

**Article Type: Study protocol**

**Study Protocol: The International Spinal Cord Injury Survey in Iran (InSCI-IR)**

**Running title: International Spinal Cord Injury Survey in Iran (InSCI-IR)**

**Enayatollah Homaie Rad<sup>1</sup> 0000-0002-9064-0380**

**Diana Pacheco Barzallo<sup>2,3</sup> 0000-0002-8816-4071**

**Leila Kouchakinejad-Eramsadati<sup>4</sup> 0000-0002-6209-866X**

**Sara Sharifnia<sup>1</sup> 0009-0002-5049-1410**

**Zahra Mohtasham-Amiri<sup>4</sup> 0000-0002-4896-6248**

**Shahrokh Yousefzadeh-Chabok\*<sup>4</sup> 0000-0002-8825-3015**

**Zahra hagdoust<sup>5,4</sup> 0009-0005-0509-9067**

**Authors' ORCID ID:**

1. Social Determinants of Health Research Center, Trauma Institute, Guilan University of Medical Sciences, Rasht, Iran.
2. Faculty of Health Sciences & Medicine, University of Lucerne, Lucerne, Switzerland.
3. Health Economics Group, Swiss Paraplegic Research, Nottwil, Switzerland.
4. Guilan Road Trauma Research Center, Trauma Institute, Guilan University of Medical Sciences, Rasht, Iran.
5. Nursing and midwifery school of shahid beheshti. Guilan university of medical science. Rasht. Iran.

\* Corresponding Author: **Shahrokh Yousefzadeh-Chabok**

Corresponding author, Guilan Road Trauma Research Center, Trauma Institute, Guilan University of Medical Sciences, Rasht, Iran.

Tel: +98333311472

E-mail: [sh.yousefzadeh@gmail.com](mailto:sh.yousefzadeh@gmail.com)

## A B S T R A C T

### Background and Aim:

Spinal cord injury patients are faced with many neglected side effects that threaten the health, wealth, and life of the patients and their families. For this purpose, the International Spinal Cord Injury Survey (InSCI) was conducted in 2017 by adding 22 countries to follow up the patients facing spinal cord injury. Iran as a developing country was added to the survey in 2022 focusing on the catastrophic health expenditures of spinal cord injury patients. The survey is named The International Spinal Cord Injury Survey in Iran (InSCI-IR).

### Methods and Materials:

This study will be performed in Guilan Province, Iran and the primary data of the patients will be gathered from the Poursina Hospital of Rasht and the Iranian National Registry of Spinal Cord Injury Patients. InSCI-IR contains two parts; the general questionnaire which gathers the data for the InSCI and the specific questionnaire which gathers data for calculating catastrophic expenditures.

### Patients and questionnaire:

It is estimated that 600 patients will participate in the study and more than 200 cases are faced with paraplegia or tetraplegia. The International Questionnaire contains 11 sections on the living situation of patients with SCI, sociodemographic questions, injury characteristics, mental and physical health, feeling and work conditions, environmental factors, and access to health services. The catastrophic expenditure part contains questions about the cost of treatment, medication,

caregiving, transportation, and household income loss related to spinal cord injury, wealth index, and household total income. Both parts will be edited in psychometrics processes.

Keywords: Spinal Cord Injury, International Study, Iran

**Highlights:**

- The International spinal cord injury survey is now conducted in Iran named InSCI-IR.
- The InSCI-IR is focused on estimating catastrophic costs of patients facing spinal cord injury.
- The InSCI-IR is started in Guilan province and 600 SCI patients (200 facing paraplegia or tetraplegia) will participate in the study.

**Plain Language Summary**

Many side effects can threaten the health, wealth, and life of the patients suffering spinal cord injury. The International Spinal Cord Injury Survey (InSCI) was developed in 2017 by adding 22 countries to follow up the patients with spinal cord injury. In 2022, Iran was also added to the survey focusing on the catastrophic health expenditures of this problem for patients and their families.

