Review

Barriers and facilitators for the implementation of health condition and outcome registry systems: a systematic literature review

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ABSTRACT

Objective: Health condition and outcome registry systems (registries) are used to collect data related to diseases and other health-related outcomes in specific populations. The implementation of these programs encounters various barriers and facilitators. Therefore, the present review aimed to identify and classify these barriers and facilitators.

Materials and Methods: Some databases, including PubMed, Embase, ISI Web of Sciences, Cochrane Library, Scopus, Ovid, ProQuest, and Google Scholar, were searched using related keywords. Thereafter, based on the inclusion and exclusion criteria, the required data were collected using a data extraction form and then analyzed by the content analysis method. The obtained data were analyzed separately for research and review studies, and the developed and developing countries were compared.

Results: Forty-five studies were reviewed and 175 unique codes were identified, among which 93 barriers and 82 facilitators were identified. Afterward, these factors were classified into the following 7 categories: barriers/facilitators to management and data management, poor/improved collaborations, technological constraints/appropriateness, barriers/facilitators to legal and regulatory factors, considerations/facilitators related to diseases, and poor/improved patients' participation. Although many of these factors have been more cited in the literature related to the developing countries, they were found to be common in both developed and developing countries.

Conclusion: Lack of budget, poor performance of managers, low data quality, and low stakeholders' interest/motivation on one hand, and financing, providing adequate training, ensuring data quality, and appropriate data collection on the other hand were found as the most common barriers or facilitators for the success of the registry implementation.

Key words: registries, health registry, disease registry, barrier, facilitator, implementation, development

INTRODUCTION

A health condition and outcome registry system (registry) is an organized system in which uniformed data (including both clinical and nonclinical ones) are systematically collected and then analyzed in order to assess the trends and health outcomes related to a specific disease, health condition, intervention, or health outcomes in predefined populations.[1]

Some registries are provided to patients with a particular disease or condition, and some of them register patients receiving a product,

service, or intervention. As well, some other registries include both diseases and interventions.[2] The epidemiological registries collect data on specific disorders in order to provide epidemiological data, so many potential patients should be covered by these systems. The clinical registries collect data on clinical care and outcomes to support physicians with one or some specialties. Accordingly, these systems play an important role in monitoring diseases and care delivery patterns and are used with an increasing trend in improving healthcare processes, developing clinical guidelines and standards, and reducing care costs.[1] Nowadays, research registries are developed for data collection that can be used for specific research programs, developing research infrastructure, and helping researchers to identify and recruit eligible cases for their studies.[3] Moreover, registries are classified according to the covered population[4] and the geographical coverage, which includes various types of registries as population-based, hospital-based, regional, national, or international registries.[2]

Some registries, such as cancer, trauma, or surgery ones, are implemented more widely. The purpose of cancer registries is to record all the cancer cases diagnosed in a clearly defined population, in order to report incidence and mortality rates of different types of cancers. The needed data are collected from 3 major data sources, including pathology departments, hospitals, and death certifications.[5] The purposes of trauma registries mostly are as follows: improving the quality of care offered to patients and improving patient outcomes. Additionally, these registries are known as powerful tools for the collection of data on trauma for comparative and cost-effectiveness investigations. Accordingly, these data may also be used for the development of standardized trauma care guidelines.[6] Surgery registries are used to collect the data to improve patient (surgery) care, monitoring devices, comparison of standards, and evaluating both interventions and performance. These registries help to obtain a better understanding of surgery epidemiology and to promote future studies in this field.[7] In all of these systems, functions such as data entry, data analysis, and developing reports should be well managed and evaluated.[8] Generally, the objectives of registries include clinical, scientific, and health policy-related programs. Of note, well-designed registries can provide a real-world vision of patient outcomes, safety, clinical practice, and comparative effectiveness.[9] Furthermore, these systems provide epidemiological data (on mortality, prevalence, and incidence) related to diseases and diseases' control programs,[10] as well as presenting an important source consisting of real-world evidence to improve health decision-making.[11]

Developing and implementing registries are complex processes that require some fundamental efforts.[10] In this regard, to develop and implement registries, various inputs (such as financial resources and guidelines), processes (such as case finding, data collection, and analysis), and outputs (such as output information and reports) should be well designed and evaluated[8] in order to ensure the success of the programs. The process of the implementation of registries is always encountered with various barriers and facilitators.[12] Therefore, finding some solutions for a successful implementation of registries is important.[13] Some previous studies in the United States have reported a number of barriers such as cost constraints, poor quality of information, and technology problems.[14] Moreover, some reviews performed previously have specifically focused on a specific disease or condition.[7,15–17]

Therefore, due to the lack of systematic reviews on identifying these barriers and facilitators, regardless of the type of disease or registry, and lack of studies on comparing these factors between developing and developed countries, we conducted the current review to identify these factors and also to provide suggestions for improving the implementation of registries.

METHODS

This review was conducted in terms of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[18]

Definition

A registry is defined as an organized system in which uniformed data are systematically collected and then analyzed for a predefined population and for a specific disease, condition, or health outcome.[1] In this review, any type of registry system related to a specific group of patients, regardless of the type of diseases, procedures, or health outcomes, was considered as a registry.

A barrier is a condition, person, or thing preventing other people, systems, or entities from doing their work, communication, or progressing.[19] Conversely, a facilitator is defined as a person or thing that either helps another person, system, or organization to do something more easily or provides a solution for a problem.[20] In this review, barriers and facilitators were included regardless of their type.

Information sources and search strategy

The Electronic search was performed on some databases including PubMed (MEDLINE), Embase, ISI Web of Sciences, Cochrane Library, Scopus, Ovid, and ProQuest. The main keywords were the following: registries, health registry, barriers, and facilitators. Moreover, we developed our search strategy (Supplement File 1, Table S1) with the combination of the used main keywords, synonymous, and related keywords in MeSH and Emtree, as well as other keywords obtained from the literature review. In addition, to check the gray literature and to ensure that the relevant studies were not omitted, the Google and Google Scholar search engines were searched. Furthermore, the reference lists of the related studies were reviewed to identify further relevant articles.

