

Part A. General and Institutional Framework for the Development of Healthcare Information Systems

The first glance at History convinces us that the actions of men proceed from their needs, their passions, their characters and talents; and impresses us with the belief that such needs, passions and interests are the sole spring of actions.

Georg Wilhelm Friedrich Hegel (1770—1831)

A.1. Conceptual Framework for Information Systems Development

Information Systems and related Technology (IS&T) are necessary in order to create, "democratize", and apply knowledge. Information systems function at many levels of sophistication and complexity — from very specific to very general. The goal is to improve the health of individuals and populations through the appropriate application of knowledge created through organized information systems.

Before embarking in the process of setting up information systems, one must clearly and explicitly identify the objectives of the system, i.e., determine the expected results. The following questions must be answered regarding what is desired from the information system: is the objective to facilitate care?; are the implemented systems going to be used to manage resources, in this case from a single organization or for the whole healthcare system?; is the system going to be utilized to allocate and control resources?; are the systems expected to contribute to preventive care and in the promotion of health of a defined population?

In order to ensure that Information Systems add value (i.e., *do something good* and "*keep one out of trouble*") by implementing systems that are the best possible answer — technically, cost-wise, and deployed effectively — *it is necessary to follow a defined and logical process*. Also, one must be aware of the technical, human, and financial resources required to carry out each stage of the process.

A.1.1. Concepts and Goals of Information Systems in Healthcare Delivery Organizations

When dealing with the issue of Healthcare Information and Technology, it is useful to start by defining certain terms. The most common term in use to refer to information systems for the support of the operation and management of healthcare services is *Healthcare Information System (HIS)*. Although

some experts have advocated abandonment of this common term, it is ubiquitous and simple enough to prove useful for the present discussion. A Healthcare Information System may be defined as a computerized system designed to facilitate the management and operation of all technical (biomedical) and administrative data for the entire healthcare system, for a number of its functional units, for a single healthcare institution, or even for an institutional department or unit.

The establishment and operation of an information function component in the context of organizations involve the development and management of three interrelated areas: Information Systems (IS), Information Technology (IT), and Information Management (IM).

- *Information Systems (IS)* — Represented by the collection of administrative and technical tasks realized with the objective of ascertaining the demand for the application portfolio of the organization. Information Systems are, therefore, concerned with “what” is required (demand issues).
- *Information Technology (IT)* — Represented by the collection of technical knowledge and tasks with the objective of satisfying the demand for applications. It involves creating, managing, and supplying the resources necessary for the development and operation of the applications portfolio of an organization; it is concerned with “how” what is required can be delivered (supply issues).
- *Information Management (IM)* — The strategic organization-wide involvement of four components: data, information systems, information technology, and information personnel.

Information Technology (IT), in a more strict sense, is a machine-based technology that actively processes information. IT is just one of a set of information-related technologies that share some characteristics. The definition, however, does not separate active information processing from other technologies, such as the telephone and the television, and from non-technological information-handling activities.

The special characteristics of IT — hardware and software, — as “physical” and “abstract” machines distinguish it from other similar technologies. Hardware and software are alternative yet complementary aspects of IT; both aspects are required for any IT system and they share a flexible symbiotic relationship. Further, the development of new instances of IT depends directly on existing hardware and software, among other factors, meaning that IT is essential to its own development.

Health information systems, to be useful, must allow for a wide scope of health data. Information is an essential element in decision making, and the provision and guidance of healthcare are a complex enterprise, highly dependent on information for a great variety of clinical and managerial decisions. To be useful, information systems must capture and process health and health-related data of broad diversity, scope, and level of detail. All organizations have always had some form of information system to help them record, process, store, retrieve, and present information about their operations.

