A Preliminary Design for a Universal Patient Medical Record
A PRELIMINARY DESIGN FOR A UNIVERSEAL PATIENT MEDICAL RECORD
RE-ENGINEERING HEALTH CARE

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A Preliminary Design for a Universal Patient Medical Record: Re-engineering Health Care
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Please note that I am not a physician and thus any medical examples in this book clearly are not meant to be used to treat or diagnose any medical condition. Examples come from medical conditions I have personally experienced or from referenced studies as noted.
Preliminary Design

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INTRODUCTION

This book proposes development of a universal patient medical record (UPR) that provides a complete medical history for the patient and that enables access to all the patient’s medical records no matter where they are located.

It is assumed that in the future most all health care organizations will use electronic patient record systems (EPRs) that automate their patient medical records. An electronic medical record system will allow clinicians to enter clinical information while seeing patients and may send orders and receive back results and other information from automated ancillary systems (e.g., test results from clinical laboratory systems, admissions from hospital admission systems, etc). Patients’ medical records for a health care organization with an EPR will thus be stored in the health care organization’s EPR. The universal patient medical record for a patient would be created by combining information from EPR systems from all the health care organizations where the patient was seen for care.

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

Health care today is largely oriented toward short-term treatment of a medical condition and upon a typical patient with that medical condition. I predict this will change in the
near future: medical care will become more long-term oriented. Care will be more personalized to the individual patient. Besides treating disease, medical care will prevent disease and promote wellness and a healthy longevity without disease. These changes in care will result in a need for an always-available, complete medical, prevention and wellness history for a patient that is accurate and up-to-date, available to any clinician caring for the patient, no matter where the patient is being seen for care.

A patient’s medical, prevention and wellness history would include biomarkers for disease or health, 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 2000). An individual’s genome could provide permanent biomarkers while other biomarkers may change over time. Through biomarkers, diseases and wellness could be predicted. A universal patient medical record is a place where such biomarkers for an individual could be stored. Biomarkers identify the inner workings of an individual’s cells and thus enable diagnoses, preventions and treatments to be tailored to the individual.

When medical records were first used, the medical records were on paper and medical care was most often performed by a physician who worked individually in the care of a patient. With managed care, national health care, and the greater mobility of people moving from place to place, care is no longer given by an individual physician but by many. Even when care occurs in a single health care organization, care is often given by multiple physicians, with a primary care physician referring the patient to a specialist physician for any complex medical condition, and care is
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often given by teams of clinicians, both physicians and non-
physicians. There is a need for a universal patient medical
record that supports communication between these many
clinicians, whether the clinicians work together or inde-
pendently in providing a patient’s care or work in different
health care organizations. A universal patient medical record
should thus be centered around an individual, not a health
care organization nor any single clinician.

Through a universal patient medical record, visits in-
volving the same medical condition could be combined into
a “case”, both supporting team-based care and continuity-
of-care whether care is provided by a team or an individual
physician over a significant period of time. Documentation
of care plans based upon standards of care for the medical
condition and documentation of the results of care (out-
comes) could be included within the case documentation,
enabling standards of care to be evaluated based upon com-
parative effectiveness.

Today, each physician is restricted to providing care in a
very specific geographic location of the world. With tele-
communications and telemedicine, this need not be so.
Health care could 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 care-
givers to be able to concurrently access the same patient
medical record in the care of a patient.

As evidenced by the HIV/AIDS and influenza pandem-
ics 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 health care workers. The world
must make better use of all its health care workers. This can
be facilitated by a universal patient medical record.
There would be a complete, immediately available, medical record. When a patient showed up for care with identification in an emergency department, even when unconscious, a universal patient medical record could provide the health history for the patient, informing clinicians of drug allergies, significant health problems, current medications or other information that could improve care or potentially save the patient’s life.

The universal patient medical record together with the EPR systems could save money in many ways, including identifying when billing was inconsistent with the care given. Discharge activities could be done concurrently, quicker and thus with less cost. Public health organizations, insurance companies, the patient’s primary care physician, or other interested parties with a need-to-know could be sent information on patient care 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 as well as saving costs due to medical errors caused by misplacement, unavailability or unreadability of such non-automated documents. The universal patient medical record could support clinical trials of standards of care to identify standards of care that produce the best outcomes for the least cost. Through the universal patient medical record, diagnostic tests and prescriptions which are duplicated or inconsistent with care could be identified—in particular, identification of duplicate prescriptions could be used to identify narcotics abuse by patients.

