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Disclosures:

Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

0894-9115/11/9011(Suppl)-00S5/0
*American Journal of Physical
 Medicine & Rehabilitation*
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DOI: 10.1097/PHM.0b013e318230fd41

INVITED REVIEW

Design of the Swiss Spinal Cord Injury Cohort Study

ABSTRACT

Post MWM, Brinkhof MWG, von Elm E, Boldt C, Brach M, Fekete C, Eriks-Hoogland I, Curt A, Stucki G, for the SwiSCI study group: Design of the Swiss Spinal Cord Injury Cohort Study. *Am J Phys Med Rehabil* 2011;90(suppl):S5–S16.

The overall goal of the Swiss Spinal Cord Injury Cohort Study (SwiSCI) is to gain a better understanding of how to support functioning, health maintenance, and quality-of-life of persons with spinal cord injury (SCI) along the continuum of care, in the community, and along their life span. The purpose of this study was to present the SwiSCI study design. SwiSCI is composed of three complementary pathways and will include Swiss persons 16 yrs or older who have diagnoses of traumatic or nontraumatic SCI. Pathway 1 is a retrospective study of medical files of patients admitted to one of the collaborating SCI centers between 2005 and 2009. Pathway 2 is a nationwide survey of persons with chronic SCI. Pathway 3 is an inception cohort study including persons with newly acquired SCI. SwiSCI is conducted in collaboration with the Swiss Paraplegic Association and the major specialized rehabilitation centers in Switzerland. Measurement instruments that are to be used in Pathway 2 and 3 cover body structures and functions, activities, participation, life satisfaction, and personal and environmental factors. SwiSCI is a prospective cohort study that will contribute to a comprehensive understanding of the lived experience of persons with SCI.

Key Words: Spinal Cord Injuries, Cohort Studies, Research Design, ICF, SwiSCI

Spinal cord injury (SCI) has a far-reaching impact on an individual's life and is a leading cause of major disability.¹ All organ systems and body functions below the level of the neurologic lesion can be affected; moreover, living with SCI is associated with a range of secondary conditions and complications.^{2,3} These impairments, however, do not solely determine the lived experience of disability in persons with SCI. The lived experience also depends on environmental factors such as family relationships and the built environment and on psychologic personal factors such as coping styles.^{4,5} Rehabilitation research therefore has to consider not only medical and functional sequela of SCI but also areas of life like employment, transportation, social support, and accessibility of the community, all of which are crucial for social integration and equal opportunities. Moreover, given that persons living with SCI in high-income countries nowadays anticipate

life expectancy that is close to that of the general population,⁶ the issue of aging with SCI has become of major importance.^{7,8}

The term *human functioning* points to the interrelatedness of body functions and structures, individual activity, and societal participation within the health-related experience.⁹ Human functioning sciences aim to understand human functioning and to identify targets for comprehensive interventions with the goal of contributing to the optimization of functioning and the minimization of the experience of disability in the population.⁹ Both the human functioning and biomedical perspectives consider contextual factors, but they do so in different ways. From the biomedical perspective, environmental and personal factors are seen as risk factors for the occurrence of health conditions. By contrast, the human functioning perspective focuses on people's participation or performance under consideration of capacity limitations and impairments.⁹

SCI rehabilitation and policy programs need to be informed by trustworthy epidemiologic data, including incidence and prevalence rates, etiology and characteristics of SCI, and data on functioning and disability across the life span of persons living with SCI. This argues for the need of large-scale longitudinal cohort studies that comprehensively cover the range of biomedical, functional, environmental, and personal factors characterizing the individual SCI patient at any age. Comprehensive longitudinal studies in SCI are sparse,¹⁰ and a review elsewhere in this issue showed that the four large ($n > 200$) longitudinal studies identified only partly covered the lived experience of persons with SCI.¹¹

The Swiss Spinal Cord Injury study (SwiSCI) is a population-based, longitudinal, and comprehensive SCI cohort study that started data collection in 2010. SwiSCI uses the Comprehensive and Brief SCI Core Sets of the International Classification of Functioning, Disability and Health (ICF)¹²⁻¹⁴ and the Minimal Generic ICF Set¹⁵ as reference sources for data collection, to ensure a database that is comprehensive and critical for evaluating functioning, disability, and health in the context of SCI. As a nationwide SCI cohort, SwiSCI is expected to provide reliable epidemiologic data, which is currently not available in Switzerland. The aim of this article was to present the design of SwiSCI.

