

## ORIGINAL ARTICLE

# The International Spinal Cord Injury Endocrine and Metabolic Function Basic Data Set

WA Bauman<sup>1,2</sup>, F Biering-Sørensen<sup>3</sup> and A Krassioukov<sup>4</sup>

<sup>1</sup>*Veterans Affairs Rehabilitation Research & Development Center of Excellence for the Medical Consequences of Spinal Cord Injury, James J. Peters Veterans Affairs Medical Center, Bronx, NY, USA;* <sup>2</sup>*Departments of Medicine and Rehabilitation Medicine, Mount Sinai School of Medicine, New York, NY, USA;* <sup>3</sup>*Clinic for Spinal Cord Injuries, NeuroScience Centre, Rigshospitalet, and Faculty of Health Sciences, University of Copenhagen, Copenhagen, Denmark and* <sup>4</sup>*International Collaboration On Repair Discoveries (ICORD), Department of Medicine, University of British Columbia and Vancouver Coastal Health, Vancouver, British Columbia, Canada*

**Objective:** To develop the International Spinal Cord Injury (SCI) Endocrine and Metabolic Function Basic Data Set within the framework of the International SCI Data Sets that would facilitate consistent collection and reporting of basic endocrine and metabolic findings in the SCI population.

**Setting:** International.

**Methods:** The International SCI Endocrine and Metabolic Function Data Set was developed by a working group. The initial data set document was revised on the basis of suggestions from members of the Executive Committee of the International SCI Standards and Data Sets, the International Spinal Cord Society (ISCoS) Executive and Scientific Committees, American Spinal Injury Association (ASIA) Board, other interested organizations and societies, and individual reviewers. In addition, the data set was posted for 2 months on ISCoS and ASIA websites for comments.

**Results:** The final International SCI Endocrine and Metabolic Function Data Set contains questions on the endocrine and metabolic conditions diagnosed before and after spinal cord lesion. If available, information collected before injury is to be obtained only once, whereas information after injury may be collected at any time. These data include information on diabetes mellitus, lipid disorders, osteoporosis, thyroid disease, adrenal disease, gonadal disease and pituitary disease. The question of gonadal status includes stage of sexual development and that for females also includes menopausal status. Data will be collected for body mass index and for the fasting serum lipid profile. The complete instructions for data collection and the data sheet itself are freely available on the websites of ISCoS (<http://www.iscos.org.uk>) and ASIA (<http://www.asia-spinalinjury.org>).

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**Keywords:** spinal cord injury; international data set; endocrine; metabolic; diabetes; osteoporosis

## Introduction

The purpose of the International Spinal Cord Injury (SCI) Endocrine and Metabolic Function Basic Data Set for individuals with spinal cord lesions is to standardize the collection and reporting of a minimal amount of information on endocrine and metabolic function in daily practice in accordance with the purpose and vision of the International SCI Data Sets.<sup>1</sup> This will also make it possible to evaluate and compare results from various published studies.

In the clinical setting, information is collected that provides a basis for treatment decisions. Although physicians who treat patients with spinal cord lesions routinely collect

clinical information, a standardized way to collect data is lacking. The use of standardized sets of outcome measures in clinical practice and in clinical trials would facilitate research collaboration between clinical centers and the translation, interpretation, and application of results to improve the management of patients with spinal cord lesions.

The information is intended to be collected by healthcare professionals with expertise in SCI at the initial evaluation and at regular follow-up sessions, and should be collected as an interview.

The information collected in this Endocrine and Metabolic Function Basic SCI Data Set will generally be used in conjunction with data in the International SCI Core Data Set,<sup>2</sup> which includes information on date of birth and injury, gender, the cause of spinal cord lesion, and neurological status. In addition, the Core Data Set contains information on whether a vertebral injury was present, whether spinal surgery was

Correspondence: Dr WA Bauman, Center of Excellence for the Medical Consequences of Spinal Cord Injury, James J. Peters Veterans Affairs Medical Center, Bronx, New York 10468, USA.

E-mail: [william.bauman@va.gov](mailto:william.bauman@va.gov)

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performed, whether associated injuries were present, whether the patient with a spinal cord lesion was ventilator-dependent at the time of discharge from initial in-patient care, and the place of discharge from initial in-patient care.

The etiology of a spinal cord lesion may be traumatic or non-traumatic. All lesions to the spinal cord, conus medullaris and cauda equina are included in the present context.

It is extremely important that data be collected in a uniform manner. For this reason, each variable and each response category within each variable has specifically been defined in a way that is designed to promote the collection and reporting of comparable minimal data.

