# Steps Toward a Universal Patient Medical Record:

## A Project Plan to Develop One

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Universal Publishers
Boca Raton, Florida • USA
2004

ISBN: 1-58112- 509-7

www.universal-publishers.com

# Preface

Why develop a *universal patient medical record* that would be available to all clinicians caring for a patient no matter where the clinician is located in the world? One should be developed because it would benefit patients and benefit mankind, and because it is inevitable.

Healthcare today is oriented toward short-term treatment of medical conditions. I predict this will change in the near future: medical care will become more long-term oriented, preventing as well as treating disease. This will result in a need for a complete medical history for a patient, no matter where the patient was seen for healthcare in a country, or in the world.

A patient's medical history would include *biomarkers* for disease, where biomarkers have been defined by the National Institutes of Health as "cellular, biochemical, molecular, or genetic characteristics or alterations by which a normal, abnormal, or simply biologic process can be recognized, or monitored."(NIH 2004) An individual's genome could provide permanent biomarkers while other biomarkers may change over time. Through biomarkers, diseases could be predicted. A universal patient medical record is a place where such biomarkers for an individual could be stored.

When the paper medical record was first used, medical care was most often performed by a physician who worked individually in the care of a patient. With managed care, national healthcare, and the great mobility of people moving from place to place, care is no longer given by an individual physician but by many. Even when a patient is assigned to a primary care physician in a healthcare organization, care is still often given in teams, and after the primary care physician sends the patient to a specialist, the primary care physician seldom follows up on the patient's care. In all these cases, there is a need for a universal patient medical record that supports communication between these many caregivers, whether they work together or independently in providing a patient's care or work in different healthcare organizations. A universal patient record should thus be centered around an individual, not a healthcare organization nor any single caregiver.

Today, each physician is restricted to providing care in a very specific geographic location of the world. With telecommunications and telemedicine, this need not be so. Healthcare can be accomplished by a physician located anywhere in the world and a patient located anywhere else in the world. Thus, there is a need for remotely located caregivers to be able to concurrently access the same patient medical record.

As evidenced by the AIDS and SARS epidemics and by global warming, the health of each person in the world can be affected by what happens in other parts of the world. There are too few physicians in the world, too few nurses, and too few other healthcare workers. The world must make better use of all its healthcare workers. This can be accomplished through a universal patient medical record.

There would be a complete, immediately available, medical record. When a patient showed up for care with identification, even when unconscious in the emergency department, a universal patient medical record could provide the health history for the patient, informing caregivers of drug allergies, significant health problems, or other information that could improve care or potentially save the patient’s life.

The universal patient medical record could save money in many ways, including by automatically capturing charges for medical services as they are identified in the medical record, and by allowing discharge activities to be done concurrently, quicker and thus with less cost. Public health organizations, insurance companies, the patient’s personal physician, or other interested parties could be sent information on patient care and charges immediately after care is given or while care is being given, providing information quicker, potentially reducing fraud, providing better care, and quickly identifying public health problems before they get worse. Costs for paper, diagnostic image film, and associated labor, time, and space to transport and store them can be saved.

With a universal patient medical record:

- Better patient care could be provided that avoids medical mistakes due to lack of information due to unavailability of the medical record.
- There would be a single, complete automated patient medical record, rather than many fragmented ones.
- Communications between all types of caregivers would be enhanced, whether they worked on a single treatment for a patient, over many treatments, or over the patient’s lifetime.
- There would a single place to permanently store the lifestyles, environmental conditions, and disease biomarkers for an individual. There could then be greater emphasis on individualized preventive care and diseases could be prevented before they occur.
- The lifestyles, environmental conditions, and biomarkers that predict diseases could be better determined as a result of a research database derived from these complete medical records.
- Healthcare workers could work across borders and provide healthcare and provide mentoring even when they were located remotely from each other, or remotely from the patient.
- Public health agencies, caregivers and the public can be more quickly informed about public health problems.
- Money can be saved.

# Contents

# CHAPTER 1

# Introduction

**CHAPTER OUTLINE**



## 1.1 THE NEED FOR AN AUTOMATED MEDICAL RECORD

Over a patient's lifetime, a patient may be seen in many different healthcare organizations by many different physicians and nurse practitioners, and thus have many separate paper medical records. There is an urgent need to combine these medical records to produce a single *automated patient medical record*.