GENERAL CHARACTERISTICS OF SWISCI

Study Aims

The overall goal of SwiSCI is to gain a better understanding of how to support functioning, health

maintenance, and quality-of-life of persons with SCI along the continuum of care, in the community, and along their life span. Its specific study aims were, first, to develop a comprehensive and in-depth understanding of functioning, disability, health maintenance, and aging with SCI. Second, SwiSCI aims to be a starting point for the evaluation of rehabilitation interventions such as the use of new assistive technologies or policy interventions with relevance to the SCI population. Third, SwiSCI aims to establish a reliable epidemiologic database for SCI that may inform Swiss social and health policy to anticipate the increasing future demand on resources for external support and specialized care.

Design

SwiSCI is composed of three complementary pathways that, taken together, will eventually establish a continuous cohort study (Fig. 1). Participants will be recruited through different pathways into one large cohort and will be followed by a 5-yr cycle of measurements for an undefined period (possibly life-long). Pathway 1 is a retrospective study of medical files, pathway 2 is a community survey that is to be repeated every 5 yrs, and pathway 3 is an inception cohort study including persons with SCI at an early stage after onset of injury. SwiSCI is performed by the Swiss Paraplegic Research in collaboration with the four major specialized rehabilitation centers in Switzerland, including the Spinal Cord Injury Center of the Balgrist University Hospital, Zürich; Centre for Spinal Cord Injury and Severe Head Injury, REHAB Basel; Clinique Romande de Réadaptation, Sion; and the Swiss Paraplegic Centre, Nottwil. All four centers have specified regional catchment areas and admit both patients with traumatic and nontraumatic SCI.

Subjects

SwiSCI will include persons 16 yrs or older who permanently reside in Switzerland and who are diagnosed with traumatic or nontraumatic SCI. It was judged important to cover the whole etiologic spectrum of SCI to acknowledge that the proportion of people with nontraumatic causes of SCI is growing. At first, only adults and adolescents will be included, but later, the study might also include the pediatric SCI population. To establish a cohort of individuals with acquired SCI in a stable condition, individuals with the following criteria will be excluded: congenital conditions leading to paraplegia or tetraplegia, including spina bifida, new SCI in the context of palliative (end-of-life) care,

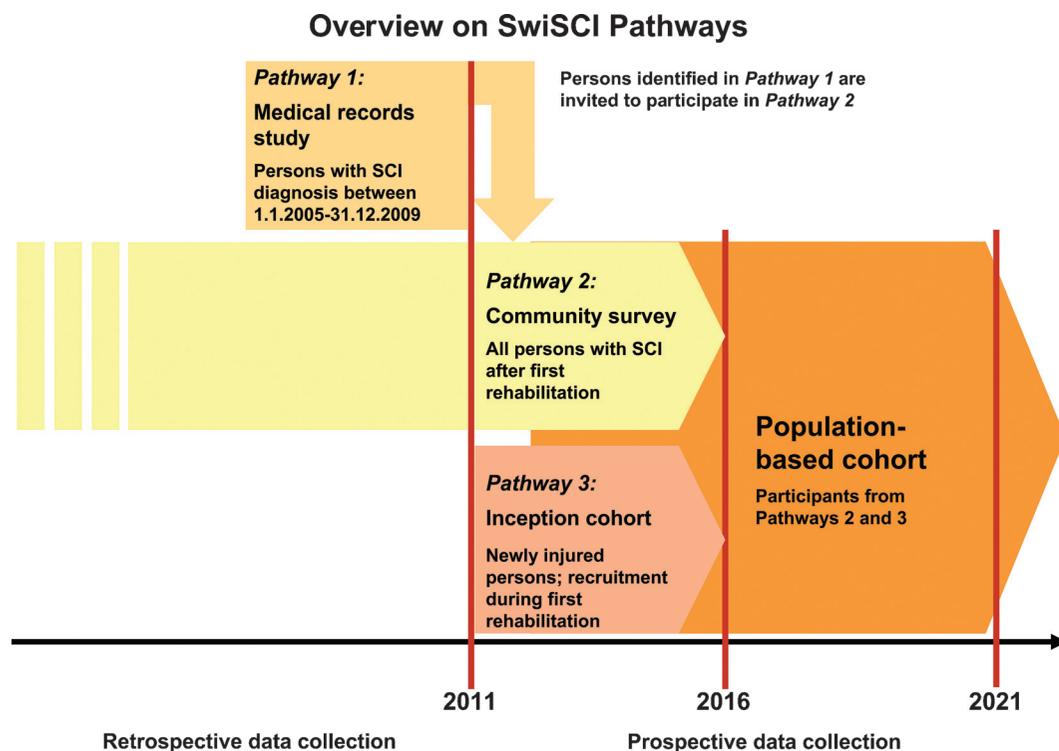


FIGURE 1 Overview on SwiSCI Pathways. SwiSCI indicates Swiss Spinal Cord Injury Cohort Study.

neurodegenerative disorders such as multiple sclerosis and amyotrophic lateral sclerosis, and Guillain-Barré syndrome. Additional eligibility criteria apply for each SwiSCI pathway.