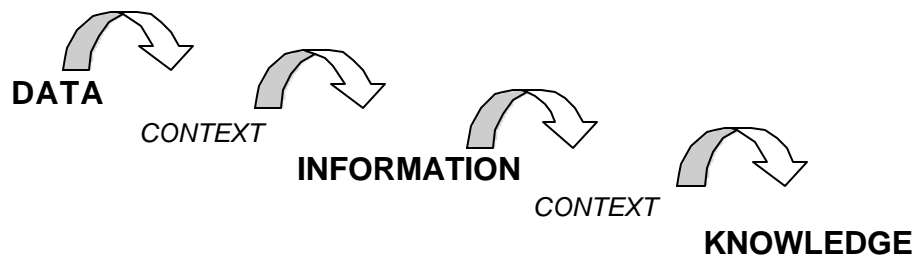
At all sector levels, the greatest need remains the establishment of continuous information systems that enable the recovery of patient-oriented, problem-oriented, and procedure-oriented data. It has been only in the last twenty-five years that organizations have come to realize that information is a most valuable asset — the quality of managerial decision making, which depends on their success in a very competitive world market, is directly related to the quality of the information available to their managers.

This realization has been gradually forcing organizations to perceive information systems in a different light, more as decision-support tools than as mere registry of past activities. Information systems are, accordingly, gradually moving out of the "back room" to which they have for so long been relegated and into the "front office" of executive suites.

Information, and the technology used to support its acquisition, processing, storage, retrieval, and dissemination, have, as a consequence, acquired strategic importance within organizations, ceasing to be elements that had to do only with operational and administrative support. The ultimate goal of computerized information systems is to improve the way we work, by increasing efficiency, quality of data, and access to stored information.

The technological basis of automated information systems is the computer program — the application software — that enables us to achieve that goal. Application, in broader terms, is defined as the use of systems resources (equipment, computer programs, procedures, and routines) for a particular purpose or in a special way to provide the information required by an organization. All hardware and operating systems, however, are worthless without properly designed and written programs that address and answer, as completely as possible, the requirements of users.

Figure 1. Data, Information, and Knowledge Relationships



The role of information systems is to capture, transform, and maintain three levels of facts: raw data, processed data, and knowledge. Processed data, traditionally referred to as *information*, conveys intelligence about a particular topic. Knowledge represents an intellectual construct of a higher order, where evidence and information from various fields and sources are linked, validated, and correlated to established scientific truths and thus becoming a generally accepted body of wisdom. We could say that information is data in context and knowledge is information in context (Figure 1).