Inclusion and exclusion criteria

In the present study, research and review studies published in conference proceedings and peer-reviewed journals (in full text) from 2000 to June 2021 were included. As well, the studies related to "any type" of diseases, procedures, and health outcome registry systems were included. Studies that specifically identified barriers or challenges or both of them were also included. Moreover, those studies that identified facilitators or barriers after the implementation of a registry or reviewed other registries were selected. However, short communication, letters to the editor, commentaries, perspectives, books, book reviews, conference abstracts, and clinical trial registry systems were excluded. We also excluded articles published in non-English languages.

Selection of studies

At first, all duplicate titles were removed using Endnote software. In the next step, unrelated studies were removed based on their title and the abstracts. Thereafter, the full text of the remained studies was reviewed. The references of the included studies were also checked to find relevant articles (Figure 1). In all these steps, the 2 researchers independently reviewed the titles, abstracts, and full text
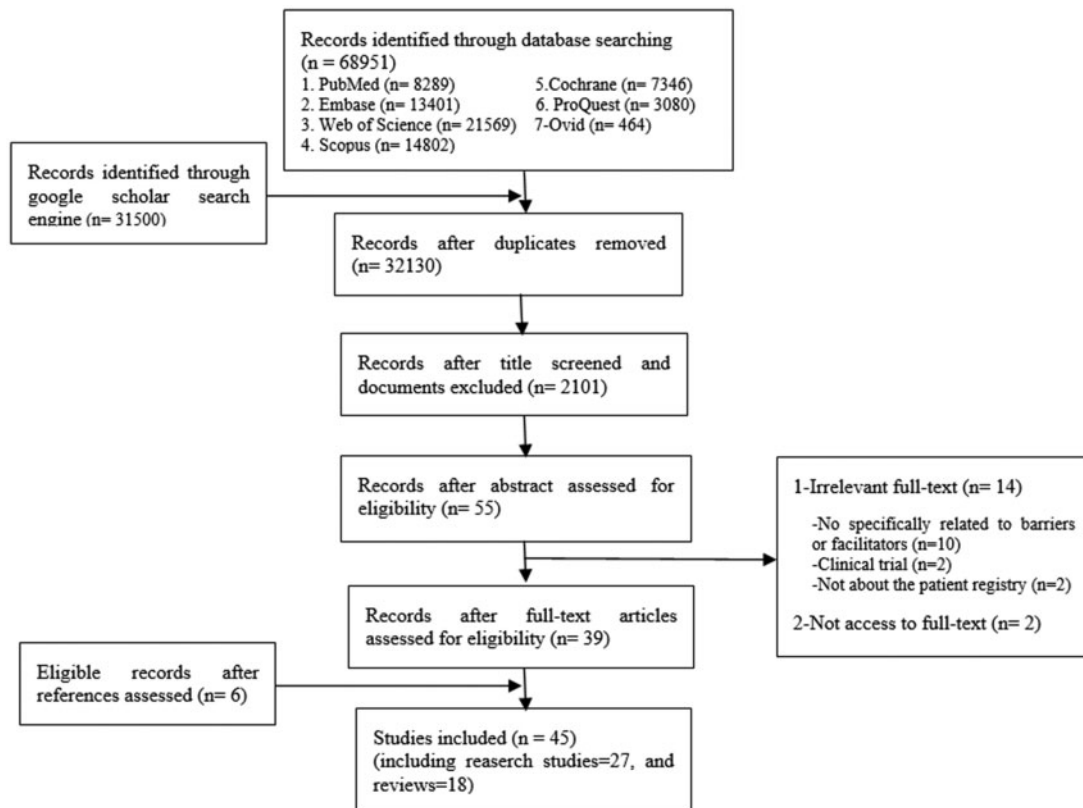
Figure 1. Selection of studies based on the PRISMA flowchart.

of the studies, respectively. In case of any disagreement, the agreement was reached through consensus.

Data extraction and analysis

To collect the required data, we developed a data extraction form and then extracted the author, year of publication, the living country of the first author, the country/countries in which those registries were evaluated, geographic coverage and type of registry, research methodology, and summary of the findings (barriers and facilitators). To do this, 2 researchers, after reviewing the articles, independently extracted the data and concepts related to barriers and facilitators of registries. If there was any difference between the findings of these 2 researchers, these cases would be reviewed in a joint meeting and agreement would be reached finally.

Data analysis was done using the content analysis method. The concepts obtained from each included study were discussed in various meetings. Finally, these concepts were organized in the form of the main themes and subthemes. The frequency of each one of the extracted concepts was reported as well. Besides, the findings were classified based on publishing in the developed and developing countries.[21] To this end, we considered the countries in which registries were evaluated. Some articles did not focus on a specific group of countries,[10,22–27] so their reported factors were considered for both developed and developing countries. Finally, the facilitators and barriers reported in reviews and research studies were analyzed separately. To calculate the percentage of these reported barriers and facilitators, the number of studies in each category (review or research studies, and studies related to the developing or developed countries) was considered as the denominator. Additionally, the frequency of barriers and facilitators was reported based on the

condition, disease, or intervention. In this subanalysis, those registries with higher number of included publications, including trauma, cancer, stroke, surgery, implant, and vaccination registries, were considered.

Ethical consideration

This study was approved by the ethics committee of Iran University of Medical Sciences, Tehran, Iran (IR.IUMS.REC.1397.374).

RESULTS

Selection of the studies

From 100,451 studies retrieved initially, 45 studies were included in this review. Figure 1 shows the processes of searching and screening the selected studies based on the PRISMA flowchart.[18] Based on our comprehensive search strategies, there were many initial results; however, many of them were related to the description or analysis of registry data, so they were considered as unrelated to our purpose and excluded thereafter.

