

An Infomediary for Outcomes Research at the Community Level

Proposed Research Plan to the National Library of Medicine

Research Concept Not for Publication or Citation

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ABSTRACT

This project establishes an information system linking patients and their caregivers, physicians and clinicians, and health services researchers in a local community into a collaborative research team for the purpose of collecting and applying self-reported outcomes data in clinical practice. The information system to be developed will embody four components:

- (1) An outcomes data management system for use in a busy ambulatory care clinic.
- (2) A common communication and information infrastructure for use by patient, caregiver, physician, and clinician within the community; and by health services researchers within a virtual community of research shared interests.
- (3) A plan for a clinical protocol that would use the information system to maintain or improve patient outcomes by giving clinicians specific evidence for patients based on outcomes measurements from standardized instruments.
- (4) A data acquisition program for testing the relationship between self-reported outcomes and clinical data in a selected cohort of patients with a confirmed chronic illness.

A central objective of the project is the creation of peer-reviewed technical specifications for a generalizable and scalable system, through the use of open standards and open source software where appropriate.

RESEARCH PLAN

Section A: SPECIFIC AIMS

This project has five specific aims to be developed over two phases. Phase I is addressed in year one; phase II in year two.

Phase I

Specific Aim #1 – Develop an information technology plan for USC’s Family Practice Clinic to support outcomes data collection and data management within the context of a busy ambulatory care clinic.

Without an information technology support function, it is unlikely that either the registration desk or patient care personnel will have the capacity to collect and manage patient outcomes data. Taking this into account, the information technology plan will explore the possible use of interactive voice response (IVR) technologies that make use of standard telephones and web-based data transmission protocols, to gather and manage patient outcomes data.

Sub-Aim #1.1 – Analyze the current work flow in the Family Medicine Clinic (e.g., registration, treatment, disposition, etc) in order to understand how data are currently collected, who uses the data, and when the data are needed.

Sub-Aim #1.2 – Explore potential information technology solutions (e.g., interactive voice response systems, web-based technologies, etc.) that might be used to gather and manage serial patient functional health status data over time in a busy clinic.

Sub-Aim #1.3 – Using information gathered in #1.1 and #1.2, develop an information technology plan for creating a patient outcome measurement system to include hardware, software, and connectivity issues.

Specific Aim #2 – Design a health services research project to pilot test the likely effects of applying the information technology in a cohort of patients with a confirmed chronic disease. We will likely focus on congestive heart failure patients as the study population.

Sub-Aim #2.1 – Plan a study to determine the value of functional health status measures as predictors of future disease status and resource use.

In order to justify the incorporation of functional health status measures into usual clinical practice, more studies are needed to clarify the role that these measures might play as *independent* variables. That is, what do such measures *predict* with respect to a patient’s future course of illness and health care resource use? A few studies have shown that self-report functional status measures are useful in singling out patients who are likely to experience a more difficult course of recovery and to consume more health care resources (24-26). In theory, if such measures are useful as predictors, it may be possible to use them to target patients for special attention. This would make it possible to manage these patients more proactively, anticipating changes in their condition before they manifest themselves as crises requiring emergency attention. Proactive management may also help reduce the incidence of avoidable acute-care hospital admissions.

The following specific activities will be undertaken to accomplish Sub-Aim #2.1. We will:

- (1) Establish an operational definition of the chronic disease population to be studied (e.g., congestive heart failure patients).
- (2) Identify appropriate (i.e., statistically reliable and valid) instruments for measuring functional health status in the identified population.
- (3) Operationally define the disease status and resource utilization variables to be predicted by the functional health measures (e.g., number of repeat hospitalizations, total length of hospital stay, hospital cost, etc.).
- (4) Design a plan for conducting a baseline sample survey of the identified population using the health status measurement instruments.
- (5) Design a plan for developing a statistical prediction model to include health status measures as predictors.
- (6) Develop a plan for incorporating such predictors into the information technology application.

