Information Engineering and Workflow Design in a Clinical Decision Support System for Colorectal Cancer Screening in Iran

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Abstract

**Background:** Colorectal cancer is a major cause of morbidity and mortality throughout the world. Colorectal cancer screening is an optimal way for reducing morbidity and mortality and a clinical decision support system (CDSS) plays an important role in predicting success of screening processes. CDSS is a computer-based information system that improves the delivery of preventive care services. The aim of this article was to detail engineering of information requirements and workflow design of CDSS for a colorectal cancer screening program. Materials and Methods: In the first stage a screening minimum data set was determined. Developed and developing countries were analyzed for identifying this data set. Then information deficiencies and gaps were determined by check list. The second stage was a qualitative survey with a semi-structured interview as the study tool. A total of 15 users and stakeholders' perspectives about workflow of CDSS were studied. Finally workflow of DSS of control program was designed by standard clinical practice guidelines and perspectives. Results: Screening minimum data set of national colorectal cancer screening program was defined in five sections, including colonoscopy data set, surgery, pathology, genetics and pedigree data set. Deficiencies and information gaps were analyzed. Then we designed a work process standard of screening. Finally workflow of DSS and entry stage were determined. Conclusions: A CDSS facilitates complex decision making for screening and has key roles in designing optimal interactions between colonoscopy, pathology and laboratory departments. Also workflow analysis is useful to identify data reconciliation strategies to address documentation gaps. Following recommendations of CDSS should improve quality of colorectal cancer screening.

Keywords: Clinical decision support system - colorectal cancer - screening program - Iran

Introduction

Medical decision making is a complex multi-stage process. Clinical decision support system (CDSS) plays an important role at data collection, diagnosis formulation, evaluation, and finally treatment planning (Patel et al., 2000). CDSS has been used in cancer detection and diagnosis for nearly 20 years (Simes et al., 1985, Maclin et al., 1991, Cicchetti et al., 1992). Colorectal cancer (CRC) is one of the most prevalent cancers in the world (American Cancer Society., 2015). According to report and documentation of the Ministry of Health of Iran, colorectal cancer is the fifth most common cancer diagnosis among men and third among women in Iran (Maserat et al., 2009). Based on the best available evidence, colorectal cancer (CRC) screening reduces CRC mortality (Navid et al., 2010). DSS is a computer-based information system that improves the delivery of preventive care services, and increase adherence to recommended care standards (Kawamoto et al., 2005). Colorectal cancer screening performance rates are based on evidence-based guidelines. CDSS has been particularly effective in acquisition greater levels of health care evidence base practice (Carney et al., 2014). A big obstacle for CDSS is the difficulty in obtaining the patient and relatives information required for decision making (Wagholikar et al., 2013). Information engineering can be used for the generation, distribution, analysis and use of information in systems. Information engineering has many purposes, including information system planning and deficiencies and information gaps analyzing. The objective of this study was to analyze workflow and information requirements of clinical decision support system for colorectal cancer screening program. Colorectal Cancer control program of Shaheed Beheshti research institute for gastroenterology and liver disease of Iran (RIGLD) supports population-based screening efforts in many provinces. The RIGLD’s goal is to increase colorectal cancer screening rates among
men and women aged 50 years. Quality improvement of colorectal cancer screening program can be increase by standard reporting (Maserat et al., 2009). CDSS provides comprehensive reports and recommendations for patients and clinicians (Guilan et al., 2008). Patient-specific advice of DSS may overcome problems in the use of paper-based reports (Kilsdonk et al., 2013). Lack of adequate data quality is a major problem for recommendation and other DSS applications. This article was determined screening minimum data set and workflow of CDSS. Generally, the aim of this article is information requirements engineering and work flow designing of CDSS for colorectal cancer screening program.

**Materials and Methods**

In the first stage was determined screening data set. Reports and minimum data set of colorectal cancer

**Table 1. Minimum Data set of National plan of colorectal cancer screening**

| Colonoscopy report | Pathological section | Surgery Section | Pedigree Section | Pathological Block & Blood Sample Survey |
|-------------------|---------------------|----------------|-----------------|------------------------------------------|
| Anatomical part   | Macroscopic         | Specimen specification | First and second degree relatives demographic information | IHC |
| Cecum             | Site of tumor       | Tumor specification | Diseases of First and second degree relatives | MLH1 (Normal-Abnormal) |
| (Right colon) Ascending colon | Maximum tumor diameter | Polyp specification | MSH2 (Normal-Abnormal) |
| Hepatic flexure   | Distance to the near nearer end resection margin | Growth pattern | MSH6 (Normal-Abnormal) |
| Transverse colon  | Tumor perforation   | Distance for margin | PMS2 (Normal-Abnormal) |
| Splenic flexure   | Relation of rectal tumors to the potential reflection | Regional lymph nodes | MSI (Stable-Low-High) |
| (Left colon) Descending colon | Microscopic | | APC: (Negative-Positive) |
| Sigmoid colon     | Histological type   | MMR            |
| Rectosigmoid      | Histological differentiation | MLH1 |
| Rectum            | Maximum extent of local invasion (pT stage) | MSH2 |
| Not Specified     | Lymph node status   | MSH6 |
| Procedure type    | Extramural venous invasion | PMS2 |
| Colon Biopsy      | Evidence of regression following therapy | Survey Result |
| Hot Biopsy        | Histologically confirmed distant metastases | HNPCC |
| Snare Excision    | Background abnormalities | FAP |
| Saline assisted endoscopic mucosal resection | TNM stage |
| Surgery           | Dukes stage         |
| Diagnosis         | SNOMED codes        |
| Tumor             |                      |
| Polyp             | other               |
| Polyp specification |                     |
screening can be used in developed and developing countries were analyzed. Screening minimum data set of national colorectal cancer screening program was defined in five sections, including colonoscopy data set, surgery, pathology, genetics and pedigree data set. Standard check list of essential data elements was designed and data base of national program was analyzed by check list. Then information deficiencies and gaps were determined. The second stage of study was qualitative survey. Study tool was semi-structured interview. Interviewing involves asking questions and getting answers from participants. 15 users and stakeholders, perspectives about workflow of CDSS were studied. Participants were informed about screening program of Shaheed Beheshti research center for gastroenterology and liver disease. Finally we presented workflow of DSS of colorectal cancer control program by standard clinical practice guidelines and perspectives.