Such an automated patient medical record could be designed so it could evolve into a patient medical record that could be used by any healthcare organization in the world and any authorized healthcare provider. This book refers to such a patient medical record as the *universal patient medical record,* or *universal patient record* for short.

Various terms have been used for what this book calls the automated patient medical record, including *electronic medical record, electronic health record, electronic patient record, computer-based patient record (CPR),* and *automated medical record*, with definitions that vary from organization to organization. This book views the term automated patient medical record as an evolving entity, so the term is given a broad definition: "Patient medical records available over a network".

## 1.2 APPROACH TAKEN BY THIS BOOK

This book shows in detail how the patient medical record could be automated in healthcare organizations to produce such a universal patient record. As an example healthcare organization where automation would first occur, it uses a *Health Maintenance Organization (HMO)*.

An HMO is a corporate entity that provides comprehensive health care for each member of the HMO for a fixed periodic payment paid in advance by the member or his employer. This

HMO has its own hospitals and medical offices spread throughout the United States. This is a fictional HMO, but is representative of a very large HMO in the United States. A national healthcare system would have many of the same characteristics as such an HMO, and thus what the reader reads in this book could equally apply to such a national healthcare system.

Because such an automated patient medical record on a large-scale does not yet exist and there may be many forms that it might take, simply describing such a patient medical record in detail would be presumptuous at this time. Instead, this book presents a *project plan* for development of an automated patient medical record in an HMO that could evolve into a universal patient record and presents possible and alternative results of this development effort. This book shows how a universal patient record is likely to evolve and how an automated patient medical record should be designed from the very beginning to be compatible with such a universal patient record.

A project to create a universal patient record, or even an automated patient medical record, is a very large one. This book defines a *project* as a well-defined sequence of steps—with constraints on time, costs, resources and quality—that leads to a clear set of products and goals. The product of our project is an automated patient medical record in an HMO that could evolve into a universal patient record. A *project plan* is a plan to do a particular project.

This project is a very complex one. To do it well, the resulting automated patient medical record must be looked at from **many different points of view** that must be **consistent with each other**. Some of these many mutually consistent points of view are the following: business, patient care and best medical practices, public health, project management and costs, universal patient record, healthcare and computer standards, current and future technology, law and legislation, caregiver workflow, user interfaces, computer software and hardware systems, and research.

## 1.3 INTENDED READERSHIP

The intended readership of this book are healthcare professionals: physicians, nurses and other caregivers, and healthcare organization managers and public health analysts. The intended readership also includes business and computer professionals: business analysts, system analysts, database analysts, and project managers. More specifically the intended readership of this book is anyone who is interested in the field of *medical informatics*, the use of computers in medical care.

## 1.4 ORGANIZATION OF THIS BOOK

The next chapter of this book describes in detail how to do any large-scale healthcare project and presents logical steps in such a project. Each chapter thereafter describes a step in a project to develop the automated patient medical record; these chapters each begin with a section labeled "project context" that describes the step in the context of a project.

Throughout the book, important terms will be italicized with these definitions included in the glossary. Because healthcare standards are important to doing any healthcare project, current healthcare standards are presented in the appendix.

Also presented throughout this book are *models,* where a model is a simplified description of a complex process. For example, the models in this book include the following:

- Models of patient care

- Models for doing a complex project

During a project, a model of the project's systems, workflows, or other products as agreed upon so far in a project can be created. This book calls such a model a *conceptual view*. A conceptual view is a vehicle for communication and critique of a project that is updated as more agreements are made on the products of the project.

## Key Terms

automated patient medical record
computer-based patient record (CPR)
conceptual view
electronic health record
electronic medical record
electronic patient record
medical informatics
model
project
project plan
universal patient medical record
universal patient record

## Study Questions

1. What are other terms for an automated patient medical record?
2. A medical record is centered around what? A healthcare organization? A provider? A patient? A medical department? Discuss.
3. What is the universal patient record?
4. What is a project? What is a project plan?