With automation, the universal patient medical record could use sophisticated approaches to security and privacy.
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For example, researchers might be able to only get medical information that does not reveal the identity of the patient (an approach consistent with HIPAA). Patients might be able to exclude some categories of mental health, wellness or other information from the universal patient medical record for view by others.

The universal patient medical record could also be designed for the patient, enabling the patient to comply with physician advice and orders, and enabling the patient to verify that advice given by the physician was indeed given, that the encounter did indeed occur, and that services stated indeed were provided.

To summarize, with a universal patient medical record:

- Better patient care could be provided that avoids medical mistakes due to lack of information resulting from the unavailability of a patient’s medical record.
- There would be a single, complete automated patient medical record, rather than many fragmented ones.
- Communications between all types of clinicians would be enhanced, whether they worked on a single treatment for a patient, over many treatments, or over the patient’s lifetime.
- Continuity-of-care and team-based care would be supported by use of cases that combine visits for the same medical condition. Cases could include overall care plans and the outcomes of care, making it easier for the evaluation of care plans based upon standards of care, and identifying best practices based upon comparative effectiveness. Biomarkers related to the medical condition that could identify
the best treatment for the medical condition could be stored with the case (e.g., the genetics of the patient’s breast cancer).

- There would be a single place to permanently store the lifestyles, environmental conditions, and disease and wellness biomarkers for an individual. There could then be greater emphasis on individualized care and preventive care, and diseases could be prevented before they occur.

- The lifestyles, environmental conditions, and biomarkers that predict diseases and wellness could be better determined as a result of a research database derived from these complete medical records.

- Health care workers could work across borders and provide consultation and mentoring even when the health care workers were located remotely from each other, or remotely from the patient.

- Public health agencies, clinicians and the public could be more quickly informed about public health problems.

- The patient could better comply with physician directives and verify that medical record information was correct.

- Privacy and security of patient information could be protected while providing adequate information for care, public health, payments and medical research.

- Money could be saved.

This book is titled *A Preliminary Design for a Universal Patient Medical Record*. A preliminary design is a first draft of how to construct a software and hardware system. A preliminary design’s principal uses are to verify that requirements
for the system as determined by the users of the system have been satisfied, and to serve as a framework and initial specifications for the final design.

Since no requirements for the universal patient medical record have yet been determined by its users (physicians, public health workers, researchers, the government, software/hardware designers, etc.), I have assumed an initial set of requirements of the system and have based my preliminary design on these requirements. This preliminary design of a universal patient medical record could serve as a starting point for gathering of the actual user requirements for such a system and creating an actual preliminary, and then final, design for such a system.

Since a universal patient medical record must be built for health care tomorrow as well as today, chapter 2 of this book predicts how health care will change in the future.

Chapter 3 identifies a set of requirements for a universal patient medical record that would result in improvement of health care both today and tomorrow and presents a preliminary design of a universal patient medical record based upon these requirements.

The basis for my requirements for a universal patient medical record are that health care in the future will provide the greatest health benefits for patients while being much more efficient and cost-effective than it is today, i.e., creating the greatest value for the patient health care dollar. In the *New England Journal of Medicine*, Dr. Michael Porter presented his ideas for health care reform based upon the same goal of creating the greatest value for the patient. Chapter 4 summarizes Dr. Porter’s ideas for health care reform and identifies how health care would have to be re-engineered to use a universal patient medical record to implement these reforms.
PRELIMINARY DESIGN

Throughout this book, words in italics are defined in the glossary.
2

HEALTH CARE TODAY AND TOMORROW

2.1 Health Care Today
Since a universal patient medical record would be enduring, it should be built both for health care today and tomorrow.

Medical care today—see figure 1—involves a clinician interviewing the patient; the clinician, anatomic pathology and the clinical laboratory looking at organs and tissues of the body of the patient to identify pathological conditions;
the clinician diagnosing and treating the medical condition; the clinician giving the patient advice on how the patient can maintain or improve his or her health; and the clinician prescribing medications, or performing or ordering other interventions.

Medical care tomorrow will function as it does today, but it will also look deeper into the chemistry within individual cells and signaling between cells to identify individual differences between patients with a particular medical condition. Care will thus be more personalized to the patient resulting in more effective treatments.

2.2 Health Care Tomorrow
I predict that health care will change in the following ways in the future:

- **Molecular medicine:** When clinicians look at the body at the cellular level, not just the tissue level, they may be able to diagnosis diseases with greater specificity (e.g., the diagnosis might be HER2-positive breast cancer instead of just breast cancer), and they may be able to determine the likelihood of a disease occurring in a currently healthy patient.

