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A real time online assessment system with modeled architecture on clinical infometrics for patient reported outcomes of prostate cancer

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ABSTRACT

Objective: The aim of this study was to establish a real time online health and decision support system with the novel information technology integrating modeled architecture and Web services for clinical infometrics on patient reported outcome (PRO) and quality of life (QOL) for prostate cancer patients.

Methods: The patient-oriented interface was practiced with object relation mapping (ORM) and clinical data warehouse to collaborate QOL measurement and medical informatics through internet by incorporating a variety of hospital information systems. The conceptual infrastructure was designed by five primary layers to organize the data flow of online assessment and clinical data for real-time decision support.

Results: A preliminary knowledge bank was formed by feedback of expert opinions to provide online guidance for decision references. Observation and assessment of prostate cancer patients' QOL and clinical markers were immediately tracked with automatic computation algorithm to improve health care quality in the treatment cycle.

Conclusions: The established Web-based system can help clinicians concurrently collect and analyze real-time PROs and QOL for enhancing communication with patients and improving the quality of care.

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1. Introduction

Rather than a single therapy for a cancer treatment, the cures with compound therapies by medical progress became new tendency in the past years. The major cancer therapies for destroying tumors usually bring side effects that could cause vomit, asthenia, and hair loss in addition to mental suffering. Therefore, patients' quality of life (QOL) was deeply impacted by their unsafe and anxious feelings for uncertainty and after-effect due to treatments of the oncology clinic. It is worthwhile to design an automatic system with flexible functionalities for immediately responding QOL assessments with clinical markers beyond the hospital information system (HIS). Insufficiently, the quality of clinical care may be diminished when clinicians explain clinical markers to their patients without presenting analytical data and visualized diagrams. Sometimes, patients are embarrassed to answer private questions as watched by health care people and probably even hide the actual conditions to lead incorrect judgments. Bridges et al. [1] formulated a vision of how a patient-based health technology assessment could be used to promote patient empowerment and patient-centered care. Based on the professional book [2] of biomedical informatics for discussing computer applications in health care, an electronic healthcare information with clinical decision support system (CDSS) is quite important for clinicians to efficiently obtain instant and reliable patient report outcomes (PROs), e.g. QOL, as well as patient clinical records (PCRs) to improve the quality of medical care in clinic. As comparing the documentation quality by electronic and paper-based medical records, the past study indicated that high workloads, shortage of bedside hardware and lack of software features were prominent influential factors [3]. Many studies reviewed a variety of computer-based CDSSs and concluded that clinical performance and patient outcome could be enhanced for active medical care and other aspects of healthcares [4,5]. To provide efficient facilities for physicians, for example, many studies developed decision aid tools or specific information systems to improve quality of care in hospitals with limited financial resources [6-8]. Obviously, it is not easy to create a universal HIS for satisfying varied clinical requirements. However, it would be possible and helpful to generate an expandable platform with flexible components for specified clinical purpose beyond a generalized framework. Therefore, the Web-based information system with customized components for health care becomes a solution to incorporate PROs and the CDSS to adapt the existing HIS according to different requirements of hospitals.

Recently, Chang [9,10] established an interactive assessment and management system, which is called clinical infometrics by technologies of information and psychometrics for measurement, statistical modeling, informatics and practice, to improve clinical assessment with computerized procedure in palliative care. The system contains informatics, predictive models, PRO item bank, computerized adaptive testing, clinical practice guidelines and practices for obtaining better treatment effects. Applied for measurement and management of PROs, infometrics technique can help clinicians precisely recognize actual feeling and response from patients and improve the quality of care with instant process as well as

data statistics for real time outcomes and online clinical decision. Clinicians can further convince patients by comparing their instant outcome with others in clinic visits.

In this study, we proposed an integration platform of Web-based infometrics system, which combines CDSS and health care information, for clinical infometrics of prostate cancer treatment by involving components of novel information technology, health care assessment, and evidence-based medicine. The methods for developing the system upon the modeled architecture were detailed to incorporate heterogeneous databases with Web services according to patient's convenience and clinical requirement. In advance, the assessment of QOL was practiced for real time online clinical decision support. Finally, the proposed system was approved by the institutional review board (IRB) and was implemented in the Hospital of China Medical University (CMUH) in Taiwan to deliver the functions of multi-disciplinary, patient-centered, evidence-based, methodology-derived, database-driven, and technology-assisted characteristics.

2. Methods

In this section, the Web-based models of the conceptual architecture are described for constructing the infometrics system by novel information technology to collate PCRs and PROs data with online QOL assessment of prostate cancer patients.

2.1. Infometrics of quality of life

When the superior standard of medical environment is served, the higher criteria for quality of health care must be enhanced. Compared to importance of survival evaluation, QOL hence becomes another significant index of health care.

The World Healthy Organization (WHO) defines the QOL as individuals' perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns. European Organization for Research and Treatment of Cancer (EORTC) creates series of QOL assessments in cancer clinical trials to provide a more accurate evaluation of the well-being of individuals or groups of patients and of the benefits and side-effects that may result from medical intervention. The reliability, validity and sensitivity of assessment are acceptable since questionnaires have been translated and validated into a variety of languages and are used in more than 3000 studies worldwide. Thus the quality of life questionnaire (QLQ) C30 can assess the QOL of cancer patients while several other modules are running for specified cancers such as breast, lung, etc., and PR25 is one of the modules designed for prostate cancer patients.