# CHAPTER 2

# How to Do a Large-Scale Complex Healthcare Project

**CHAPTER OUTLINE**



## 2.1 A LARGE-SCALE HEALTHCARE PROJECT

This book describes how to do a project to create an automated patient medical record in a large health organization that could evolve into a universal patient medical record. This is a very large-scale complex project. This chapter describes in detail how to do any large-scale project in a healthcare organization and provides the structure for the remainder of this book. This chapter is summarized in section 2.11.

## 2.2 A SUCCESSFUL PROJECT

The purpose of a project is to improve an organization or to fulfill governmental or industry mandates. The characteristics of a successful project within an organization, or within each organization for a multi-organizational project, are the following:

1. **Fulfills organizational needs:** The project fulfills a logical set of important needs of the organization.
2. **Integrated:** The project produces products that work together with pre-existing systems and employee workflows, and other projects, to support the organization.
3. **Adaptable:** The project produces products that can be changed as the organization changes to continue to fulfill the needs of the organization.

### 2.2.1 Fulfills Organizational Needs

Organizational needs, also called *organizational objectives,* are those things an organization needs to do to run the organization and have a quality organization.

For an organization to be successful, upper management of the organization must continually identify and work toward achieving organizational objectives. For example, for an HMO these *organizational objectives* might be the following: (1) provide excellent patient care, (2) generate sufficient money to run the HMO well and to expand the HMO, and (3) fulfill all the requirements of government and regulatory organizations.

Projects are selected which, together with the existing organization, fulfill these objectives with the greatest benefit to the organization. The objectives for each project, the *project objectives*, must be compatible with, and support, the organizational objectives.

For example, a project to develop a medical billing system, might have the project objective of supporting the collection of money from medical insurers and patients. This supports the organizational objective of generating money for the HMO.

The objectives of doing our project to automate the patient medical record might be the following: (1) to provide better patient care by providing an immediately available patient medical record, (2) to save money for the healthcare organization, (3) to assist healthcare workers in their jobs, and (4) to provide better information to manage the healthcare organization. These four project objectives potentially support all three of the organizational objectives.

To be useful in the evaluation of the success of a project, project objectives must be measurable, so the organization can determine whether these project objectives have been achieved once the project is complete. To measure a project objective, the organization can set targets to be met that can be measured and that lead to the final objectives. Such targets are called *goals* (King 1988)**.** A goal can be set after a particular phase of the project or at the end of the project to measure whether or not an objective is being achieved. For example, a "goal" for a five-year project might be to have an immediately available automated patient record for 40% of the HMO patient visits after three years and 95% of the HMO patient visits at the end of the project. The project's final success can be determined by how closely the project meets the project objectives as measured by the final goals for the project.

*Strategies* (King 1988) that lead more quickly to the objectives and fulfillment of the goals also need to be established. For example, one strategy might be to create a Clinical Data Repository as a first step in automation of patient medical record. (A Clinical Data Repository is a database that combines clinical data related to a patient from various healthcare organization clinical systems, but is only a portion of the information in the automated patient medical record—see chapter 15.)

### 2.2.2 Integrated

In addition to producing products that fulfill the needs of the organization, a project must produce products that are integrated. *Integrated* in the context of an organization means that all the employee workflows, automated systems, and other parts of the organization function well together, ideally meeting the totality of the objectives of the organization. Once completed, the products of projects must be integrated into the organization.

For this integration to be done efficiently, there must be communication between these various parts of the organization. Of particular importance to the automated patient medical record system for speed and consistency is that patient and medical information should not have to be entered a second time into an automated system when it is already available—This requires communication between automated systems.

### 2.2.3 Adaptable

*Adaptable* means that an organization can change in the future to adapt to new business needs without great difficulty.

The products of a project should be created so they can be easily changed to meet changing organization business requirements. The most efficient way to do this is for business managers to anticipate future changes in the organization at the beginning of the project. This anticipation of the future requires management ”vision”. In anticipating such future business needs, management assumes a significant probability of being wrong, as anticipating the future is extremely hard to do.

One change this book anticipates is that there will eventually be a single universal patient medical record shared by many different healthcare organizations. This anticipated change should be built into the automated patient medical record project from the very beginning so the automated patient medical record could evolve into a universal patient record.

