling the dynamic needs of busy clinical providers.

Level 2. Intra-organizational HIT for Data Management: At the hospital and whole organization context, the HIT has to support the whole of organization activities and support the sharing of appropriate data across the many departments participating in the organization. The administrators are interested in whole of hospital usability, which is dominated by the back-office functions of the organization. As many people have to use such a system and the work is less dynamic and more static, CERP systems is the best way to systematically define this wide range of activities such as billing and supply management enabling analytics across disparate collection sources of data and fulfiling all the legal and accounting record keeping responsibilities of large health delivery organizations. The CERP has often been touted as a whole of organization solution without accounting for variable contexts within the organization. This has led to CERP solutions being imposed on clinicians at the coalface of care with conviction from the administration that it would solve data collection and management problems, but unwittingly creating much extra work, so worsening their productivity and quality of patient care [5].

Level 3. Interorganizational IT for sharing data rapidly: The whole of system needs, e.g., a State health department, has to deal with usability across multiple hospitals and organizations and can only assess that by enabling the collection of standardized data across all organizations. Fundamentally, usability for this group is the interoperability, and their focus is about creating effective interoperability across all health institutions in the jurisdiction. It is true that both levels 1 and 2 have an interest in interoperability, but it neither has the core role nor the massive scale for implementation that is required at Level 3.

When we embrace the varied requirements at these three contextual levels, we will see real productivity emerge from HIT. Otherwise, we will continue to squander money on lofty business plans serving personal goals and making the work harder for the clinicians at the coalface of care while endangering patients.

An Integrated Architecture for HIT Usability

In an assessment of the different requirements between the three levels of HIT, there arises a tension between usability and interoperability. The value of each of these functions to an organization needs to be assessed to understand the

competing tensions between the 3 levels of HIT function and to enable a mature discussion about the trade-offs needed when making informed choices about opting to procure significant technology acquisitions.

Interoperability is undoubtedly valuable in many settings and has proven a useful improver in productivity. Interoperability is wanted because clinicians want to have more reliable information by linking clinical care systems with ordering/results systems (pathology and radiology) in order to:

- Interpret the patient's condition,
- Use most current, up-to-date patient records to save costs on retesting,
- Understand the decisions of prior carers in the patient's journey,
- Avoid contradictory treatments (including contradictory meds).

However, interoperability has a limited effect in clinical care and ROI, even though every clinician can give an example of where it would have helped them and it wasn't available. How do clinicians manage without interoperable systems: (a) not badly; (b) they haven't had it for a long time; (c) there is no study of the effect of not having it but it is likely to show small results only; (d) because clinicians are well trained and conscientious; (e) yes, they would like it but its impact would be low; and, (f) yes, everyone has examples where it would have helped.

But, the contribution of interoperability is not so great that clinicians can't do without it because: (a) its scope is very localized to individual situations; (b) the complexity of providing it everywhere is gigantic; (c) the co-operation required from unwilling vendor partners is monstrous; and (d) for vendors, it is a large task with relatively small value.

System Adaptability

One of the major themes across the HIT field is the need for better adaptability of a feature of a system or of a process. In ecology, adaptability has been described as the ability to cope with unexpected disturbances in the environment. Consequently, adaptability and efficiency are held to be in opposition in biological and ecological systems, requiring a trade-off, since both are important factors in the success of such systems [6]. To determine the adaptability of a process or a system, it should be validated concerning some criteria [7]. HIT is under constant scrutiny to deliver better user interfaces and this is often couched in calls for more usability research.

There is much reference to the academic usability research and its failure to impact delivered products from vendors [8]. While the vendors are variously reported as claiming, it is not needed or they are doing it anyway. We present here a new way to view usability as the importance of being able to adapt a system rapidly and easily. Such a technology would enable the efficient and inexpensive means of changing a system when it is needed or a new idea of processing or workflow is introduced. To our knowledge, it is not recognized as part of the paradigm of "usability" but we believe that is where it is most appropriately positioned.

Immediate Adaptability (IA)

Most academic researchers on HIT usability and safety concede that there is little impact of this work on vendor product design or thinking [9]. Furthermore, usability research at *any* point in time can become moribund or irrelevant because technology moves on or the context of use of the product changes while it is in situ, e.g., work practice changes due to new medical practices and government legislation. The literature of professional lists, blogs, and newsletters is replete with examples of complaints from physicians that they cannot get change to their user interfaces because the vendor will not accept the changes or it will take inordinate amounts of time and money to complete [10].

We understand that vendors are reluctant to make changes because it increases their cost of maintenance, potentially increases the complexity of their product, and the financial reward may be insufficient [11]. While complaints about the usability of interfaces in most publications are

couched as "usability" problems that does not address the functional behavior required of the software and thus imposes huge cognitive loads on nurses and physicians [12]. What are physicians implicitly complaining about? That the software is not adaptable or what is practically the same: that adaptations cannot be made immediately or within days, but remarkably takes, months, or years due to the complex designs. In short, they are actually asking for "immediate adaptability" in the software to avoid conditions that facilitate or actually enable errors [13].

Objections to Immediate Adaptability (IA)

EMR systems built by large vendors have code development operations similar to Enterprise Resource Planning (ERP) ventures like the large multinational company SAP, arguably the most successful ERP provider globally. We identify big health vendor EMR technology as Clinical ERP (CERP). Smaller but older vendors no doubt have similar models. Only recent vendors appearing in the last 10 years are likely to have different software approaches. The problems with IA for CERP are that it ostensibly requires the vendor to:

- Give up control of the design of their CERP to the user community.
- Have highly qualified programmers on call to respond when users require changes.
- Have built-in mechanisms to manage automatic version control, including roll back.
- Have built-in mechanisms to manage data such that data collected before a given change remains available after the change.
- Change their interoperability functions on-demand to send and receive data from dynamically changing EMRs.
- Have confidence that their technology can undergo continuous changes.