In this study, a web-based platform of real time online assessment was developed for infometrics system to serve prostate cancer patients. The core measurement of QLQ C30 with prostate cancer module PR25 were selected in the system as well as connected to PCR database. The QLQ-C30 incorporates nine multi-item scales: five functional scales (physical, role, cognitive, emotional, and social); three symptom scales (fatigue, pain, and nausea and vomiting); and a global health and quality-of-life scale. Several single-item

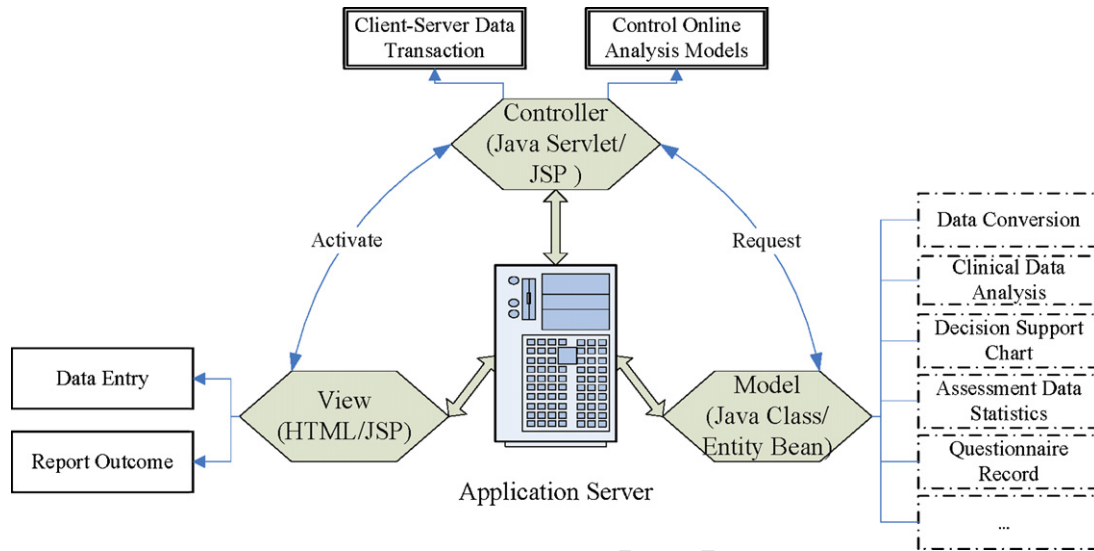


Fig. 1 – Model-View-Controller components.

111 symptom measures are also included [11]. The PR25 is a 25-
 112 item questionnaire designed for use among patients with
 113 localized and metastatic prostate cancer. It includes sub-
 114 scales assessing urinary symptoms (9 items), bowel symptoms
 115 (4 items), treatment-related symptoms (6 items) and sexual
 116 functioning (6 items).

117 All questionnaires with enlarged font and selection buttons
 118 were displayed on a touch screen by patient-oriented design
 119 for an accessibility interface. Besides, an optional functional-
 120 ity of multimedia was available for patients who cannot read.
 121 Patients were arranged to complete questionnaires easily in
 122 a private space as waiting for outpatient service, and then
 123 clinicians can evaluate instant assessment results with online
 124 analysis report by practicing automatic process of computa-
 125 tion and statistical modeling.

126 **2.2. Modelized architecture**

127 To acquire QOL data of patients from the Web-based infomet-
 128 rics system and adapt to the legacy HIS, a concept of modelized
 129 architecture would be implemented as the foundation. The
 130 base of this architecture reflects the model-view-controller
 131 (MVC) design pattern, which was established in 1970s by
 132 including several design patterns to describe proven strate-

gies for building reliable object-oriented (OO) software system
 [12]. The concept was first made available by Gamma et al. [13]
 to introduce 23 patterns related to creational, structural and
 behavioral models for software design to progress recurrent
 elements. The MVC theoretically divides system responsibil-
 ities into 3 parts: the model, which maintains program data
 and logic; the view, which provides a visual presentation of the
 model; the controller, which processes user input and makes
 modifications to the model [14]. In the other word, the system
 based upon the modelized architecture may be imagined as
 a human being who has organs (model) to create physiologi-
 cal functionalities; has eyes, ears, or limbs (view) to sense or
 behave responses; and has a brain (controller) with the neural
 system to structure persistent communications throughout
 the whole body. Hence the MVC-based framework uses its
 input control to solve the problems on consuming compu-
 tation resources when the user is not interacting with the
 interface and avoid unnecessary performance loss [15].

According to the architecture, the approach of online QOL
 infometrics would be constructed on the Web-based platform
 with the open source framework. The framework is required to
 support less services but it is much less intrusive than enter-
 prise modules; and the driving force behind this shift is the
 need for greater productivity and reduced complexity in web

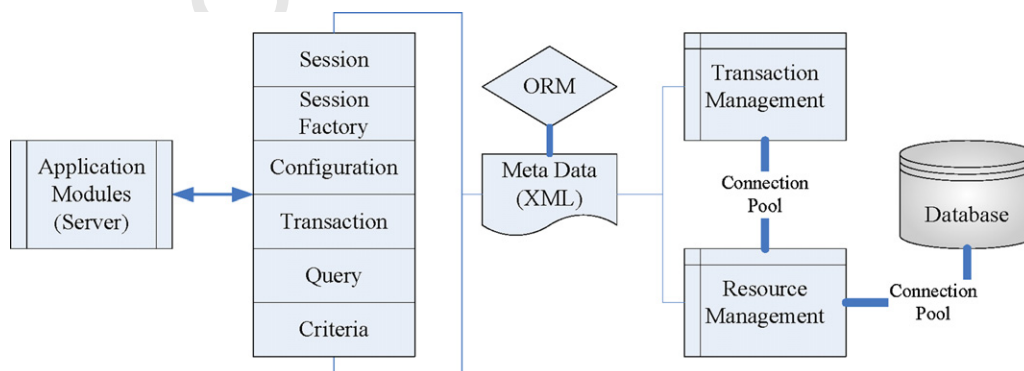


Fig. 2 – Data flow in object relational mapping.

application development and implementation [16]. Herein, the system must request assessment components with flexible functionality and patient-oriented interface. The conceptual frame is outlined in Fig. 1, and main components are organized by three parts containing the model, view and controller, which provide individual modules but support one another due to system requirements such as QOL assessment, decision support, and so on.