**Introduction:**

Spinal cord injury (SCI) is a life-altering and debilitating condition that often has substantial impacts on patients, their caregivers, and the healthcare system (1-4). Depending on the level of injury, SCI can lead to persistent neurological deficits, causing sensory, motor, and autonomic dysfunctions (1, 5). Each year, between 250,000 and 500,000 people suffer from SCI worldwide

(6). Traumatic injuries, such as road traffic accidents, falls, and violence are the leading causes of SCI. Nonetheless, the rate of non-traumatic SCI seems to be increasing (7, 8). However, these trends may be shifting, as traffic crashes are declining in developed countries due to advanced transportation facilities. In addition, the rate of fall-induced SCI is also increasing within an aging population (1, 9). The global incidence of traumatic SCI is estimated to be 10.5 cases per 100,000 people (10). In Iran, a developing country, the prevalence of spinal cord injuries is close to 30 cases per 100,000 people, which is three cases more than the global estimates (11).

The International Spinal Cord Injury Survey (InSCI) was established in 2017 in 22 countries of six World Health Organization regions. InSCI is the first international effort to collect comparable data about the living situation of people with SCI. The survey repeats every five years; the last phase started in 2022. In the second phase, Iran joined this survey with the financial support of the State Secretariat of Research and Innovation (SERI) and the Leading House of South Asia and Iran. The goal of the project was to collect high-quality data that allows the study of how people with SCI live in the country and comparison with other countries. The Trauma Institute in Guilan Province was responsible for this project in Iran, and in the first phase, the survey was conducted on patients living in Guilan Province. The Iranian version of InSCI had two parts: the international module, which collected the data from the InSCI, and the local module, which collected data about the catastrophic costs of SCI patients. The national module targeted catastrophic expenditure as it is found to be the essential factor for being studied in Iran because the financial protection of SCI patients seems to be important due to weak health insurance coverage of SCI patients for both treatment and rehabilitation. A recent study on SCI patients in Guilan Province showed that the majority of SCI patients are not covered by social security and unemployment insurances (self-employed cases, daily wage workers, and housewives) (12).

In the survey, we focused on the catastrophic costs experienced by patients with SCI. As SCI is an irreversible physical impairment accompanied by a series of comorbidities (13, 14), the associated costs are not limited to medical treatment costs. There is no definite treatment for SCI, especially for the complete type of injury, and the primary process of caring, and rehabilitating continues in the post-discharge period by caregivers (15), which may be very expensive, especially in the absence of health insurance (16).

Ten years after SCI, 32.4% of patients with paraplegia were employed, whereas only 24.2% of those with tetraplegia were employed (17). Thus, income loss in many cases is inevitable. The cost of SCI imposes a significant financial burden on households, leading to further induced poverty.

There is a clear consensus that health systems must ensure the financial protection of individuals and households who experience financial hardship due to health spending. Lack of financial protection is recognized as a failing of health systems. The catastrophic expenditure approach estimates the burden of health expenditure on households. The rate of households' exposure to catastrophic health expenditure (CHE) index shows the number of households that fall into poverty due to the financial burden of diseases (18). This index is very important for health policymakers to make new efforts to help households facing catastrophic health costs related to traumatic SCI. The findings of the Global Burden of Disease (GBD) study showed that the prevalence of traumatic SCI was high in Iran (921 per 100000 population) in 2016, which shows the importance of noticing SCI patients in Iran (19). Several studies have been carried out to estimate the prevalence of SCI costs worldwide. However, nothing was found about the percentage of catastrophic costs in Iran. Furthermore, it is important to assess the status of facing SCI-related catastrophic costs. Therefore, this project aimed to calculate the catastrophic costs of SCI in Guilan, North of Iran.