Use of a standard format is essential for combining data from multiple investigators and locations. Various formats and coding schemes may be equally effective and could be used in individual studies or by agreement of the collaborating investigators. Suggestions for variable names and database structure are available at the websites of the International Spinal Cord Society (ISCoS) (<http://www.iscos.org.uk>), the American Spinal Injury Association (ASIA) (<http://www.asia-spinalinjury.org>), and the National Institute of Neurological Disorders and Stroke (NINDS), the Common Data Elements (CDE) Project website (<http://www.commondataelements.ninds.nih.gov>).<sup>3</sup>

This document was produced under the auspices of ISCoS and ASIA.

## Methods

An initial version of the International SCI Endocrine and Metabolic Function Basic Data Set was prepared by a working group consisting of the three authors. All members in this group have both clinical and research experience with the topic of the data set. These efforts were guided by the need to prepare a basic data set that could be used by clinicians without cost in various settings and countries without the need of advanced technical equipment. The data collected would provide a minimal amount of standardized information necessary for a basic evaluation of the SCI patient. In order to ensure consistency in the data collection and facilitate interpretation, detailed information is provided in a syllabus for each specific variable and response category.

The process for developing this version of the International SCI Endocrine and Metabolic Function Basic Data Set followed the steps given below:

1. The working group of the International SCI Endocrine and Metabolic Function Basic Data Set finalized the first draft during extensive e-mail contact between the group members.
2. The data set has been reviewed by members of the Executive Committee of the International SCI Standards and Data Sets.
3. Comments from the Committee members were discussed in the working group and appropriate adjustments made to the Data Set.
4. Members of the ISCoS Executive and Scientific Committees and ASIA Board were also asked to review the data set.
5. Comments from the Committee/Board members were discussed in the working group and a response was made and further adjustments of the data set were performed.
6. Relevant and interested scientific and professional (International) organizations and societies (around 40) and individuals with an interest were also invited to review the data set. In addition, the data set was posted on the ISCoS and ASIA websites for over 2 months to allow comments and suggestions.
7. Comments were discussed and responded to by the working group. Where appropriate, adjustments to the data set were made.
8. To conclude this part of the consultation, members of the ISCoS Executive and Scientific Committees and ASIA Board received the data set for final review and approval.
9. The International SCI Endocrine and Metabolic Function Basic Data Set was then further scrutinized by the team working on the NINDS, CDE Project, in cooperation with the Executive Committee of the International SCI Standards and Data Sets committees.<sup>3</sup> This additional scrutiny has provided data management changes to the data set.
10. Finally, the data set was used to collect information on several cases to confirm its function in actual practice.

## Results

The data sheet is included in the Appendix and the data sheet and syllabus are available on the respective websites of ISCoS (<http://www.iscos.org.uk>) and ASIA (<http://www.asia-spinalinjury.org>). Training cases are also available on these websites.

Listed below are the variables included in the International SCI Endocrine and Metabolic Function Basic Data Set:

### *Date of data collection*

Because the collection of data on endocrine and metabolic conditions may be performed at any time following the spinal cord lesion, the date of data collection is imperative for computing the time that has lapsed after the initial spinal cord lesion. This will permit the information obtained to be related to other data collected on the same individual at various time points.

### *Endocrine and metabolic conditions diagnosed before spinal cord lesion (collected once)*

This variable documents the history of endocrine and metabolic diseases that pre-dated the spinal cord lesion, including type 1 and 2 diabetes mellitus, lipid disorders, osteoporosis, thyroid disease, and other specified endocrine or metabolic diseases.

At the time of injury, a patient may present with a history of type 1 or type 2 diabetes mellitus,<sup>4</sup> which may be more difficult to manage after acute SCI due to glucocorticoid administration, heightened stress, variable caloric intake and severe immobilization. Chronic injury may be associated with a further increase in insulin resistance in association

with a reduction in muscle mass (the primary insulin-responsive tissue). The designation of type 1 or type 2 diabetes mellitus is usually a clinical one. Patients with juvenile onset should be classified as having type 1 diabetes, and all others as having type 2 diabetes. It is appreciated that a type 2 diabetic may have features of a type 1 diabetic, including a tendency for ketosis, but such patients are clinically classified as insulin-requiring type 2 diabetics. As such, the clinician must use his/her judgement to decide whether a patient has type 1 or type 2 diabetes mellitus.

There may be a reduction in the serum HDL cholesterol value observed in the lipid profile in those with acute or chronic SCI. Therefore, if fasting serum lipid values before the spinal cord lesion are available, the most recent values should be provided, with the date obtained.

