BrightOutcome
COLLABORATIVE SYMPTOM MANAGEMENT

BrightOutcome technologies

Our technological framework incorporates validated innovations in a variety of areas, including Computerized Adaptive Testing (CAT), Patient Education, Telemedicine, Care Coordination and IT.

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BrightOutcome Technologies

A Computerized Adaptive Testing

CAT/IRT reduces patient burden by dynamically selecting questions from a large pool without sacrificing measurement precision.

Computerized adaptive testing (CAT) is a method of administering tests that integrates advanced computer technology and item response theory (IRT). CAT is a special type of computerized testing that targets the "difficulty" of questions to the trait "level" of the person (e.g., level of fatigue). CAT can produce an accurate estimate with fewer questions by selecting and administering subsequent items based on a person's prior responses. This is in contrast with the classic testing approach where all questionnaire items must be selected and ordered before a fixed-format assessment starts. Each person only needs to answer a subset of targeted items in order to obtain a measure that accurately estimates what would have been obtained had the entire set of items been administered. In fact, the capacity to measure all patients on the same latent trait continuum, even if they have not been presented any items in common, gives rise to the possibility of a test that is individually tailored to each patient.

IRT is the theoretical foundation of CAT and is a statistical theory consisting of mathematical models expressing the probability of a particular response to a test or survey item as a function of the quantitative attribute (latent "unobservable" trait) of the person, and of certain characteristics (parameters) of the item. IRT models have been routinely applied in educational testing to measure ability or proficiency and psychological assessment to measure personality traits. More recently, the use of IRT models in PRO assessment has grown considerably over the past decade. Its gain in popularity and acceptance is mostly due to the observation that it provides more adaptable and effective methods of measurement instrument construction, analysis, and scoring which complement those derived from classical test theory. CAT/IRT application in medicine is a recently advocated novelty and its growth has also been evidenced by the many publications in the area (see Medical Care, Volume 38, Number 9, Supplement II, 2000, pp. 28-82).

PROMIS is an NIH Roadmap Initiative, attempting to produce new PRO instruments based on CAT/IRT. We are collaborating with PROMIS.

The National Institutes of Health recognized the importance of the use of PRO in medical care and specifically the use of CAT/IRT technologies for PRO assessment, it funded a 5-year $25MM Roadmap Initiative project called PROMIS (Patient-Reported Outcomes Measurement Information System) to "establish a national resource for accurate and efficient measurement of patient-reported symptoms and other health outcomes in clinical research and practice" utilizing CAT/IRT technologies. We are proud to be one of the PROMIS collaborators dedicated to integrating PROMIS adaptive measurement products (called "item banks") into clinical practice.

B Telemedicine

The Institute of Medicine defines telemedicine as "the use of electronic information and communications technologies to provide and support health care when distance separates the participants". Telemedicine is considered a technology with great promise. With the expectation of improved efficacy and cost-effectiveness, there has been increased worldwide interest in telemedicine to address a number of problems in health care delivery. Although initially developed by NASA to facilitate the medical care and physiologic monitoring of astronauts while in space, telemedicine use has spread to rural, geographically dispersed populations and urban areas where access to basic or specialty care is difficult. Today, there are thousands of telemedicine programs worldwide. The technology is not regarded as experimental.

According to the 2004 report “Innovation, Demand, and Investment in Telehealth” published by the Technology Administration of the Department of Commerce, the main driving forces behind the telemedicine market include access to quality healthcare, seamless continuum of care, home healthcare, and homeland security (i.e., military and public health). Federal and state government agencies as well as private hospital chains have invested significant resources in promoting the use of telemedicine. For instance, the Veterans Health Administration (VHA) has implemented a Community Care Coordination Service program to “provide the right care at the right place at the right time where the place of residence is the site of care.” The State of Arizona has implemented a statewide telemedicine program. The New Mexico State Department of Corrections uses telemedicine to provide health service for inmates. The Shriners Hospitals for Children started their telemedicine program back in 1998. These are just examples of practical telemedicine applications where the proposed work could be potentially utilized.

In the same report, home healthcare agencies are one of the best business models that can actually project self-sustainability for telehealth investments. Some of these agencies have already worked with Veteran Affairs to provide telehomecare and telemonitoring services. The telehomecare market opportunity does not stop at home healthcare agencies. The VHA and DoD are government agencies that are particularly interested in telehomecare technologies. Cancer centers/hospitals, hospices, assistant living facilities, and skilled nursing facilities could all benefit from this product. In addition, we will pursue licensing partnership with vendors of telehealth systems and disease management systems.