These criteria would not just increase the cost to maintain CERP technology, but also raise protests from vendors that maintaining large systems cannot be sustained intellectually as the systems are too complex to change rapidly and thus vulnerable to creating unexpected consequences. This protest would seem to be entirely valid. It is this very scale and complexity that inhibits changes to "usability" beyond the minimum, not to mention to support IA. The best-of-breed HIT system vendors have done a better job with usability because they do not suffer the same complexity problem, and their aim is to deliver a smaller range of functionality; however, IA would still be a difficult concern for them.

The technical difficulty in delivering IA can be discerned from the process of creating a CERP system in the first place. The process is a sequence of tasks consisting of requirements gathering, systems analysis, data modeling, code writing, systems testing, and deployment. The CERP providers have escaped part of this process by removing the first two steps on the basis that they have built so many systems they know the generalizations of clinical requirements and analyses. Indeed, they have built large code repositories relying on these generalizations and are unwilling to change them because changes will affect so many of their products and customers. Moreover, the code bases are so large that they are unwilling to risk a large number of unexpected consequences from changes.

The CERP approach was state-of-the-art in the general IT industry of the 1980s, but it is now outdated for most modern applications. The method suits large volume data transactions with stable patterns of work and processing such as in banking and insurance industries, which may be acceptable for back office work, including health organizations. This does not suit the needs of dynamic clinical workplaces where workflow is as important as data capture, data volumes are relatively low, local data flow and analytics are crucial for efficiency, and staff need to run continuous process improvement capabilities. In fact, imposing immutable CERPs on patient-facing clinical operations blocks processes to create clinical efficiencies and productivity, as is frequently testified in the protests from clinicians in many fora [14]. These systems encourage "work-arounds," defeating many of the HIT benefits and opening the door to patient harm.

The professional discussion lists have many conversations about how different HIT systems

need more cross-consistency because as staff move from one clinical site to another, they have an extra cognitive load to learn how to use the many different systems leading to errors, waste of time, and potential patient harm [15]. Training for CERP systems is both highly costly and difficult, hence the complaints. A system optimized for IA will be customized for its community of use and so staff working across multiple communities will need to train on different IA systems. Would the same objection apply? Most likely not. CERP "solutions" that fit the local workflow poorly will need significant workarounds in addition to the standard training that still has to be learned by migratory workers. Claims that the same technology from the same vendor has the same workflow and functions are often spurious—there are cases where two large systems, ostensibly the same, cannot even communicate with each other. Furthermore, locally designed systems customized to the needs of the clinical ecology are truly optimal for the local workflow and so training on them is about learning how the local community actually works, surely a necessary criteria for successful healthcare [16]. Training on locally designed systems has little training costs for local users and modest costs for new users. Also, they are of significant value where senior staff responsible for the training of junior staff use the IA system to train them in the processes of work and thus increase reliability and safety.

It is often the case that a CERP system is training staff in processes that are considered undesirable, whereas an IA system would enable the senior staff to create an ideal training system. This over time would lead to better standardization of work practices where appropriate, and easier adoption of these better practices as they are defined by the professional community because the IT behavior is immediately adaptable [17].

Functional Specifications of IA Clinical Information Systems

The intrinsic definition of an immediately adaptable system is in the name: *immediate*. We consider this to be a period of hours or days, not weeks, months, or years! However, the requirements as defined by the complaints to the professional discussion lists and elsewhere have a wider ranging scope.

The *first level of the problem* is the concept of the EMR which describes a medical record as placed into an electronic storage bin instead of a filing cabinet. Such an EMR fits the CERP model that is focused on collecting content and storing it on a large scale and then processing the data for highly stable requirements, e.g., billing. Furthermore, the CERP methodology requires deconstructing the data into normalized storage structures of permanent definition and storage representation. In the CERP paradigm, the "efficient" storage of data is paramount to the processes of "capturing" the data and only then subsequently "reusing" the data, that is, moving the data from the context in which it is collected to the contexts in which it is reused, which unfortunately blight the storage efficiency criterion by the effort and complexity of programming for the internal movement of the data. This involves elaborate methods for putting data into fixed data structures and reading it back out whenever it is called for. Intrinsically, the storage mechanisms are tightly coupled with the data capture and display processes. As an alternative, modern web technologies enable a significant loosening of this coupling but the CERP developers have been slow to embrace these innovations due to their years of investment in older software engineering and data management methods.

The greatest limitation of installed CERP systems is the effort, cost, and risk associated with changing the structures by which the data is defined and stored when a new data element needs to be inserted into a design, or changing the semantic meaning of an existing data item. This requires changing the underlying storage design and creating the code to store that data element and to retrieve it at all the points where it is reused *without disrupting anything of the existing processings*. The large vendors, whose systems have thousands of data tables that are beyond the scope of any one person or even a team of engineers to comprehend, are aware that their data management is brittle where even a single accident in a new design or coding can

bring down the entire system. This is one of the crucial reasons for the very strong resistance to modifications of CERP systems.

The process of separating the captured data in one context, storing it in a rigid data structure, and then moving it for reuse into another context is fundamental to moving away from the idea of an EMR model, towards one of a Clinical Information System (CIS). A CIS is a software technology that is integrated into the processes of the users so as to support their work in the most active and sense-making manner possible [18]. Critically, it is NOT a system that cements the processes of data collection and dissemination as found in a CERP EMR system. A CIS matches the users requirements for both the flow of data from one context to another, and their movement through activities of work that the users have to perform in a seamless manner such as when a surgical patient is moved from admissions to preoperative suite, operating room, and then to the intensive care unit. A CIS supports both dataflow and workflow for the user in a transparent and measurable way. The third key benefit of the CIS is the physical screen layout and design. The optimal design of a CIS is a dominant part of clinical usability research, but, due to the nature of the CERP methodology, very few usability discoveries have been incorporated into present CERP systems [19].

An IA-CIS has to be easily and readily changeable and accept real-time changes (or nearly so). An underlying architectural consequence of real-time changeability is that it has to have dynamic data structures along with revision control that does not affect the previous versions of storage organization or access to previously recorded data so that real-time use is uninterrupted and seamless.

We have named the data flow requirement of IA-CIS: native interoperability. The idea is that data created or input at one point in a data flow can be referred to by its name wherever else it needs to be reused. There should be no need to write code to read tables to transfer such data, but rather it should behave more like a link. Thus, when you invoke the name of the data at a time for its reuse in a new context, it appears at that point of invocation, without needing to do anything else. This introduces interesting questions about the protocols for naming data but stable solutions are available to solve them [20].