Osteoporosis present before the injury would be expected to be accelerated because of the adverse effects of paralysis and immobilization on the skeleton below the level of SCI.<sup>5-7</sup> The diagnosis of osteoporosis may be made by routine radiograph, but this is a relatively insensitive method; at present, the method of choice to diagnose osteoporosis is dual-energy X-ray absorptiometry, but quantitative computerized tomography may also be employed. As such, the method used to make the diagnosis of osteoporosis should be specified. According to most recommendations, osteoporosis is defined from the dual-energy X-ray absorptiometry scan or from a radiograph. Although it may certainly provide interesting and useful information on a patient, computerized tomography/quantitative computerized tomography is not an accepted manner to diagnose osteoporosis. Therefore, if osteoporosis is stated to be present, the method used may be a radiograph, dual-energy X-ray absorptiometry or another methodology.

Obviously, having SCI does not protect against having other endocrine abnormalities. Autoimmune thyroid dysfunction may be precipitated or made worse by an acute stressful event.<sup>8,9</sup> Abnormalities of the gonads may also have been present before SCI and may be exacerbated by SCI (for example, acute and chronic testicular dysfunction in males and acute ovarian dysfunction in females).<sup>10-12</sup> Therefore, it is important to document these endocrine and metabolic conditions that were present before sustaining the SCI. If the information has been documented once, it is not necessary to complete the response to this variable again, in order to avoid collecting redundant data.

#### *Endocrine and metabolic conditions diagnosed after the spinal cord lesion within the last year*

These variables document endocrine and metabolic complications or conditions that have occurred after the spinal cord lesion and within the last year, and include the same and some additionally specified items to the variables presented above.

Carbohydrate and lipid abnormalities are recognized to be strong contributing factors to cardiovascular disease and one of the leading causes of mortality in individuals with spinal cord lesions.<sup>13,14</sup>

Impaired glucose tolerance and diabetes mellitus are relatively common, yet they may be frequently unrecognized

conditions in individuals with spinal cord lesions.<sup>4,15</sup> Paralysis and immobilization may predispose to type 2 diabetes mellitus. There are no reports of SCI increasing the prevalence of type 1 diabetes mellitus. However, patients who have an antecedent history of type 1 diabetes mellitus may require higher doses of insulin to maintain adequate glycemic control after SCI.

Lipid abnormalities, especially a depressed serum HDL cholesterol concentration with or without elevated serum triglyceride values, may be present in association with impaired glucose tolerance and/or diabetes mellitus.<sup>15-17</sup>

Osteoporosis below the level of the spinal cord lesion is an expected finding with paralysis and immobilization.<sup>5-7,18,19</sup> Thus, it is important to record this information. As presented above, if osteoporosis is stated to be present, the method used may be a radiograph, dual-energy X-ray absorptiometry or another methodology.

As with advancing age in the general population, other endocrine and metabolic conditions may develop after sustaining a spinal cord lesion and may include gonadal disease, thyroid disease, adrenal disease, and pituitary disease.<sup>8,20</sup> Head trauma associated with acute SCI may result in selective or global pituitary-hypothalamic insufficiency; bilateral abdominal trauma may be associated with adrenal insufficiency.<sup>21,22</sup>

#### *Gonadal status*

For both genders, the state of sexual maturation (for example, prepubertal, pubertal or adult), and for females, menopausal or postmenopausal status, will be recorded.

The stage of gonadal development or senescence will provide insight into concentrations of circulating sex steroids. Muscle-skeletal development, if not completed, may be adversely affected by SCI. Postmenopausal osteoporosis may worsen the bone loss of immobilization.<sup>23</sup> Female gonadal status is usually a clinical diagnosis, which may or may not be confirmed with laboratory studies (for example, serum gonadotropins and/or estrogen, in the case of menopause). Male gonadal status should be primarily a laboratory diagnosis (for example, low serum testosterone) that is reinforced by clinical findings (small testes, reduction in muscle mass/tone, weakness, fatigue, loss of libido, depressive mood, loss of energy and motivation, difficulty in concentrating, memory impairment, and decreased sense of well being). In the present data set, it is sufficient to make the diagnosis of hypogonadism or postmenopausal status as a clinical judgement.

#### *Height (or length) and weight*

There are adverse body composition changes that result from spinal cord lesions and immobilization.<sup>24</sup> An absolute or relative increase in adiposity increases the risk of developing metabolic disorders of insulin resistance, diabetes mellitus and associated lipid disorders.<sup>15,17</sup> Body mass index (body mass index = weight in kg/(height in m)<sup>2</sup>) to be calculated from height and weight is a facile and good surrogate measure of total adiposity in the able-bodied population. With the appropriate adjustment of the cut-off values of

body mass index for the designations of overweight and obesity, body mass index retains its utility as an index of adiposity in persons with spinal cord lesions. Lower cut-off values have been proposed in SCI populations as more appropriate to define overweight and obesity.<sup>24–26</sup>

#### *Fasting serum lipid profile performed within the past year*

Lipid abnormalities are relatively common after spinal cord lesions, especially low serum HDL cholesterol,<sup>15,17</sup> which is recognized as an independent risk factor for coronary heart disease. There is no reason to assume that persons with spinal cord lesions should be protected from having elevated levels of serum LDL cholesterol, as reported in the ‘normal’ distribution of values in the general population. As such, serum LDL cholesterol levels should be determined to permit appropriate intervention to reduce progression of coronary heart disease in persons with spinal cord lesions.<sup>16</sup> There is value in obtaining a fasting lipid profile, whether or not it is performed while on therapy with an antilipid medication.