There are also other ways the project can be made adaptable that do not require anticipating future business requirements, and thus are less risky:

- Use industry-wide standards
- Document why project decisions were made so future decisions can be based upon these decisions
- Think of the products of the project in terms of components where a component can later be replaced without affecting other components—this is called *component adaptability*
- Use a phased approach to doing the project that enables adaptability during the project—this is explained in the next section.

## 2.3 A PHASED APPROACH

Figure 2.1 presents a phased approach to doing a project. This phased approach to doing a project promotes the three requirements for a successful project: fulfills organizational needs, integration, and adaptability.

Large-scale complex projects such as ours need to be broken into smaller sub-projects, or *phases*. An *overall design* of the entire project is done at the very beginning that includes breaking the project into phases. At the beginning of the second and each later phase there is a determination of whether the overall design has to be re-done because a previous phase or next phase changes the overall design.

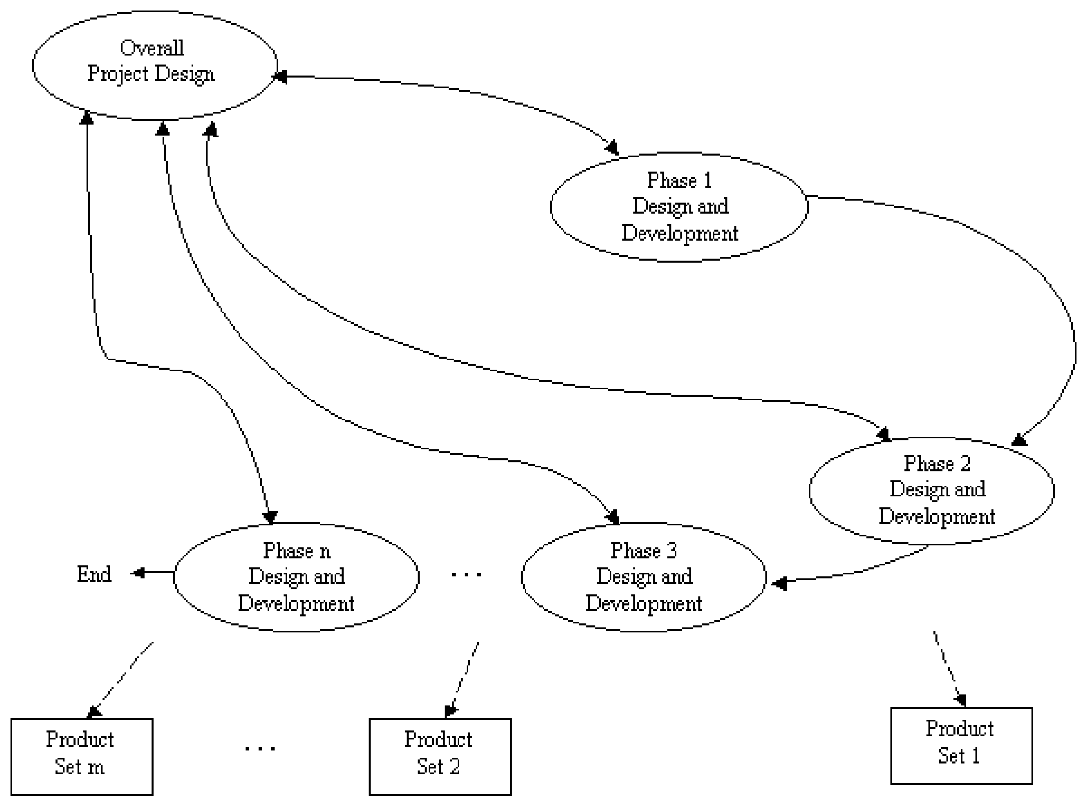


**Figure 2.1** A phased approach to doing a project

For example, our project begins with a complete overall design of the automated patient medical record. The project is then broken up into phases to implement the automated patient medical record. One phase might be to interface the automated system to encounter systems that identify encounters such as outpatient visits, inpatient admissions, etc. Another phase might be to integrate a caregiver ordering system. During the design of the caregiver ordering system, it may be discovered that additional encounter information is needed and the overall automated patient medical record system may require some redesign.