IA implies real-time design, which requires a design toolkit for specifying all the requirements of the user including, data definition, screen layout and behaviors, business rules, data flow, and workflow. Underlying these design utilities is a need to use a design language universal to all CIS designs that become the specification of the operational system. This has an important consequence: the design of the users' system is independent of the software that manages their data. The benefit is that design can be changed without affecting software code, and code be changed without necessarily effecting designs. Software maintenance is done independently of any CIS design processes. This radically simplifies the nature of system maintenance as there is no enmeshment of a given system design and the program code required to implement it. This is a radical departure from present system architecture and software engineering practice.

Furthermore, it opens the door for usability research to be directly incorporated into an operational system. To support usability research, the only software engineering requirement is to have a library function that performs according to the usability task being investigated. If the feature to be investigated is not available in the design tool kit, then the only software engineering task is to enhance the design tool to carry the function as an element of the design toolkit. To create an executable instantiation of the design as defined in the design language, there needs to be libraries for all design functions and auto generation of data structures that are invoked at the point of real-time system generation.

While not an absolute requirement for an IA-CIS, built-in analytics are needed to achieve the user demands in order to pursue Continuous Process Improvement (CPI) for clinical care [21]. The role of using a CIS for improving direct operational workflow is fundamental to its conception. However, optimizing the CIS over time requires the analysis of the behavior of the CIS and the users as an integrated entity. This analysis is best achieved by having analytical tools built

into the CIS that can actively monitor the CIS and its users to establish the value of changes as they are implemented [22]. Omitting analytics functionality as an intrinsic part of the CIS will severely limit the ability of the user team to identify behaviors of the microsystem (staff, technology, equipment, etc.) that warrant change and later to measure those changes.

A Generic Architecture for IA-CIS: Repurposing the EMR Model

The IA-CIS methodology is in some ways a counter positive to the CERP. Over time, the CERP methodology has diminished the role of requirements gathering and systems analysis to the point, where it serves only to direct system configuration of fixed data structures and concomitant code bases. IA-CIS does the opposite: it treats requirements and design as the primary function of creating a system for the specific needs of the user community. It then generates an implementation process from the choices defined in the design, creating dynamic storage structures served by an engineered library of adaptabilities.

The value of CERP-engineered systems lies in their capacity to massage large volumes of data for repetitive, infrequently changing processing. The disadvantage is their inability to satisfy the needs for representing intricate and different workflows in multiple clinical contexts. Although all clinical contexts are ostensibly the same, actually they are steeped in subtle and significant differences both between medical specialties and across institutional contexts, with the added complication of fast-changing and diverse work that needs to adapt practices immediately for any number of social, legislative, or professional reasons. Using an IA-CIS for clinical care systems will reduce the maintenance load on the CERP so they don't have to be continually adaptable and hence will lower the costs of managing them. The CERP will contribute better to the HIT ecology if it is rightly positioned as the data warehouse backbone of the organization fed by the highly efficient limbs manifest as IA-CISs.

We can achieve better care, more satisfied users and less expensive outlays by repurposing CERP systems for back office functions and removing them from the clinical coalface locations where IA-CIS technology can provide better support for work and better efficiency gains for the relative costs of installing them. Customization of IA-CIS is the most likely pathway for reducing workarounds, but with the more important positive benefits of increasing data collection completeness, improving patient safety, enabling cultures of continuous process improvement, and, of course, both simplifying and accelerating training [23].

An important extension to the IA-CIS is that it is a coherent method for creating a single application for one clinical department that can be repeated for many clinical departments in the organization. Although each department designs their own system as an autonomous community, they all use the same design tools and the same instantiation library; hence, the technical implementation can house them all in the same software installation. This is equivalent to providing multiple customized best-of-breed systems in the one software installation. This architecture introduces a different type of interoperability, that is, CIS to CIS by means of within-system native interoperability. So while users are operating under the belief they are autonomous, they are actually all working within one infrastructure with a single data management process that enables the direct sharing of data (given the appropriate permissions) and introduces an inherent cohesion that is not part of the consciousness of the different user communities but nevertheless enables interoperability at a subliminal level. Figure 16.1 is a high-level diagram showing multiple systems including clinical care, research, and registry systems built on the one software platform using native interoperability to share data with each other and a single gateway to communicate with external systems.

IA-CIS do not solve the problems of interoperability between different systems supplied by various vendors. Hence, it is unavoidable that a CERP system and an IA-CIS will have to use