Sub-Aim #2.1 – Plan a study to determine how selected functional health status measures are affected by the application of a designed clinical quality improvement protocol.

In order to develop a clinical protocol that incorporates measures of patient functioning and well being, more research is needed to determine how such measurements behave when viewed as *dependent* variables. That is, how are functional health status measurements affected by specific treatment protocols? Previous unpublished work of the a co-Principal Investigator, for example, has shown that statistically significant change occurs in generic SF-36 Questionnaire responses following cardiac bypass surgery, but a disease-specific measure (the Seattle Angina Questionnaire) is more sensitive to this change as measured by Guyatt's Responsiveness Statistic (27). We will develop a research plan designed to evaluate the behavior of selected functional health status measures when used to measure the outcomes of a specific clinical quality improvement protocol in a defined chronic disease population.

The following specific activities will be undertaken to accomplish this Sub-Aim #2.1. We will:

- (1) Use the population definition and measurement instruments previously defined to develop a clinical quality improvement protocol that could make use of functional health status data to maintain or improve the average outcome in the identified population.
- (2) Design a research plan to test the effects of the clinical protocol on the functional health outcome measures.

Specific Aim #3 – Create a master plan for a scalable outcomes infomediary based on open source software.

Sub-Aim #3.1 – Develop a prototype of the outcomes infomediary based on the master plan with the goal of supporting an offered load consistent with the health services research project (Specific Aim #5, below).

Sub-Aim #3.2 – Define technical specifications for integration with the outcomes infomediary based on open standards for XML documents. This will enable low cost integration of clinical systems and physician practice management systems with the infomediary.

Sub-Aim #3.3 – Evaluate the system design via peer review with experts in clinical informatics in the local community, potential adopters in different areas of the country, and other industry experts.

Sub-Aim #3.4 – Address HIPAA issues in a satisfactory manner.

Specific Aim #4 – Deploy and test an outcomes infomediary that will provide the information flows between patients and their caregivers, physicians and other clinicians, and health services researchers.

Sub-Aim #4.1 – Integrate the outcomes infomediary with clinic, hospital, and CHSPR and put resulting system into operation.

Phase II

Specific Aim #5 – Operate (guided by the requirements of Specific Aim #2) a health services research project to test the relationship between self-reported outcomes measures and traditional clinical measures for chronically ill patients. We will likely focus on congestive heart failure patients as the study population.

Sub-Aim #5.1 – Configure the outcomes infomediary and clinical practice system to fulfill the information gathering requirements of the study.

Sub-Aim #5.2 – Operate the study for an extended period of time (one year) to collect outcomes and clinical measures from which to develop refined hypotheses and interventions.

Sub-Aim #5.3 – Propose potential feedback mechanisms for clinicians based on the results.

Section B: BACKGROUND AND SIGNIFICANCE

This grant application is a collaboration of two health sciences organizations at the University of South Carolina: the Norman J. Arnold School of Public Health's Center for Health Services and Policy Research (CHSPR), and the School of Medicine's Department of Family and Preventive Medicine. Another key participant is the Palmetto Health Alliance Office of Medical Education and Research.

With this application, we propose to establish an information system linking patients and their caregivers, physicians and clinicians, and health services researchers into an on-going collaborative research team for applying self-reported outcomes data in clinical practice. The information system to be developed will embody four components:

- (1) An outcomes data management system for use in a busy ambulatory care clinic.

- (2) A common communication and information infrastructure for use by patient, caregiver, physician, and clinician within the community; and by health services researchers within a virtual community of shared interests based on research questions arising from the application of new therapies in clinical practice.
- (3) A plan for a clinical protocol that would use the information system to maintain or improve patient outcomes.
- (4) A data acquisition program for testing the relationship between self-reported outcomes and clinical data in a selected cohort of patients with a confirmed chronic illness.