A.1.2. The Process of Setting Up Information Systems

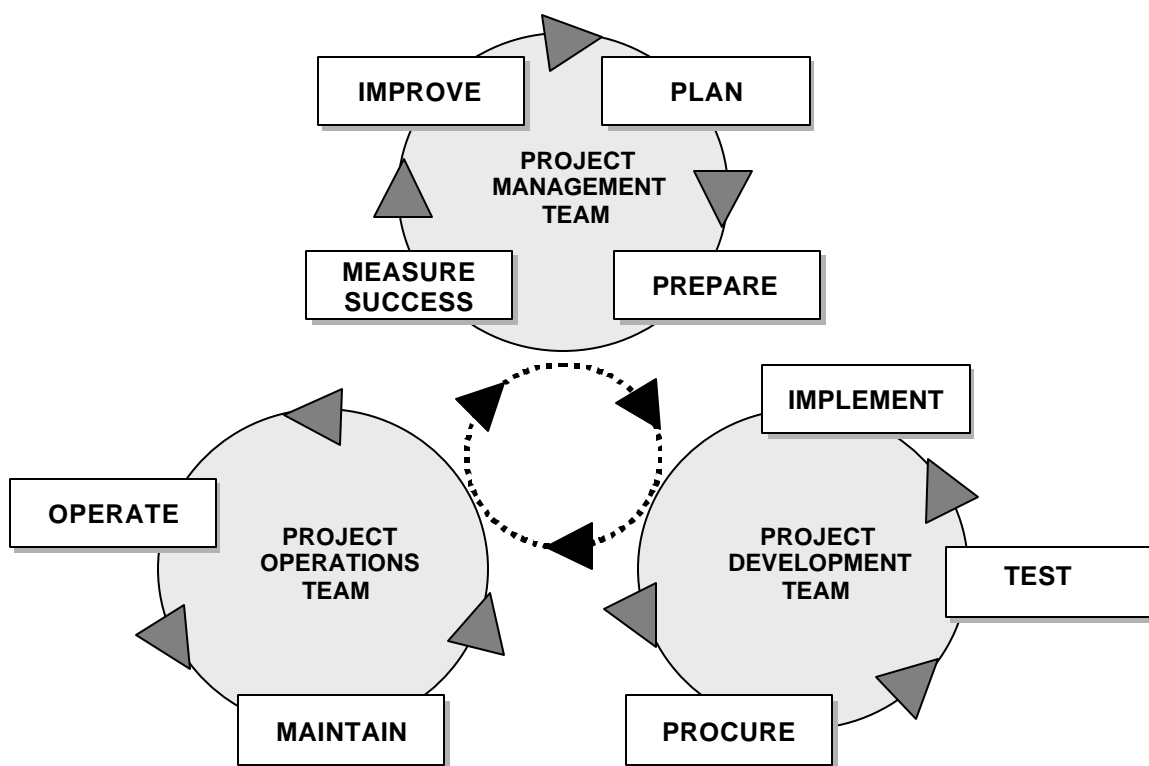
Development and implementation of information systems is seen by many decision makers as a paradoxical mixture of opportunities to harness modern solutions and gain new technology and, at the same time, an intimidating situation, as they become aware of the limitations of their own understanding and knowledge of the variety and complexity of issues brought forth by IS&T. From the

identification of the simple essential steps through to reference material on many technical details there is a wealth of available published materials to assist in those processes.

Fundamental to the understanding of the process of setting up IS&T is the concept of added value — all participants must get out of an information system at least as much as they put in, as well as the system — it must generate benefits greater than its own cost, otherwise the system by definition becomes a burden. Information systems are almost totally dependent upon the staff who provide and record the information, yet these are usually the lowest valued and least involved. If this fact is not recognized and benefits realized for these contributors, there is a high probability of building inaccuracy, instability, and future failure into any information system. Good practice and positive guidelines do exist and some are reproduced in this Guide, along with lists of positive learning points as well as warnings of hazards to avoid.

A.1.2.1. The Process

Figure 2. Dynamics of the Process of Developing and Operating IS&T



The nine components (Figure 2) involved in developing, deploying, and operating IS&T are:

- Plan
- Prepare
- Procure
- Test
- Implement
- Operate
- Maintain
- Measure Success
- Improve

There follows a brief description of each of the first three components (Plan, Prepare, and Procure), which are pertinent to the initial phase of systems development. They will be discussed in detail throughout this document.

Component 1. PLAN

- [a] Define knowledge needs
 - define information outputs
 - define data needs and sources
- [b] Define scope of the project
 - is it too large?
 - is it feasible?
- [c] Understand legacy information systems — electronic or not
- [d] Do cost/benefit analysis (business case)
- [e] Identify Resources
- [f] Do process analysis
- [g] Identify appropriate technical experts
- [h] Define users
- [i] Define indicators of success
- [j] Ensure top level commitment
- [k] Define project management methodology
 - all viewpoints
 - business
 - technical
 - user
- [l] Identify Change Agent
 - is there someone with the SKILLS internally or externally?
 - respected
 - knowledgeable
 - energetic

Component 2. PREPARE

- [a] Design new/refined processes (if required)
- [b] Designate project director
- [c] Define functionalities required
- [d] Identify training needs (immediate and continuing)
 - IT staff
 - operations staff

