Original Article

# Feasibility Study and Design of Registration System for Upper Gastrointestinal Bleeding Patients in Isfahan Province

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## Abstract

**Background:** Disease registration is an organized system for collecting, storing, retrieving, analyzing a particular disease or exposure to known substances in a specific population. The aim of this study was to assess the feasibility and design of the registration system for upper gastrointestinal bleeding patients based on patients referring to Al-Zahra and Khorshid hospitals, Isfahan, Iran.

**Materials and Methods:** This study is a research action study in which the members of the registration system team are hospital triage physicians, internal residents in the Emergency department of hospital, subspecialty assistants and gastroenterologists, statisticians (epidemiologists and methodologists), and two trained persons were specified to collect medical information and documents. The data collection tool is a researcher-made checklist. Based on the available tools, the most important criteria related to gastrointestinal bleeding were selected. In the next step, the criteria selected in the council, including team members, were reviewed and a preliminary draft was prepared to record the information of patients.

**Results:** The results indicated the final version of the checklist in three parts including demographic variables (age, sex, education, *et al*.), main variables (as the minimum data required by a person to register in the checklist (patient's clinical signs)), extended main variables (its information is designed to be used to diagnose, treat, and follow-up the patient in later stages).

**Conclusion:** It seems to be predictable by establishing a system for recording gastrointestinal bleeding diseases, disease prevalence, monitoring services and treatment of patients, survival analysis and evaluation of clinical care outcomes, finding patients at higher risk for emergency treatment, reviewing drug interventions, and interventional activities.

**Keywords:** Al-Zahra hospital, disease registration system, gastrointestinal bleeding, Khorshid hospital

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## Introduction

Upper gastrointestinal bleeding is a common medical emergency associated with high mortality and treatment costs.[1] These patients are important in two ways:

1. Proper management and treatment of the disease, which has a high prevalence and mortality
2. Managing hospital beds, especially emergency ward beds, and allocating them to patients who benefit the most from hospitalization, and not allocating beds for out-patients.

The prevalence of this disease is increasing with increasing use of nonsteroidal anti-inflammatory drugs and high prevalence with infection and *Helicobacter pylori* in patients with bleeding peptic ulcer. In unstable patients with severe bleeding, rapid

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evaluation and resuscitation of the patient should be performed earlier than diagnostic measures.[2]

In this disease, the location of bleeding is not always clear. For example, 15% of patients with severe hematochezia are associated with the source of upper gastrointestinal bleeding.[3,4] In the United States and Europe, the annual incidence of hospital admissions due to upper gastrointestinal bleeding is approximately 0.1%,[5] with more than 500,000 (170 patients per 100,000 population) admitted to hospitals annually.[6] According to studies conducted in Scotland, the rate of hospital admissions, for this reason, is 170 patients per 100,000 population and the mortality rate is estimated at 8.2%.[7] According to a study in Semnan, the rate of patients with upper gastrointestinal bleeding was 40.1 cases per 100,000 people in 2004, the most common cause of which is duodenal ulcer with 40.9%.[8]

The mortality rate of patients under 60 years of age due to upper gastrointestinal bleeding in the absence of major concomitant diseases is < 0.1%.[5] In 80% of patients with upper gastrointestinal bleeding without special treatment, the disease is self-limiting and in the remaining 20% of cases, the mortality rate is between 30% and 40%.[9,10] The prevalence of upper gastrointestinal bleeding in men is twice as high as that in women.[11,12]

Due to the high prevalence of this disease and high occupancy rate of hospital beds and a high percentage of inter-hospital and inter-city referrals and disagreements about how to manage and treat patients, including the timing of emergency endoscopy, there is a need for blood transfusions and drug treatments. On the one hand, increasing patient satisfaction and improving quality and increasing life expectancy, the existence of an integrated and effective clinical system for patients, is strongly felt and is an inevitable necessity.[4] On the other hand, in health systems, the most important goal of providing health services is to produce and provide a product called health. Proper and quality presentation of this product requires the use of clinical tools that guarantee the improvement of services in the long run. One of these tools is the disease registration system.

Due to the development of information technology in the field of healthcare, the use of efficient information systems to increase the efficiency, effectiveness, and satisfaction of the client and its effects on increasing the quality of patient care is an inevitable necessity.[3-7] Among the benefits of these systems are reduced treatment costs and medical errors, increased quality of care, safety, and satisfaction. One of the new technologies in recent years is the disease registration system.