CHRONIC DISEASE AS A FOCUS OF STUDY

Chronic disease accounts for a substantial portion of U.S. health care expenditures (1). Most chronic diseases, such as coronary artery disease, congestive heart failure, diabetes, or Parkinson's disease, are degenerative in nature, often related to genetics, the aging process and/or life style habits. Cure is often not an available option. Rather the ultimate goals for the care of such patients are to alleviate symptoms, to prolong the onset of disability, and to maintain or improve patient functioning and well being (2-3). Accomplishing these goals may also reduce health care costs, especially the costs associated with treatment in acute care hospital facilities (4-6).

For these reasons, functioning and well being are outcomes that are highly valued by patients and third-party payers. Physicians too are intuitively aware of the importance of functional health status as an ultimate treatment goal among patients with a chronic illness. However, scientifically valid quantitative measures of functional health status, although common in research settings, have not been widely embraced by physicians for use in routine clinical practice.

FUNCTIONAL HEALTH STATUS AS AN OUTCOME OF MEDICAL CARE.

Physicians customarily rely on intermediate treatment results measured in commonly-understood physical units. Examples of such measurements are:

- (a) Blood pressure measured in mmHg.
- (b) Low density blood lipid level measured in mg/dL.
- (c) Prostate-specific antigens measured in ng/dL.

While these represent important *technical* measures of care, they do not encompass the ultimate outcomes that matter most to patients. Patients care more about their overall functioning and well being, which ultimately determine their quality of life. Outcomes of this sort are typified by questions such as:

- (a) Am I able to return to work?
- (b) Am I able to fulfill my family and social role?
- (c) Am I feeling less anxious or depressed?
- (d) Am I feeling less pain?

Even though these kinds of functional health outcomes represent important human phenomena, they are also typically regarded as soft data compared to technical measures of care. In fact,

expressions of a patient's functioning and well being are often not regarded as acts of measurement at all, being viewed instead as expressions of personal judgment belonging to the art, as distinct from the science, of medicine.

However, to manage functional health effectively as an outcome of care, it is necessary to have statistically reliable and valid measures (7). Fortunately, well-researched measures now exist (8-10). Global or generic measures have been developed over the past 25 years to gauge an individual's general level of functioning without regard to any particular illness or constellation of symptoms. Examples of global health status measures are the Short Form 36-Item Health Questionnaire or SF-36 (11-13), the Nottingham Health Profile (14-15), and the Sickness Impact Profile (20).

Similar measures have been designed to assess functioning in relation to the characteristics of a specific disease. Examples of disease-specific measures are the Seattle Angina Questionnaire or SAQ for patients with coronary artery disease (18), the Minnesota Living with Heart Failure Questionnaire for patients with congestive heart failure (19), and the Diabetes Quality of Life Measure for diabetic patients (20).

These instruments, and others like them, have been thoroughly studied, their statistical reliability and validity are well known, and many of them, such as the SF-36, come with population norms. Normed comparisons are helpful in identifying specific functional deficits that occur as a by-product of undergoing certain medical procedures or suffering from particular chronic illness.

HYPOTHESES AS TO WHY HEALTH STATUS MEASURES ARE NOT PART OF ROUTINE MEDICAL PRACTICE.

Functional health status measures are now commonly used to evaluate research outcomes. For example, such measures are frequently employed to measure "quality of life" in pharmaceutical trials of new chemotherapy regimens in cancer patients (21). Such measures are also used in health services research to test the effects of new clinical practices or health policies (22-23). However, despite their acknowledged value for measuring outcomes in a research setting, formal quantitative health status measures are not routinely used to assess patient outcomes in the normal course of their practice. This proposal hypothesizes that there are at least two reasons for this:

***Hypothesis #1* – Clinicians would incorporate a patient outcomes monitoring process into their routine practice if they had the information technology needed to support this activity.**

Physicians are accustomed to using various *clinical* support functions, such as the laboratory, X-ray, or pharmacy, to support their care delivery process, but an outcomes measurement support function is simply not a part of usual physician practice. What is needed is an automated system to support:

- (1) Data collection activities so that registration staff and patient care personnel are relieved of this burden as much as possible.
- (2) Data management activities so that long-term community-based outcomes data can be accumulated in a secure database over time and later retrieved for analysis.