The project model pictured in figure 2.1 has a number of advantages over others, foremost of which is always knowing that you are going the right direction to produce the final products. Doing a complete initial overall design allows the final products of the project to be predicted at the beginning, with each phase then developing products or immediate products that can be adapted into producing the next product leading to the final products of the project. Possibly redoing the overall design after an analysis later in the project during the start of a phase allows redirection of the project, with the project personnel again knowing what products to develop. Thus, the people doing and controlling the project always know where they are heading!

Other advantages of this approach are the following: (1) Going from one consistent design to another is much easier than trying to fix an inconsistent design. (2) The final products of a large-scale complex project often cannot be completely defined at the beginning; this project model allows redefinition of the overall products as more is learned about the project over the life of the project. (3) Breaking the project into phases allows the results of the project to be given to the organization at bit at a time, early on, with early payback to the organization—phases can be ordered such that those producing immediate results are done first. (4) The project can be evaluated early on and continuously to determine if it is meeting the project and organizational objectives and goals, with this evaluation possibly resulting in early revision of the project or termination of the project before too much money is spent. (5) This approach minimizes the cost of expensive re-working of the project, as re-working is done as soon as possible, before it becomes too costly. (6) Phases of the project may be done concurrently, effectively using available resources.

*Products* of a project could include automated systems, changes in the way employees function in doing their work, rewired buildings with installed workstations, etc., or different combinations, or "sets", of these products that function together. Each product set during the lifetime of the project should be adaptable, allowing change of the products to produce the next product set.

The "phased approach" project model in figure 2.1 is similar to project models referred to as the "incremental model" (Whitten 1995), the "iterative model" (Whitten 1995), the "evolutionary delivery method" (Gilb 1988), the "staged model" (Rajlich and Bennett 2000), and the "spiral model" (Boehm 1988).

Doing the overall design up front, and potentially re-doing it again before each phase, insures both that the project meets the needs of the organization and that the final product is integrated and adaptable.

Revisiting the overall design of the project before each phase allows upper management to verify that goals are being met and strategies are being followed to work toward the final objectives of the project. Costs can be reviewed after each phase and kept under control. Return on investment can be evaluated. **It thus allows upper management to have control over the project**.

It will insure adaptability by allowing early redesign of the project if necessary. After each phase, the phase and the overall project can be reviewed, revised, improved or restructured. New or changed requirements can be incorporated.

It will insure that other automated systems using the same information are integrated by allowing redesign of the project as necessary so that all automated systems are properly integrated.

In order to make the model in figure 2.1 somewhat more flexible, we allow the project model to have the following additional characteristics:

- Re-visiting the overall design may involve only reviewing a part, rather than the whole, of the overall design. Prior to simple phases and phases where much was known ahead of time, the review of overall design phase may not be needed at all.
- Phases may be added or changed as a result of revisiting the overall project design.
- Maintenance of a phase, for example a subsystem, occurs immediately after a phase is complete and could result in such significant changes that a new phase is required, with possible revisiting of the overall design.
- Phases may be added or deleted from the project plan for other reasons, for example, because of changes in organizational strategies or cost considerations.
- It may be appropriate to re-visit the overall design to account for multiple upcoming phases, rather than just one.
- Unlike what is shown in figure 2.1, phases can partially or completely overlap one another in time.

This project model is necessary because a large project takes a long time to complete and thus must be broken down into phases to simplify the project and to account for changes in the organization while the project is being done.

Use of this project model is not an excuse to do bad design. In fact, a large complex project is only feasible if the total of the design at each step fits together impeccably. Any significant error in the design may be embedded into the project and require significant re-work to get rid of it. Fixing multiple errors in a large project later on in the project may be cost-prohibitive or impossible. The earlier in a project a problem is detected, the lower the cost to fix it. For example, it has been estimated that fixing a problem early on in a project to create an automated system could be 1% as costly as making the fix after the automated system has been implemented in the organization (Pfleeger 1988).

## 2.4 THE PLAYERS

Many people, of varying roles, and aptitudes and interests, must be participants in a large project for it to be successful. These many diverse groups must work together as equals with the professionalism of each group respected by the other. The reason this cooperation is required is that a large-scale complex project is a **single organism rather than the sum of its parts**, with any one decision in one part of the project (e.g., a database design decision) potentially affecting any other part of the project (e.g., the user interface, with—in our project—a possible consequential effect on patient care).