Disease registration is an organized system for collecting, storing, retrieving, analyzing, and disseminating information about individuals with a particular disease or in the face of the adverse effects of known or suspected substances in a given population and geographic area. This tool is used to develop clinical trials in various diseases. Launching this system will lead to improve patient care and planning to provide health services, increase the quality and productivity of the health service delivery system, and patient satisfaction. This tool is also suitable for collecting critical data and information from patients' backgrounds and following up clinical trials.

Registration of diseases has been on the agenda of the Deputy Minister of Research and Technology of the Ministry of Health since 2014. The information collected through this system is used to better manage and organize the disease and conduct research. Disease registration plays an effective role in diagnosing and measuring the prevalence of a particular disease or a health event in the community and enables the health system to better and more effectively monitor the quality of provided health services. This system provides a good resource for diagnosing patients for further research studies such as cohort studies and clinical trials.

In recent years, in Iran and abroad, several registration systems have been designed for various diseases, which can include cancer registration system, cardiovascular diseases, cystic fibrosis, congenital anomalies, pulmonary artery hypertension, sarcoidosis, rare pediatric lung diseases, endocrine in endocrine and metabolic sectors. Therefore, considering the importance of setting up a registration system and the need for such a system to integrate services provided to gastrointestinal bleeding, in this study, feasibility study and checklist design were performed to record the information of patients with upper gastrointestinal bleeding referring to Al-Zahra and Khorshid hospitals.

## Materials and Methods

The present study is a research action study performed with the aim of recording, monitoring, performing intervention activities, controlling, and managing the information of patients with upper gastrointestinal bleeding referring to Al-Zahra and Khorshid hospitals. Considering that Al-Zahra and Khorshid hospitals are referral center for receiving patients with gastrointestinal bleeding and it covers patients referred from neighboring provinces (Chaharmahal, Khuzestan, Ilam, Yazd, etc.), the study population consisted of patients admitted to this center. Written licenses and referrals were obtained and collected according to the ethics regulations of Isfahan University of Medical Sciences. Then, a meeting was held with the presence of hospital officials about the need to fully record patients' information in the files and to attract their cooperation in terms of familiarity and use of information forms designed by hospital staff.

The panel of specialists in the present study consisted of clinical team members (hospital triage physician, internal residents in the hospital emergency department, gastroenterology assistants and gastroenterologists [7 people]), and epidemiologists.

The data collection tool is a researcher-made Delphi checklist. The intended approach for compiling the checklist was to produce a tool that includes various dimensions of patients' treatment and care needs and can be implemented and uploaded to the electronic file of the hospital while having a uniform and one-handed structure. Therefore, in addition to the main information about gastrointestinal bleeding disease, additional

information was collected to design a checklist so that a relatively comprehensive tool could be designed to assist in the treatment process at all stages. Therefore, the checklist of this study was designed by Delphi method in three parts: Demographic information, specialized information about the patient's clinical symptoms and expanded specialized information.

### *Checklist design steps*

To design tools and prepare the content of tools, first tools, and various indicators in reliable information sources and databases such as PubMed, Scopus, up-to-date, science direct, web of science, internal databases such as Magiran and SID regarding gastrointestinal bleeding disease and diseases registration system were examined. Many studies have been performed in other countries to determine the risk factors for upper gastrointestinal bleeding to determine the prognosis of patients. Based on these risk factors, the main variables of the checklist were identified. All these risk factors were related to gastrointestinal bleeding and the patient's condition can be determined based on it. Among the items that can be mentioned are tools such as Rockall and Blatchford.[13-15] Based on the available tools, the most important variables related to gastrointestinal bleeding disease including demographic variables, drug records, laboratory information, disease symptoms, epidemiology, risk factors, lifestyle, prognosis, complications and treatments were selected. In the next step, the selected variables for designing a checklist in a panel of experts, including three subspecialists in gastroenterology and epidemiology, statistical expert, pathologist and librarian were examined, and they were asked to study the selected variables scientifically (based on the items in the Rockall and Blatchford tools) and to express their opinions about them. Each of the variables was introduced and people expressed their opinions about that variable, how it was evaluated and its efficiency, and then a vote was taken for each of the variables, and the variables that had received less than half of the votes for inclusion in the list were removed. They were also asked about the content of the checklist in terms of appearance, choice of words and sentences, and comprehensibility. Finally, according to the experts' opinions, the variables were reviewed and corrected and a new edition was prepared. Then, an initial draft was prepared to record the information of patients with upper gastrointestinal bleeding.