Description of the included studies

The specifications of the registries mentioned in the included studies are reported in Table 1. The description of the included studies is presented in Supplement File 2, Tables S2 to S4.

As shown in Table 1, the highest frequency of registries belonged to hospital-based (14 studies), followed by population-based registries (10 studies). Most registries were national (15 studies) and local registries (9 studies). Furthermore, the highest number of studies belonged to trauma registry programs (9 studies).

Table 1. Specifications of health condition and outcome registry systems in the included studies

Specifications		Number of studies	References
1. Type of registry	Hospital-based	14	6,16,23,27–30,36,38,40,41,54,57,58
	Population-based	10	5,22,31,32,34,47_49,55,56
	Clinical/research-based	6	14,17,24,26,37,52
	Clinical	4	33,35,45,53
	Clinical/hospital-based	3	7,39,42
	Research-based	2	44,51
	Not mentioned	6	10,15,25,43,46,50
2. Registry geographical coverage	National	15	5–7,30,33,34,36,39,40,42,47,49,50,54,55
	Local	9	35,38,41,43,44,48,52,53,57
	International	4	22,37,45,58
	National/local	4	14,23,24,29
	Not mentioned	12	10,15–17,25–28,31,32,46,51,56
3. Condition, disease, or intervention	Trauma	9	6,15,16,25,27–29,41,57
	Cancer	3	5,43,55
	Stroke	3	40,42,54
	Surgery	3	17,45,58
	Implant	3	7,36,39
	Vaccination	3	47–49
	Diabetes	2	53,56
	Primary care	2	38,44
	No limited to a health condition (outcome) or intervention	2	10,50
	Spinal cord injury	1	30
	Herpes virus	1	31
	Emergency care	1	32
	Bone infection	1	22
	Cardiac rehabilitation	1	33
	Rare diseases	1	34
	Familial hypercholesterolemia	1	35
	Acupuncture in premature ovarian insufficiency	1	37
	Urology	1	14
	Neurological diseases	1	46
	Lupus	1	26
	Human embryonic stem cells	1	51
	Psychological problems during pregnancy and after childbirth	1	52
	Cystic fibrosis	1	24

Figure 2 shows the geographical distribution of studies based on the living countries of the first authors. The United States with 16 studies (35.5%) and United Kingdom and Australia each one with 4 studies (8.8%) had the highest number of investigations.

Figure 3 shows the most studies were published in 2019 ($n = 7$, 15.5%).

Of 45 studies included, 26 (19 research studies and 7 reviews), 12 (6 research studies and 6 reviews), and 7 (2 research studies and 5 reviews) discussed the barriers or facilitators related to the registries of developed and developing countries, or both of them, respectively.

Barriers and facilitators

The detailed findings related to these barriers and facilitators are presented in Supplement File 2, Tables S2 to S4. Overall, 607 concepts were extracted from these included studies, which were then organized into 175 unique codes by integrating similar concepts. Of these, 93 codes (Supplement File 3, Table S5) and 82 codes (Supplement File 3, Table S6) were related to the barriers and facilitators, respectively. Thereafter, these codes were classified into 14 themes (including 7 barriers and 7 facilitators), namely management, data management, stakeholder cooperation, technology, ethics/confiden-

tiality/data security, patient's participation, and disease-related factors (Tables 2 and 3).

Comparison of the developing and developed countries

As shown in Figure 4, it was indicated that some barriers, especially registry management barriers (including inadequate financial, human, and training resources, poor-performance managers, and inappropriate guidelines) and data-related problems (including poor data quality and inappropriate data collection methods), as well as some technological constraints (including the lack of system interoperability and infrastructure deficiencies) are reported more in the developing countries than in the developed ones.

The most of the other reported barriers were mentioned relatively equally in these 2 types of countries; however, some barriers such as insufficient working space, patients' nonparticipation due to privacy concerns, their low knowledge on registries, and the possibility of additional costs were not reported in those studies published in the developing countries at all. As well, lack of technical architecture was not reported in the studies published in the developed countries.