2.3. Object relation mapping mechanism

Object-relational mapping (ORM) is a programming technique for converting data between incompatible type systems in relational databases and OO programming languages. It uses metadata that describes the mapping between the objects and the database to relate the automated and transparent persistence of application objects to the tables within database. The ORM, in essence, works through reversibly transforming data from one representation to another [17]. Therefore, we coordinate the infometrics and clinical data flow on the conceptual interface of ORM, shown as Fig. 2, to convert persistent objects and manage data transaction and resource prior to database. Based upon the mechanism, the session interface conducts lightweight instances of application in safe as the necessary data are requested on the web tier all the time; the application obtains session instances from a session factory to share many application modules and cache scripted database transaction and other mapping metadata at runtime for data conversion. Then, the configuration interface configures the location of mapping documents and specific properties for data retrieval; thus a transaction interface can be optionally selected to keep applications portable between different execution environments. Furthermore, the query interface performs instances to control data queries against the database, while the criteria interface executes OO criteria queries.

Herein, the assessment of QOL questionnaires and integrity of Web services for online analysis are implemented by the ORM modules to concurrently process and share light weight data over the Web-based system through rearranging storage, organization, and retrieval of structured data. By using XML-based configuration, metadata with mapping information and necessary parameters can be generated to synchronize application request from interfaces and database. Therefore, the framework exposes a configuration-time-meta model that declares the information in XML mapping documents for extension by user-written code.

2.4. Clinical data warehouse

To incorporate infometrix data with existing PCRs for online analysis, a clinical data warehouse was planned and practiced in this study. The data warehouse is an integrated, subject-oriented, time-variant and non-volatile database that provides support for decision making, and used to build up an integral database for historical data repository with lack of systematic arrangement by information technique [18,19]. It allows complex queries and analyses on the information without slowing down the operating system. The raw clinical data would be rigorously unified by the extract-transform-load (ETL) procedure, shown as Fig. 3, into database through extraction, consol-

idation, filtering, transformation, cleansing, conversion and aggregation [20]. As planning the data warehouse, the fact tables and related cube dimensions are key elements while classifying several schemas in different dimension models; i.e., the fact table contains facts that are linked through their dimensions, which qualify characteristics that provide additional perspectives to the given facts. In this study, we created the clinical and infometrix data warehouse in which the fact table represents data of QOL and PCRs while cube dimensions present advanced statistical information. Herein, we developed the control modules by inducing three primary database functions to build up the data warehouse: dynamic view, stored procedure and trigger. They were programmed by pre-stored database transaction scripts to generate dimensional cubes and enable the automatic processes while integrating diverse data in the data warehouse.

2.5. Web services and online analysis

Web services represent an interface for describing a collection of operations that are network accessible through standardized XML messaging [21]. The W3C defines a Web service as "a software system designed to support interoperable machine to machine interaction over a network." The key components within the infrastructure follow the standards of SOAP (simple object access protocol), WSDL (Web service definition language), UDDI (universal description, discovery, and integration) to interact heterogeneous service data with standard, formal XML notation; i.e., the services take the form of XML documents to translate metadata depicted by WSDL definition, transport data communicated through SOAP framework, and search information registered in UDDI mechanism. In our design, the historical data of QOL assessment stored in database were queried with statistical estimation and yielded the reference indexes to avoid laggardly processing upon large data; moreover, the computation model would retrieve decision criteria from unified document to create online statistical diagrams through Web services.

The technique of online analytical processing (OLAP) has been functional to decision support for an enterprise system since early period of network boom-up era [22]. It provides efficient functionalities on the backbone of data warehouse to explore historical data. To manage and analyze infometrix and clinical data in the study, we extended the OLAP over the Web server and database as online computation models of the CDSS. The QOL assessment and PCR query were integrated with heterogeneous database while accessing the server. This progress kept complex query behind data mining for knowledge bank but left simple data transaction through dynamic views in data warehouse.

3. System developments

3.1. Requirement analysis

With the limitation for security manners of hospital management, the architecture of proposed clinical and infometrics system was requested to integrate two individual networks which concurrently worked with the legacy HIS for PCRs

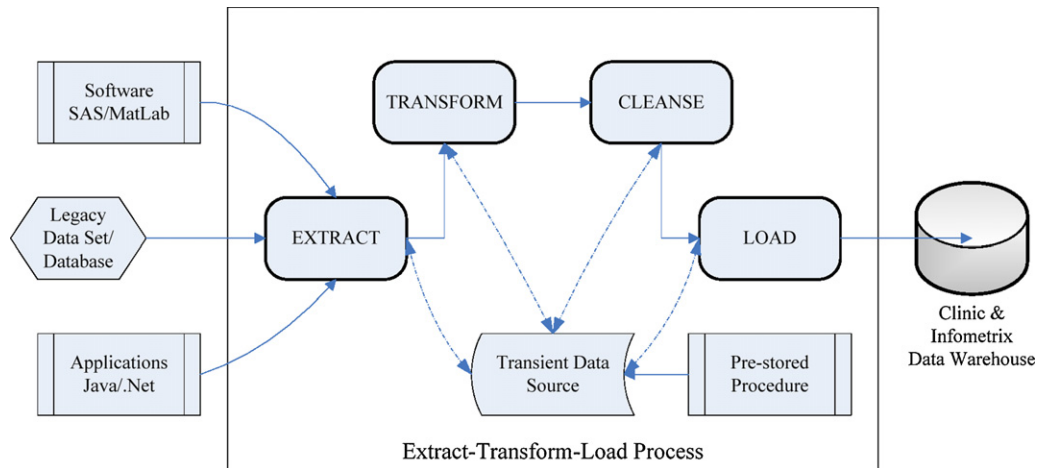


Fig. 3 - ETL process for clinic and infometrix data warehouse.