Medical Ethics

SwiSCI projects will adhere to applicable national and international standards for research in humans including the Declaration of Helsinki of the World Medical Association,¹⁶ the Council for International Organizations of Medical Sciences “International Ethical Guidelines for Epidemiological Studies 2009,”¹⁷ and the national guidelines for research integrity.¹⁸

Measurement Instruments

The selection of domain sets and ICF category specifications is described in detail elsewhere in this issue.^{19–22} Briefly, the bases for the selection of the Basic Domain Set are the Brief ICF Core Sets for SCI,^{12–14} which have been developed to guarantee that critical domains of functioning and disability of persons with SCI are systematically considered in clinical practice and research,¹⁹ and the ICF Minimal Generic Set, developed as a minimal set of ICF categories to be used in any study.¹⁵ Literature reviews, protocols of existing longitudinal studies,¹¹ and the data sets of the International Spinal Cord Injury

Society (www.iscos.org.uk)^{23,24} were used to select the domain sets and measurement instruments in the following three domains: biomedical factors,²⁰ environmental factors,²¹ and psychologic personal factors.²² A systematic appraisal of psychometric properties, feasibility, and other criteria, such as comparability with other studies, efficiency, and non-redundancy, led²⁵ to the selection of measurement instruments.

THREE SWISCI PATHWAYS

Retrospective Study of Medical Files (Pathway 1)

Design

Data of persons with recent SCI that occurred between January 1, 2005, and December 31, 2009, are being extracted from the medical records of the four participating SCI centers. The 5-yr period was chosen to ensure that the data and quality are broadly comparable between centers.

Measurements

Sociodemographic data will include age, sex, education, area of residence, insurance status, living arrangement, and marital status. Data definitions were derived from the International Spinal Cord Core Data Set.²⁶

SCI characteristics will include etiology, lesion level, and the American Spinal Injury Association Impairment Scale score²⁶ and presence of concomitant injuries, complications, and comorbidities.²⁷

Community-Based Survey (Pathway 2)

Design

Pathway 2, which is scheduled for 2011, is a survey of persons with SCI living in the community. It is planned to repeat the community survey at 5-yr intervals to obtain longitudinal and up-to-date descriptions of the SCI community in Switzerland. A particular challenge of Pathway 2 is to obtain a comprehensive and detailed picture of the participants' situation while keeping the questionnaire to a length that is acceptable for participants, to minimize response rate bias.²⁸ Consequently, the SwiSCI questionnaire will consist of a common main questionnaire (basic module) and three different subsequent modules (Fig. 2).

Patients

Using the inclusion criteria described earlier, the community survey will include as many persons with SCI as possible. Recruitment will include former patients of the collaborating centers and members of the Swiss Paraplegic Association and wheelchair clubs. Approximately 2000–2500 persons with SCI are expected to be invited for the study.

Procedure

The collaborating organizations will collect eligible patients from their records. A few demographic and SCI characteristics will be retrieved from these records, if available, to allow future nonresponse analysis. The questionnaire will be sent out to the identified persons with SCI through these organi-

zations in three waves. First, a letter of invitation will be sent together with the study information, an informed consent form, and a very brief (18 items) questionnaire including basic sociodemographic data, lesion characteristics, and some questions related to care situation. Persons with SCI who consent to participate will be sent the Basic Module about 1 mo later. Approximately 2 mos after that, the randomly assigned specific modules will be distributed as a third wave.

Measurements

The Basic Module will include core measurement instruments to assess mood, activity limitations, participation, and quality-of-life and will be sent to all participants. The connection between the selected ICF Categories and their category specifications and the selected measurement instruments is highlighted in Tables 1 and 2. The total number of items (including subitems) of the Basic Module is 155, and the time needed to complete the questionnaire is about 45–60 mins.