Furthermore, insufficient time and working space, limitations of biological sample collection, patients' nonparticipation due to pri-
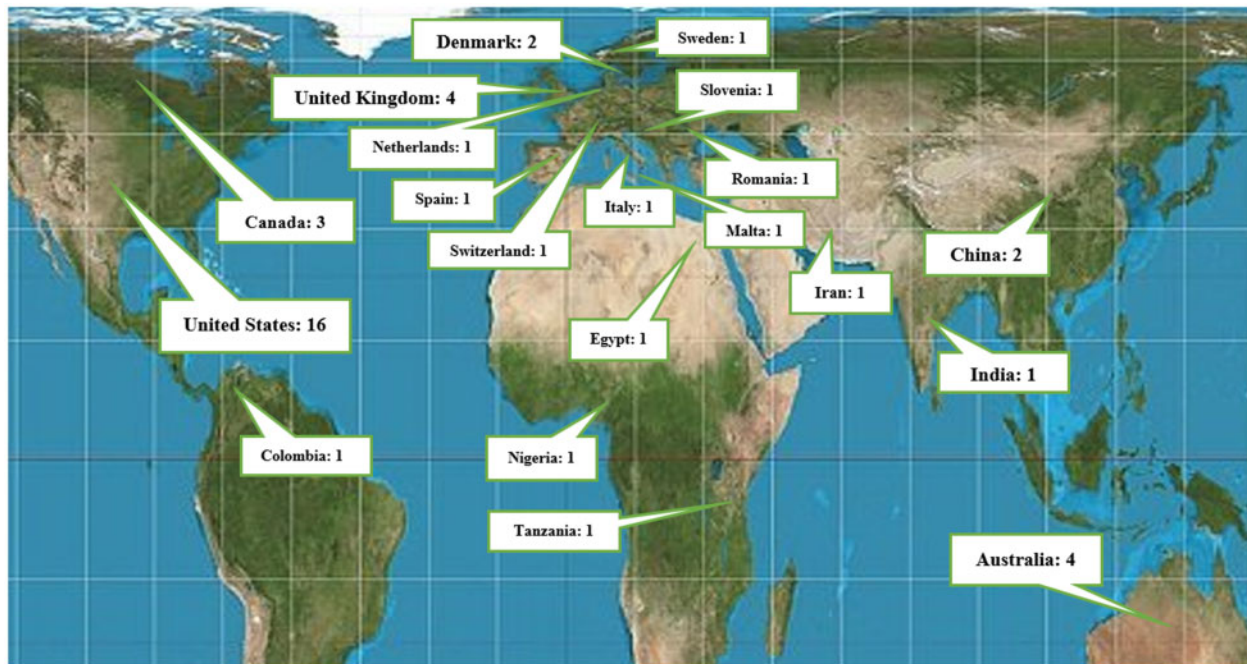
Figure 2. Geographical location and number of included studies.
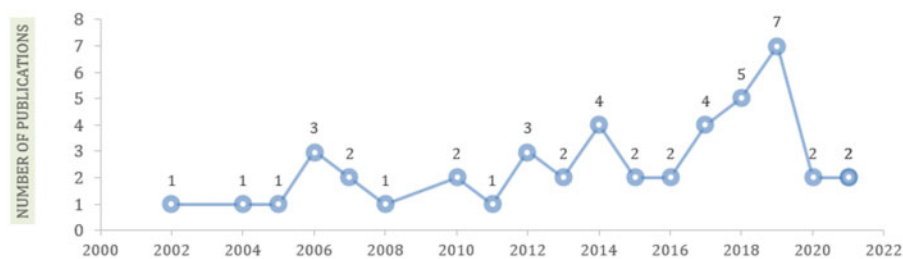

Figure 3. Distribution of studies by publication year.

vacy concerns/additional visits/costs, difficult administrative process of patients' participation, and lack of patients' knowledge about registries were not reported in previous reviews.

According to Figure 5, all 7 facilitator themes were indicated in both types of countries. However, management facilitators (including providing adequate training, financing, managers' good performance, and developing registry guidelines), increasing stakeholders' participation, and data-related solutions (including data quality assurance and appropriate data collection methods) were more reported in the developing countries compared to the developed ones.

Most of the other facilitators were cited relatively equal in studies related to both developing and developed countries. However, some facilitators, such as allocating enough time and workspace, developing questionnaires to evaluate registry software, patient's involvement in registry management, setting a separate goal for patient's follow-up, considering the patients' needs/interests, and existence of standard disease screening and biological sample collection tools/methods, were not reported in the studies related to the developing countries.

Moreover, research studies did not mention some facilitators such as developing a general technical architectural document of software, using Electronic Medical Record (EMR)/Electronic Health Record (EHR) as the infrastructure of registries, developing auto-

matic patient's follow-up systems, patient's involvement in registry management, and using evidence-based solutions for patient's evaluation. Furthermore, allocating enough time and workspace, developing a comprehensive questionnaire to evaluate registry software, considering the patients' needs/interests, setting a separate goal for patient's follow-up, and using the standard disease screening and biological sample collection tools/methods were not reported in previous reviews.

The subanalysis performed based on the common reported registries (Supplement File 4, Tables S7 and S8) showed that lack of financial/human resources and other management problems, poor data quality, inadequate data collection, and limited cooperation of stakeholders as well as some facilitators such as financing and supplying human resources, data quality assurance, appropriate data collection methods, and increasing stakeholders' cooperation were the most frequently cited barriers in trauma, cancer, stroke, surgery, implant, and vaccination registries.

It is noteworthy that some specific barriers such as the complexity, diversity, and extent of disease and unclear geographical patterns of a disease in a population were reported only for trauma/stroke and trauma/vaccination registries, respectively. On the other hand, facilitators such as the patient's involvement in registry management and developing a comprehensive questionnaire to evaluate

Table 2. Barriers to implementation of health condition and outcome registries

Themes and subthemes (References)

Theme1: Management barriers
1. Lack of or insufficient resources
Lack of financial resources[5–7,10,14–17,22,23,27–29,31,34,36,37,39,41,43,50,52–54,57]
Inadequate human resources[6,15,23,28–31,36,41,43,50,53,55,57]
Inadequate training[5,10,15,16,22,27,29–31,33,35,43,53,57]
Insufficient time[6,35,36,42,52,53,57]
Insufficient working space[52]
2. Poor performance of managers[5,15,16,22,26,27,31–33,35,36,50,52,55,56]
3. Inappropriate instructions and guidelines for registries[10,14–16,22,23,26,27,31,32,34,44,50,54]
4. Use of inappropriate processes[10,15,25,32–34,36,43,47,50,58]
5. Inappropriate formulation of registry purposes[10,24,27,34,43,50,51]
6. Inappropriate steering committee[10,16,33,50]
Theme 2: Data management barriers
1. Poor data quality[5,7,14–16,22–25,28,30–33,36,37,41,43,45,47,48,51,54,56–58]
2. Inappropriate data collection methods[6,7,15,17,24,25,27,28,30–33,41–43,45,51,54–57]
3. Lack of data standardization[10,15,23–25,27,33,34,36,39,48,49,54,55,57,58]
Theme 3: Barriers to collaboration
1. Low interest and motivation[7,28,29,31,33,46,47,49,50,52,55,56]
2. Limited participation of stakeholders[7,10,28,31,34,43,46,49]
3. Limited coordination between stakeholders[23,33,49,51,55,58]
Theme 4: Technological constraints
1. Lack of integration and interoperability with other information systems[5,26,27,29,31,33,34,37,47,49,57]
2. Poor design or acquiring inappropriate software[26,31,33,46,47,50,51]
3. Deficiencies and limitations of infrastructure, software, hardware, and maintenance[6,10,14,23,27,31,41,54]
4. Failure to determine the technical architecture of the registry system[50]
Theme 5: Legal and regulatory barriers
1. Inappropriate guidelines for confidentiality and data security[10,15,24,26,31,34,36,39,40,46,47,51,52,57]
2. Non considering ethical, legal, and regulatory principles[6,10,26,28,36,37,40,50,51,57]
Theme 6: Considerations related to diseases
1. Uncertain and various consequences of a disease[16,31,33,34,37,56]
2. Complexity, diversity, and extent of disease[27,40]
3. Inappropriate tools for diagnosing disease and evaluating patients[16,51]
4. Unclear geographical patterns of a disease in a population[27,48]
5. Difficulty and limitations of biological sample collection[22]
Theme 7: Poor patients' participation
1. Patients' nonparticipation due to privacy concerns[35,46,52]
2. Lack of knowledge of patients with a registry program[35,52]
3. Lack of a tracking and follow-up system or lack of patients' referral[27,43]
4. Difficulty in long-term participation of a large number of patients[6,26,32]
5. Difficulty in the administrative process for negotiating and contracting with patients[22]
6. Nonparticipation of patients due to the possibility of additional visits and costs[46]