and clinical diagnostic interface. The initial development was planted on prostate cancer treatments in urology clinic for reflecting relationship between QOL and pretreatment parameters such as prostate-specific antigen (PSA), clinical classification stage, and Gleason score, etc. Referring the literature [23], prostate cancer rarely causes symptoms early in the course of the disease because the majority of adenocarcinomas arise in the periphery of the gland distant from the urethra. Growth of prostate cancer into the urethra or bladder neck can result in obstructive and irritative voiding symptoms. Local invasion of prostate cancer can involve the trigone of the bladder and lead to ureteral obstruction that, if bilateral, can cause renal failure. Through urologic treatments such as transurethral resection, radical prostatectomy, hormone therapy, etc., prostate cancer has greatly benefited from the discovery of tumor markers.

Hence analytical fundamentals of the system with automatic computation algorithm should be required by following scopes: (A) instantaneous observation of QOL assessment, online clinical markers tracked in the treatment cycle, immediate comparison with overall patients' QOL, and (D) real time cross-evaluation of QOL and clinical markers.

3.2. Integration design

From right to left in Fig. 4, the system was designed for collaborating database, analysis, management, presentation, and acquisition layers, upon the modeled architecture by implementing previous methodology.

1. The database layer founds the system base for building clinical and infometrix data warehouse. Fig. 5 illustrates the primary object relationship diagram and related schema, where the field attributes denote correlation between QOL domains and treatment effects. The designed schema combines two sets of fact tables for infometrix and clinical records so that "Answer.Full" and "Answer.Domain" tables store assessment data and transform to QOL domain scores, respectively, while "Patient.Info" and "Prostate.Cancer" tables retrieve data from PCR including essential information and clinical

biomarkers. The index table "Answer_Index" is the bridge to join both of fact table sets, "Answer" and "Question" tables which request and arrange assessment data, and derives cube dimensions of PSA, treatment, clinical stages and Gleason scores.

2. The analysis layer assists researchers in analyzing data and feeding back statistical results as resources of knowledge bank. In this study, several formats for converting data files were defined in advance to satisfy different database progresses that analysis tools could support. The layer incorporates both database and Web servers through remote computation or offline data mining and feeds back expert opinions into the knowledge bank of CDSS.
3. The management layer plays the role of control center for managing data flow within entire system. A management interface was designed for enhancing capability of data access functions to catch online charts, identify single sign-on, process data conversion, administrate user privilege, and acquire QOL assessment. All modules were created for sharing functionality but secured with privilege roles of health care people, clinicians and researchers.
4. The presentation layer yields the platform of real time decision support to provide communication interface between patients and clinicians. The visualized design can present coincident statistical information by expert opinions after automatically updating assessment database and knowledge bank. Herein, for prostate cancer infometrics, it simultaneously performed the real time QOL evaluation corresponding to the mean value of other patients with similar age, initial PSA, Gleason score, treatment stage, etc. Clinicians hence were able to improve efficiency of communication by indicating online treatment indexes through the graphical interface for advanced decision support.
5. The acquisition layer becomes the data receiver of system to react online QOL behind accessibility interface design. Perhaps most of patients felt uncomfortable, either in physical or mental status, while answering assessment questions by hand-written paper in person. For this design, the touch screen was installed for patients who are not familiar with operating computer by mouse; large font was

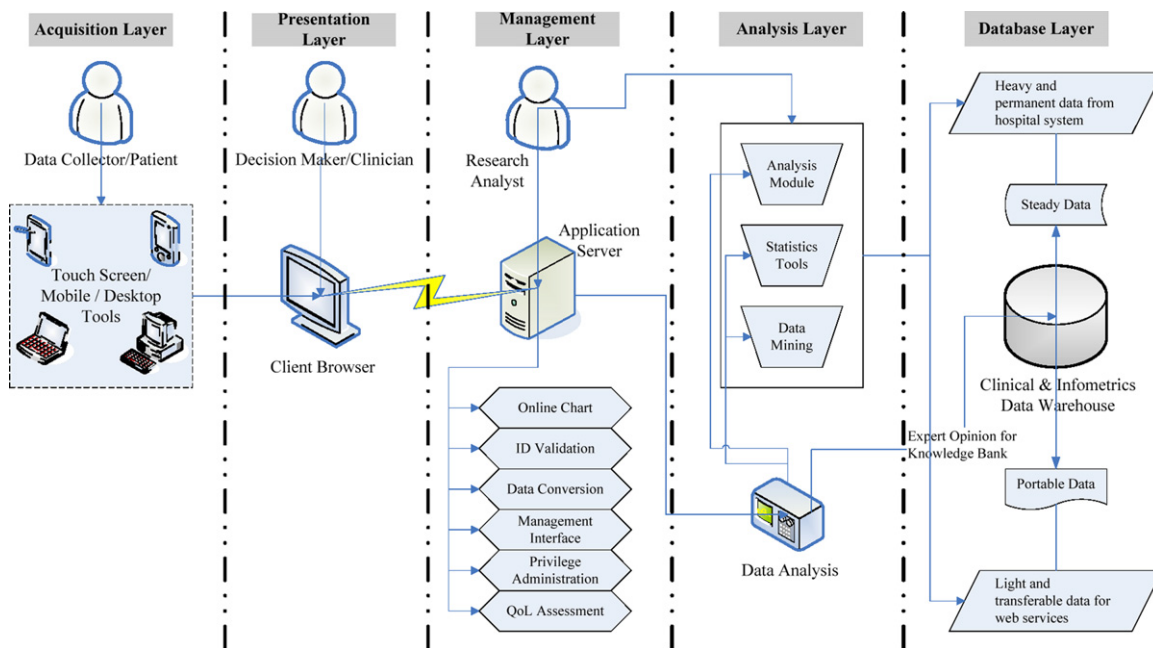


Fig. 4 – Five-layer development of CDSS infrastructure.

designed for senior patients who do not have good eyesight; audio-video media playing with ear or head phones were considered for low education level patients who could not recognize lettered questions.