Then, after applying the group's opinion, the checklist was given to them again, and this time, the more detailed variables (subset of the main variables) were polled and voted on in the checklist. Finally, after collecting the comments of the second stage and applying them, the final approval in terms of science, appearance and writing of the checklist was obtained.

In the last stage, four residents of the field, one member of the hospital triage, and one of the emergency nurses were trained on how to fill out the questionnaire, terms, and variables, after preparing the checklist for the pilot project. Then, 50 questionnaires were completed by trained people from patients referring to the emergency department to identify deficiencies and problems, and they were asked to identify the existing problems. After collecting the questionnaires, the shortcomings and problems in obtaining and registering the data were raised again in the council of the registration team and the members consulted about these cases. In the end, the final version of the checklist was prepared by applying the opinion of the registration team and fixing the existing problems and shortcomings.

A Persian language manual has been prepared for users to complete the checklist. The information of all patients referring to Al-Zahra and Khorshid hospitals including the complete details and history of the patient based on the designed information collection form, were completed and the data were checked for accuracy by an internal medicine or gastroenterologist. After the patient enters the hospital with symptoms of gastrointestinal bleeding, the patient's information will be recorded in the relevant form and additional information will be added if necessary after endoscopy.

Each month, a training session was held to update the experts, team nurses, and re-evaluate the questionnaires and address potential problems for these individuals to enter information.

In this study, the researcher studied all the principles related to research ethics, such as obtaining informed consent from patients participating in the study, explaining to them about the research and its objectives, observing the principle of confidentiality, keeping information confidential, the freedom of individuals to leave the study at any time of research and respect for the rights of authors in the use of printed and electronic texts. In order to use the registration information, according to the instructions approved by the Ministry of Health, permission was obtained from the research ethics committee.

## Results

The collected variables were classified into three levels:

1. Demographic Information: The first part of the patient demographic information checklist includes first and last name, father's name, national number/identity card, date of birth, gender, contact number, place of residence and occupation
2. Main Variables: The second part of the checklist includes specialized information about the patient's clinical symptoms. These variables are designed as the minimum data a person needs to record in a checklist (patient's clinical symptoms). Information about these variables was collected in two ways, direct and indirect. In the direct method, the necessary information will be recorded by conducting an interview with the patient, and in the indirect method, information will be collected from the patient's file

   The main variables include the six main areas of disease symptoms, vital signs, current or concomitant medical history, medical history, laboratory information at the place of dispatch and at the time of arrival at the hospital.
3. The Extended Main Variables: It is not mandatory for the patient to complete these variables, but the information can be used to diagnose, treat, and follow up with the patient at a later stage [Tables 1 and 2]

**Table 1: Information on the upper gastrointestinal bleeding record checklist**

| Description | Setting | Source of data collection | Expanded variables | Main variables |
|---|---|---|---|---|
| In the case of patients referred from other centers, the information will be collected at the place of dispatch upon arrival from the patient file. In the case of patients, who will go directly to the center, the source of information will be the patient or the person accompanying it | Hospital base | Interview with the patient | First name and last name<br>Father's name<br>National ID number<br>Date of birth<br>Gender<br>Phone number<br>Address<br>Occupation<br>Mobile | Demographic information |
| | Hospital base | Interview with the patient | Hematomas<br>Melena<br>Hematochezia<br>Sanguine<br>Accompanying symptoms | Symptoms of the disease |
| | Hospital base | Patient file | Awareness level<br>PR<br>BP<br>Temperature<br>Hypotension<br>Orthostatic | Vital signs |
| | Hospital base | Interview with the patient | PUD record<br>Previous GIB records<br>History of liver disease<br>History of device malignancy<br>History of upper gastrointestinal cancer<br>Type of treatment<br>History of upper gastrointestinal surgery<br>History of cardiovascular disease<br>History of kidney disease<br>History of lung disease<br>History of large vascular disease<br>History of blood disease<br>History of HPYLORI infection<br>Recent weight loss | Current or concurrent medical records according to ICD9 |
| In the case of patients referred from other centers, the information will be collected at the place of dispatch on arrival from the patient file | Hospital base | Interview with the patient | History of taking antiplatelet drugs<br>History of taking anticoagulants<br>NSAID history<br>Cox ii inhibitor<br>PPI<br>H2 blocker<br>Antacids<br>Corticosteroids<br>SNRI, SSRI<br>Calcium blocker<br>History of aldosterone antagonist use<br>Smoking<br>Alcohol consumption | Medication history |
| In the case of patients who will go directly to the center, the source of information collection will be the patient or the person accompanying it | Hospital base | Patient file | CBC<br>LFT<br>RBC<br>HCT<br>Hemoglobin<br>LFT<br>ALT<br>AST<br>PIP | Laboratory information at the place of dispatch and at the time of arrival at the hospital |