Note: Some themes do not have subthemes; therefore, only the relevant codes were reported in this table, and the details related to the codes of other themes were reported in Supplement File 3 (Table S5).

registry software were respectively mentioned only for implant and surgery registries. Coordinating among stakeholders as well as using EMR and evidence-based patient evaluation tools were only mentioned in cancer and trauma registries-related publications, respectively.

DISCUSSION

In the present review, 607 barriers and facilitators were identified and then classified into the following 7 categories: (1) management, (2) data management, (3) collaboration, (4) technology, (5) legal and regulatory, (6) considerations related to diseases, and (7) poor/improved patient's participation. Stanimirovic et al.[34] in their study have previously identified barriers to registry development and classified them in the following 7 themes: inability in anticipating clinical benefits, lack of registry prospects, weakness of infrastructure, weakness of legal and regulatory frameworks, weakness of

conceptualization of registries, insufficient budget, and nonparticipation of stakeholders. Moreover, Mandavia and Knight[36] in their study have categorized barriers into the following 9 themes: lack of completion of data, lack of agreement on a data set, insufficient resources, weakness in managing the registry, weak data management, inadequate legal factors, lack of paying attention to information protection, weakness in information governance and data security/ownership, and uncertainty regarding data quality. They have also categorized the facilitators into 7 classes, including determining the leadership committee; stakeholders' cooperation; simple registry design; creating a minimum data set as well as maximizing data completeness; hiring legal, administrative, and technology consultants; establishing a pilot program; and user feedback. Although the classifications of the barriers and facilitators in these studies are different from that of our study, the details of these categories are somewhat similar to ours. In the current study, we also compared these factors between the developing and developed countries, and

Table 3. Facilitators to implementation of health condition and outcome registries

Themes and subthemes(References)

Theme 1: Management facilitators
1. Securing the required resources
Providing adequate training[7,22,23,25,28,31,33,35,41,43,46,51–53,56,57]
Financing[5–7,15,16,22,23,28,31,38,39,41,43,46,56,57]
Supplying human resources[15,22,23,33,38,41,42,57]
Allocating enough time[33,38]
Allocating enough working space[38]
2. Managers' performance[5–7,22,23,31–33,38,41,43,50,52,53,56]
3. Formulating appropriate purposes[6,7,22–24,26,32,33,44,46,50,51,57]
4. Developing registry guidelines and protocols[5,7,16,22–26,29,44,46,50]
5. Developing an appropriate steering committee[7,22,23,32,33,36,50,52,56,57]
6. Implementation of appropriate and well-defined processes[36,42,50,53]
Theme 2: Improving collaborations
1. Creating interest and motivation[6,7,23,25,28,33,38,43,44,46,52–54,56,57]
2. Increasing stakeholders' participation[6,7,22–25,29,30,35,42,46,51,54,57]
3. Better coordination between stakeholders[5,43]
Theme 3: Data management facilitators
1. Data quality assurance[7,16,23–26,28,31–33,36,41–43,45,52,57]
2. Appropriate data collection methods[6,7,16,23–26,28,31–33,41,42,56–58]
3. Data standardization[7,15,16,22–25,33,36,39]
Theme 4: Implementing appropriate technologies
1. Compatibility and integration of the registry software with other information systems[23,30,31,38,45,47,51]
2. Appropriateness, simplicity of the software, and support and maintenance services[5,7,23–26,31,33,56]
3. Developing a general architectural document to determine all technical specifications of appropriate software[50]
4. Establishment of Internet-based disease registry network[51,58]
5. Use of Electronic Medical Records/Electronic Health Records (EMRs/EHRs) as an infrastructure for a registry[16]
6. Developing a comprehensive questionnaire to identify and evaluate registry software[58]
Theme 5: Increasing patients' participation
1. Trying to attract the informed participation of patients with trust[22,24,31,33,35,52]
2. Development of automatic patient tracking or follow-up systems[16,56]
3. Considering the needs and interests of patients[31]
4. Patient's involvement in the management of a registry[7]
5. Setting a separate goal for patient follow-up[53]
Theme 6: Legal and regulatory facilitators
1. Developing appropriate guidelines and mechanisms for data confidentiality and security[22,24,31,39,40,57]
2. Appropriate setting of ethical, legal guidelines[23,39,40,50]
Theme 7: Facilitators related to disease conditions
1. Existence of standard disease screening tools[52]
2. Use of standard biological sample collection methods[42]
3. Use of evidence-based solutions for patient evaluation[16]