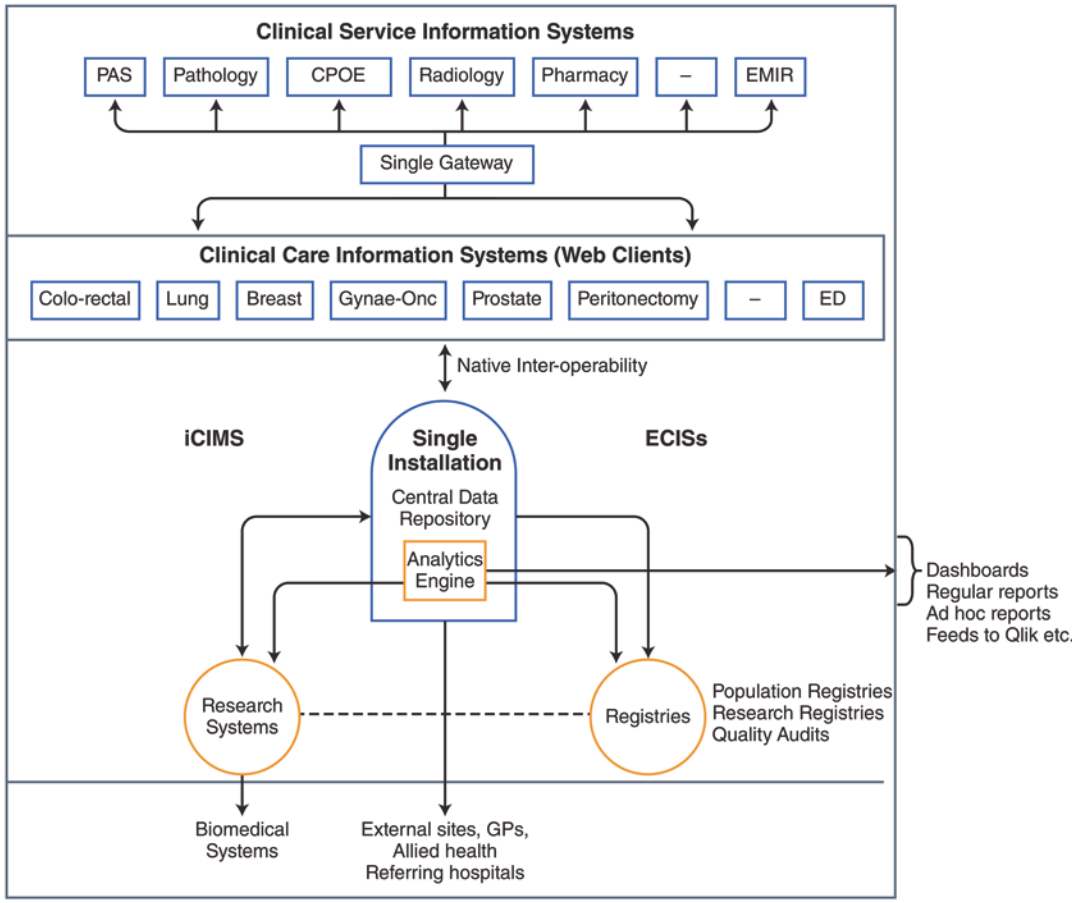

Fig. 16.1 An architectural diagram of the relationship between clinical care information systems and clinical research systems and registries as part of the ECIS paradigm

some external coding standard to share data between each other. Methods for solving this problem are well established by HL7 or ODBC direct procedure calls. (ODBC Direct is an alternate mode of Data Access Objects (DAO) that accesses ODBC data sources directly, and taking full advantage of the remote data source's processing capabilities.) But within the IA-CIS paradigm, the problem is solved at a much more efficient level by native interoperability.

The IA-CIS also has another significant advantage in that it eliminates silos of data, and maintenance and support for multiple systems. In this data architecture, it is important not to take a stance that assumes all data needs to be available in one place. Most data needs to be usable by the people who collect it, and then appropriate selected pieces passed on to those who have secondary use purposes. Just as the results of every research experiment are not required by the back office so not every action taken by the clinical staff needs to be defined by the back office. Autonomy at the front office with a requirement to deliver the essentials to the back office enhances the efficiency of both communities.

There is an argument in some circles that there needs to be a single source of truth which can only be provided by a CERP. This is a false assertion when it is claimed. The extensive dispersion of a complex care process delivered by many disciplines with many different technologies has already led to an irreversible distribution

of data across multiple information systems, such as surgery, radiology, pathology, and pharmacy. Advocates for this position, who already operate multiple systems successfully, use this as an argument to exclude evaluating the local systems value. The solution proposed here is to ensure that local systems have appropriate interoperability and support.

The imposition of inefficient and burdensome HIT in clinical workers has led to a Stockholm-like syndrome and worse such as:

> *"It is well understood in psychology that when people repeatedly experience unpleasant events over which they have no control, they will not only experience trauma, but will come to act as if they believe that it is not possible to exercise control over any situation—indeed, that whatever they do is largely futile. Attempts to remedy the operational and social disadvantage of clinicians subjected to inefficient systems depends, fundamentally, on understanding the effects of past trauma and its potentially cumulative effects."* [24]

In summary

- Front-line staff productivity will make greater gains from immediate adaptability than interoperability,
- Organizations will better protect patients with immediate adaptability technology,
- Interoperability, CERP, and best-of-breed systems each represent usability at different types of context, and
- ROI needs to be interpreted and assessed at their appropriate context, and efforts to conflate them into alternative competitive solutions is a misunderstanding of their different contributions.

An Architecture That Supports the Levels of HIT Context

A data architecture to satisfy all the requirements of the three levels of health organizations has to have these features:

Feature 1. Immediate adaptability for the Level 1 context so that patient-facing clinicians can work within a paradigm of continuous process improvement. Intra-interoperability with other non-service clinical departments is useful but not essential in that it enables in-hospital information to be provided in a more amenable manner, but the care of patients will continue regardless of its absence.

Feature 2. Intra-interoperability between specialty clinical systems and service clinical departments for the Level 1 context is useful so that the normal operational care of patients can run smoothly with the service disciplines which service many of specialties with the same service functions such as pathology, imaging, and pharmacy. This local intra-interoperability has for the most part been solved by the use of certain standards such as HL7 messaging and DICOM picture standards. Immediate adaptability has not been strongly advocated by the service clinical departments, probably because of the more routine nature of their work and smaller extent to which the information system capabilities effect their work processes.

Feature 3. Analytics is an important function at each of the levels of HIT context, but it is a different type of analytics for each. Clinical care units need analytics to understand the statistical profile of their operational activities, while a health organization needs analytics to understand the trends of activities aggregated over multiple units of activity, that is, what is common between each of their different clinical units. They also have to investigate the relationships between the costing of activities and the resources they put into those activities. Finally, they need to develop models of future activities to support resource planning and allocation.

Feature 4. Inter-interoperability requires the sharing of data within a large Level 3 organization such as a multihospital organization or a state or provincial government with many disparate health services. These organizations are dominated by the effort at getting data it can standardize for predictive analytics and to identify both acute and long-term health trends, in the first case to react to public health scares, and in the latter case to plan the delivery of health resources at a society wide scale. These orga-

nizations reduce the health organizations data to a "common data set" of limited dimensions, as it is too difficult to get data from many different types of health organizations to do anything that might be more reliable. The interoperability problem at this level is much greater than at the intra-level because there is a large number of organizations to deal with and so the complexity of the task is exponentially larger than at the intra-level. Adaptability of clinical information systems is of little consequence at this level because they are only dealing with a synthesis of data collected from many diverse settings. Often this is the level at which HIT acquisitions are determined and hence the success of CERP vendors who appeal to the HIT problem at this level.