We are partnering with the Arizona Telemedicine Program in product development and validation efforts..

We are proudly partnering with the Arizona Telemedicine Program (ATP) for our product development and validation efforts. The ATP is a large, multidisciplinary, university-based program that provides telemedicine services, distance learning, informatics training, and telemedicine technology assessment capabilities to communities throughout Arizona. The program has succeeded in creating partnerships among a wide variety of non-profit and for-profit healthcare organizations, and has created new interagency relationships within

the state government. Functioning as a "virtual corporation," the ATP is creating new paradigms for healthcare delivery over the information superhighway. The program is recognized as one of the premier programs at the University of Arizona, and has received numerous awards at the national level for its research and innovations. The Program was initially funded by the Arizona state legislature. Current funding also includes competitive funding from federal and foundation grants.

Since its inception in 1996, the ATP has provided medical services via both real-time and store-and-forward technologies. The ATP has performed over 3,000 clinical telemedicine consultations, nearly 2000 telepathology cases, and 208,555 teleradiology sessions, of which 63,692 were digital mammograms read via teleradiology at the Tucson Breast Center. In addition to clinical services, this year, 500 hours of continuing medical education and continuing education will be delivered by ATP to thirty-four communities using bi-directional, fully interactive videoconferencing.

C Patient Education

The Institute of Medicine (IOM), in its report, *Crossing the Quality Chasm*, concludes that there are severe deficiencies in the current quality of health care and describes a set of ten rules for repairing the broken system, each of which contributes to a more patient-centered focus. A majority of these rules have tremendous relevance to innovative, timely, and evidence-based, patient education models:

- *Health care based on continuous healing relationships*: This calls for improved access to care, through multiple means, for patients. The IOM emphasizes that patients are discouraged by the lack of access to information and difficulty in finding the resources they need, when they need them.
- *Customization based on patient needs and values*: This calls for a provision of care that accommodates patient-specific requirements and desires. The IOM emphasizes that patient preferences require active solicitation and incorporation into clinical decision-making.
- *Patient as the source of control*: This calls for improvements in the patient's access to information about his care and greater choice for the patient regarding his level of involvement in his care. The IOM emphasizes that patients need better access to information about wellness and disease.
- *Evidence-based decision-making*: This calls for greater use of scientific evidence as the basis for medical decision-making. The IOM emphasizes that the best evidence needs to be available at the time and place where decisions are made.
- *Anticipation of needs*: This calls for more proactive management of patient needs, particularly for patients with chronic conditions. We need to do more to draw patients into preventive care and screening.

To help achieve the IOM rules above, we integrate just-in-time, context-sensitive, and evidence-based patient education opportunities into our collaborative symptom management model in such a way that the patient can receive high-quality self-

management instructions specific to his or her own needs exactly when they are needed. By empowering the patient to play a more active role in the healing process through this collaborative symptom management model without worrying about access to quality care issues, we strive to improve quality of care, patient outcomes, and reduce cost in the care of chronic diseases.

D Care Coordination

Wertenberg et al. (2006) described the work by the VHA Office of Nursing Service Strategic Planning Work Group (ONSWG) defining care coordination components as follows. We discuss how our PRO management and care coordination solution addresses issues pertaining to each of these components.

VHA Care Coord. Components	Comments
Assessment/reassessment of patient: physical, emotional, psychosocial	This is an essential piece of our PRO management solution. By integrating PROMIS instruments and providing the flexibility to add additional instruments, our solution facilitates the assessment of patient health status, concerns, and needs.
Patient education provides survivor skill sets; provides the beginning information to make informed healthcare choices, and participate in his or her treatment planning process	Our solution provides a convenient vehicle to deliver just-in-time, context-sensitive instructional materials tailored to the patient's disease status and treatment regimen. Currently our focus is on the management of cancer treatment side effects. However, the framework can be extended to include fully developed patient education programs covering other topics such as survivor skill sets.
Disease management facilitating lifestyle changes/health-promoting behaviors.	This is addressed indirectly via appropriate patient education materials in the long run. Lifestyle changes and health-promoting behaviors are long-term commitment.
Facilitates communication between provider, patient and family	This is an essential piece of our care coordination, which implements a routine communication channel to facilitate and monitor dialogues between providers, patients and caregivers for symptom management and patient education.
Prompt intervention based on close, frequent monitoring/just-in-time care leads to improved compliance	This is an essential piece of our PRO management and care coordination solution. The alert and auto-notification features are designed to facilitate frequent collection of patient status data on a regular basis and prompt timely intervention when necessary.
Navigates/coordinates the healthcare system; acts as patient advocate	Our solution currently does not address this issue.
Coordinates care based on identified patient need	Our solution facilitates the coordination of care by identifying patient needs based on self-reported status and routing the case to appropriate parties.
Supports the caregiver; sustains the patient outside of the facility through communication	Our solution directly involves caregivers in the care process with roles ranging from directly using the system to help assess the patient's status and needs, to being notified automatically when certain events arise.