Note: Some themes do not have subthemes; therefore, only the relevant codes were reported in this table, and the details related to the codes of other themes were reported in Supplement File 3 (Table S6).

as a result, we found that problems and subsequent solutions for implementing registries are almost similar in both the developed and developing countries. However, most of them such as insufficient resources (especially financial issues) and problems related to the management of registry setup, data management, poor patients' participation, and technological constraints have been more frequently reported in the developing countries. Notably, remaining issues in this regard are common to all registries in both the developing and developed countries. In the following, the most reported barriers and facilitators are discussed.
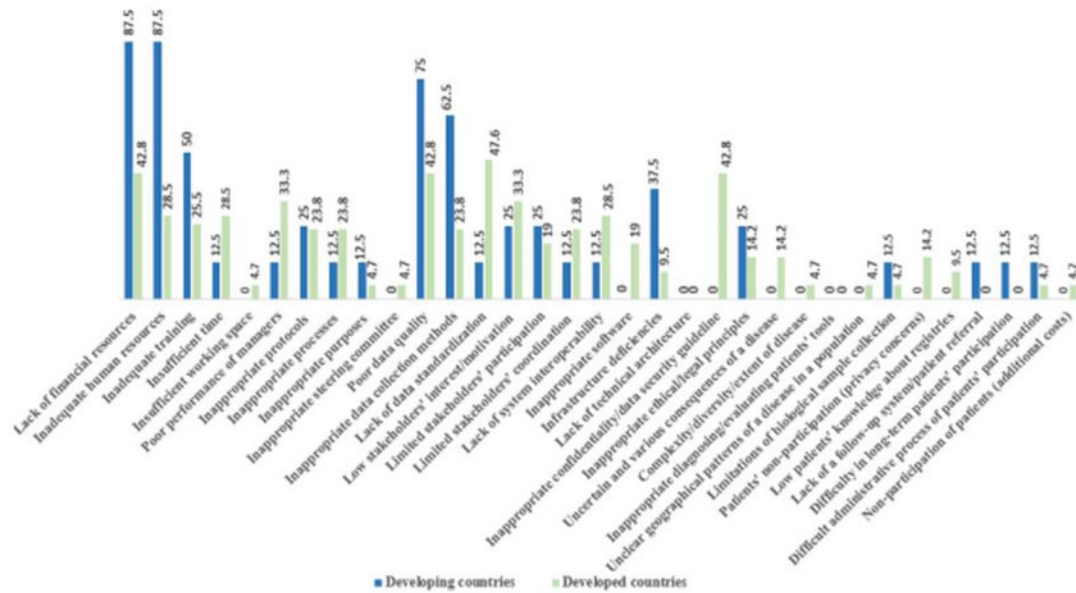
Management

Some barriers such as insufficient funding and budget[6,7,15,16,28] and high costs related to infrastructure and equipment[10,14–16] are among the most frequently cited problems. Correspondingly, these barriers could delay the progress or result in a failure of the implementation of registries, because registries heavily depend on resources and manpower. Therefore, having a plan to secure sustainable funds[22,31,43]

should be considered as one of the concerns of the registry managers from the start of the implementation of these programs.

Inadequate staff training[5,10,22,33,43] is known as another most reported barrier leading to a lack of knowledge and skills, and doing unscientific and unprincipled activities. Therefore, providing adequate training and continuous feedback to registrars[7,23,28,41,52] may possibly increase the scientific mastery of employees and guarantee their skills consequently. Having limited dedicated staff[6,15,28,29] results in continuous rotation of the staff, rework, the increased training costs, and inconsistent activities. Therefore, one of the solutions in this regard is having the initial planning for hiring or employing more dedicated staff,[22,33,38] which is known as one of the most basic facilitators to provide a permanent and informed staff in registries.

Poor performance of managers[15,16,32,36,52] along with the lack of complete and accurate registry guidelines[5,10,14,26] consequently lead to ambiguity or inconsistency in the registry operations. In this regard, registry managers should carefully develop the registry protocol, inclusion and exclusion criteria[7,22,24] and registry guidelines.[16,29]
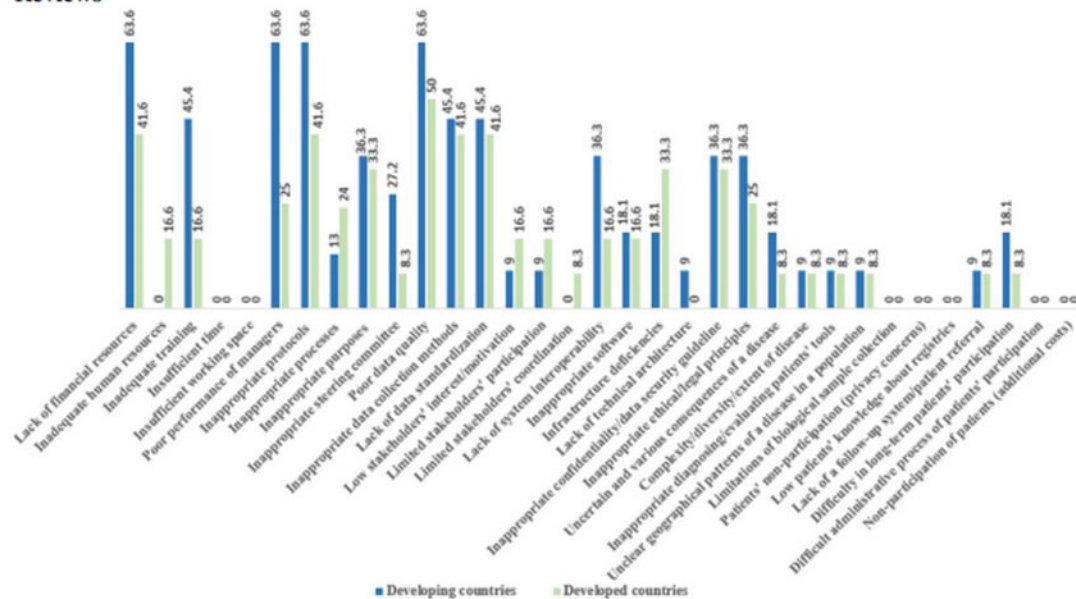
Figure 4. The reported barriers in developed and developing countries in research studies (A) and reviews (B).