Emotional functions will be measured using the Mental Health Scale of the Medical Outcome Study Short-Form 36 (SF-36).⁴⁷ The SF-36 has acceptable reliability and validity in persons with SCI.⁴⁸

Activity limitations will be measured using the Spinal Cord Independence Measure III.³⁵ This measure has been extensively validated and has been recognized as the best SCI-specific functional status measure available.²⁹ Because the Spinal Cord Independence Measure III is an observational instrument, a self-report version is currently being developed and tested by the SwiSCI study team.

Participation will be measured using the Utrecht Scale for Evaluation of Rehabilitation–Participation.^{48a} This ICF-based measurement instrument has recently been developed in response to the need to assess both objective and subjective participation. The Utrecht Scale for Evaluation of Rehabilitation–Participation showed satisfactory validity,^{48a} test-retest reliability,³⁰ and responsiveness in rehabilitation populations.⁴⁹

Life satisfaction will be measured using the short version of the World Health Organization Quality-of-Life Scale (WHOQOL-5),⁵⁰ a measurement instrument with five items that showed good internal consistency reliability and cross-cultural validity in persons with SCI.³⁷

The ICF Minimal Generic Set: categories of the ICF Minimal Generic Set¹⁵ that are not already included in one of the previously described measurement instruments will be covered by single items and, when possible, will be taken from existing

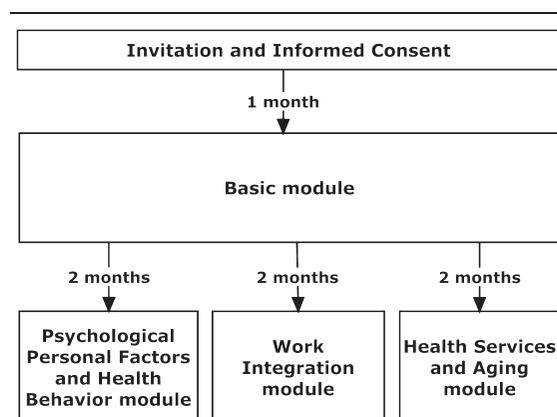


FIGURE 2 Modular structure of community survey (pathway 2).

TABLE 1 List of ICF categories included in the basic SwiSCI Domain Set, the category specifications, and measurement instruments in the survey of pathway 2

Code	ICF Categories	Source	Category Specification	Measurement Instrument
b130	Energy and drive functions	1	Fatigue	Rating scale from 0 to 3 (from insignificant problem to chronic problem)
b152	Emotional functions	1,2,3	Mood	Mental Health Scale of the SF-36
b280	Sensation of pain	1,2,3	Severity of pain	SCI-SCS item
b440	Respiration functions	2	a) Control, devices b) Breathing problems	International SCI Basic Pain Data Set item a) SCIM-SR item (7) b) SCI-SCS
b525	Defecation functions	2,3	a) Control, devices b) Bowel problems	a) SCIM-SR item (9) b) SCI-SCS
b620	Urination functions	2,3	a) Control, devices b) Urinary tract infections	a) SCIM-SR item (8) b) SCI-SCS
b640	Sexual functions	3	a) Fertility b) Sexual function	a) Item on having had children after SCI b) SCI-SCS
b710	Mobility of joint functions	3	Contractures	SCI-SCS and localization
b730	Muscle power functions	2,3	Level and severity of spinal cord lesion	Items on level (paraplegic/tetraplegic) and completeness (complete/incomplete)
b735	Muscle tone functions	2,3	Spasticity	SCI-SCS and localization
b810	Protective functions of the skin	2,3	Pressure ulcer	SCI-SCS and localization
s120	Spinal cord and related structures	2,3	Level and severity of spinal cord lesion	Items on level (paraplegic/tetraplegic) and completeness (complete/incomplete)
s430	Structure of respiratory system	2,3	Impairment through tracheal tube	SCIM-SR item (7)
s610	Structure of urinary system	2,3	Pressure ulcer	SCIM-SR item (6)
s810	Structure of areas of skin	3	Carrying out daily routine in quiet circumstances	SCI-SCS and localization
d230	Carrying out daily routine	1,3	Task execution in stressful circumstances	IMPACT-S item (4)
d240	Handling stress and other psychologic demands	3	Turning body, sitting up	IMPACT-S items (5)
d410	Changing basic body position	2,3	Independence	SCIM-SR items (11)
d420	Transferring oneself	2,3	Proxi estimation through independence in d510-560	SCIM-SR items (12, 13, 18, 19)
d445	Hand and arm use	2,3	Independence	Proxy estimation with SCIM-SR items (1,2,3,4,5,6,10)
d450	Moving around	1,2,3	Independence	SCIM-SR item (14, 15, 16)
d465	Moving around using equipment	3	Using assistive devices	SCIM-SR item (14, 15, 16)
d470	Using transportation	3	a) Independence b) Transfer in/out of car	SCIM-SR item (14, 15, 16) a) Item on ability to drive b) SCIM-SR item (18)
d510	Washing oneself	2,3	Independence	SCIM-SR item (2, 3)
d520	Caring for body parts	3	Independence	SCIM-SR item (6)
d530	Toileting	2,3	Independence	SCIM-SR item (10)
d540	Dressing	2	Independence	SCIM-SR item (4, 5)
d550	Eating	2,3	Independence	SCIM-SR item (1)
d560	Drinking	2	Independence	SCIM-SR item (1)
d850	Remunerative employment	1	Having paid work	USBR-Participation item (1)
e110	Products or substances for personal consumption	1,3	Medication	Items on medication use NEFI-SCI item (1.10, 2.9, 3.3)