Component 3. PROCURE

- [a] Write RFP specifications
 - technology
 - capabilities
 - training
 - accountabilities (both parties)
 - maintenance needs
 - project management responsibilities
 - vendor
 - purchaser
 - guarantees, etc.
- [b] Prepare negotiation strategy - "buy", don't be "sold"
- [c] Prepare proposal evaluation and selection process
- [d] Identify possible vendors
 - advertise
- [e] Distribute RFP
- [f] Short list responses
- [g] Demonstrations on site - define expectations
- [h] Select according to predefined process
 - ensure decision is defensible
- [i] Manage unsuccessful vendors
- [j] Write contract

A.1.2.2. Standards — the Principal Strategic Issue

The most important strategic issue in information systems is standards. Data processing, technical, and electronic standards are essential if equipment is to be able to interconnect. Data definitions and terminologies will be essential if health professionals are to communicate. Specific technical components such as the recording and transmission of images have their own international standards. And in the country-specific setting, the requirements for statistical and other analyses to be passed upwards to support informed decision making must be compatible and follow specific standard definitions.

This Guide gives a wide range of references to international standards, enabling local decision makers to draw directly upon best international practice. Failure to adhere to open technical standards will result in isolated "islands of automation"; failure to adopt data and terminological standards will result in "islands of information". Only compliance with recognized standards, which are too complex for local development, will ensure an integrated information system.

A.1.2.3. Cost-Benefit Analysis

The only justification for any information system, or particular component, is that the benefits justify the costs. Those benefits must be identified, being justified not only in monetary terms but also considering improvement of access, quality of care, better return of resource utilization, better clinical end results, user satisfaction, and improvement of the overall community health status.

There may be more than one way of meeting an information need; there will almost certainly be competing calls for application of information system development funds; and there will certainly be other competing demands such as for diagnostic equipment or increased pharmaceutical supplies. Given limited and finite resources, the right decisions can be reached only by appraising the alternative options to see which gives most added value, as well as being affordable within budget.

A.1.2.4. Incremental Development

Rarely can one develop a complete Information System in less than two years. Even in the most industrialized countries, where fully integrated electronic patient record systems are appropriate in very large hospitals, attempts to specify and implement major systems in one exercise have been fraught with difficulties and have often gone seriously over budget. A stepped approach, adding compatible components in a phased basis, has major attractions.

A.1.2.5. Stakeholder Support

Obtaining the support of key stakeholders and their interests is essential. Good and bad experiences abound; Canada has considered it worthwhile to invest heavily in identifying local views and obtaining stakeholder support — by contrast, the Department of Health in England minimized this step, which led to mistrust of some of the perceived objectives and technical standards of the strategy and consequent definition of requirements and project implementation delays. Key amongst stakeholders are staff, whose understanding and commitment are essential to information system success, commencing with the data recording process. In the U.S. a high failure rate of technically sound medical information systems has been identified due to user or staff resistance. Systems must therefore be defined, then procured or developed, using organizational methods that are openly focussed on all user needs.

A.1.2.6. Security and Confidentiality

Given the very sensitive nature of health care information, and the high degree of reliance by health professionals in particular on reliable records, security and confidentiality must be seen to be clearly and effectively addressed. Security relates to the physical safety of information, including protection against accidental loss as well as against unauthorized alteration. Confidentiality relates to ensuring that only persons with a clinical responsibility see patient-specific information. At the same time, the regulations and technical standards developed must be realistic in terms of recognizing the realities of health care delivery.

A.1.2.7. Education and Training

The importance of education and training cannot be overemphasized. Education relates to change in professional practice, as information systems often give opportunity to work in a new and more appropriate manner. This can apply as much to finance staff, maintenance staff, and pharmacists as it can to clinical health professionals, and the education in new ways of healthcare practice must be undertaken through professional channels. Training, on the other hand, is specifically related to the information system itself, for which all staff must be trained on how to use the equipment, how to enter data, and how to get out appropriate analyses. Training in particular must be ongoing, both to give update training as staff become more familiar with the system and wish to make better use of the functionality, and also to ensure that new staff are trained in information system use as part of their induction training.