Data management

Incomplete and incorrect medical records[14–16,28,32] and invalid reports in patients' records[22,31,33] were the most cited problems for data collection in disease registry programs. Registries usually collect data retrospectively from patients' records. Hence, data deficiencies are difficult to be corrected, and it is not easy to obtain high-quality data from these data sources, due to the reason that each of which is documented in the health-care facilities based on different perspectives and definitions. Correspondingly, continuous data validation and auditing with ongoing feedback[7,28,33,42] by data quality managers in registry centers as well as holding periodic data

quality control workshops can help to identify data quality issues and also to improve data quality in registries.

Inappropriate data collection may possibly occur due to several reasons such as the large amount of required data items[24,41,42] and the lack of appropriate guideline or method for data collection. A large number of data elements make the process of data collection difficult, time-consuming, and costly, and finally result in incomplete data collection. In determining the required data elements, registry managers should always pay enough attention to its appropriateness for the purposes and feasibility of data collection in terms of providing appropriate data format and the available methods and tools for data collection in participant centers,
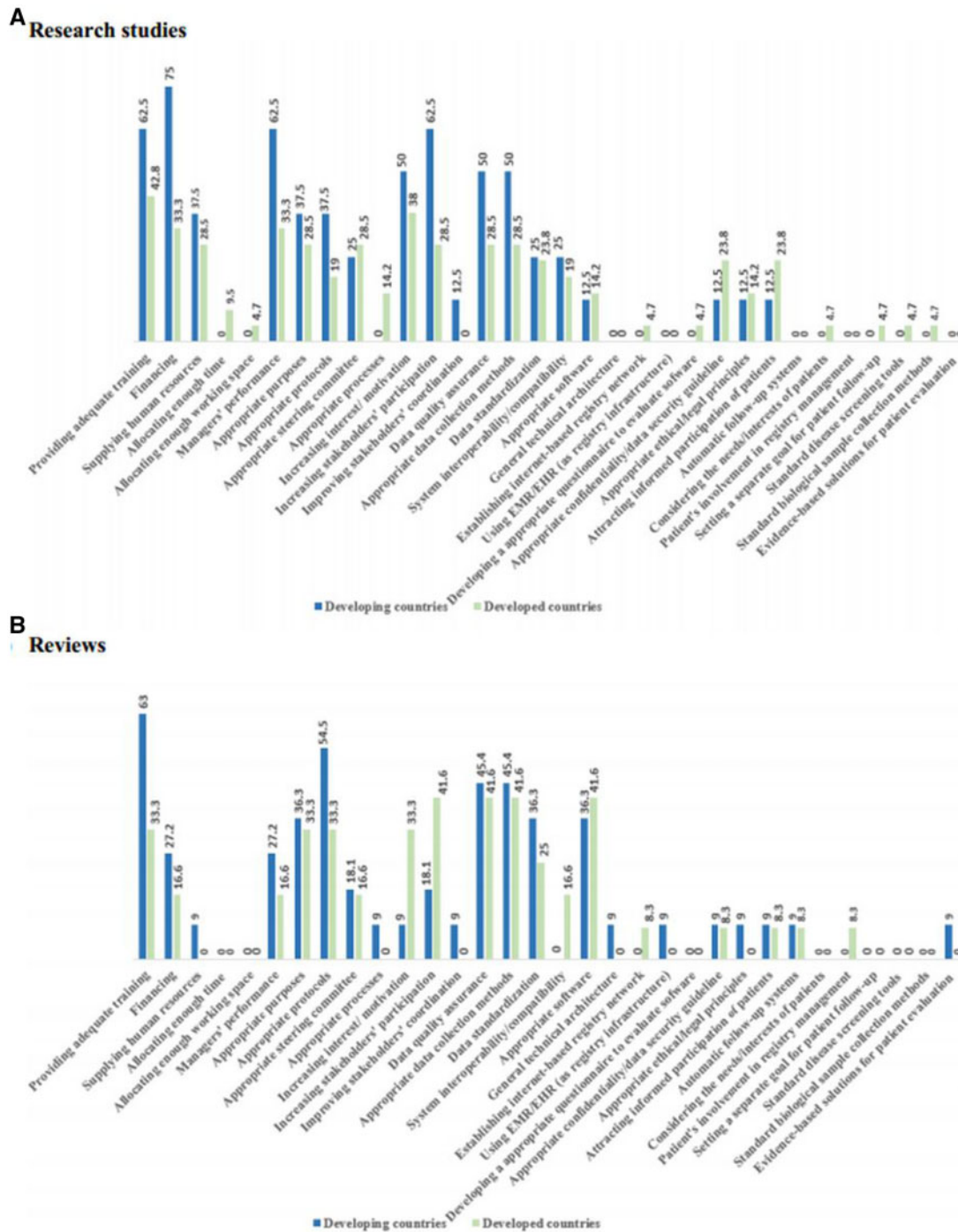
Figure 5. The reported facilitators in developed and developing countries in research studies (A) and reviews (B).

and they should also make sure of data availability[23,36]; otherwise, the registry will face a lack of resources, unnecessary data, or the increased missing data. Integrating data collection into daily clinical and managerial activities[6,33] and automating data entry into registry software, for example, using EHRs[6,28,32] with a standard data format, are some of the solutions proposed for facilitating data collection.

