Short Communication

National Spinal Cord Injury Registry of Iran (NSCIR-IR) — a critical appraisal of its strengths and weaknesses

Mahdi Sharif-Alhoseini [a], Zahra Azadmanjir [b], Mohsen Sadeghi-Naini [a], Zahra Ghodsi [a], Khatereh Naghdi [a], Mahdi Mohammadzadeh [c], Amir AzarHomayoun [a], Kazem Zendehdel [d], Moein Khormali [a, e], Farideh Sadeghian [f], Seyed Behzad Jazayeri [a], Mojtaba Sehat [c], Habibollah Pirnejad [g], Edward C. Benzel [h], Gerard O'Reilly [i], Michael G. Fehlings [j], Alexander R. Vaccaro [k], Vafa Rahimi-Movaghar [a, l, *]

[a] Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Tehran, Iran
[b] Department of Health Information Management, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran
[c] Trauma Research Center, Kashan University of Medical Sciences, Kashan, Iran
[d] Cancer Research Center, Cancer Institute, Tehran University of Medical Sciences, Tehran, Iran
[e] Students' Scientific Research Center, Tehran University of Medical Sciences, Tehran, Iran
[f] Center for Health Related Social and Behavioral Sciences Research, Shahroud University of Medical Sciences, Shahroud, Iran
[g] Department of Health Information Technology, Urmia University of Medical Sciences, Urmia, Iran
[h] Cleveland Clinic Foundation, Department of Neurosurgery, Cleveland, OH, USA
[i] Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia
[j] Toronto Western Hospital, University Health Network, Toronto, Ontario, Canada
[k] Department of Orthopaedic Surgery, The Rothman Institute, Thomas Jefferson University, Philadelphia, USA
[l] Brain and Spinal Cord Injury Research Center, Neuroscience Institute, Tehran University of Medical Sciences, Tehran, Iran

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ABSTRACT

The National Spinal Cord Injury Registry of Iran (NSCIR-IR) is a not-for-profit, hospital-based, and prospective observational registry that appraises the quality of care, long-term outcomes and the personal and psychological burden of traumatic spinal cord injury in Iran. Benchmarking validity in every registry includes rigorous attention to data quality. Data quality assurance is essential for any registry to make sure that correct patients are being enrolled and that the data being collected are valid. We reviewed strengths and weaknesses of the NSCIR-IR while considering the methodological guidelines and recommendations for efficient and rational governance of patient registries. In summary, the steering committee, funded and maintained by the Ministry of Health and Medical Education of Iran, the international collaborations, continued staff training, suitable data quality, and the ethical approval are considered to be the strengths of the registry, while limited human and financial resources, poor interoperability with other health systems, and time-consuming processes are among its main weaknesses.

Introduction

The National Spinal Cord Injury Registry of Iran (NSCIR-IR) is a not-for-profit, hospital-based, and prospective observational registry of individuals who sustained a traumatic spinal cord injury

(SCI). It is funded and sustained by the Ministry of Health and Medical Education of Iran (MOHME).[1] The NSCIR-IR appraises the quality of care, long-term outcomes and the personal and psychological burden of traumatic SCI in Iran based on the patients' hospitalizations. The long-term follow-up involves patients' re-hospitalization due to the complications of spinal fracture and SCI. Therefore NSCIR-IR is a research infrastructure for developing and preparing related research projects. There are some ongoing studies using the registry data.

The NSCIR-IR has been implemented in eight university trauma centers, including Sina Hospital (Tehran University of Medical

Sciences), Firoozgar Hospital (Iran University of Medical Sciences), Poursina Hospital (Guilan University of Medical Sciences), Shahid Beheshti Hospital (Kashan University of Medical Sciences), Emam Khomeini Hospital (Urmia University of Medical Sciences), Shahid Rahnemoon Hospital (Yazd Shahid Sadoughi University of Medical Sciences), Emam Reza (Tabriz University of Medical Sciences), and Emam Hossein (Shahrood University of Medical Sciences) (Fig. 1). Although the NSCIR-IR is not a population-based study registry, it is ready to expand to the other cities of the country. The registry administrators are providing the technical infrastructure and educational needs for universities that want to participate in the registry. Fig. 2 shows the schematic process of the NSCIR-IR.