Based on the system design, clinicians and researchers were able to access infometrix data after patients finished assessments through patient-oriented interface. For improving work efficiency and balancing dataflow loads of Internet data transportation, the Web server requests infometrix diagrams for decision support by processing lightweight data, thus the database server provides statistical analyses with querying heavy data. Furthermore,

the technique of remote backup and disaster recovery in database was practiced in the proposed system to ensure the integrity of clinical data warehouse. The procedure can remotely track the state of a primary system and take over data transaction processes when disaster hits the primary site [24]. In order to secure the privacy of patients, the PCRs must be forbidden from internet users except of particular clinical people; therefore, the primary database server for instant infometrix becomes the data center at the clinic site; meanwhile, a backup database server at the research site is allowed to routinely restore data through specified protocol.

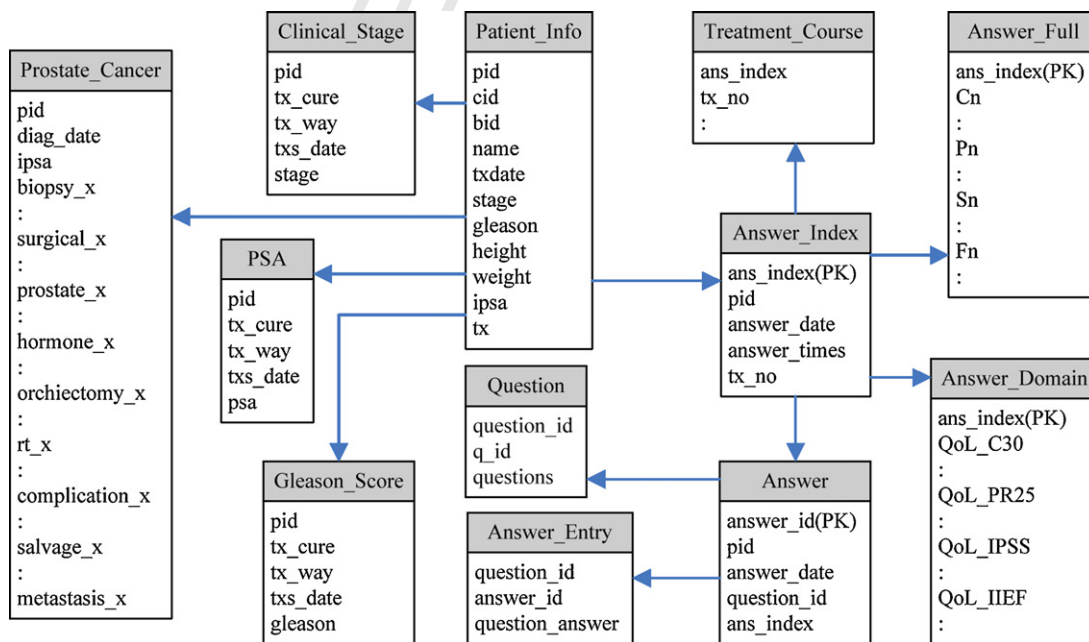


Fig. 5 – Object relationship diagram and schema.

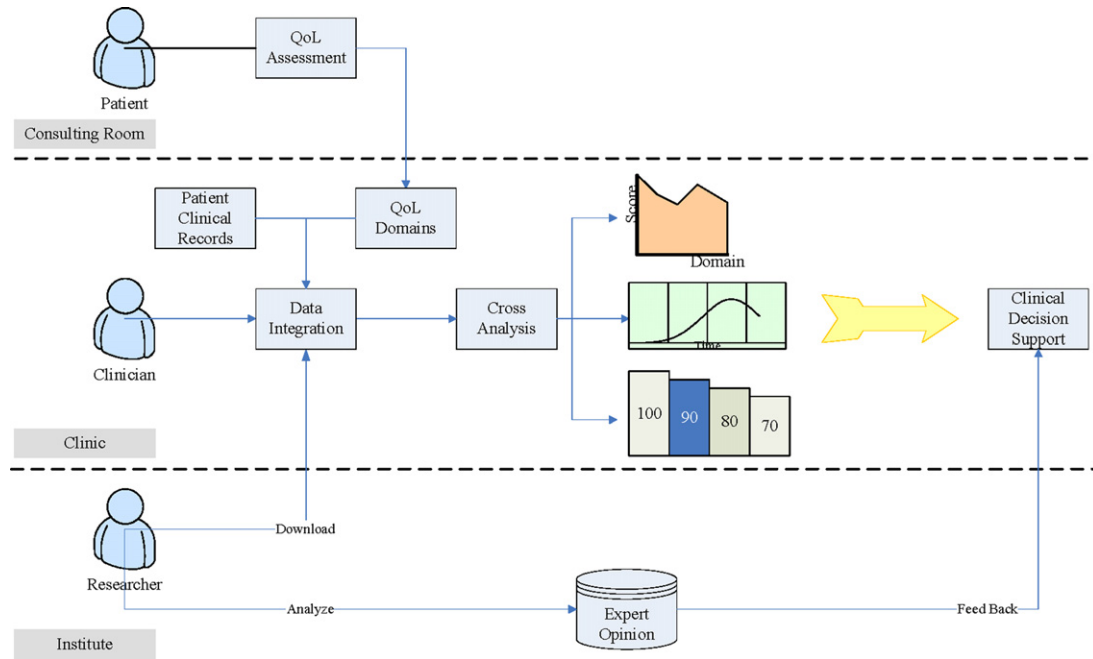


Fig. 6 – Clinic progress practiced with clinical infometrics system.