E Information Technologies

E.1 EMR Standards

There has been enormous interest both within government and private industry in developing interoperability standards in order that heterogeneous healthcare information systems can communicate and exchange data with each other. To foster and facilitate the adoption of PRO in clinical practice, we strive to make our solution standards-based.

A major standardization effort for the healthcare industry in general is the Health Information Technology (HIT) Initiative from the Department of Health and Human Services (DHHS). Under the HIT Initiative, a series of Use Cases have been developed for Consumer Empowerment, Electronic Health Records, and Bio-surveillance by the American Health Information Community (AHIC). The Healthcare Information Technology Standards Panel (HITSP), an ANSI standards body, then developed the interoperability specifications for each of the three use case sets by critically evaluating and harmonizing numerous overlapping and competing standards such as Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), Digital Imaging and Communications in Medicine (DICOM), just to name a few. By defining and embracing these standards, automatic data transfer between information systems at different healthcare organizations will become much more manageable.

The collection of patient-reported outcomes (PRO) is not mentioned explicitly in the recently published (May 2007) HITSP Interoperability Specifications V2.0. However the concept of PRO has started to appear in standards used by HITSP. Of particular interest to this proposal is the Functional Status Assessment (FSA) Integration Profile of the IHE Patient Care Coordination Technical Framework Volume I (PCC-TF-1) Rev. 3.0. FSA is a new and first attempt in standardizing the representation of PRO assessment data in medical records. The FSA Integration Profile is highly related to three other PCC Integration Profiles: Cross-Enterprise Sharing of Medical Summaries (XDS-MS), Exchange of Personal Health Record Content (XPHR), and Emergency Department Referral (EDR), since FSA is part of these higher-level of clinical documentation.

The IHE PCC specifications are included explicitly in the HITSP Interoperability Specifications for Bio-surveillance and Consumer Empowerment. The EHR specification is currently defined narrowly for laboratory results only and hence does not include the broader PCC specifications. Since FSA is a new specification still under review, it is unclear when it will be adopted by HITSP. Nevertheless, we believe FSA, and hence PRO in general, will eventually be incorporated into HITSP standards.

E.2 Development Process

This development methodology comprises of four major development tasks: Analysis, Design, Implementation and Quality Assurance. These tasks do not necessarily imply a

"waterfall" approach, where distinct development phases are executed in a consecutive sequence. For object-oriented (OO) system development, it is common to follow an "iterative" process, where a group of software components can be designed and developed first and used as the basis for the analysis and design of another group of components. An iterative approach allows the incremental construction of the system instead of a "big-bang" approach and is likely to result in the shorter overall project duration with better quality because of its "divide-and-conquer" strategy.

Analysis. The primary goal of the Analysis task is to capture the complete business and technical requirements and determine a high-level technical direction. For OO system development, system requirements are commonly documented in Use Cases, which define how a user interacts with the system. To separate graphical user interface (GUI) requirements from backend business processing requirements, it is also common to use static mockup screens to document screen/page flows and behaviors.

Design. After the completion of pertinent Use Cases and mockup screens, the Design task can start with the goal to translate the requirements into programmable constructs using OO analysis and design (OOAD) methodologies. Class Diagrams and Sequence Diagrams are two major artifacts produced during this task. Class Diagrams specify the structures and relationships between system components. Sequence Diagrams document how pertinent system components interact with each other to implement a particular functionality.