- (3) Data linkage functions so that episodic acute-care hospital data can be retrieved and related to long-term community-based patient outcomes.
- (4) Data analysis and reporting functions to support clinical improvement activities in the outpatient setting.

Relevant information technologies, such as computerized interactive voice response (IVR) systems and web-based data transmission protocols, exist today and are being used in business and marketing environments. These technologies are only starting to be used in medicine.

***Hypothesis #2* – Clinicians would incorporate a patient outcomes monitoring process into their routine practice if they had clinical protocols that included functional status measures as relevant outcomes of the care delivery process.**

As described above, most physicians focus on what are perceived as objective technical measures of care, thereby classifying concepts such as patient functioning and well-being as part of the art, rather than science, of medicine. As a result, important humanistic aspects of care go unmeasured and, although such aspects are accounted for in the subjective patient-physician relation, they are excluded from formal scientific consideration when evaluating the results of a care management process.

When functional health data are omitted, groups of patients may seem similar because they all have the same diagnosis and the same technical result, but, in fact, the groups may be quite variable with regard to outcomes that have the greatest impact on the future course of their illness, their future capacity to function, and their future utilization of health care resources. Clinical protocols are needed that incorporate formal measurements of functional health and well-being into the daily care delivery process.

NEEDED: AN INFORMATION SYSTEM THAT LINKS A VIRTUAL COMMUNITY FOR OUTCOMES RESEARCH

In this proposal we supplement the model of an *ad hoc* medical outcomes research project making use of functional health status instruments with an information system to facilitate the collection and distribution of specific outcomes data. Figure 1 shows a diagram of the proposed information system as it relates to different processes (Registration, Admissions, Clinical, .etc) and functional activities (Identity, Coding, etc.)

One challenge of such an information system is to organize a workflow across different organizations with loosely coupled actors. The notion of an information intermediary or *infomediary* (28) provides the central organizing concept.

The purpose of an infomediary is to provide a hub for the exchange of information between members of a *virtual* community, in this case between patients and their caregivers, physicians and other clinicians, and health services researchers. The information would be available at home, at the clinic, in the hospital, and (in de-identified form) to health services researchers in a university setting.

The concept of an infomediary is that of a trusted person or web-enabled organization that specializes in information and knowledge services for, about and on behalf of a virtual community. The infomediary facilitates and stimulates intelligent communication and interaction among the members of the virtual community. It administers and cultivates a proprietary

knowledge asset that contains content that are of specific interest to the community. In accordance with the privacy constraints that are mandated by the community, the infomediary gathers, organizes and selectively releases information about the community and its members in order to fulfill its needs. Outcomes research is a natural virtual enterprise; indeed "...all that is needed to form a virtual enterprise is at least one common goal, a shared information space, a means of coordinating users' efforts, and people willing to share their work." (29)

In this research project we envision a system, an *outcomes infomediary*, in which the hospital, its ambulatory care providers, patients, and possibly the patient's caregivers (immediate family or others) interact via an Internet-based service to facilitate outcomes monitoring and management outside of the provider's physical location (clinic, physician's office, or hospital). The nature of the interaction is to facilitate the collection of functional health status measures as embodied by various standard instruments, of which there is a great variety.

The infomediary provides the continuity for maintaining longitudinal clinical data and functional health status measures -- protected health information as defined by HIPAA (30) -- that can be used in its de-identified form for population-based studies of the effectiveness of treatments by health services researchers. The infomediary needs to be connected to relevant existing clinical systems.

We envision a network technology mix that will encompass several different modes of access. For example, laptop "kiosks" in the clinic, web-based pages accessed from a browser in the patient's home, appropriate security safeguards for accessing such information from public-use workstations (such as may be found in public libraries), and potentially IRC (Internet Relay Chat) and IVR (interactive voice response) elements for following up on the collection of various outcomes studies. A team of health services researchers would use the acquired data (in its de-identified form) to help the hospital and its affiliated practice groups perform research studies to make that would support changes in care decisions.