4. Results and discussions

4.1. Results

A pilot study of the proposed system was employed on the department of urological cancer of CMUH. Before the system development, hundreds of prostate cancer patients were tracked by handwriting QoL assessment for six times per cycle during cure period but lacks of the automatic electronic progress. Because of physical or mental suffering, patients used to complete paper works through conversation with health care people. Meanwhile, doctors took many efforts to explain patient outcomes at clinic visits by printing out PCRs for advices. Therefore, the designed system was established by practical user requirements of each layer to increase interaction with patients to consolidate relationship as well as reduce official burden of health care people.

The patients were scheduled in a consulting room for online assessment as waiting for the clinic time. In the practice, the patient read the introduction page and login with personal ID to start the QoL assessment. There is only one question per browser page and the patient can adjust suitable font size on the touch screen in addition to consider the voice control button for assistance. On the other hand, the clinician was able to compare patient's record with others who match similar markers and evaluate assessment results by figures or charts for advanced consultation. Fig. 6 performs the operating procedure in which the clinician can reciprocally compare overall cure information and quality of patient's life during the treatment cycle. The expert opinion can be feed back by researchers after analyzing data. Patients are able to discuss and learn information with the doctor during clinic time since all online diagrams are immediately updated once the QoL assessments are finished. The result charts for clinical

infometrix matching the requirement analysis are highlighted below.

- A. *Assessment amendment*: The tablet denotes all answered items for final modification that reminds the patient or health care assistants to make double-check if there are unexpected missing items occurred by careless manipulation. In the pilot study, some patients were not familiar with operation on the touch screen so that several questions could be lost. The health care people were able to help patients make up mistakes.
- B. *Statistics of QoL domains*: The chart in Fig. 7 details the final assessment results involving the questionnaire, range and scale in each domain, effect and missing items while answering questions. All domains reflect patient's functions and symptoms regarding the physical or mental conditions during the treatment cycle. The clinician can assist the patient to recognize how many questions, including the effect and missing items, have been answered for each domain, and what scale for each domain is scored. For this example, the patient gets a 50% scale of the global health status/QoL domain which contains 2 questions ranged in 6, it means each question grades the QoL level from 1 (very poor) to 7 (very good) points and the patient obtains 50% of total 14 points, thus the assessment is effective since no required item is missed. Due to the brief bar chart, the patient can conveniently realize the better QoL circumstance by the higher function scale and lower symptom scale, and vice versa.
- C. *Cross-comparison*: The chart supports the clinician and patient a platform to take an overview on assessment records for discussing the variation of QoL compared with the mean value of other patients in similar conditions. The presented case shown in Fig. 8 indicates that the patient

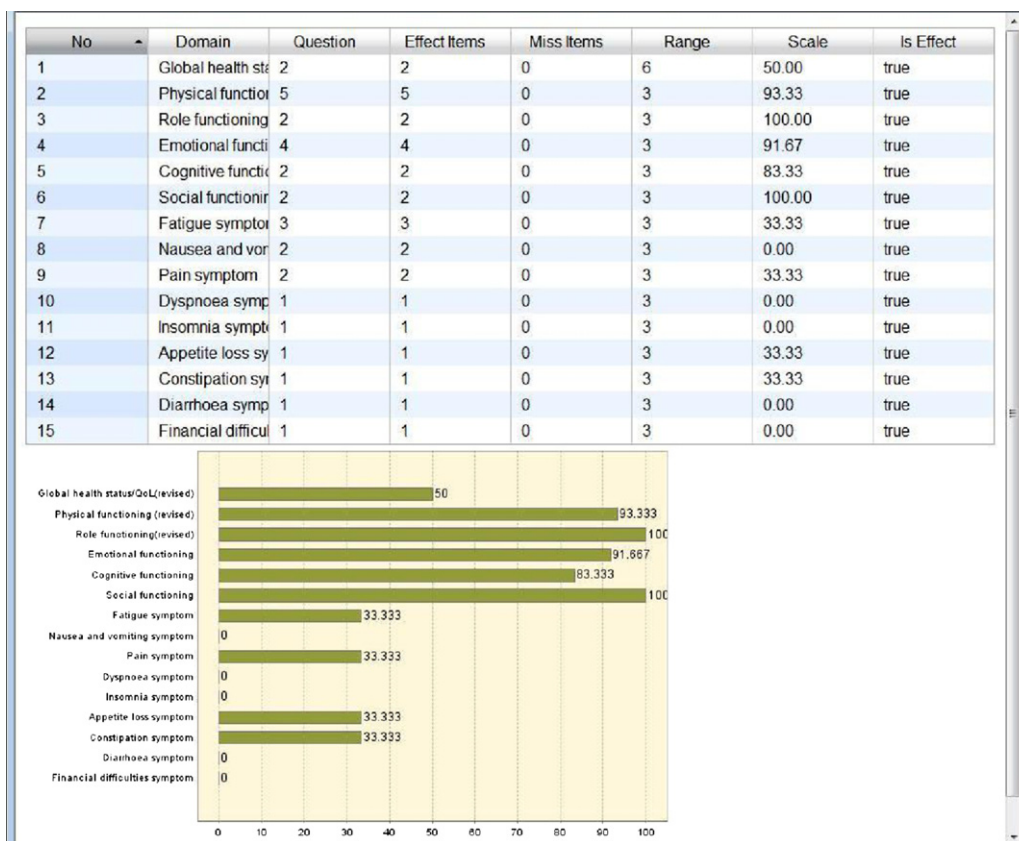


Fig. 7 – Statistics of QOL domains.