We are advocating for a new architectural configuration that embodies methods for tackling these problems. The inherent notion is to change the common architecture of the Level 2 context so that it has the benefits of the Level 1 architecture without its drawbacks for Level 2, and the benefits for the Level 2 context without the disadvantages it creates for the Level 1 users. Conceptually, this requires a shift to a new viewpoint of CIS architecture in that it inserts the ideas of immediate adaptability, user-controlled design, native interoperability, and in-built analytics into the debate and aligns those ideas with the established technology of data warehousing.

The Architecture in Practice: Clinical Care Information Systems (CCIS) and Clinical Services Information Systems (CSIS)

We define two classes of health information technology (HIT): Clinical care information systems (CCIS) and clinical services information systems (CSIS). The CSIS are systems required by most of the clinical departments in a hospital setting such as surgery, pathology, radiology, pharmacy, and EMR. The CCIS are the systems required by the clinical specialties that in the past have used best-of-breed solutions but now are being swept into the EMR vortex. Crucially, when they are drawn into an EMR solution, they lose the ability to have the system adapted to their needs, and they are provided with workflows that predominantly make their work less efficient, require more manpower, and lead to much pushback.

Effectively, the work of a data warehouse is being harnessed to serve the work of a dynamic workplace with shifting practices, workforce, and demands on the capacity to adapt and change. The need for a CCIS solution is readily defined in a few criteria: Immediate adaptability (and hence near real-time adaptation), user-controlled design, native (in-built) interoperability, and in-built analytics. The software engineering solution for these criteria produces a very different type of architecture that creates the optimal blending of function of levels 1 and 2 systems while overcoming most of the drawbacks.

The software architecture as explained below has been implemented after a number years of experimentation and has demonstrated the proposed benefits are real. Underneath these four criteria is a key architectural requirement that the means of designing such systems has to be systemized [25]. The architecture has at its kernel a design tool that enables a user to create a design of an information system, this includes screen design, data flow design, and workflow design. The design is maintained internally in a design database in the form of a design language. Adding new design functions requires adding the capability of describing them to the design team and developing a formal method of expressing them in the design language. Then, the library code needs to be written which is invoked on calling the feature in a particular CIS. The data modeling function is managed internally by the software and is not available for the user to be concerned with or to tamper with. It is a basically an object-orientated strategy using relational stores for the management process. The critical objects are the screens or forms into which is embedded the dataflow, workflow, data management, and business rules.

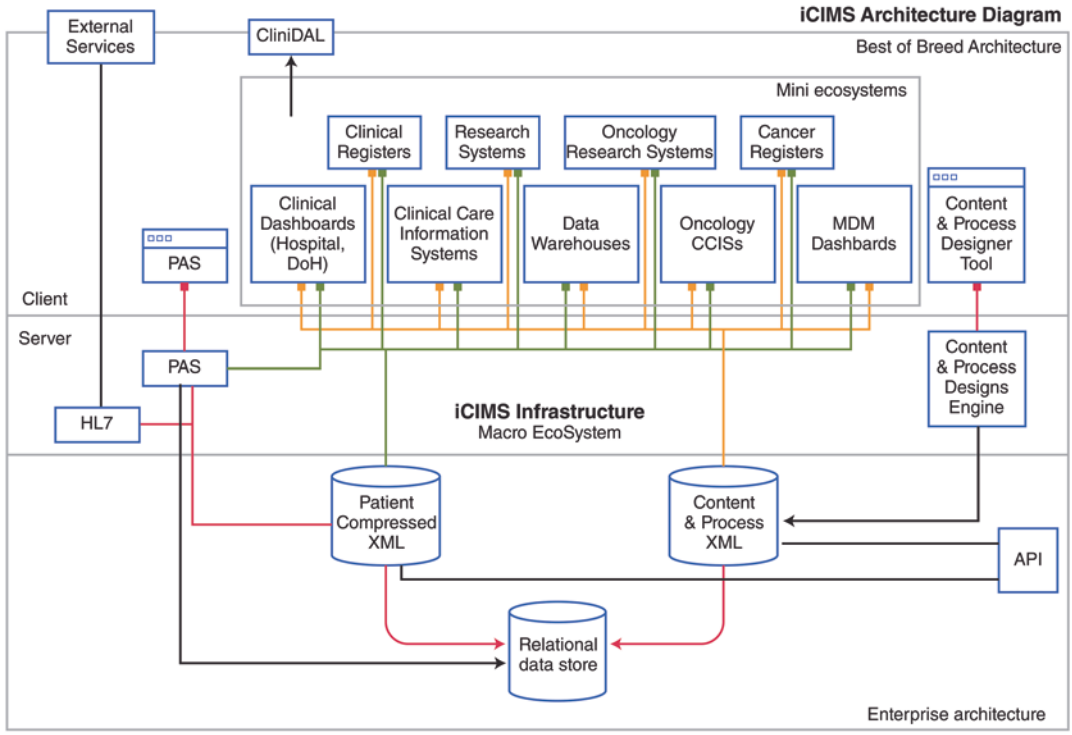

Fig. 16.2 ECIS architecture supporting a variety of clinical information systems within its own paradigm

Years of work since the original publication have solved many of the technical problems and demonstrated that a feasible and practicable solution can be achieved. Figure 16.2 displays the basic engineering architecture for creating multiple CISs in the one software environment and the access to the data via APIs, HL7 messaging, and a clinical data analytics language (CLINIDAL).

There are some interesting emergent properties from this approach that strengthens its merits:

Property 1. Painless expansion and incremental design: Firstly, a system runs by invoking the design which is executed by a library function. A system that is defined entirely by the act of design intrinsically means that only the design has to be changed to create a new function in the CIS. Subsequently, a design can be prepared to cover a minimally necessary amount of workflow and then be added to regularly over time. This in effect enables a system to be not only a mechanism for experimental design with a roll back that can be executed at any time, but also a strategy for incremental development where after completing and operationalizing one subsystem the next most suitable subsystem can be chosen for implementation.