THE INFOMEDIARY NEEDS TO CAPTURE PROPER CODING OF THE RESULTS OF CLINICAL AND BUSINESS PROCESSES

A second challenge for an infomediary is to integrate sources of data that originate from workflows in clinical and business processes and to successfully encode it in a form that will be statistically significant and subsequently useful.

We envision that a major benefit for the testing of new therapies in clinical practice will result when there is little or "no" effort to create new information flows into the infomediary. This implies that the infomediary must implement technical structures that will enable it to be configured for new information sources, where the cost of configuration can be reduced through the use of appropriate user interfaces. Although one can not eliminate the cost of local system adaptation (i.e., the cost to collect or create coded data at the source,) one can minimize the cost to configure the common system.

Recent technological standards associated with XML (31) provide a general framework for such information *once it has been collected*. XML defines standards for a document-centric view of information. Specific standards for the documents needed in an outcomes infomediary based on XML need to be prototyped and developed. We envision that the infomediary will define a set of standard document types that will enable clinical results to be captured and associated with the longitudinal record for the patient.

Organizations differ widely, however, on the degree to which coding is performed for clinical processes. What is done in practice frequently depends on the specific information systems in use and other historical developments in the organization and potentially its future plans. The quality of coded results may vary depending on clinician's view of the value to them.

Initially, the Family Practice Clinic of the University of South Carolina Medical School and the teaching hospitals of the Palmetto Health Alliance will serve as the organizational vehicles for deploying the outcomes infomediary. The information technology plans for both of these organizations are in transition. However, both organizations have made commitments to the creation of a clinical repository, from which data can be collected.

THE INFOMEDIARY NEEDS TO MANAGE PATIENT IDENTITY ACROSS ORGANIZATIONS

A third challenge for an infomediary is to integrate the identity of the patient at the time they present for care and to convey this information in a form that will be useful to the patient themselves when they are using infomediary services. A specific requirement is that clinical data needs to be tagged to the specific patient. We do not want to assume that some existing organizational function, for example, a medical records function in a physician practice or a medical records department in a hospital, is required to manage the identity of patients. Each organization knows its patients by information and processes unique to its scale and needs.

This project does not propose to create, promote, or assume a universal health care identifier. We recognize that there are many political and social issues surrounding the notion of a universal health care identifier in America. Instead, we will allow for the possibility that a patient has multiple identities in the infomediary, just as one might have multiple identities – in the form of different login names – at different web sites on the public Internet today. This reflects the fact that patients are known individually at different care providers, by which we mean that each care provider knows its patient population idiosyncratically, in a way that is fundamentally uncoordinated between them. In fact, the only thing that establishes the patient's identity in common is the fact that the patient consistently refers to herself by the same set of demographics. We envision that the patient has control over the use of these identities in the infomediary.

We intend to use a patient-centric model for merging identities in the infomediary. The central idea is to let the patient manage their multiple identities as they see fit. They will of course be encouraged to manage their multiple clinical identities in a way that will enable research benefit. A patient has multiple identities because they see different care providers. This implies that the infomediary will support the ability of the patient to create a synthesized identity that is the logical union of their separate identities at each of the establishments from which they receive care. Among other things, because the synthesized identity results from the patient's action, the potential mis-matching of clinical data is avoided. Naturally, the ability to opt-out of a merged dataset would be a necessary condition for patient control.

The workflow process of the organization needs to support the patient's use of the infomediary. This means that the registration/admission and discharge processes need to support the use of the patient's identity in the infomediary. These processes will need to support the use of collateral materials (for example, specially printed instruction sheet reminders) for being able for issuing a "shared secret" so that the patient may log-on to the infomediary. The front-desk of a clinic may need to support questions from patients on how to perform specific infomediary functions.