(Continued on next page)

TABLE 1 (Continued)

Code	ICF Categories	Source	Category Specification	Measurement Instrument
e115	Products and technology for personal use in daily living	1,2,3	Devices for respiration, urination, defecation	NEFI-SCI item (1.10, 2.9, 3.3)
e120	Products and technology for personal indoor and outdoor mobility and transportation	1,2,3	a) Devices for indoor/outdoor mobility b) Transportation (1.8, 2.7, 3.7)	a) NEFI-SCI item (1.7, 2.7, 3.6) b) NEFI-SCI -item (1.8, 2.7, 3.7)
e150	Design, construction, and building products and technology of buildings for public use	1,3	Accessibility of public places	NEFI-SCI item (1.1, 2.12, 3.1)
e155	Design, construction, and building products and technology of buildings for private use	1,3	Accessibility of private places	NEFI-SCI item (1.14, 2.4, 3.14)
e225	Climate	1	Climate conditions	NEFI-SCI item (1.2, 2.8, 3.11)
e310	Immediate family	1,2,3	Attitudes of immediate family	a) NEFI-SCI item (1.4, 2.1, 3.12)
e320	Friends	1	Attitudes of friends	a) NEFI-SCI item (1.5, 2.2, 3.13)
e340	Personal care providers and personal assistants	2,3	Influence of personal assistants on life	NEFI-SCI item (1.9, 2.11, 3.10)
e375	General social support services, systems and policies	1	Public policies	NEFI-SCI item (1.13, 2.14, 3.2)
e580	Health services, systems, and policies	1,3	a) Use of health services, kind of health services b) Last vaccination against flu	a) Item adapted from Swiss Health Survey 2007 (9) b) Item adapted from Swiss Health Survey 2007 (13)

Environmental ICF categories e135, e355, and e450 are not covered by NEFI-SCI and were therefore excluded.

Under the column "Source," 1 indicates minimal generic ICF Set¹⁵; 2, Brief ICF Core Set for SCI in the early postacute context¹²; 3, Brief ICF Core Set for SCI in the long-term context.¹³

SwiSCI, Swiss Spinal Cord Injury Cohort Study; SCIM-SR, self-report version of Spinal Cord Independence Measure III²⁹ (in preparation); USER-Participation, Utrecht Scale for Evaluation of Rehabilitation-Participation³⁰; NEFI-SCI: Notwil Environmental Factors Inventory Spinal Cord Injury²¹; Swiss Health Survey 2007⁵¹; IMPACT-S³²; SCI-SCS: Spinal Cord Injury Secondary Conditions Scale,³³ adapted with the Self-Administered Comorbidity Questionnaire.³⁴

Other tests used are the Hospital Anxiety and Depression Scale³⁵ and International Spinal Cord Injury Basic Pain Data Set.³⁶

measurement instruments because those items have been tested.²⁵ For example, an item on handling stress and daily routine will be taken from the Impact on Activities and Participation measure.³²

Most relevant complications will be evaluated using the Spinal Cord Injury Secondary Conditions Scale,³³ with additional response categories from the Self-Administered Co-morbidity Questionnaire.³⁴ Pain will be assessed using items from the self-report version of the International Spinal Cord Injury Basic Pain Data Set.⁵¹

Finally, environmental factors relevant to functioning and health will be measured using items from a newly developed measure, the Nottwil Environmental Factors Inventory.²¹ The Nottwil Environmental Factors Inventory is based on new theoretical assumptions on how environmental factors influence participation.^{42,52} The environmental factors covered in the Nottwil Environmental Factors Inventory have been determined based on the ICF Core Sets for persons with SCI.^{13,44} Items have been developed in English, French, and German by an international research team based in Switzerland, the Netherlands, the United States, and Quebec, Canada. The measure is currently being cognitively tested and, after modification, will undergo field testing, including the examination of psychometric properties.