Results

Standardization of the screening reports is a key issue for quality improvement of CRC screening. Also screening minimum data set has principle role for future research of national program of CRC screening. Minimum data set and standard reports are essential infrastructures of CDSS. We identified minimum data set of national plan of RIGLD. Table 1 was illustrated minimum data set of CRC screening program of Iran. Then we designed work process standard of screening (Figure 1). Functions of colorectal cancer screening contain research, education, clinical activities and health information management and other activities. Education department contain contentious education to patients and high risk people. Educational tools were website, forum, newspaper, educational package, workshops and conference. Clinical activities include

i) Colonoscopy and other related activities. Target population is fist degree relatives of proband. ii) Pathology examination and CRC block analyzing. iii) Genetic testing: Surveying IHC, MSI and detection of hereditary non-polyposis colorectal cancer (HNPCC) and (familial adenomatous polyposis) FAP. One of positive view of plan is special attention to genetics because this issue has impacted on high risk populations diagnostics.

Figure 1. Work Process of Colorectal Cancer Screening

Research Institute for Gastroenterology and Liver Disease

Colorectal cancer screening center

Patient finding
Educational Counseling
Medical documentation and drawing pedigree
Blood sampling and taking pathology block
Genetic and pathology examination
Identify high risk population
Colonoscopy and detecting poly & tumor
Tracking of covered population by CDSS

Table 1. Minimum Data Set of National Plan of CRC screening Program in Iran

| Data Set | Description |
|----------|-------------|
| Colonoscopy | Colonoscopy data set |
| Surgery | Surgical data set |
| Pathology | Pathology data set |
| Genetics | Genetic data set |
| Pedigree | Pedigree data set |

Figure 2. Context Classification of Clinical Decision Support System for Colorectal Cancer Screening Program

High risk
- Genetic or clinical diagnosis of FAP
- Genetic or clinical diagnosis of HNPCC
- Inflammatory bowel disease, clonal, familial adenomatous polyposis

Increased risk
- Patient with colorectal cancer
- Patient with history of polyps
- Patient with family history

Low risk
- Patient without family history
- Patient without colorectal cancer

Data entry flow of Clinical Decision Support System for Colorectal Cancer Screening Program

Following questions and getting answers from participants. 15 users and stakeholders, perspectives about workflow of CDSS were studied. Participants were informed about screening program of Shaheed Beheshti research center for gastroenterology and liver disease. Finally we presented workflow of DSS of colorectal cancer control program by standard clinical practice guidelines and perspectives.

Discussion

Designing standard work flow increases quality performance of screening process. CDSS workflow of screening plan identifies three groups: high risk, increased risk and low risk population. Then data entry stage, individual classify in this three groups by expert CDSS. Then system presents recommendation and advice for per patient. Many studied country have registry for demographic and clinical information. Screening data was registered without expert analysis. Thus CDSS
prepare accurate and quick recommendation for covered population of screening. This system is optimal tool for following of covered population. Also Wagholikar and coworkers from Arizona State presented workflow of CDSS for colorectal cancer screening (10). This study was illustrated coordinating of departments by standard workflow of CDSS. Designing of CDSS workflow is integral part of implementing expert system. Also we create coordinating of colonoscopy, pathology and genetic departments. A main obstacle for CDSS is gathering information required for decision making. In this article; information deficiencies and gaps were determined and corrected. Genetic information is main item for better decision of CDSS. According to studies; CDSS can assistance to identify recurrences and survivability of cancer (Joseph et al., 2006). We designed minimum dataset for CDSS that assistance to predict many variables for example health statues of first and second relatives of patients.

Clinical decision support system of preventing plan facilitates complex decision processing of screening by comprehensive and integrated information. With regarding to high volume of screening information; CDSS improve decision processing. A major obstacle for clinical decision support is the difficulty in obtaining the medical information required for decision making (Wagholikar et al., 2013). Then information requirements engineering before implementing of CDSS is vital part. In this article; colonoscopy data set, surgery, pathology, genetics and pedigree data set was surveyed. The lack of good quality registration is a barrier for CDSS development (Wagholikar et al., 2013). Standard templates and unified terminologies for colorectal screening reports are essential. In additional, CDSS has key role in optimal interactions between colonoscopy, pathology and laboratory department. Also workflow analysis was useful to identify data reconciliation strategies to address documentation gaps. Our study presented essential dataset and workflow CDSS for decision making of colorectal cancer screening.

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