THE OUTCOMES INFOMEDIARY IS NOT AN IOM ELECTRONIC MEDICAL RECORD

The focus of the outcomes infomediary is to be a longitudinal repository for the study of chronic disease. The outcomes infomediary links clinicians, patients, and health services researchers.

How far is outcomes infomediary from the concept of the electronic patient record envisioned by the Institute of Medicine over a decade ago? (32)

We suggest that it is important to distinguish the need for a longitudinal record focused on health services research from the electronic medical record hypothesized by the IOM. Its many cogent and meaningful examples demonstrate the value of a ubiquitous information network. Yet building such a network is extraordinarily difficult without clear definition of the workflows that it needs to support. The IOM study could not define the common workflows that need to be present, but it could envision the benefits of ubiquity.

We are proposing to create specifications, prototypes, and a working example of an outcomes infomediary. The scaling of this kind of system to all providers in a community will lead to the ubiquity proposed by the IOM. Adding the incidental information will be easy.

The purpose of this research is to build an information system for a valuable set of workflows, which will make a difference in the practice of medicine.

Section C: PRELIMINARY STUDIES

In April, 2002, the two co-PIs (Woods and Lammie) were awarded a USC School of Medicine/School of Public Health Collaborative Research Incentive Program for a “Feasibility Plan for Developing and Testing a Patient Outcomes Systems.” This plan has led to the initial conceptualization of an outcomes infomediary.

In the fall of 2001, the PI (Druseikis) and co-PI (Woods) engaged the Palmetto Health Alliance in a series of informatics planning meetings in which two facts were discovered. First, plans for the creation of a organizational clinical repository were under way, but there was a serious concern about the ability of clinical staff to make use of the information in terms of on-going clinical studies. Health services researchers at the University could not engage in studies with a wealth of (de-identified) data because the sharing mechanisms were always ad hoc. Second, it was becoming increasingly clear to executive physician management that the ability to track outcomes after patients leave the acute care setting would be necessary in order to make significant progress in continuous quality improvement initiatives.

Section D: RESEARCH DESIGN and METHODS

THE FUNCTIONS OF AN OUTCOMES INFOMEDIARY ARE DEFINED BY WORKFLOW

We will utilize use case analysis in this project for two purposes: (1) to define the scope of different activities required of an outcomes infomediary in concept (the system as it is expected to be) and (2) to define the actual information flows of the Family Practice Clinic (systems in place.) The deployment of the system rationalizes these two different views.

We have identified seven use cases: Research Program Definition & Analysis, Patient Identity & Enrollment, Definition Standard Instruments & Data Collection, Clinical Protocols, Consents, Coding, and Configuration.

Research Program Definition & Analysis

These use cases deal with the activities involving the definition of research programs the acquisition and use of de-identified data. These activities involve the collaboration of clinicians and health services researchers.

Patient Identity & Enrollment

These use cases deal with activities involving the identity of the patient in the infomediary. They intersect the activities involving patient registration, admission, or discharge. It would include enrollment of the patient in the infomediary. These activities involve interaction between clinic support staff and the patient. It is our goal to implement a structure that will enable organizations with “arms-length” relationships to participate in the infomediary within a specific locale.

Definition of Standard Instruments & Data Collection

These use cases deal with the collection of self-reported outcomes collected via standard instruments. They support the definition of new instruments, the collection of instruments via different networking technologies, and the storage of data. These activities involve health services researchers and (indirectly) the patient (as one reporting information), either at the clinic or at home, as the target for collecting functional health assessments.

Clinical Protocols

This use case deals with the definition of research protocols and interventions that might be recommended based on clinical evidence. These use cases close the feedback cycle to the clinician based on statistical evidence accumulated from health services studies. These activities involve the interaction between health services researchers and clinicians.

Consents

These use cases deal with the administrative issues of gathering “informed consents” and documents related to HIPAA. These activities involve the support staff as and the patient.