Modules

The first module is the Psychologic Personal Factors and Health Behavior module.²² The module aims to evaluate psychologic factors and behaviors in the context of the ICF's integrative biopsychosocial model of functioning in SCI. Its specific aim is to examine how psychologic factors influence, mediate, or moderate mental health, activity, participation, and quality-of-life of persons with SCI. The following category specifications and corresponding measurement instruments are included: Feelings, measured using the Positive/Negative Affect Schedule⁴⁵; Self-efficacy, measured using the General Self-Efficacy Scale⁵³; Motives, measured using the Purpose in Life Scale⁵⁴; Coping, measured using the COPE-Bref^{55,56}; and Personality, measured using the Ten-Item Personality Inventory⁵⁷ (Table 2). This module will cover health behaviors with items on smoking; alcohol consumption, using the Center of Disease Control methodology³⁶; cannabis consumption; nutrition, using relevant questions from the Swiss Health Survey 2007⁵⁸; and physical activity with one scale from the Physical Activity Scale for Individuals with Physical Disabilities.³¹ SCI-specific preventive behaviors will be

TABLE 2 List of areas of psychologic personal factors included in the SwiSCI Domain Set, the specifications, and measurement instruments in the survey of pathway 2

Areas of Psychologic Personal Factors	Specifications	Measurement Instruments	Reference
Cross-cutting	Life satisfaction	WHOQOL-5	37–39
Basic sociodemographic personal characteristics	Age, sex, nationality, citizenship, educational background, occupational background, economical background, religious affiliation	Items on these characteristics	
Position in the immediate social and physical context	Marital status/relationship status/children	Items on these characteristics	
Feelings	Positive and negative affect	Positive and Negative Affect Schedule	40
Thoughts and beliefs	Self-efficacy	General Self-Efficacy Scale	41
Motives	Purpose in life	Purpose in Life Scale Short-Form	42,43
Patterns of experience and behavior	Coping	COPE-Bref	44,45
	Personality	Ten-Item Personality Inventory	46

SwiSCI, Swiss Spinal Cord Injury Cohort Study; WHOQOL-5, World Health Organization Quality-of-Life Scale.

evaluated using the adapted version of the Spinal Cord Injury Lifestyle Scale.^{59,60}

The second module consists of the International Labor Market Integration Assessment in Spinal Cord Injury (ILIAS) questionnaire. ILIAS is an international project used to examine the labor market participation of people with SCI in up to 23 European countries. The Swiss part of ILIAS will be integrated in SwiSCI pathway 2.²¹ ILIAS considers the current and past employment situation. The social situation and capital of people with SCI are surveyed based on questions of the European Social Survey⁶¹ and the European Union Statistics on Income and Living Conditions.⁶² Work strains are examined using the Effort-Reward-Imbalances Measure by Siegrist et al.⁶³ Moreover, reasons for working and not working as well as the participation and satisfaction with vocational consultation are assessed, which are also based on questions of the European Union Statistics on Income and Living Conditions.⁶²

The third module is the Health Services Research and Aging module, with the aim of evaluating the care situation and health services utilization with a special focus on issues of aging. Healthcare utilization will be assessed using adapted questions from the Swiss Health Survey 2007.⁵⁸ In addition, questions developed in collaboration with persons living with SCI concerning the specific care situation in Switzerland will be included in this module to address the issue of aging and prevalent co-morbidities, including diabetes mellitus, stroke, myocardial infarction, rheumatoid arthritis, obesity,

and cancer, and their date of diagnosis will be assessed based on the Self-Administered Comorbidity Questionnaire.³⁴

Inception Cohort Study (Pathway 3)

Pathway 3 will be an inception cohort that includes all Swiss residents with new SCI, recruited at the time of entry to their first rehabilitation program in one of the collaborating rehabilitation centers. This entry point has been chosen because early identification is hampered by the circumstance that patients with acute SCI are commonly admitted to one of many different acute care hospitals, may not have long-lasting SCI (e.g., after spinal contusion), or may not yet be capable of giving an informed consent to participate in the study. Standardized and more detailed information from the acute and early rehabilitation period will be collected prospectively with foci on biomedical, functional, and community outcomes during the first 5 yrs after SCI. The regular cohort follow-up will take place at 1, 3, 6, 12, 24, and 60 mos after SCI (Fig. 3). This time schedule will allow a close monitoring of early postacute and long-term settings. In addition to the fixed time points, relevant clinical data gathered at the time of discharge and during yearly appointments will be integrated into the data set to make best use of the routine data that are gathered outside SwiSCI.