## Discussion

The data collected in the International SCI Endocrine and Metabolic Function Basic Data Set will be available in conjunction with the data in the International SCI Core Data Set, which among other items, includes information on date of birth and injury, gender, the cause of SCI, and neurological status.<sup>2</sup> To make this basic data set as useful as possible in a clinical setting, we have kept the number of items as small as possible. However, the working group finds that the items included cover the most clinically relevant information regarding possible endocrine and metabolic dysfunction in individuals with SCI. Despite the limited items proposed to be collected in this basic data set, this information will provide relevant and previously unobtainable findings on the acute/subacute and chronic changes on a global epidemiological scale in the SCI population that will provide increased awareness and insight into the topics previously discussed: carbohydrate and lipid metabolism, osteoporosis, gonadal and thyroid disease, as well as other endocrine conditions. More detailed information will be provided when using the International SCI Endocrinology and Metabolism Extended Data Set, which is anticipated to be available in the future; this data set will not be intended for widespread clinical use, but primarily intended for clinical research purposes. The more comprehensive data set will permit greater appreciation and understanding of the pathophysiological changes that occur as a result of acute SCI, as well as the evolving nature of such neurological injury and associated immobilization in those with chronic SCI. The working group recognizes that information in the endocrine and metabolism data sets could be extended by other clinically important information whenever appropriate.

To facilitate the use of the International SCI Data Sets, this International SCI Endocrine and Metabolic Function Basic Data Set and its data collection (the form is included in the Appendix) have been developed similarly to that of previous International SCI Basic Data Sets. To validate and translate

this data set into use, additional effort and study will be needed. The authors invite all those who are interested to participate in this open and ongoing process.

## Conflict of interest

The authors declare no conflict of interest.

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## Appendix

### Appendix: INTERNATIONAL SPINAL CORD INJURY ENDOCRINOLOGY AND METABOLISM FUNCTION BASIC DATA SET - FORM (Version 1.1)

Date performed: YYYY/MM/DD

#### Endocrine & metabolic conditions diagnosed before spinal cord lesion (collected once):

None

Diabetes mellitus  Type 1  Type 2

Fasting serum lipid values, if available, provide the most recent values prior to injury: Date YYYY/MM/DD

Total cholesterol (TC) \_\_\_\_\_ mg/dL      Triglycerides (TG) \_\_\_\_\_ mg/dL

HDL cholesterol \_\_\_\_\_ mg/dL      LDL cholesterol \_\_\_\_\_ mg/dL

Lipid disorder      Specify diagnosis: \_\_\_\_\_

Osteoporosis      Method:  DXA  Other (e.g. CT, radiograph)

Thyroid disease      Specify diagnosis: \_\_\_\_\_

Other, specify \_\_\_\_\_

Unknown (any endocrine disorder)

If information was obtained other than from the medical record, please specify source:

#### Endocrine & metabolic conditions diagnosed after the spinal cord lesion within the last year:

None

Diabetes mellitus  Type 1  Type 2

Lipid disorder      Specify diagnosis: \_\_\_\_\_

Osteoporosis      Method:  DXA  Other (e.g. CT, radiograph)

Thyroid disease      Specify diagnosis: \_\_\_\_\_

Adrenal disease      Specify diagnosis: \_\_\_\_\_

Gonadal disease      Specify diagnosis: \_\_\_\_\_

Pituitary disease      Specify diagnosis: \_\_\_\_\_

Other, specify \_\_\_\_\_

Unknown (any endocrine disorder)

If information was obtained other than from the medical record, please specify source:

#### Gonadal status (check appropriate stage):

Male:  Prepubertal  Pubertal  Adult

Female:  Prepubertal  Pubertal  Menopausal  Postmenopausal

#### Height (or length) and Weight:

Height (or length) \_\_\_\_\_ m      Weight \_\_\_\_\_ kg

#### Fasting serum lipid profile within the last year:

During anti-lipid therapy:  Yes  No

Total cholesterol (TC) \_\_\_\_\_ mg/dL      Triglycerides (TG) \_\_\_\_\_ mg/dL

HDL cholesterol \_\_\_\_\_ mg/dL      LDL cholesterol \_\_\_\_\_ mg/dL

(TC, HDL or LDL cholesterol: mmol/L x 39 = mg/dL; TG: mmol/L x 89 = mg/dL)