Benchmarking validity in every trauma center registry involves rigorous attention to data quality.[2] We reviewed the strengths and weaknesses of the NSCIR-IR while considering the methodological guidelines and recommendations for efficient and rational governance of patient registries.[3]

A high-quality data registry should address four key dimensions, including "governance", "data quality", "information", and "ethical issues, security, and privacy".[3]

Governance

Broadly speaking, a governing body establishes a framework for the registry, assists with its implantation, and assures the quality of the registry. Specific elements pertaining to governance are reviewed below.

Procedures and methods

Although the steering committee of the NSCIR-IR has outlined basic strategies, the purpose and procedures of the registry must be clearly established. Also, the application of digital technology can help lower costs, improve data quality, and help monitor staff's performance.

Education

The registry staffs are all dedicated nurses who have been trained on the patient registry protocol and procedures in addition
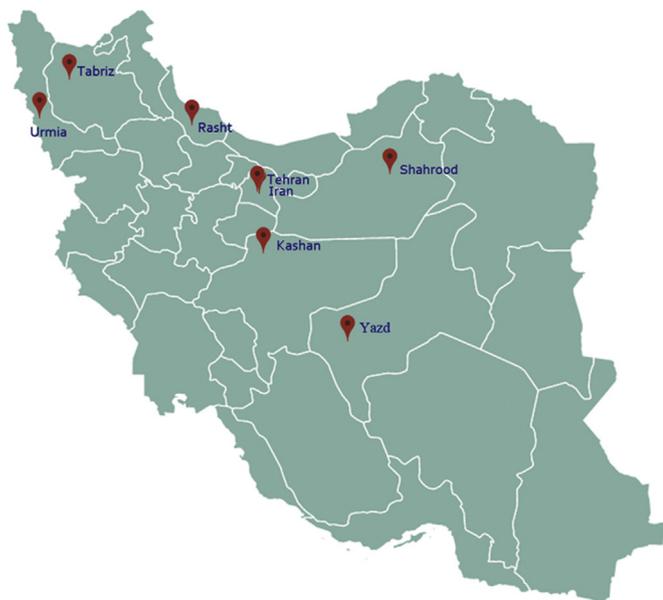

Fig. 1. Collaborative university centers of the National Spinal Cord Injury Registry of Iran.

to being educated on the American Spinal Injury Association (ASIA) impairment scale, international standards for classification of SCI, the AOSpine Fracture Classification System, and the World Health Organization Quality of Life-BREF assessment. Periodic retraining is essential for maintaining and developing updated skills to better manage the registry. The development of online learning tools and certification programs has made the process of retraining staff more feasible.

Resource planning and financial sustainability

The NSCIR-IR has a single director, an executive manager, 9-11 dedicated and educated registrars, and at least four data collectors, as part of multi-hospital registry.[3] However, some collaborating centers could benefit from allocating a facility solely for data registry. In addition, available resources must be allocated directly to the development and upkeep of the registry. Given the limited financial and human resources available to the MOHME, the use of such resources must be managed efficiently by an executive manager. The steering committee should also plan ahead in order to have future resources available and ensure the sustainability of the registry. International organizations, such as the World Health Organization, AO Foundation, nursing or rehabilitation agencies, medical devices industries, and insurance companies can be valuable assets as sponsors of the registry.

Interoperability

The integration of outside partnerships is another key element that assists with the exchange of information. For example, a large international workgroup contributed to the creation of the framework of NSCIR-IR.[1] Also, a representative of the Spinal Cord Injury Association of Tehran (a non-governmental organization) participates as an advisory member in the strategic workgroup. The pre-hospital data, injury mechanism, demographic data, diagnosis, and in-hospital procedures are extracted from the hospital information system. Initial steps are being taken to share the database with the Statistics and Information Technology Office of the MOHME and the National Trauma Registry of Iran. Data exchange between the NSCIR-IR and National Trauma Registry of Iran can be helpful to avoid duplication of data entry on pre-hospital care. Additionally, integrating acute care and rehabilitation facilities as well as local and national survival and death census bureaus are also crucial.

Self-assessment

Self-assessment is a responsibility of the governance to ensure that the quality of data is appropriate and the functional oversight of the registry is in place.[3] For instance, the case identification rate was one of the lowest results in the NSCIR-IR during a pilot study (70.8%)[1] which might be due to a misunderstanding of the inclusion and exclusion criteria. Such a shortcoming could be addressed through training webinars and local review seminars. Likewise, missing data should be regularly reported and handled with the appropriate oversight. Also, each data point that meets the purpose and goals of the registry should be included in the registry by the steering committee.[3] For instance, while the timing of presentation to an acute care setting is considered in the present registry, it would be beneficial to also incorporate the corresponding surgical procedure.