As in Pathway 2, the ICF Core Sets for SCI and the Minimal Generic Set will serve as a basis for defining measures, and the same measurement instruments as in Pathway 2 will be applied at

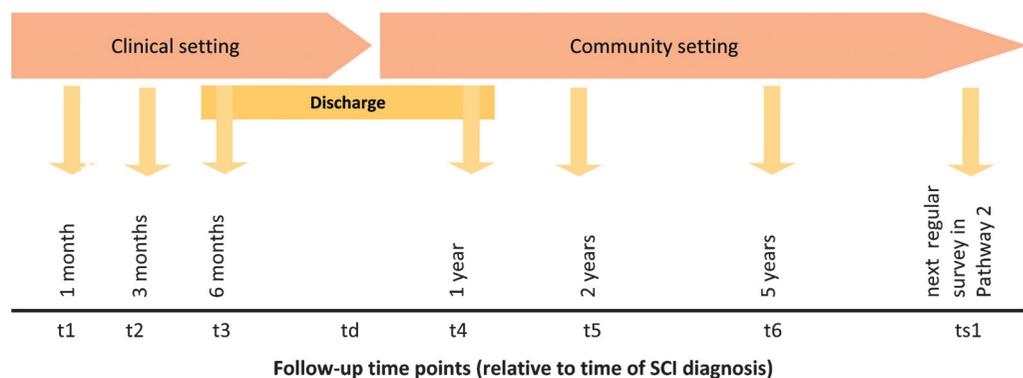


FIGURE 3 Follow-up time points in SwiSCI Pathway 3 (inception cohort). SwiSCI indicates Swiss Spinal Cord Injury Cohort Study.

appropriate time points. Unlike Pathway 2, however, Pathway 3 will also include data from medical and functional examinations (e.g., complications, secondary conditions or co-morbidity, mobility, hand function, and rehospitalizations). This part of the protocol has yet to be developed. For health economical analyses, key data on medical procedures, such as specific therapies or surgery, will be collected, as well as data on the length of acute care and rehabilitation stays (clinical setting) or sick leave from work that occurred since the last follow-up (community setting). After the last assessment at month 60, the participants will join the data collection in the community survey with its 5-yr cycle. This continued monitoring will allow addressing research questions relevant to the “life-long” experience of SCI.

GOVERNANCE STRUCTURE

SwiSCI governance structure will include a steering committee, host institution, study center, review panel, interest groups, collaborating institutions, and project partners (Fig. 4). Partnership with the Swiss community of people living with SCI is a key consideration. Researchers and clinicians who share a common perspective on SCI will meet in so-called “interest groups.” As think tanks, these groups can help channel the researchers’ interest in SwiSCI toward the development of specific projects.

RESEARCH PLATFORM

Within the SwiSCI framework, both nested projects and joint projects will be possible: nested projects will be based on the main SwiSCI database and will allow an efficient use of the available study data. For instance, a follow-up measurement of a randomized trial focusing on rehabilitation technol-

ogy could be integrated into the long-term follow-up of the inception cohort. Furthermore, in-depth surveys can be conducted in smaller subsamples of the study population, such as in a specific age group or in persons with SCI currently employed. Joint projects will combine SwiSCI data with data from other sources, such as from international SCI studies or population databases. In such collaborations, research questions can be tackled that require larger sample sizes or international comparisons. To evaluate mortality and other outcomes between people living with SCI and the general population in Switzerland, SwiSCI will further collaborate with the Swiss National Cohort.⁶⁴ The Swiss National Cohort facilitates the linkage of patient records to various Swiss databases, including the Swiss vital statistics database. Finally, the development of a biobank for storage of blood-derived plasma and white blood cells acquired shortly after injury and at regular time intervals thereafter is currently being investigated. Such samples may provide the vital material for studying immunosenescence on the individual level and are also an unrelenting resource for genetic material.^{8,65–67}