## **Methods and Analysis**

### **Patients:**

The initial information on SCI patients will be gathered from the health information system of Poursina Hospital, Rasht, Iran, and the National Registry of Spinal Cord Injury Patients (NSCIR-IR) (20). The NSCIR-IR gathers data on patients facing traumatic spine fracture (TSF) without noticing traumatic SCI (21). The NSCIR-IR dataset includes socio-demographics, medical history, injury information, prehospital and hospital vital data, interventions, discharge, and outcomes (22). Poursina Hospital is a provincial-level trauma hospital where all SCI patients from all over the provinces are referred for treatment. Yearly, nearly 300 patients are referred to the Poursina Hospital for traumatic SCI problems. However, many of them are discharged from the hospital without treatment or interventions. The Guilan province in the north of Iran has a population of nearly 2.5 million. Guilan is a densely populated province (177 per km<sup>2</sup>). The province is located beside the Caspian Sea.

The inclusion criteria of the InSCI-IR project were people older than 18 years, having traumatic SCI, living in Guilan Province, and being able to respond to the questions in the Persian language, and the exclusion criteria were congenital etiologies of spinal cord damage, neurodegenerative disorders, or peripheral nerve damage. In this survey, all patients who meet the inclusion and exclusion criteria and are fully treated or facing paraplegia and tetraplegia will be enrolled. The initial data contain 1066 patients (from March 2015 to September 2023). With a response rate of about 60%, it is estimated that about 600 patients will participate in this study with about 200 patients facing paraplegia and tetraplegia.

### **Questionnaire**

The InSCI-IR questionnaire contains two parts: the International Spinal Cord Injury Questionnaire and the SCI-related catastrophic costs questionnaire.

### **SCI-related catastrophic costs questionnaire:**

There is no designed questionnaire for calculating SCI-related catastrophic costs. Thus, semi-structural interviews will be done with two health economists, four neurologists, three neurosurgeons, two SCI patient home care managers, three caregivers of SCI patients, and three SCI patients. Questions about the costs of SCI (containing direct, indirect, and job loss costs) will be asked of the participants. After that, an online focus group will be done to finalize the cost items.

In the next phase, using the content validity index (CVI) and content validity ratio (CVR), content validity will be conducted with ten health experts. Questions that their scores do not meet the accepted CVI and CVR values will be deleted or revised. After reviewing the questionnaire, the data of 20 participants is collected and after 45 days, the questionnaires are sent to the participants again. The differences between the first and second answers will be assessed using test-retest analysis. Questions, which do not meet the test-retest score will be revised in an expert panel.

The following parts will be designed in the questionnaire:

- 1- Pre-interview questions: Patients' information to be obtained from the NSCIR-IR
- 2- Inclusion and exclusion criteria, informed consent, and a treatment phase checklist

- 3- Overview of SCI treatment costs, including surgical, inpatient, outpatient, and drug costs and other treatment costs
- 4- Caregiving and rehabilitation costs: All costs related to caregiving, physiotherapy, buying maintenance facilities, and job loss of family members of the patient related to SCI
- 5- Income loss costs, including all income loss costs related to SCI-related income loss of the patient and caregiver, changing the type of work, etc.
- 6- Calculation of income and other variables: calculating catastrophic costs needs data on household income. Thus, some questions will be designed about household income before SCI. In addition, the wealth status of the family will be calculated by gathering household asset ownership. The income will be calculated indirectly from the wealth index.

#### **InSCI Questionnaire:**

The InSCI Questionnaire has 11 sections on the living situation of patients with SCI, including personal information, lesion characteristics (level and type of SCI, time and cause of being injured), energy and feelings for the last four weeks before the questioning, health problems for the last three months before the questioning, activity and participation for the last four weeks before the questioning, independence in activities of daily living, work conditions, environmental factors, utilization of healthcare services, personal factors, and quality of life. The questionnaire was developed in English. The version of the questionnaire applied in Iran was first translated into Persian by two independent translators working on SCI and trauma. In a second round, the translated version was again translated into English to assess the accuracy of the questionnaire. Two neurosurgeons and a translator checked for the accuracy of the items, and for items with limitations, they worked on a better Persian translation. The reliability of the InSCI Questionnaire will be assessed using test-retest analysis.