Data quality

In order to ensure that high-quality data are obtained, seven important elements need to be reviewed.[4]
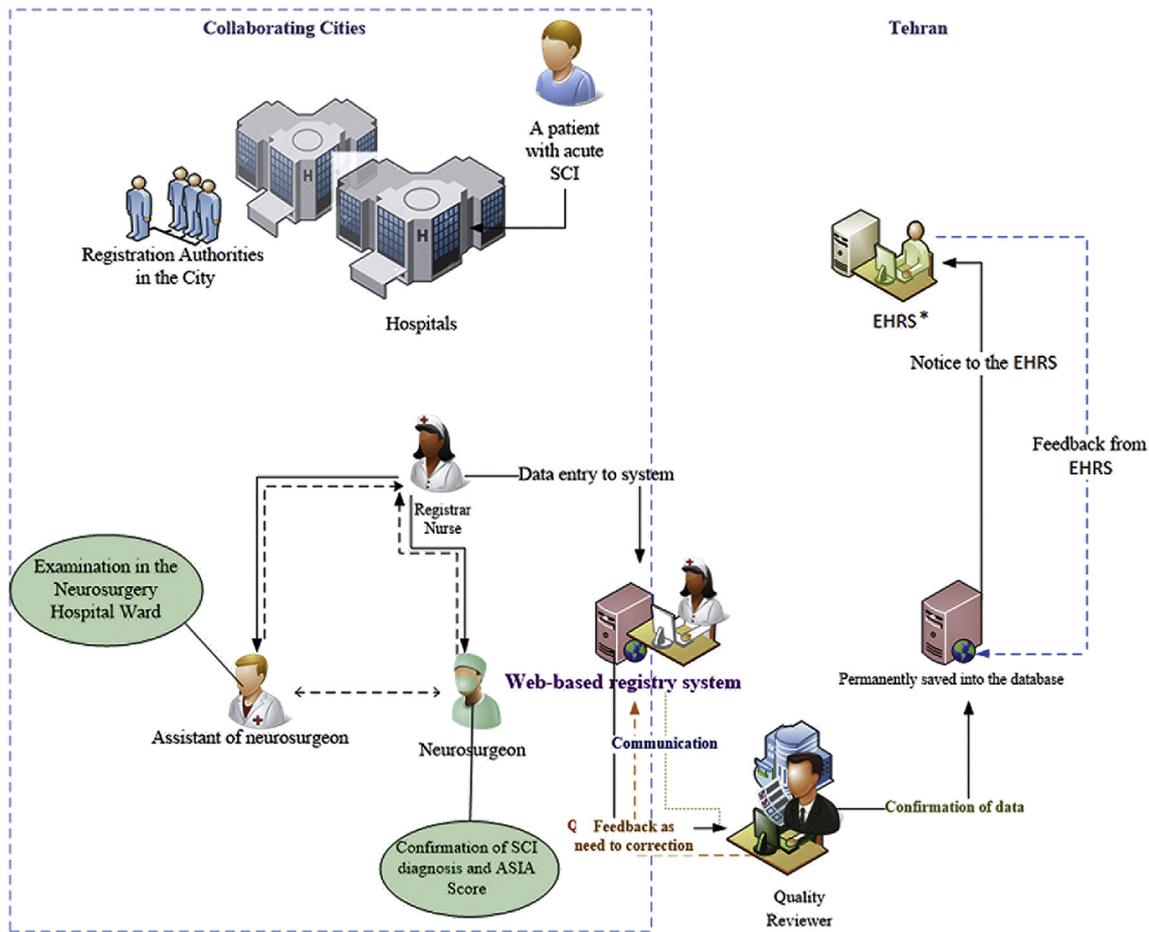
Fig. 2. Schematic process of the National Spinal Cord Injury Registry of Iran.
*Electronic Health Record System, Statistic and Information Technology Office of Ministry of Health and Medical Education, Iran. SCI: spinal cord injury.

Completeness

In the NSCIR-IR, trained and dedicated registrars input all the appropriate data, while reviewers verify that all the available data have been indeed registered. Moore and Clark[5] reported that some of the most important data items in the registry were not recorded in the patients' medical records. The NSCIR-IR's registrars attempt to resolve this issue by communicating with treating physicians, nurses, patients, or family relatives to obtain the missing data.