DISCUSSION

In this article, the aims and design of the Swiss Spinal Cord Cohort Injury (SwiSCI) cohort study, a longitudinal, comprehensive study of people living with SCI in Switzerland are described. As a prospective ICF-based cohort study, SwiSCI will serve as the basis for comprehensive and patient-oriented research into the functioning, disability, health maintenance, and aging in individuals living with SCI. SwiSCI would also provide reliable epidemiologic data for SCI in Switzerland and serve as a platform for nested and joint studies in persons with SCI and other collaborative research. Current large ($n > 200$) cohort studies with subjects in early stage

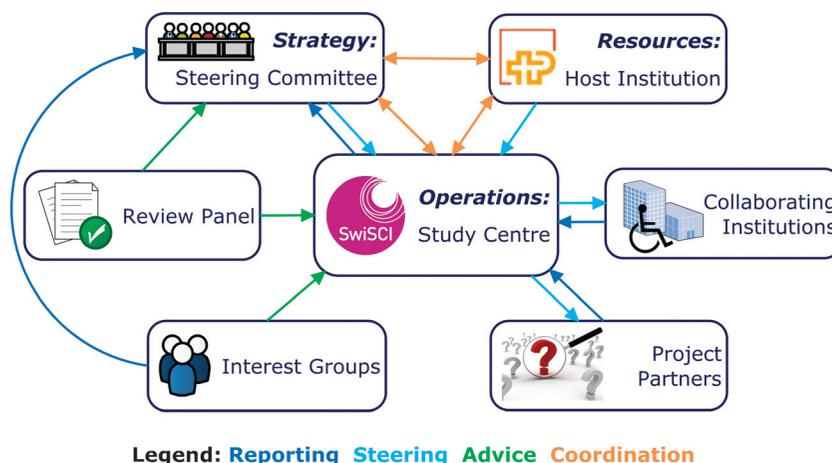


FIGURE 4 SwiSCI governance structure. SwiSCI indicates Swiss Spinal Cord Injury Cohort Study.

after SCI include the National SCI Database in the United States,⁶⁸ the Australian SCI Register,⁶⁹ the European Multicenter Study about SCI,⁷⁰ and the Dutch research program “Restoration of mobility in SCI rehabilitation.”⁷¹ Other important longitudinal cohort studies are in England³⁸ and in South Carolina.³⁹ SwiSCI aims to complement these existing studies with its ICF-based comprehensive and life-long perspectives.

There are two major methodologic challenges to the success of longitudinal and population-based studies like SwiSCI: (1) ensuring broad and representative recruitment of participants and (2) preventing, detecting, and correcting attrition bias in data collection.⁴⁰

Broad and representative recruitment of participants from the Swiss SCI population is facilitated through the participation of the four principal rehabilitation centers for SCI in Switzerland and the Swiss Paraplegic Association. We assume that, in the past 10–20 yrs, almost all patients with SCI in Switzerland will have received their first rehabilitation after SCI in one of these four centers. Consequently, SwiSCI will probably reveal nationwide and representative data, assuming that there is a high response rate. The community survey of pathway 2 is inevitably at much higher risk of recruitment and nonresponse bias. The success of community recruitment will critically depend on the collaboration with the Swiss Paraplegic Association and its associated wheelchair clubs, with which a substantial proportion of people living with SCI in Switzerland hold membership.

The dropout of participants is common in epidemiologic research.⁴¹ Participants may have changed address and cannot be located. Older or tetraplegic persons may have died or have become

too incapacitated or experience barriers to continuing their participation in the study. Selective dropout may result in attrition bias, which may affect the external and internal validity of longitudinal research, undermining the generalizability of the study and the correlation structure among key variables, respectively.⁴⁰ To prevent attrition, SwiSCI will undertake several actions, including creating a project identity and, through its collaborating centers, keeping contact information about participants up to date; keeping follow-up questionnaires short; offering incentives; and providing telephone reminders and follow-up postcards to improve retention. In addition, effort will be made to identify unavoidable attrition bias and to correct for this bias using appropriate statistical techniques.⁴³

CONCLUSIONS

As a long-term research program, SwiSCI will provide an opportunity to develop research capacity in terms of robust conceptual models, well-established study methods, and trained researchers.^{9,46,66,71,72} The experience to be gained in SwiSCI can be applied to the study of many other disabling health conditions. SwiSCI researchers will have an opportunity to learn for people with SCI and also from people with SCI. Therefore, SwiSCI can inform and promote SCI-related policy programs, best practices, and innovative research that enable people with SCI.

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