#### **Starting the survey:**

The survey will be conducted using the phone number of the patients provided by NSCIR-IR. The interviewers were educated on how to complete the questionnaire and will be informed about potential biases. To contact patients, first, some notifications will be sent via the website of the Trauma Institute and Poursina Hospital to inform them about the survey and its objectives. After that, a text message will be sent to the patient's phone number to prepare them for the interview. Then, the survey secretary will call the patient and reserve a time for a telephone-based survey. At the end, the trained interviewers will gather the data in written form and send them to the survey portal. The data-gathering process will be done in nine months. To ensure the quality of gathered data, after ending the interviews for each interviewer, three phone numbers of interviewees will be selected randomly and they will be asked again. If the accuracy rate of each questionnaire is less than 75%, the questions related to that interviewer will be deleted, and a new interview schedule will be created for the missing data.

#### **Analysis:**

To analyze the data, first, the total SCI costs of households will be calculated, and it will be compared with the household income. The total costs will be calculated by multiplying inpatient and outpatient costs of SCI, surgical and drug costs, and other treatment costs related to SCI. The income loss, rehabilitation, and caregiving costs will be added to the total costs, as well. Some of the investment costs (which do not impose any additional costs in one year, like inpatient costs, home modifications, etc...) have a one-year timing nature. These costs will be adjusted to one month. Some others, like drug costs, and rehabilitation costs, which can be imposed on the patients frequently will be gathered and calculated in one month. The total yearly income of the household (both temporary and permanent income of all household members) will be gathered for one year and calculated for one month. If the total SCI costs exceed 20% (catastrophic costs' threshold) of the total income, the family is recorded as having SCI-related catastrophic costs. One of the household strategies to escape from catastrophic costs is selling the household property to earn more money. This strategy might lead the family to long-term poverty and impoverishment. The percentage of catastrophic costs will be calculated with and without coping strategies. The catastrophic costs will be calculated using income from the indirect regression model and compared to the results of catastrophic costs calculated by direct self-reported income.



Furthermore, the results will be estimated for direct and indirect costs only to show changes in catastrophic costs of SCI related to direct and indirect costs separately.

<p>Ethical Considerations Compliance with ethical guidelines: The study was approved ethically by the National Research Ethics Committee of Iran (Ethics code: IR.NREC.1401.003). Verbal informed consent will be asked before each interview. The research team will ensure that no individual data will be sent to any third parties without the permission of the patient.</p>
<p>Funding: This Study was funded by ZHAW- the Leading House in South Asia and Iran.</p>
<p>Authors' contributions:</p> <p>Conception and design: DP and EHR Data Collection: Data Analysis and Interpretation: Not applicable. Drafting the article: DP , EHR,SY,ZH and ZM Critically revising the article:DP,HER, Reviewing submitted version of manuscript: EHR Approving the final version of the manuscript: all of the authors.</p>
<p>Conflict of interest: The authors declare no conflict of interest.</p>
<p>Acknowledgments: The authors thank the Swiss Paraplegic Research and Trauma Institute of Iran.</p>

#### References:

1. Kudo D, Miyakoshi N, Hongo M, Kasukawa Y, Ishikawa Y, Ishikawa N, et al. An epidemiological study of traumatic spinal cord injuries in the fastest aging area in Japan. *Spinal Cord*. 2019;57(6):509-15.
2. Chen J, Chen Z, Zhang K, Song D, Wang C, Xuan T. Epidemiological features of traumatic spinal cord injury in Guangdong Province, China. *The journal of spinal cord medicine*. 2021;44(2):276-81.