433 performed 50 points of global QOL with respect to 30 points
 434 in average for the similar age range. It enhanced the patient
 435 with confidence to follow doctor's comments for advanced
 436 treatment. In the pilot study, the patients reflected eager

437 motivation with more interaction to clinicians as recogniz-
 438 ing QOL history with clinical markers.
 439 D. Overall evaluation: The charts provide optional choices on
 440 the domain scale of all historical assessments that patients

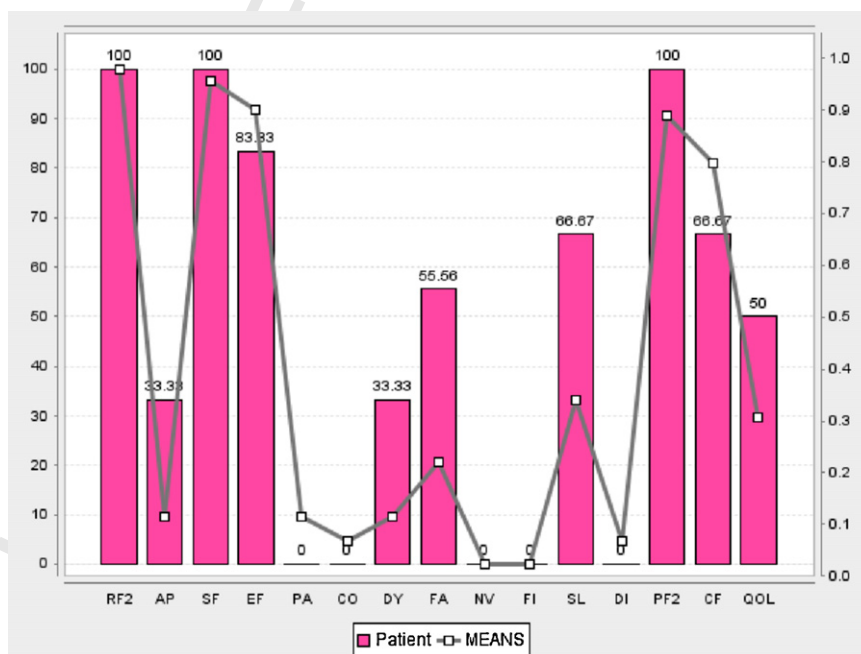


Fig. 8 – Cross comparison after assessment.

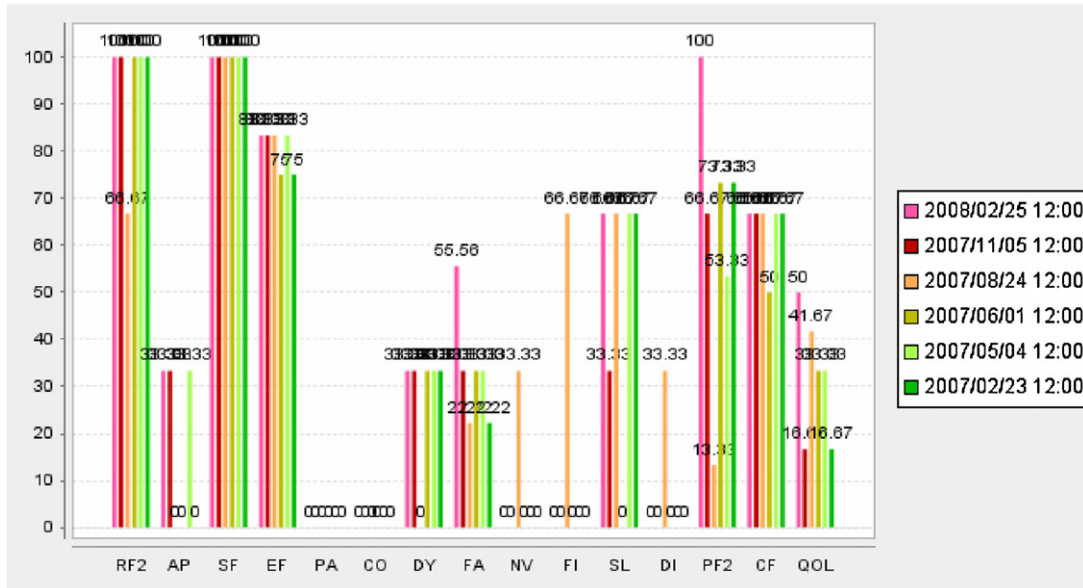


Fig. 9 – Overall evaluations with historical records.