- **Team-based care and greater continuity-of-care:** In the future, there will be greater use of team care, which will result in saving money and providing greater continuity-of-care for a patient.

- **Preventive care:** In the future there will be greater use of preventive care with biomarkers being used to identify when preventive care is most beneficial and cost effective.
Today and Tomorrow

- **Wellness**: Lifestyles will be correlated with rates of disease. Education, together with a greater scientific understanding of the brain and how humans make decisions, will be used to change lifestyles.

- **Patient values and non-compliance**: Because of a patient’s life situation or a patient’s attitude or because of the complexity of proper use of medications, proper care may be provided by a clinician but the patient may not comply with the clinician’s dictates. In the future, there will be greater use of non-clinicians to overcome these compliance impediments, including pharmacists, counselors, psychologists and patient educators. Also there will be greater use of written communication with the patient to enhance compliance.

- **Multiple medical conditions**: There will be better care for multiple medical conditions, including when care crosses multiple medical specialties.

- **Other Changes**

2.2.1 Molecular Medicine

See figure 1. Medicine today is performed at the organ and tissue level with diseases, treatments and preventive medicine working primarily with organs and tissues. Medicine tomorrow will also be at the cellular level, with differences in the functioning of the cells within a tissue identifying a disease, healthy or possible pre-disease condition. (*Systems biology* is study of biological systems at the cellular level.)

Cells function by chemical reactions that occur within the cells and by communication between cells. Figure 2 shows an example of the chemical reactions within a cell, showing what occurs in a muscle or fat cell as a result of the cell encountering insulin.
A cell has receptors embedded in its cell wall (membrane) or in the cytoplasm of a cell (the interior) that bind hormone, neurotransmitter or drug molecules. In this example, the molecule is a hormone, an insulin molecule. As a result of this binding of an insulin molecule with an insulin receptor, chemical reactions occur within the cell. For example, for muscle or fat cells, insulin causes an influx of glucose into the cell. These chemical reactions may involve the cell nucleus that contains the genome.

**Figure 2** Example of cell signaling and interactions within a cell. (Pathway diagram reproduced courtesy of Cell Signaling Technology, Inc. (www.cellsignal.com)).
A cell, the smallest structure capable of basic life processes, is simply a complex chemical factory. The cell has receptors on its outside. Hormone molecules (such as insulin) or drug molecules can bind with the cell’s receptors which initiate chemical reactions within the cell. The nucleus within a cell contains DNA (the genome) which forms a template for creating polypeptides that can fold and combine with other molecules or polypeptides to form proteins; proteins are involved in reactions and transport activities within the cell. Some proteins may be created automatically by the cell on an on-going basis, while some may be created only when chemical reactions occur within the cell as a result of a hormone, neurotransmitter or drug molecule binding to a receptor. Chemical reactions within a cell could result in the cell secreting a hormone that provides a signal to another cell (e.g., the insulin molecule in figure 2 that binds with the receptor of the muscle or fat cell came from a pancreas cell).

A hormone, a chemical created by one of your body’s cells, is a way that cells within your body communicate with each other, with the hormone matching a receptor on a different cell, for example causing a chemical reaction in the receiving cell.

Neurotransmitters are chemicals that enable communication between neurons. Chemicals called neurotransmitters are released by a neuron to communicate with other neurons that have receptors very close to the release of the neurotransmitter; the small distance between the releasing neuron and receptor neuron is called a synapse.

Drugs are created to bind with receptors or affect neurotransmitters. In this way, drugs can change what happens within cells of the human body.

Figure 3 is a cartoon diagram of cell receptors. A receptor is most often itself a protein—a protein embedded in the
cell membrane of the cell. Cells of different types (e.g., liver cell, pancreas cell, etc.) could have receptors which are totally different from each other, could have some receptors that are the same, or could have similar receptors that are different but are able to bind the same hormone or drug.

Figure 3 Cell receptors.

A cell that has a receptor that binds with a particular drug or hormone is called a “target cell” for that drug or hormone. As shown in figure 3, a drug that is meant to bind with a receptor of a particular type of cell—a intended target cell such as the prostate cell—may also bind with a receptor on another type of cell—an unintended target cell such as a liver cell. This is one reason drug side effects occur.