A.1.2.8. Project Management

Information systems projects are notorious for running over-time, and over-budget, yet often still failing to deliver all the specified functions satisfactorily. This could be largely avoided by effective project management, including planning, quality assurance, and resource management components. Obtaining an effective system is not simply a process of competitive tendering, local development, or acceptance of an externally funded donated system. The procurement process should be planned and structured, in order to match the solution to the need and circumstances. This in turn needs a systematic approach to defining the requirements and the available resources, including running costs and staff availability.

A.1.2.9. Ongoing Evaluation and Development

Information systems must never become static, or they lose their value. The context in which they operate, the clinical patterns they support, and the policy environment will all change, and therefore so must the information systems. Additionally, the development and progressive roll-out of new technical infrastructures means that new opportunities will also arise, which should be exploited when cost-benefit analysis shows this to be justified. Scientific evidence from formal evaluations should be

sought for any health information technology application. Equally important, and more within the control and responsibility of the operational implementing organization, is ensuring that information systems are evaluated and adjusted in the light of how they are perceived, and how they change practice within the organization, and ultimately change the organization itself. Evaluation of the use and effects within the organization should therefore start from the time of implementation, using structured approaches.

Beginning Automation: A Case Study

Background

A hospital of 120 beds, located in a major city, decided to automate information. At the time, the hospital had two desktop computers and three laptops, and only a few of their personnel knew how to use a computer to perform basic tasks. The administration was willing to make another effort to create a network to automate all the information. It is important to mention that the same administration had tried to develop systems in the past few years, but the vendors had provided solutions that led to poor results, creating a very skeptical environment for any new companies trying to offer products or services.

The Plan

Needs assessment is performed and creation of a three-year project is suggested to the administration, following priorities and budget limitations:

1. First-year objectives were to buy some workstations, start training personnel, and to develop a Human Resources/Personnel and a Financial-Billing module.
2. Second year, start installing a network and initiate the development of an Admission module and Medical Inventory.
3. During the third year, integration of all the modules and completion of training all the necessary personnel.

Results

The first year of the plan started on schedule, equipment was bought, training was provided and requirements were gathered for the HR/Personnel and Financial-Billing modules. Development of the modules started slowly due to the lack of experience of some engineers, and precious time was lost setting standards and getting everyone at the same level. Modules were implemented on schedule.

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In the second year there were problems with the budget, several months were lost, and installation of the network was left behind. The Admission and Medical Inventory modules were developed and implemented. By the end of this year, people were getting tired and the interest from management and employees was very low.

Training was provided for the new modules but problems persisted because employees were expecting that the modules would make work easier and not so much detail oriented and complex. Also, duplication of data and concomitant added effort to record data was being questioned by some employees.

At the beginning of the third year, problems with the quality of data started to appear. Employees were careless about data entry and management was getting reports with very questionable results. Management started to question the quality of work of the modules and the integration was postponed. A few months later the administration of the hospital changed, and due to the questionable results of the data in the modules, no priority and budget were assigned for the next year.

Commentary

Expectations in data automation are too high in many of our institutions. It is incredible the amount of money and effort involved not only in development but also in maintenance and training in corporations and governments. This amount of effort never ends, technology is taking us into a very complex environment where only the people with a realistic, systematic, and objective-oriented vision will accomplish the goals and expected results proposed for IS&T implementation.

Lessons Learned

- Vendors will provide anything to anyone. Selection of vendors should be done using a very objective evaluation, and by getting professional help to make your selection a successful one. Poor design in computer systems creates future complex automation problems.
- Full commitment from management is indispensable, and integration of employees into the automation process will make for better acceptance of new working procedures, due to a better understanding of the institution goals, while automation will be accepted as a normal process of institutional development.
- Consistency in every automation process is necessary to guarantee good data and analysis information.