Property 2. Multisystem design on the one software platform: With a functionality to continuously expand one system, it is entirely possible to create a different clinical system on the same platform. There are an unlimited number of CISs that can be created and operate from the one software installation. So although this architecture is a pseudo-best-of-breed technology, it is also a multi-best-of-breed solution, effectively allowing users to create systems *as if* they are wholly autonomous, but all the while the underlying infrastructure is using the same code and data management strategies behaving like an enterprise architecture.

Property 3. User-controlled design: It is an advancement on user-directed design that enables the user to specify exactly the design they want. It is often the case that users don't understand what they really want until after they have been disillusioned by being delivered something they thought they wanted. With real-time adaptation, the user can experiment with designs to their own knowledge depth and revert to older designs if new ones are proven to be non-optimum.

Property 4. Rapid prototyping: The ability to modify implementations at will means that prototypes can be built rapidly, tested, adapted, and generally system development be progressed at a faster rate than other technologies.

Property 5. Automatic version control: The design is implemented in such a way that it stores all versions of all designs; this includes screen designs, embedded business rules, data flows, and workflows. Hence, all version control is an in-built feature of the design tool, and reversion back to an earlier version of the system can be achieved by just nominating the version number.

Property 6. Universal data storage: Because all CISs built within this paradigm use the same design language and storage management functions they all use the same data storage to preserve patient data. Hence, all systems have access to all other systems data provided appropriate permissions are set.

Property 7. Universal attribute coding: To ensure that data elements can be semantically shared the system has a mechanism for identifying a variable by its SNOMED CT concept identifier, or any other useful data standard the user wishes. In this way, the semantics of data fields between systems is well defined making data sharing much more reliable.

Property 8. Radically reduced maintenance: An interesting emergent property of this paradigm is the significantly reduced software maintenance required for the installed software. This approach effectively separates the process of CIS design from the preparation of executable program code. The design is the responsibility of the clinical team and the software that of the software team. There is very limited overlap and the software team does not have the workload of understanding or managing the system design. They are only required to ensure the code computes correctly.

Figure 16.3 demonstrates the manner in which the EMR can be repurposed as a data warehouse and the clinical care and clinical services can fulfil their own roles while delivering information to each other and to the EMR as each needs.

This technology supports a methodology for creating user designs with an incremental iterative feedback process. We denote the underlying architecture, as Emergent Clinical Information Systems (ECIS), which automatically uses a predefined run-time library of code to directly execute the user designs; hence, no programming is required to move from design to implementation. The ECIS architecture is defined on the principle of *Ockham's Razor of Design*, *i.e.,* the principle that simplicity is preferred to complexity in *design*, so that given the choice between functionally and simplicity, simplicity will always take higher consideration. In the ECIS, this means that the elements of design that are engineered for the designer are a minimum number of design objects with maximal generalization [25]. The CIS design is created by a principle of *Agile Design* where designs are created and tested incrementally within an iterative process.

With this functionality, the capacity to make near real-time adaptation of an implementation is made available, giving enormous power to the design team to explore alternative designs before commissioning a specific implementation. At the same time, the underlying data management for all CISs built in the ECIS paradigm is the same, and hence it has the unification of the code base and data stores in a single application. In essence, it is a best-of-breed solution on the user side and an enterprise system on the server side. The ECIS model with user-controlled design, real-time changeability, native interoperability to move data from the collection process to where it has to be reused, and in-built analytics to monitor the effect of change represents a much superior approach to providing effective methods for Clinical Process Improvement (CPI) in any clinical setting.

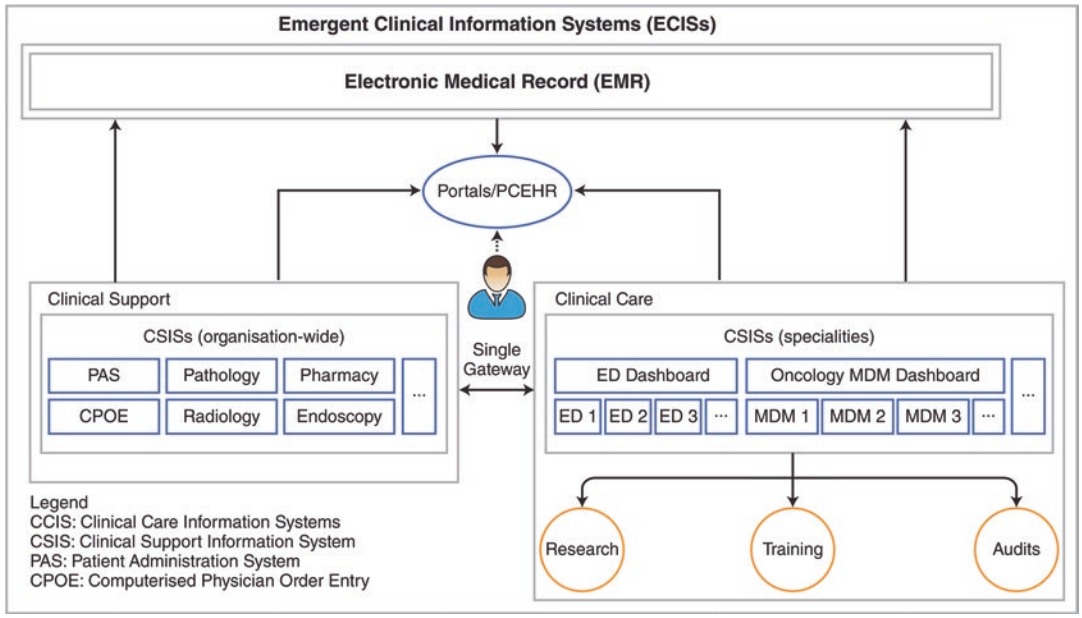

Fig. 16.3 An ECIS configuration with an external EMR acting as a data warehouse and other clinical service information systems (CCIS)

Case Study Results

The system development approach espoused in this chapter has been tested in a practical setting with the development of a number of oncology systems but by far the largest is an Emergency Department Information System (EDIS) at Nepean Hospital, NSW, Australia. A prototype of the idealized technology was built and subsequently the ED staff created their ideal design for an EDIS that was optimized for their environment. The system was denoted as Nepean Emergency Department Information Management System (NEDIMS). NEDIMS performance was compared to the incumbent CERP, from one of the large international EMR providers. A full report on the project has been prepared and is available on request [26], and some of the results most pertinent to emergency medicine have been published [27] which is followed by an editorial on the merits of the technological approach [28].