*Contd...*

**Table 1: Contd...**

| Description | Setting | Source of data collection | Expanded variables | Main variables |
|---|---|---|---|---|
| | | | Bill total, bill direct | |
| | | | INR | |
| | | | PT | |
| | | | Bun | |
| | | | Renal function | |
| | | | Cr | |
| | | | Electrolyte | |
| | | | Cr، Na، K، Ph، Mg، Alb، | |
| | | | Other ESR، CRP، Fe، tibe، ferritin | |

BP: Blood pressure, NSAID: Nonsteroidal anti-inflammatory drugs, CBC: Complete blood count, RBC: Red blood cell, Hct: Hematocrit, LFT: Liver function tests, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, PT: Prothrombin time, INR: International normalized ratio, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate, PR: Pulse rate, PUD: Peptic ulcer disease, GIB: Gastrointestinal bleeding, HPYLORI: *Helicobacter pylori*, PPI: Proton-Pump Inhibitors, SNRI: Serotonin and norepinephrine reuptake inhibitor, SSRI: Selective serotonin reuptake inhibitor, PIP: Proximal interphalangeal

**Table 2: Defining the main variables extended in the checklist**

| Main variable | Variable name | Definition |
|---|---|---|
| Symptoms of the disease | Hematomas | Bloody vomit in the form of light blood or brown grains |
| | Melena | Black, loose, sticky, and smelly stools |
| | Hematochezia | Excretion of fresh blood together or in the stool |
| | Sanguine | Decreased level of consciousness and muscle strength quickly-in the short term and with spontaneous release |
| Severity of disease | Rockall score | Age, hemodynamic shock, major comorbidities, diagnosis, recent hemorrhage |
| Current or concurrent medical records | Cirrhosis | Chronic liver, cell disease, inflammation, and fibrosis occur |
| | Chronic hepatitis | Chronic inflammation that lasts at least 6 months |
| | Hypertension portal | Increased pressure in the system |
| | CVA | When blood flow to a part of the brain stops due to blockage or rupture of arteries |
| | CHD | Coronary artery stenosis 60 (%) |
| | MI | Heart attack and myocardial infarction due to lack of blood supply |
| | CKD | Abnormal kidney structure or function for <3 months |
| | ESRD | Kidney failure that requires permanent dialysis |
| | COPD | Obstructive airway disease |
| | Thrombolysis | Platelets <150,000 |
| | Coagulation disorder | 2/1< INR or increase PT and PTT |
| Endoscopic data | Gastric ulcer and its type | According to endoscopic report |
| | Duodenal ulcer and its type | |
| | Esophageal avarice | |
| | Gastropathy | |
| | Duodenopathy | |
| | Malignancy | |

ESRD: End-stage renal disease, CKD: Chronic kidney disease, COPD: Chronic obstructive pulmonary disease, CHD: Coronary heart disease, PT: Prothrombin time, PTT: Partial thromboplastin time, MI: Myocardial infarction, CVA: Cerebrovascular accident

Each of these six main parts has subdivisions. In the symptoms section, information about the time and number of hematomas, melena, hematochezia, sanguine, and accompanying symptoms is recorded. In the vital signs section, the patient's level of consciousness, PR, BP, temperature, hypotension, and orthostatic are examined. Cause, time, history of previous bleeding diseases, liver disease, history of malignancy, type of treatment, history of surgery on the gastrointestinal tract, history of kidney, lung, large arteries, blood, infection, etc., are also recorded in this section. Drug records include anticoagulants, antacids, corticosteroids, calcium blockers, aldosterone antagonists, cigarette and alcohol use, SSRI, SNRI, NSAID history, cox ii inhibitor, PPI, Blocker H2, antiplatelet drug history in checklist and at the end of the checklist, the patient's laboratory information, including complete blood count CBC, liver function test, coagulation, renal function, electrolyte, is recorded at the dispatch site and at the time of arrival. The Rockall scoring method was also used to score and determine the criteria for inclusion in the study.

## Discussion

There is a growing demand for high-quality data to improve healthcare services. Gastrointestinal diseases often

provide patients with serious or life-threatening conditions. Complications may affect treatment outcomes and lead to increased mortality or decreased quality of life. Continuous and consistent monitoring of risk factors in this disease is very important to improve the quality of health care.