3. Alizadeh A, Dyck SM, Karimi-Abdolrezaee S. Traumatic Spinal Cord Injury: An Overview of Pathophysiology, Models and Acute Injury Mechanisms. *Frontiers in neurology*. 2019;10:282.
4. McDaid D, Park AL, Gall A, Purcell M, Bacon M. Understanding and modelling the economic impact of spinal cord injuries in the United Kingdom. *Spinal Cord*. 2019;57(9):778-88.
5. Khazaeipour Z, Rezaei-Motlagh F, Ahmadipour E, Azarnia-Ghavam M, Mirzababaei A, Salimi N, et al. Burden of care in primary caregivers of individuals with spinal cord injury in Iran: Its association with sociodemographic factors. *Spinal Cord*. 2017;55(6):595-600.
6. Organization WH, Society ISC. International perspectives on spinal cord injury: World Health Organization; 2013.
7. Ahuja CS, Wilson JR, Nori S, Kotter MRN, Druschel C, Curt A, et al. Traumatic spinal cord injury. *Nature Reviews Disease Primers*. 2017;3(1):17018.
8. Maitan P, Frigerio S, Conti A, Clari M, Vellone E, Alvaro R. The effect of the burden of caregiving for people with spinal cord injury (SCI): a cross-sectional study. *Annali dell'Istituto superiore di sanita*. 2018;54(3):185-93.
9. Lee BB, Cripps RA, Fitzharris M, Wing PC. The global map for traumatic spinal cord injury epidemiology: update 2011, global incidence rate. *Spinal Cord*. 2014;52(2):110-6.
10. Kumar R, Lim J, Mekary RA, Rattani A, Dewan MC, Sharif SY, et al. Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume. *World neurosurgery*. 2018;113:e345-e63.
11. Saheban Maleki M, Khedri B, Ebrahimpour Roodposhti M, Askari Majdabadi H, Seyedrezaei SO, Amanat N, et al. Epidemiology of Traumatic Spinal Cord Injuries in Iran; a Systematic Review and Meta-Analysis. *Arch Acad Emerg Med*. 2022;10(1):e80.
12. Keihanian F, Homaie Rad E, Samadi Shal S, Pourreza N, Eramsadati LK, Hosseini Malekroudi SM, et al. Return to work after traumatic spinal fractures and spinal cord injuries: a retrospective cohort study. *Scientific Reports*. 2023;13(1):22573.
13. Amanat M, Vaccaro AR, Salehi M, Rahimi-Movaghar V. Neurological conditions associated with spinal cord injury. *Informatics in Medicine Unlocked*. 2019;16:100245.
14. Pilusa S, Myezwa H, Potterton J. Prevention care for secondary health conditions among people living with spinal cord injuries: research protocol. *BMC Research Notes*. 2019;12(1):179.
15. Grimmer K, Moss J, Falco J. Becoming a carer for an elderly person after discharge from an acute hospital admission. *Internet Journal of Allied Health Sciences and Practice*. 2004;2(4):4.
16. Cao Y, Chen Y, DeVivo M. Lifetime direct costs after spinal cord injury. *Topics in Spinal Cord Injury Rehabilitation*. 2011;16(4):10-6.
17. Ottomanelli L, Lind L. Review of critical factors related to employment after spinal cord injury: implications for research and vocational services. *The journal of spinal cord medicine*. 2009;32(5):503-31.
18. Uplekar M, Weil D, Lonroth K, Jaramillo E, Lienhardt C, Dias HM, et al. WHO's new end TB strategy. *The Lancet*. 2015;385(9979):1799-801.
19. Global, regional, and national burden of traumatic brain injury and spinal cord injury, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet Neurology*. 2019;18(1):56-87.
20. Sharif-Alhoseini M, Azadmanjir Z, Sadeghi-Naini M, Ghodsi Z, Naghdi K, Mohammadzadeh M, et al. National Spinal Cord Injury Registry of Iran (NSCIR-IR) – a critical appraisal of its strengths and weaknesses. *Chinese Journal of Traumatology*. 2019;22(5):300-3.
21. Zahra A, Zahra M-A, Seyed-Mahdi Z, Leila K, Hamid H, Mina M, et al. Sustaining the National Spinal Cord Injury Registry of Iran (NSCIR-IR) in a Regional Center: Challenges and Solutions. *Iranian Journal of Public Health*. 2020;49(4).
22. Azadmanjir Z, Jazayeri SB, Habibi Arejan R, Ghodsi Z, Sharif-Alhoseini M, Kheiri G, et al. The data set development for the National Spinal Cord Injury Registry of Iran (NSCIR-IR): progress toward improving the quality of care. *Spinal Cord Series and Cases*. 2020;6(1):17.

IRJNS In-press Article