The evaluation of the NEDIMS system had these objectives:

1. Assess the capacity of staff to design their own CIS;
2. Assess the capacity of the ECIS technology used for the design process to satisfy all the demands of the design team;
3. Assess the differences between the NEDIMS and the CERP for:
   (a) Efficiency of operation;
   (b) Cognitive load;
4. Assess the effect of the clinicians' design on:
   (a) Workarounds;
   (b) Paper processes;
5. Assess the trainability of NEDIMS;
6. Build a model of patient journeys and assess it for differences between NEDIMS and the CERP for that model;
7. Identify the processes of interruptions and consider methods for minimizing them;
8. Make a qualitative assessment of the differences between the two systems for patient safety, staff productivity, and clinical audit;
9. Assess the costs and ease of modifying the system and provide an evaluation of the ROI in making those changes.

A process analysis for each of the six activity centers in the ED is described: Clerking, Triage, CIN (Clinical Initiatives Nurse), Fast Track, Acute Care, and Nurse Unit Manager (NUM). The process analysis formed the basis of understanding the design needs of the department. It was also used subsequently to identify the task types that needed to be used in the quantitative comparison between the two systems. A total of 43 task types were identified of which 27 were present in the CERP system, 40 were present in NEDIMS and 14 were completed on paper.

The department staff were observed for 22 days where each task instance was measured for time duration and number of mouse clicks in live usage on the CERP and paper forms. A total of 722 task instances were recorded from 43 task types. Subsequently, 374 matched observations of 17 task types were measured for those tasks that could be repeated in NEDIMS of which 332 were matched task instances between NEDIMS and the CERP, the remainder being matched to paper forms.

The results demonstrated that NEDIMS is about 40 % more efficient than the CERP using directly measured times and on normalized results greater than 50 % more efficient [26]. NEDIMS was better on 14 out of 16 tasks for time costs of which 7 were statistically significant for NEDIMS and 2 were significantly better for the CERP.

The cognitive load, as represented by click counts, showed that NEDIMS significantly reduced the cognitive load on users by up to 30 % overall. In 9 out of 16 tasks, the NEDIMS required fewer clicks to get the same job done, of which 5 were statistically significant with 5 significantly fewer for the CERP.

A number of workarounds discovered in the process analysis phase of the research were identified and the efforts to eliminate or minimize them in NEDIMS revolved around the current workflow processes of the department. For instance, terminals were used by multiple staff but they often would leave the terminal due to interruptions or to collect other information. When they return to the terminal, they assume that the current session is under their own account when in fact, in the time of their absence from the terminal, another staff member needed the terminal and switched accounts. The first user continues entering data into a patient record without realizing they are working under the name of a different staff member, which becomes apparent when they have to try to save and commit the record and they do not have the password of the logged on user. As a result, they sometimes need to redo potentially long tasks such as ordering tests after restarting the system with their own credentials. NEDIMS implemented a validation step of "signing off" that allowed switching accounts seamlessly.

A model of patient journey through the department consisted of four scenarios of short and long Fast Track patients and short and long acute care patients in a proportional ratio of 15:15:30:30. The resulting analysis showed that NEDIMS would provide a staff time saving of on average 23.9 h per day [26].

A qualitative analysis of opinions from staff comparing the two systems on three key performance criteria of patient safety, staff productivity, and clinical audit over 19 tasks, giving a total of 57 cases. It showed NEDIMS was ranked higher on 39 cases, the CERP for two cases; the two systems were equal for 15 cases and one case non-determinable.

The time cost of the effort in remodeling the designs showed that the time-savings were returned within a few days to a week of operations in the department; hence, the return-on-investment indicates a high yield under the ECIS methodology. The total cost of designing and testing NEDIMS amounted to about 140 person days, which will be regained by the department after about 50 days of operations.

Finally, here is the conversation that transpired between the process analyst who helped install a cancer CIS using this technology and clinical staff at the St. George Hospital, Sydney, a sister hospital to Nepean Hospital in New South Wales, Australia, about the impact of the ECIS methodology in supporting their EMR needs:

> *Senior Nurse: "I am the worst person in the unit for IT, I know nothing about it and if anything will go wrong it will happen with me."*
>
> Process Analyst: *"I spent a lot longer than I would normally explaining the system, about 10–12 minutes then I got her to go through the whole system and there was not one problem."*

Subsequently after system testing Senior Nurse, *"you know I think it is so good I could have gone through the whole system without your help. This is great because it is just the way we imagined it would be and it is exactly the way we work."*

Conclusions and Some Observations About the Future of HIT

Engaging and supporting clinical staff in the design and testing processes of HIT, in a manner that reflects their local workflow processes, ensures it is better suited to their needs and will be a better aid to their work than an incumbent CERP system. Information systems designed for and by a clinical team using a technology that enables real-time adaptation provides much greater efficiency for the staff in decreasing the time to complete standard tasks. Additionally, it creates a continuous process improvement environment that enables the workflow processes to be adapted dynamically to optimize the efficiency improvement, and the ECIS technology enables measurement and recoupment of the costs of supporting the ongoing adaptation of these processes.

The ECIS model of system development posits that a system is never "truly complete" but rather it is evolutionary, being stable for certain constraints and time and nimble enough to be changed as the clinical ecology around it changes. ECIS provides an efficient and inexpensive methodology on which to achieve those changes. Hence, the point in time when a system should be commissioned is when the community of users believes it can give them efficiency gains without unacceptable negative downsides. From that point on, it needs to be added to at will with few barriers to innovation. Indeed, the community of users can reliably identify the next most valuable activity to computerize in order to gain the maximum efficiency given their system's current capabilities. Such egalitarian decision-making makes for an orderly and systematic progression in computerizing their work activities and ensures much higher engagement [29]. Hence, the ECIS model is a new paradigm, a credible alternative to a large-scale sudden-death system changeover using many foreign, impractical workflows. It capitalizes on local knowledge and wisdom, flexible work practices and heuristics, and optimizes the local environment in contrast to clunky, slow moving enterprise solutions.