Coding

These use cases deal with the explicit issue of capturing clinical coding of diagnoses (e.g. ICD-9) labs, evaluations and assessments, and treatments. These activities involve the clinical staff and their use of information technology at or near the time a clinician comes in contact with the patient. This may also involve support staff functions and the capture of billing codes. The capture of valid coded information is a key issue for this research program.

Configuration

These use cases deal with the issues of configuring and operating the infomediary.

HYPOTHESIS CONCERNING THE FORM OF THE OUTCOMES INFOMEDIARY

Of great concern for this proposal is the notion of being able to generalize the outcomes infomediary beyond the context in which specific work is undertaken at the University of South Carolina, the Palmetto Health Alliance, and the Family Practice Clinic. We use the term “scalability” to refer to the issues involving the operation of a “busy clinic” – that is, the ability for the systems to operate at a level that can sustain the offered load. Such systems involve support staff in addition to computers. A second requirement for being able to generalize the outcomes infomediary is to specify interfaces at well defined boundaries.

***Hypothesis #3* – Information systems supporting medical informatics could be more easily integrated with the outcomes infomediary across different organizations if there are standards to define the specific flow of information and the management of patient identity.**

We observe that the overarching goal of collecting functional health status assessments for use in clinical practice defines the flow of information for such a standard. We will test the flexibility of the model comparing it in context with other practitioners. We will engage other physicians in private practice in the Columbia, South Carolina, metropolitan area to critique and improve the basic model.

The best current example of specific standards for integration between *different* organizations is defined by the HIPAA standard transactions. These standards (based on ANSI X.12N and NCPDP) define the integration for the purposes of claims administration, not clinical practice.

There are standards that address clinical integration between different departments in the *same* organization, for example, HL7 and DICOM. We note that the issues of system integration when all of the constituent systems are owned by a single organization are vastly different from the issues of integration in an open (not centrally controlled) system.

As mentioned above, we will develop the outcomes infomediary to be independent of specific instruments and capable of generalization to accommodate not only current instruments but future ones as well. We note that the capabilities of new information technologies put standards and frameworks in place that enable tools based on XML to be selected for this purpose.

We envision system integration at low cost to be driven by a complete, published open specification. We envision that such a specification could be taken to a recognized ANSI SDO (Standards Development Organization, e.g. HL7) to vetted industry-wide through their standards development process. A wide variety of specification techniques and middleware technologies are available to support this vision. Such open specifications are best achieved via peer review of technical experts.

Finally, we envision that the ability of these adopted by others will depend on the availability of technologists able to deal with the system architecture. Open source software provides an optimal least cost implementation strategy for some components of the infomediary. However, we believe other commercially software (for example Windows) will be needed also.

Six products will result from this project:

- (1) A patient outcomes data management system integrated into the operation of a specific busy clinic.

- (2) A peer reviewed master plan for an outcomes infomediary based on open source and commercial software as appropriate.
- (3) A deployed instance of the outcomes infomediary scaled for the level of operation envisioned for initial data collection studies in Columbia, South Carolina, integrated from available components.
- (4) A health services research project designed to utilize patient data from the outcomes infomediary to test the relationship between self-reported outcomes and clinical data measures for chronically ill patients.
- (5) A feasibility plan for a clinical quality improvement protocol designed to maintain or improve the functional outcomes of patients with the specified chronic disease.
- (6) A feasibility plan for a health services research project designed to test the effectiveness of the clinical protocol on long-term patient outcomes.

Section E: HUMAN SUBJECTS

The human subjects of this study will all be patients presenting at the Family Practice Clinic of the Department of Family and Preventative Medicine with confirmed diagnoses of congestive heart failure and who agree to participate. This project involves no medical intervention, only the gathering of personally identifiable protected health information.

This study will not exclude women or minorities from participation. The Family Practice Clinic operates under an explicit mandate for under-served and minority populations.

Because of the initial focus of congestive heart failure in adults, children will not be part of this study.