On the other hand, a particular drug might bind only to a receptor on the intended target cell (e.g., prostate cells) and not bind to receptors on other cells. This explains how a drug can be created that has an effect on a specific type of cell and not others (e.g., a drug to relax prostate muscle to enhance urinary flow).
Molecule-receptor interactions could be more complicated: For example, one type of molecule could bind with a receptor causing no internal cell chemical reaction but could result in blocking out these receptors from molecules that could cause chemical reactions. A molecule could also interact with a receptor, changing its configuration and thus changing the way the receptor works.

The study of the signaling between cells and the interworkings of cells for purposes of medical care is referred to as molecular medicine. Genomics, the study of the genome—the blueprint for creation of proteins within the interior of the cell—is part of molecular medicine; in particular, errors in the genome could result in cancer. Personalized medicine is diagnosing and treating patients based upon the interworkings of their cells resulting in diagnoses and treatments tailored for the individual patient.

Somatic cells are all the cells in the human body excluding reproductive cells (eggs and sperm). A general category of somatic cells in the human body are adult stem cells as opposed to non-stem cells. A stem cell is “a cell that can incur unlimited division and which has the potential to differentiate into other types of cells.” For example, an adult stem cell might be able to produce other adult stem cells and non-stem cells upon division while a non-stem cell would either not be able to divide at all or would only be able to divide to produce other non-stem cells for a limited number of generations.

For a particular organ, there are often many non-stem cells and a smaller number of stem cells; for example, when part of a liver is removed, it grows back which appears to be due to the activation of liver stem cells (Sell 1990). Often the adult stem cells are hard to distinguish from the non-stem cells. Some authorities contend that cancer occurs in the adult stem cells, not the non-stem cells (Wade 2006).
A type of stem cell that occurs in an embryo is an embryonic stem cell (ESC) that has the potential to divide to produce all other types of human cells. Somatic stem cells occurring within the human body, adult stem cells, can only divide to produce a much limited number of types of other cells. Scientists have been able to reproduce ESC-like stem cells from adult skin stem cells and neurons; these new cells were termed induced pluripotent stem cells (iPSCs) (Kim et al. 2009).

Every cell in a particular human’s body has the same genome and set of genes, with genes being sections of the genome that are templates for producing polypeptides that fold and combine to produce proteins. Embryonic stem cells differentiate into many different types of cells. This differentiation is done by particular genes being turned off for a particular type of cell (e.g., differentiation of embryonic stem cells to produce a liver cell); in this case, turning off of genes occurs through epigenetic processes, i.e., by mechanisms other than changes in the underlying DNA sequence (Wikipedia 2009). Differentiation of cells in embryos results from signaling between cells with different signaling dependent upon the location of the cells in the embryo (Microsoft ® Encarta ® 2007).

The DNA in a cell is wrapped around spool-like protein structures called histones. Epigenetic changes in the DNA that turn off or turn on genes (i.e., keep them from being or allow them to be transcribed and thus to be expressed to produce proteins) involve at least two phenomena: (1) the physical blocking of genes by the packaging of the genome on histones, which may cause a gene to not be transcribed, and (2) the addition of methyl groups to some cytosine bases in the genome—termed DNA methylation (Watters 2006). These two phenomena are related: the methyl groups are what
change the histone packaging and cause suppression of gene expression.

Besides being responsible for creation of the different types of cells in the human body from embryonic stem cells, epigenetic changes occur in all cells in the human body over their lifetime. Random changes in genes in the genome, *mutations*, together with epigenetic changes in cells could result in the occurrence of cancer. According to reference (Pelengaris and Khan 2006), “Cancers arise by the stepwise accumulation of mutations and epigenetic factors that alter gene expression to confer cancer properties on the cell. The presence of inherited cancer-causing mutations will give a would-be cancer cell a head start, but somatic mutations and epigenetic alterations are still needed for cancer development.”

DNA (*deoxyribonucleic acid*) is a long double-stranded molecule in the genome of a cell. RNA (*ribonucleic acid*) is a shorter single-stranded molecule that is used to transcribe genes to produce polypeptides by combining various types of amino acids. RNAi (*RNA interference*) is a naturally occurring micro-RNA that can be used to *knock down* a protein, in other words to stop the protein from being expressed. RNAi is used by drug companies to determine what happens to cells if a particular protein that is normally expressed is not expressed and upon positive results could identify to the drug company to create a drug that could have the same effect; in the future RNAi could also potentially be used in drugs to fight diseases by stopping protein expression in a cell.

Living things that can cause disease, and also viruses, have either DNA or RNA. Some misfolded proteins (*prions*)—containing neither DNA or RNA—can also cause disease (bovine spongiform encephalopathy, Creutzfeldt-