It was found that lack of data standardization such as uncertain minimum data set [15, 23, 34] and nonuniform definitions of data items[10,25,33] cause differences in the volume, type, and structure of data, which consequently result in data incomparability, poor data quality, and nonuniformed data collection. Therefore, developing a common and agreed-upon data set[7,15,16,22,33,36] and a uniform method used to collect data[31,42] from different data sources should be considered by the managers from the very initial steps of the development of registries to the final stages.

Collaboration

Insufficient interest and motivation, poor participation, and coordination of stakeholders can lead to a failure of a registry. As well, ignoring financial or nonfinancial incentives[7,28] leads to loss of

interest and motivation, as well as the increased discouragement and resistance in registry staff. In this regard, some measures such as creating financial or nonfinancial incentives or credits[6,33,38,46] are highly suggested for improving the collaboration. Poor stakeholders' participation and involvement,[7,10,28,31,34] such as their disagreement in the characteristics of a registry,[51,58] lead to a lack of cooperation. Hence, promoting an active and sustainable participation among stakeholders[7,29,30] in doing various activities of registries by holding regular meetings of the steering committee, and collaborative design and formulation of purposes, activities, and protocols from the very beginning of the pilot program can increase trust in the program and improve agreement and collaboration among stakeholders.

Technology

Lack of integration and interoperability with other information systems[29,31,33,34] limits the possibility of the use of the available data once again in other information systems in registries. Consequently, this can lead to the increased costs due to duplicate data collection. Interoperability and integration of registry software with other systems and automatic data importing from available systems[23,30,45] were the most cited measures that can be used by registry managers to enable data exchange between systems, and even to develop registry networks[51,58] for taking the advantages of shared facilities. Inappropriate design and acquiring inappropriate software,[31,33,46] usually due to the lack of initial needs assessment and nonstandard technical requirements, along with the lack of infrastructure and technical support,[6,10,14] were the other most frequently reported barriers. In this regard, the appropriateness and a standard development of registry software, appropriate support and maintenance services,[7,23,33] and identifying technical requirements[58] are highly recommended.

Legal and regulatory factors

The inappropriate formulation of data confidentiality and security principles as well as noncompliance with the ethical and legal principles can cause a serious challenge to registries. Many studies have previously addressed privacy and security concerns of registries as well.[15,31,36,52] Accordingly, the lack of appropriate plans for the privacy and security of patients' data subsequently threatens the patients' sensitivity and also leads to identifying information with unauthorized access and then the misuse of this information. Therefore, developing legal and principled measures to keep the patient anonymous,[24,31,39] such as separating identity data from clinical data and not disclosing information without any permission,[40] is an example of the strategies that should be implemented in this regard. On the other hand, the uncertain intellectual property of data[10,36,50] causes ambiguity in data ownership, concerns and legal disputes, and reluctance in sharing patients' data. It is suggested that registry managers should transparently formulate and agree on data ownership[23,50] as well as on accurate data access and disclosure policies,[40,50] especially in multicenter registry programs.

Disease's considerations

Limitations and considerations related to a specific disease or the subject of the registry such as uncertainty and various outcomes of a disease,[16,31,34] or on the extent of a disease,[27,40] may result in both ambiguity and complexity for the development of a registry. For example, having difficulty in agreeing on the minimum data set, case finding criteria, or the covered population of a registry are some affected areas in this regard. Hence, involving specialized clinical and epidemiological teams along with considering evidence-based guidelines[16] can consequently decrease ambiguities and increase the body of knowledge of a registry for patients' evaluation and treatment methods. Therefore, it can lead to the appropriate design of a registry.

Patients' participation and involvement

Patients' participation in registries is considered as an important process in ensuring patient's follow-up and assessment of disease's outcomes; however, concerns related to privacy,[35,46,52] poor patients' awareness,[35,52] or the possibility of additional visits and costs[46] may reduce this rate of participation. Increasing patients' trust and awareness levels,[22,24,35] considering patients' interests,[31] and involving patients' representative in the management of a registry[7] are some of the strategies effective on increasing patients' participation in registries or on improving patients' follow-up.

CONCLUSION

The present review showed the barriers and challenges of implementing and continuing the registry programs as well as proposing some common strategies to eliminate or reduce these barriers. Overall, 93 and 82 unique barriers and facilitators were identified, respectively, which were organized into 7 themes. The barriers and facilitators related to the management and data management were the most reported registry success factors. Moreover, 4 common barriers were the lack of budget, the poor performance of managers, poor data quality, and low stakeholders' interest/motivation, and 4 common solutions were providing adequate training, financing, data quality assurance, and appropriate data collection methods. Although many of these factors have been more cited in the literature published in the developing countries, they were common in both the developed and developing countries. Considering these barriers and facilitators, disease registry managers and policymakers can play more effective roles in the success of the development and implementation of registries. As an operational solution, registry managers can use the results of this review to develop a guideline or a roadmap for the evaluation or setting up their registry programs, in order to improve the chance of the registry success.

LIMITATIONS OF THE STUDY

In the current review, we aimed to identify and classify all the possible barriers and facilitators; however, the quality of the included studies was not investigated, and all types of registries were considered as well. Despite searching and reviewing a large number of studies, still there may be some studies that have not been reviewed. Finally, it should be noted that the reported frequency of the studies can only indicate which barriers/facilitators have been more or less reported in the literature, and it should not be considered as an indicator for the relative importance of these factors. Most studies included in this review did not report the importance of the barriers or facilitators. Therefore, prioritization of these factors can be considered in further studies.

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AUTHOR CONTRIBUTIONS

The authors contributed to the study as follows: ML: Conceptualization, methodology, data curation, formal analysis, writing—original draft, investigation, and visualization. AS: Conceptualization, methodology, validation, formal analysis, writing—review and editing, supervision, project administration, and funding acquisition.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

CONFLICT OF INTEREST STATEMENT

None declared.

DATA AVAILABILITY

The data underlying this article are available in the article and in its online supplementary material.

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