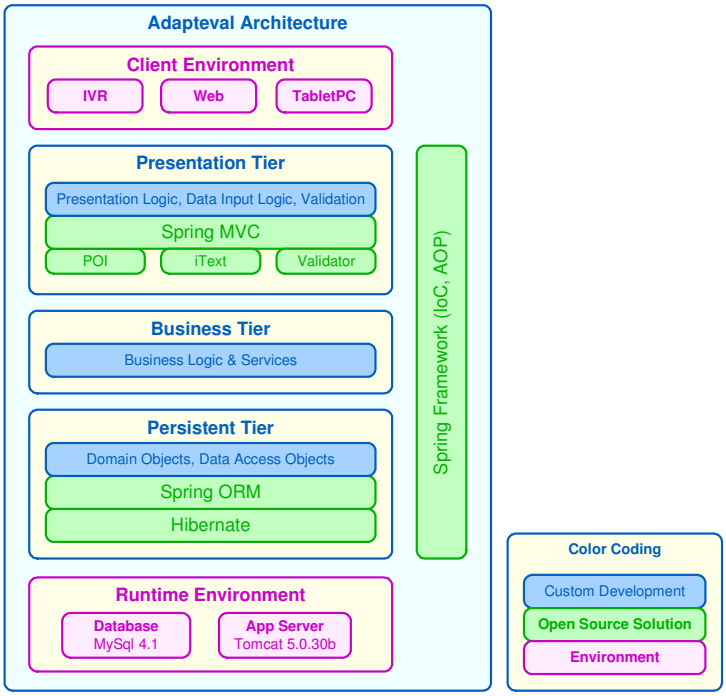
Implementation. The Implementation task converts the design artifacts into executable programs. We use Java as our implementation language. The implementation task also includes necessary unit/integration tests. All tests are self-contained programs and must be executed successfully before each of the development builds is completed. This focus on testing during implementation is the central theme to the concept of Extreme Programming and helps ensure the quality of the software.

Quality assurance. The Quality Assurance task is to eliminate functional defects from the product and to understand system characteristics such as performance and scalability via functional and performance testing. Defects are produced during the tests and tracked as developers make software fixes. This is an iterative process that may go through many cycles. To better control the scope and schedule of the project, defects are prioritized based on functionality importance and technical complexity.

E.3 Technical Architecture

We used a tiered architecture as the foundation to build our application, including the Presentation Tier, the Business Tier and the Persistence Tier. This architecture is a common design for J2EE-based web applications with each tier utilizing the functionality provided by the immediate lower tier, but not vice versa. The following diagram illustrates

the relationship between these tiers as well as certain open-source software solutions that we leveraged for our product development.



Presentation Tier. This tier is responsible for interfacing with the user directly in presenting business data generated from the Business Tier to the user and collecting and forwarding user input to the Business Tier for processing. The presentation tier is Model-View-Controller (MVC)-based (see below) and mostly uses JSPs as the scripting/templating language. This JSP-based approach directly supports HTML, VXML, and XML as the output format. Other output formats such as PDFs and Word documents are also possible via Spring (see below).

Business Tier. This tier is responsible for the implementation of business logic and services. It has no concern about how the data will be presented or stored. Ideally, this tier is where the bulk of Java development should focus and various techniques (see below) have recently been introduced to help Java developers focus on this aspect of development without worrying about other infrastructure/plumbing issues plaguing many applications. Also, another thin layer of web services will be built on top of this layer to expose our business services as SOAP-based web services accessible from other systems.

Persistence Tier. This tier is responsible for persisting business domain objects, typically in relational databases. Data access objects (DAOs) are often designed in this tier to encapsulate data access logic. Because of the disparity between tables and rows in relational databases and objects in object-oriented applications, it is common to have a persistence framework to bridge the gaps between these two different conceptual models rather than resorting to direct JDBC/SQL calls.

This system is protected using various technologies at different levels. At the transport layer, we use the https protocol for data encryption and transmission. At the application level, we will use JAAS-based security mechanism that authenticates off a database server, which is also a common J2EE application design.

Software Frameworks. To improve product quality and reduce development efforts, we use several well-known open-source software solutions to facilitate the implementation of our system. Some of these software solutions are used only in the development environment, not in the runtime environment. The Spring J2EE application framework and the Hibernate persistence framework are the two frameworks that we heavily leverage to build our system.

Spring Framework. The Spring Framework is a relatively new paradigm in developing J2EE applications that has attracted considerable attention lately, with the initial intention to provide a lightweight alternative to EJB-based solutions. EJB is a comprehensive solution to an array of complex enterprise computing issues. However, the power of EJB brings a level of complexity that is difficult to justify for many enterprise applications. In general, Spring is a viable alternative when EJB is used to provide just declarative transaction management and object persistence, while EJB may be more suitable when distributed transactions are involved.

Hibernate Framework. Hibernate is a very popular high-performance open source object-relation mapping (ORM) solution. Not only does it provide basic ORM functionality where developers are concerned only with business objects but not the underlying relational database table structure, but also sophisticated features such as lazy loading, eager fetching, caching, and cascading. Using hibernate can improve both development productivity and runtime performance.