Accordingly, this book, unlike many others, does not look at a project from the single point of view of a project manager, but from the points of view of the many participants in a large-scale project.

The most successful projects involve meetings involving a diversity of different categories of people who meet together and learn from each other, creating a group dynamics to exchange information, thus creating a unified product that meets the many diverse needs of the organization (e.g., provide excellent medical care, have good system response time, supply information needed by government and regulatory agencies, record medical supplies used).

There are four important categories of people who should be involved in a large-scale complex project: domain experts, content facilitators, upper management, and process facilitators. *Domain experts* are experts in the project subject area (e.g., patient care and medicine). *Content facilitators* gather information from the domain experts to design and produce the product. *Upper management* pays the bills and determines the organizational objectives for the project. *Process facilitators* work in group meetings to insure that meetings are productive, that group dynamics are established and that participants learn to run their own meetings.

Domain experts include *workers in the organization* (including upper management), who know how the organization functions, *customers* who know how the organization provides services, and experts from *the outside world* who know what happens outside the organization.

In our project developing an automated patient medical record system, the organization will be a particular type of healthcare organization, a Health Maintenance Organization (HMO). An HMO is a corporate entity that provides comprehensive health care for each member of the HMO for a fixed periodic payment paid in advance by the member or his employer; such a payment system is referred to as “capitation”. Our HMO has its own hospitals and medical offices spread throughout the United States. This is a fictional HMO, but is representative of a very large HMO that may exist in the United States.

Upper management in our example are management physicians who control the operations of the HMO. Being management physicians, they care very much about quality patient care as well as about the financial health of the HMO.

The workers in the organization include everyone in the HMO, but especially “caregivers”, those who provide medical care to patients: physicians, nurses, medical assistants, hospital unit assistants, etc. The customers are the members and patients of the HMO, and a patient’s family members. The outside world includes people in the following types of organizations: suppliers, the government, regulatory agencies, software and hardware suppliers, and other healthcare organizations.

Content facilitators for a project include *business analysts*, *system analysts*, *database analysts*, *domain analysts,* members of the *technical staff*, and *project managers*, and *standards analysts*. Business analysts gather information from upper management, workers, customers and outside experts to identify what an improved organization would look like and to identify business requirements that would accomplish these improvements. System analysts take the business requirements and a description of the improved organization to create requirements for automated systems. Part of system analysis is determining new and changed databases—databases are places to save information; database analysts work with system analysts and domain experts or domain analysts to define databases for a project or for an organization, or change existing databases. A domain analyst is an expert in how a particular type of business functions and works with domain experts to facilitate solutions; for example, a domain analyst might be an analyst who is also an expert on provision of medical care and work with domain experts (e.g., the caregivers) in an HMO to reengineer medical care, changing work flows. The technical staff create and implement automated systems. Project managers schedule activities making up the project and guide personnel in their execution. A standards analyst insures that the standards of the organization and of the industry—in our case the healthcare industry—are followed.

For a large-scale complex project, meetings between project members are likely to occur over an extended period of time. For any long-lasting meetings of project group members, there should be a *process facilitator*, or simply “facilitator”, to guide the group in making decisions until the participants in the group or sub-group learn how to work together (in which case the whole group assumes the responsibilities of the process facilitator). Along with the participants, the process facilitator develops **processes to be followed during meetings** to enable the group to work efficiently and make decisions (e.g., “It seems that our group has decided upon the following process: Any agreement this week will be written down. During the following week’s meeting we will either finalize the agreement or retract the agreement. This allows us to think over our agreements between meetings and discuss the agreements with our various groups.”). The process facilitator also teaches the group about *interventions* to be used if the group bogs down; for example, when multiple people are talking at once, the process facilitator might say, “Just a moment, one person at a time. Joe you were first, and then Carol”. An excellent book on *facilitation* is (Kaner et al. 1996).

When there are automated systems, members of the technical staff are involved in the procurement, development and implementation of these automated systems. This staff may include the following: *system architects*, people who define how computers and other devices are linked logically and physically, how data is distributed between databases on the computers, and how software is distributed; *capacity planners*, people who get information from business planners on anticipated number of users and customers, and who determine and anticipate the activity within systems and networks, thus identifying hardware and network requirements; *software developers*, who design software; and other data processing personnel such as