Section G: LITERATURE CITED

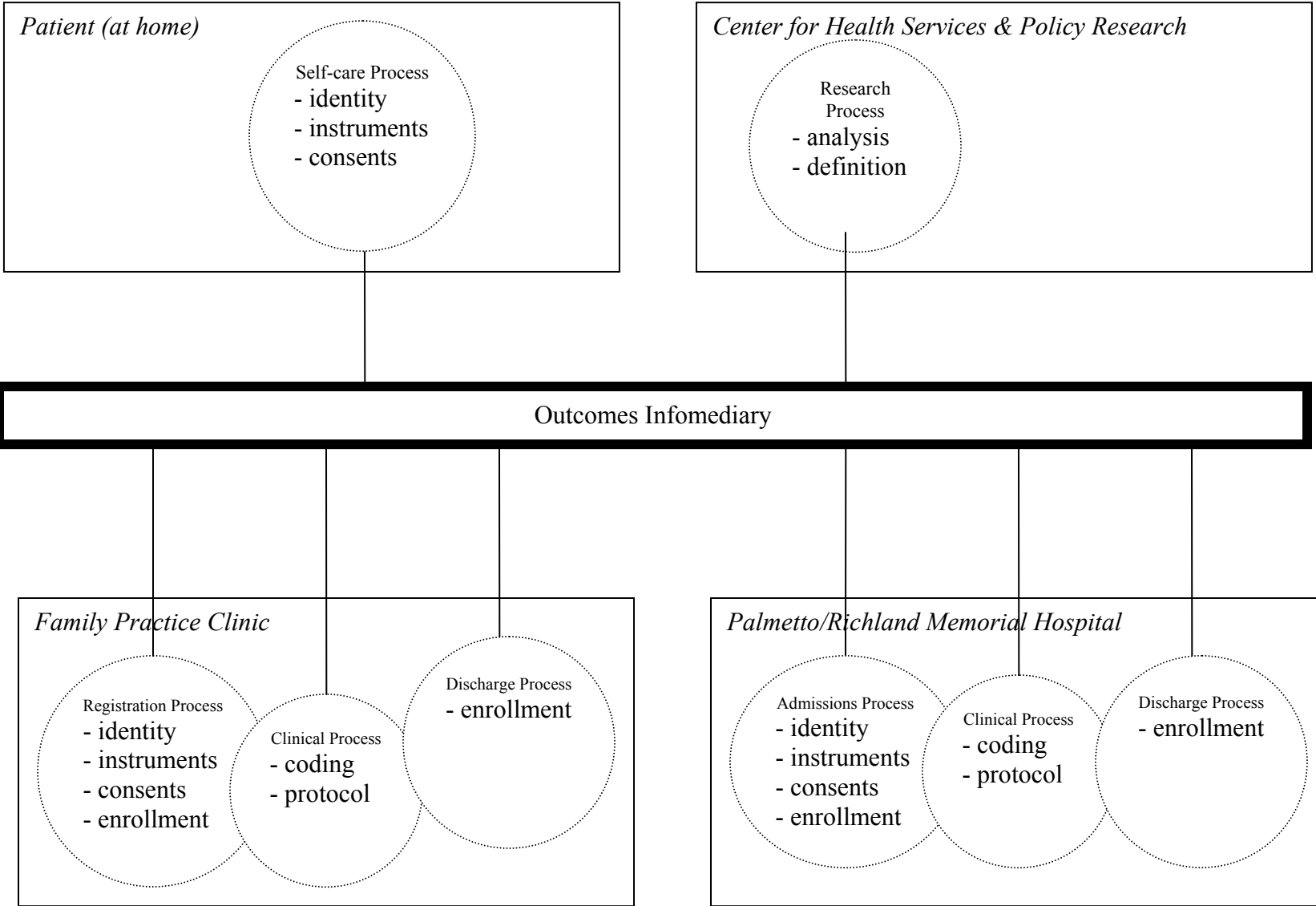
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