The aim of this study was to set up a system for registering upper gastrointestinal bleeding diseases for patients referring to Al-Zahra and Khorshid hospitals. Gastroenterologists, epidemiologists, and computer programmers participated in the design of this study.

Many registration systems have been designed in Iran, but so far, no study has been done on gastrointestinal bleeding diseases. In this study, a checklist was designed based on risk factors related to this disease and uploaded in HIS software to collect information from patients referring to Al-Zahra and Khorshid hospitals.

In the present study, Baghaei *et al*. conducted a study aimed at recording and monitoring inflammatory bowel disease. In their research, they concluded that the inflammatory bowel disease monitoring project in Isfahan has more accurate information compared to other registry systems designed in Iran. The project is also designed to collect data step-by-step. The process of data control and quality by the strategic committee was one of the valuable aspects of this project.[16]

The present study is consistent with Dr. Navarrock's study in 2006 on the launch of YPCR software in Yaounde, Cameroon. Using this system, the symptoms of the disease and its risk factors have been studied over a specific period of time. In general, the comparison of its system with that of the present study shows that the stakeholders in both programs were similar.[17]

In addition, the findings of this study are consistent with another study that was conducted to investigate the necessary infrastructure to create a health care information network. In this study, it has been suggested that information be provided nationally and internationally to researchers in this field to help reduce the financial burden and medical errors in the diagnosis, treatment, and follow-up of patients. According to this study, all these goals can be achieved by setting up a registration system. These findings are consistent with a study by Choi *et al*. (2021) in the United States that aimed to record family information based on genetic studies. In this study, in addition to genetic issues, the behavioral sciences of patients and their families are emphasized.[18] In their study, D'Agnolo *et al*. stated that to diagnose the pattern of gastrointestinal diseases, it is necessary to set up a system for registering these diseases. In this study, it was indicated that the registration system is very efficient for conducting clinical studies and gathering scientific knowledge about the course of the disease, diagnosis of patterns, treatment results and prevention in these patients.[19]

Lassen *et al*. created a new national registry in their research related to gastrointestinal surgery in Norway along the present study. The results of this study are a complete set of variables that show risk factors, treatment methods and clinical results. In this study, information recording was recognized as a suitable tool to provide complete specifications to improve the quality of treatment services as well as future researches.[20] However, in the present study, in addition to the risk factors associated with gastrointestinal bleeding, the patient's para clinical information is also included in the checklist.

Maharaj *et al*. examined the system of registration of gastrointestinal diseases in their research. In their study, they established regular reports of risk factors for gastrointestinal diseases using the collected information. In their research, care indicators and clinical outcomes of patients have been identified.[21]

In this regard, the results of other researches showed that the use of disease registration systems in the diagnosis and epidemiology of diseases is cost-effective. This has led to a clear picture of the cost of treatment methods during different stages of the disease in relation to the effectiveness of the treatment method.[22] In addition, most developed and developing countries seek to improve the level of health, correct policies, and micro and macro planning, by launching various disease registration systems. The results of the present study and other studies conducted in the field of gastrointestinal diseases registration system show that by launching this software in the database of hospitals, especially in Iran, with the cooperation of gastroenterologists and hospitals in Isfahan Province, this software can be used to evaluate and monitor the overall disease and risk factors, medication regimens, side effects, intervention activities, and other cases. Further studies can be performed on the causative agents of gastrointestinal bleeding, the role of genetics in such diseases, the collection of blood samples and biomarkers to monitor and diagnose the etiology and activity of the disease, its prevalence and incidence.

Compared to studies on the gastrointestinal disease registration system, there are several strengths in this study, including the prospective design, the use of a valid questionnaire based on the minimum entered data, uploading to the hospital HIS software mentioned flexible options for recording information and registering patients with their unique national identities that allow data to be linked to other national studies.

## Conclusion

It seems that by establishing a system for recording gastrointestinal bleeding diseases, the prevalence of the disease, monitoring patient services and treatment, survival analysis and evaluation of clinical care outcomes, finding patients at higher risk for emergency treatment, evaluation of drug interventions and interventional activities in these patients can be predicted. Reducing in-patient costs by leveling patients, creating a database for research studies, creating a resource for clinical trial, case–control, and cohort studies, evaluating the cost-effectiveness of interventions and estimating costs, and budgeting were other things that can be achieved by

designing this system. Therefore, the use of online registry and software in the field of health should be considered to provide an opportunity to fill important gaps in the knowledge of rare diseases, including upper gastrointestinal bleeding through national and international cooperation.

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### *Conflicts of interest*

There are no conflicts of interest.

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