The ECIS technology enables a new HIT architecture that propels the needs of the patient-facing staff to the forefront of the HIT, which can bring significant advantages in efficiency and ROI for health organizations as well as enhancing workplace satisfaction. The shifting of emphasis on the role and function of HIT requires a shift in perceptions on how to utilize whole-of-organizations CERP installations. This means being thought of more as a data warehouse, something that such systems are more akin to and can serve better the needs of organizational infrastructure.

References

1. Patrick JD, Ieraci S. Good HIT and bad HIT. Med J Aust. 2013;198(4):205. doi:10.5694/mja12.11350.
2. AMIA Implementation List is a discussion group of many of the leading Health Informatics specialists. Almost on a weekly basis the difficulties of using CERP systems is discussed.
3. Rodríguez B, Moiduddin A, Ketchel A, Mohr J, Williams J, Benz J, Gaylin D, Fitzpatrick M, Barach P. EHR final report on case studies and state-wide IT survey analysis. Report submitted to the Florida Agency for Health Care Administration (AHCA), 29 June 2004.
4. Patrick J. The validity of personal experiences in evaluating HIT. Appl Clin Inform. 2010;1(4):462–5.
5. Barach P. Final report on the recommendations for implementation of the Florida Patient Safety Corporation, Florida Safety Network, 29 June 2004.
6. Andresen K, Gronau N. An approach to increase adaptability in CERP systems. In: Managing modern organizations with information technology: Proceedings of the 2005 Information Resources Management Association international conference, 2005.
7. Conrad M. Statistical and hierarchical aspects of biological organization. In: Waddington CH, editor. Towards a theoretical biology, vol. 4. Edinburgh: Edinburgh University Press; 1972. p. 189–220.

8. Barach P. An organizational social technical review of the CTI standards recall process at NEHTA, National E Health Transition Authority, April 2012.
9. Staggers N, Xiao Y, Chapman L. Debunking health IT usability myths. Appl Clin Inform. 2013;4(2):241–50.
10. Ash JS, Sittig DF, Dykstra R, Campbell E, Guappone K. The unintended consequences of computerized provider order entry: findings from a mixed methods exploration. Int J Med Inform. 2009;78:S69–76. doi:10.1016/j.ijmedinf.2008.07.015.
11. Karsh BT, Weinger MB, Abbott PA, Wears RL. Health information technology: fallacies and sober realities. J Am Med Inform Assoc. 2010;6:617–23. doi:10.1136/jamia.2010.005637.
12. Koch S, Westenskow D, Weir C, Agutter J, Haar M, Gorges M, Liu D, Staggers N. ICU nurses' evaluations of integrated information integration in displays for ICU nurses on user satisfaction and perceived mental workload. Pisa, Italy: Medical Informatics Europe; 2012.
13. Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL. Role of computerized physician order entry systems in facilitating medication errors. JAMA. 2005;10:1197–203. doi:10.1001/jama.293.10.1197.
14. Koppel R, Wetterneck T, Telles JL, Karsh BT. Workarounds to barcode medication administration systems: their occurrences, causes, and threats to patient safety. J Am Med Inform Assoc. 2008;4:408–23. doi:10.1197/jamia.M2616.
15. Barach P. Human factors and their impact on patient and staff outcomes. In: 11th International conference on rapid response systems and medical emergency teams, 2014.
16. Mohr J, Barach P. The role of microsystems. In: Carayon P, editor. Handbook of human factors and ergonomics in health care and patient safety, handbook of human factors and ergonomics in health care and patient safety. Mahwah: Lawrence Erlbaum Associates, Inc.; 2006. p. 95–107.
17. Barach P, Chiong LW. Impact of electronic medical records on the clinical practice of medicine. The College Mirror, College of Family Physicians, Singapore 2012; 38:16–8.
18. Barach P, Phelps G. Clinical sensemaking: a systematic approach to reduce the impact of normalised deviance in the medical profession. J R Soc Med. 2013;106(10):387–90. doi:10.1177/0141076813505045.
19. Jensen PF, Barach P. The role of human factors in the intensive care unit. Qual Saf Health Care. 2003;12(2):147–8.
20. Barach P. The impact of the patient safety movement on clinical care. Adv Anesth. 2003;21:51–80.
21. Johnson J, Barach P. Quality improvement methods to study and improve the process and outcomes of pediatric cardiac surgery. Prog Pediatr Cardiol. 2011;32:147–53.
22. National E health Technology Agency, NEHTA. Delivery quality assurance, SMS, management and technology, April 2012.
23. Barach P, Cosman P. Teams, team training, and the role of simulation. In: Barach P, Jacobs J, Laussen P, Lipshultz S, editors. Outcomes analysis, quality improvement, and patient safety for pediatric and congenital cardiac disease. New York: Springer Books; 2014. ISBN 978-1-4471-4618-6.
24. Adapted from Carmen Lawrence's essay "The memory ladder: learning from the past, living with doubt", published in Griffith Review 51: Fixing the System, edited by Julianne Schultz and Anne Tiernan.
25. Patrick J, Budd P. Ockham's razor of design. In: Proceedings of the 1st ACM international health informatics symposium, Washington DC, Nov 2010. http://portal.acm.org/citation.cfm?id=1882998&CFID=116605072&CFTOKEN=43603995.
26. Patrick J, Besiso A. Comparative appraisal of Nepean Emergency Department Information Management System (NEDIMS) versus a clinical ERP (CERP). White paper, June 2014, iCIMS. www.icims.com.au/publications. Accessed 6 June 2016.
27. Bishop R, Patrick J, Besiso A. Efficiency achievements from a user-developed real-time modifiable clinical information system. Ann Emerg Med. 2015;65(2): 133–42.e5. doi: 10.1016/j.annemergmed.2014.05.032.
28. Wears RL. Health information technology and victory. Ann Emerg Med. 2015;65(2):143–5.
29. Phelps G, Barach P. Why the safety and quality movement has been slow to improve care? Int J Clin Pract. 2014;68(8):932–5.