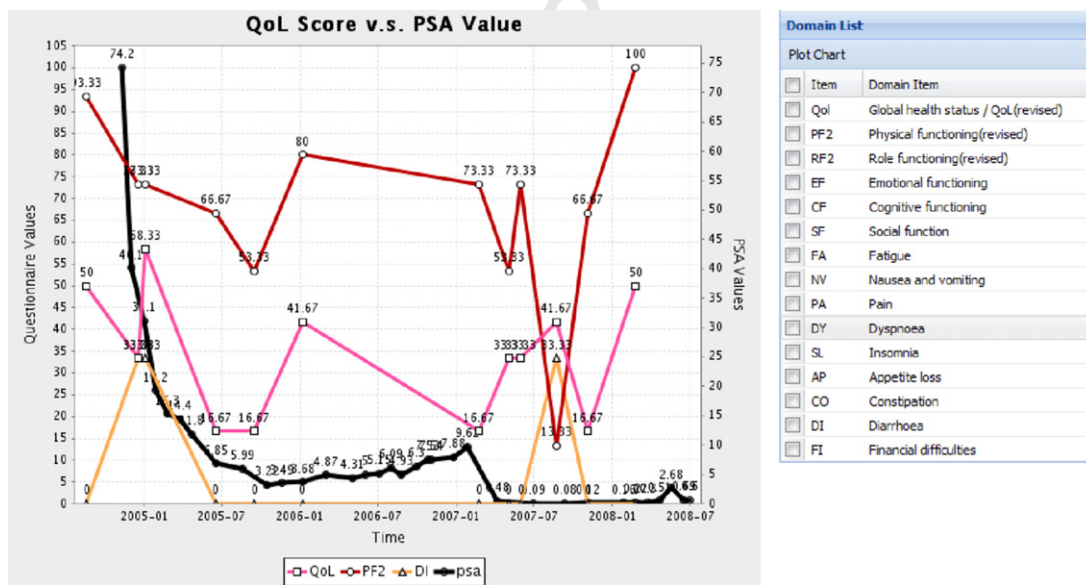


Fig. 10 – QOL vs. PSA history of a specified patient.

441 had experienced to make detailed evaluation and judgment. These functions also imply the decision support
 442 model that works for the system architecture shown in Fig. 1 because the diagrams may remind the clinician to
 443 make decisions by the visualized reference data. The specified case in Fig. 9 displays the change of QOL, which
 444 became better after some particular time because of the successful prostate surgery. Referring the PSA history compared
 445 with selected QOL domains in Fig. 10, the patient accepted surgery operation in early-2007 and improved the
 446 PSA value. It explains the reason of the better QOL assessment result. However, a suspected point was observed in
 447 the period around July in 2007 under stable PSA baseline, the patient felt uncomfortable since the physical function
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455 was suddenly getting worse (73.33-13.33) while the diarrhoea symptom became significant (0-33.33). Meanwhile,
 456 the corresponding global QOL score did not reflect it but at next point. It assisted the clinician in recognizing whether
 457 the problem was caused by the prostate disease.
 458
 459

460 4.2. Discussions

461 In this study, clinicians indicated that they use the system mainly for functional assessment as well as for high-
 462 lighting patients' most bothersome symptoms. The most common benefits would include enhancing communication
 463 with patients, identifying under-reported symptoms for clinicians and increasing efficiency in clinics. To assess the
 464
 465
 466

467 advantage of the developed system for users, some problems
468 are discussed below.

469 A. *Real time infometrix categories for patients*: The best prac-
470 tice of the developed system should be applied for patients
471 whose disease can be chronically and periodically tracked
472 by specified clinical markers. Therefore the design of real
473 time infometrix for prostate cancer patients displays their
474 PSA values associated with QOL domains to provide cat-
475 egories of physical, role, cognitive, emotional, and social
476 functions in addition to that of fatigue, pain, nausea
477 and vomiting symptoms. Particularly, it reflects urinary,
478 bowel, treatment-related symptoms and male-related sex-
479 ual functioning. Patients are able to recognize personal
480 health conditions immediately with respect to others
481 through the instant graphical chart in the clinic.

482 B. *Users' experiences on system operation*: The participant doc-
483 tors began to explain the disease conditions to patients by
484 the overall evidence-based diagrams like Fig. 10. A satisfac-
485 tion survey for 100 users' experiences on system operation
486 shows that 92% of users felt easy to operate the function-
487 ality through the system, and 97% of them sensed friendly
488 for the designed interface. When patients answered the
489 questionnaires, 10% and 24% of them thought that the
490 font is too small and the content is too much, respectively.
491 With overall statistics, 92% of users approved the innova-
492 tive setup and new technical design. The investigation data
493 certainly encourage the advanced study in the future.

494 C. *Information security for risk avoidance*: As generating
495 the infometrix system, patients' assessment data were
496 secured by both of questioning environment and elec-
497 tronic software. Patients were led to a consulting room to
498 answer the questionnaires so that they could finish the
499 assessment with full privacy. Moreover, all personal data
500 were encrypted as being written into the database to avoid
501 being falsified and stolen. Hence the risk avoidance for the
502 security problem is approved and patients have enough
503 confidence to comply with clinicians' guidance.

504 D. *Improvement in clinician-patients relationships*: Several stud-
505 ies in chronic diseases suggested that feedback of
506 health status data may facilitate communication between
507 patients and clinicians and enhance patients' care [25][26].
508 Accordingly, incorporating standardized QOL assessments
509 in routine clinical oncology practices can heighten physi-
510 cians' awareness of their patients' [27]. Correspondingly,
511 herein, the developed system obviously assists clini-
512 cians in discovering reliable QOL information of prostate
513 cancer patients since they would like to confess more
514 factual illness status. Therefore, data quality is ensured
515 by the automatic transportation procedure with no man-
516 ual mistakes. It confirms that the web-based individual
517 QOL assessment through the real time clinical infometrix
518 system with immediate outcomes to improve clinician-
519 patients relationships is possible and feasible.

5. Conclusions

520 This study revealed the progression of the clinical info-
521 metrics system with the novel information technology to

establish fundamentals of real time online analysis and deci-
sion support on the modeled architecture. The proposed
system incorporated the methodologies including Web ser-
vices, online analysis, database warehouse, and object relation
mapping. The infrastructure consists of five layers with flexi-
bility to develop expandable modules and provides accessible
functions to reach requirements of prostate cancer in clinic
applications. A patient-oriented interface designed with the
touch screen was considered as a major subject to assist
patients in fulfilling QOL assessment. In a variety of het-
erogeneous database systems distributed in hospital, clinic
and campus networks were integrated for an expert bank
with remote data backup and disaster recovery. In advance,
the patient outcome was available to offer instant statistical
charts for decision making as well as improved communica-
tion and relationship between clinicians and patients.

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