Accuracy and precision

In order to ensure accuracy and precision, data should be gathered in a reliable manner and directly from the source.[2] In the current registry, injury characteristics as well as pre-hospital and emergency department information are directly collected through patient interviews and medical records, while the neurological exam is re-examined by trained registrars. Also, diagnostic imaging and fracture classification are assessed by registrars and reviewers, but still some diagnostic and therapeutic data are extracted from the hospital information system administrative database. Therefore, care providers play a vital role in the accuracy and precision of data by ensuring the validity of the data entry and the appropriate use of International Classification of Diseases (ICD) codes. The use of the existing databases could have both pros and cons. With decreasing cost and eliminating duplicate work by sharing the database, use of the

existing databases might compromise the control and monitor of the data accuracy. Phillips et al[4] showed that the accuracy of different databases (e.g. an administrative database or a registry) was affected by the different purposes of each database. In the future, the inter-rater reliability between registrars should be measured to ensure the accuracy of the registry. Likewise, providing continuing education and training courses for physicians and medical coders are advisable.

Correctness

Data correctness is the process of identifying and correcting data inconsistencies. In NSCIR-IR, a smart web-based system is used to automatically reject incorrect values or values that are outside the range, while generating some computations for numerical data.

Consistency

Data consistency is the process of maintaining uniform data values in an application. Defined rules and constraints have been implemented into the web-based registry software to recognize inconsistent data that falls outside the established rules, especially numerical inconsistencies. Afterwards, trained neurosurgeon reviewers carefully examine the submitted data for clinical inconsistencies.

Compatibility

The aggregation of data from various sources emphasizes the need to collect data in a consistent manner so that the different data types are congruent. For example, there are 285 data elements in the data set, including 163 elements from the ASIA impairment scale and international standards for the classification of SCI. Furthermore, diagnostic images (X-Ray, CT scan, and MRI) are assessed to determine injury morphology based on the AOSpine fracture classification system. Besides, the validated Persian version of the World Health Organization Quality of Life-BREF questionnaire was used for quality of life assessment.[1] The data from each source must be compatible with the other in order to efficiently use the available data.

Timeliness

Maintaining data in the registry which is up to date is an important challenge. Timeliness can be measured as the time between when data are released and when they are accessible.[6] In the NSCIR-IR, the registry has become timelier following the transition to electronic data collection and software promotion. However, due to the various sectors that patients' files are referred to, tracking files is often difficult. Revisiting medical records to find and correct the defects by reviewers is another time-consuming problem.

Information

Information is an output of the entire data gathering process.[3] Its quality can be measured based on the purpose of the registry (scientific publications, outcomes, and surveillance), which can ultimately control the methodological basics and ensure quality data. For instance, information from surveillance registry can be used to improve facilities treatment protocols. So far, the NSCIR-IR has not produced such information and should actively pursue this following sufficient data gathering.

Ethical issues, security, and privacy

This dimension is concerned with the secure use of patient health information.[3] The Ethics Committee of the Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, reviewed the security and privacy protocol of the registry leading to its approval.[1] Likewise, researchers should be trained and required to sign a statement indicating an understanding of their responsibility in maintaining confidentiality of patient health information while accessing it. In the NSCIR-IR, several safeguards have been set in place to protect patient health information during the collection, storage, back-up, and access to the data. In order to improve the security of the data, an encrypted block chain-based cloud storage network can be implemented in future designs.

Data quality assurance is essential for any registry to make sure that correct patients have been enrolled and the collected data are valid. In the NSCIR-IR, retraining the registrars could improve case identification rate, accuracy, consistency, and timeliness of the registry. The processing and correction of data should be facilitated by registrars, reviewers, and care providers. Regular self-assessment of governance, close supervision and monitoring of all collaborating centers are equally essential. Improving the quality of data by critically and continuously reviewing these elements will allow a more efficient registry.[6]

Summary

While the steering committee, funded and maintained by the MOHME, the international collaborations, continued staff training, suitable data quality, and the ethical approval are considered to be the strengths of the NSCIR-IR; while the weaknesses include limited human and financial resources, poor interoperability among health systems, and time-consuming processes.

Funding

Ethical statement

Patient health information has been secured. The local ethics committee reviewed the security and privacy protocol of the registry and thereafter approved the study.

Conflicts of interest

The authors declare no conflicts of interest.

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