

INTERNATIONAL SPINAL CORD INJURY DATA SETS

ENDOCRINE AND METABOLIC BASIC DATA SET (Version 1.0) – COMMENTS

The working-group consists of:

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The purpose of the International Endocrine and Metabolic Basic Data Set for Individuals with Spinal Cord Injury (SCI) is to standardize the collection and reporting of a minimal amount of information on endocrine & metabolic function in daily practice in accordance with the purpose and vision of the International Spinal Cord Injury Data Sets (Biering-Sørensen et al. 2006). This will also make it possible to evaluate and compare results from various published studies.

The information collected in this Endocrine & Metabolic Basic SCI Data Set will generally be used in conjunction with data in the International SCI Core Data Set (DeVivo et al. 2006), which includes information on date of birth and injury, gender, the cause of spinal cord lesion, and neurologic status. In addition, the Core Data Set contains information on whether a vertebral injury was present, whether spinal surgery was performed, whether associated injuries were present, whether the patient with a spinal cord lesion was ventilator-dependent at the time of discharge from initial inpatient care, and the place of discharge from initial inpatient 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.

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VARIABLE NAME: Date of data collection:

DESCRIPTION: This variable documents the date of data collection.

CODES: YYYY/MM/DD
Unknown

COMMENTS: Because the collection of data on endocrine & 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.

VARIABLE NAME: Endocrine and metabolic conditions diagnosed **before** spinal cord lesion (collected once):

DESCRIPTION: This variable documents the history of endocrine and metabolic diseases that predated the spinal cord lesion.

CODES: None
Diabetes mellitus (type 1 or type 2)
Lipid disorders
Osteoporosis
Thyroid disease
Adrenal disease
Gonadal disease
Pituitary disease
Other, specify
Unknown

COMMENTS: These codes include endocrine and metabolic conditions diagnosed **prior** to the spinal cord lesion that may negatively impact health and function after injury. At time of injury, a patient may present with a history of type 1 or type 2 diabetes mellitus, 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 (e.g., the insulin responsive tissue). Dyslipidemias may be worsened by a reduction in the serum HDL cholesterol value in those with acute or chronic SCI. Osteoporosis present prior to 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 (Biering-Sorensen et al. 1990). Having SCI does not protect against having other fairly prevalent endocrine abnormalities. Autoimmune thyroid dysfunction may be precipitated or made worse by an acute stressful event (Ladenson et al. 2000; Sonino et al. 1993).

Abnormalities of the gonads may also have been present prior to SCI and would be exacerbated by SCI (e.g., acute and chronic testicular dysfunction in males and acute ovarian dysfunction in females) (Sipski 1991; Huang et al. 1996; Kostovski et al. 2008). Therefore, it is important to document these endocrine and metabolic conditions that were present prior to 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.

VARIABLE NAME:	Endocrine and metabolic and conditions diagnosed after the spinal cord lesion within the last year.
DESCRIPTION:	This variable documents endocrine and metabolic complications or conditions occurring after the spinal cord lesion and within the last year.
CODES:	None Diabetes mellitus (type 1 or type 2) Lipid disorders Osteoporosis Thyroid disease Adrenal disease Gonadal disease Pituitary disease Other, specify Unknown
COMMENTS:	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 (DeVivo et al. 1999; Garshick et al. 2005). Impaired glucose tolerance and diabetes mellitus are relatively common, yet they may be frequently unrecognized conditions in individuals with spinal cord lesions (Bauman et al. 2001, Bauman et al. 2005). Paralysis and immobilization may predispose to type 2 diabetes mellitus; there are no reports of SCI increasing the prevalence of type 1 diabetes mellitus, but 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 (Bauman et al.2001; Bauman et al. 2002). Osteoporosis below the level of the spinal cord lesion is an expected finding with paralysis and immobilization (Biering-Sorensen et al. 1990; Bauman et al. 1999; Eser et al 2004). Thus, it is important to record this information in detail, whenever possible. 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 (Ladensen et al. 2000; Blackburn et al. 2001). Head trauma associated with acute spinal cord injury may result in selective or global pituitary-hypothalamic insufficiency; bilateral abdominal trauma may be associated with adrenal insufficiency (Klose et al. 2007; Sinelnikov et al. 2007).

VARIABLE NAME: Gonadal status

DESCRIPTION: This variable will provide the stage of gonadal development/senescence.

CODES: Prepubertal, pubertal, and adult (male and female)
Menopausal, postmenopausal: (female only)

COMMENTS: 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, although not documented.

VARIABLE NAME: Body mass index (BMI):

DESCRIPTION: This variable will provide a surrogate measure of total body adiposity.

CODES: BMI

COMMENTS: There are adverse body composition changes that result from spinal cord injury and immobilization (Spungen et al. 2003). An absolute or relative increase in adiposity increases the risk of developing metabolic disorders of insulin resistance, diabetes mellitus, and associated lipid disorders (Bauman et al. 2001; Bauman et al. 2002). BMI is a facile and good surrogate measure of total adiposity in the able-bodied population, and with the appropriate adjustment of the cut-off values for the designations of overweight and obesity, it retains its utility as an index of adiposity in person with spinal cord lesions (Weaver et al. 2007).

VARIABLE NAME: Fasting serum lipid profile:

DESCRIPTION: This variable will document a disorder in lipid metabolism.

CODES: Total cholesterol
High density lipoprotein (HDL) cholesterol
Triglycerides

Low density lipoprotein (LDL) cholesterol

COMMENTS:

Lipid abnormalities are relatively common after spinal cord lesions, especially low HDL cholesterol (Bauman et al. 2001; Bauman et al. 2002), 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 against elevated levels of LDL cholesterol, as described in the general population. As such, LDL cholesterol levels should be determined to permit appropriate intervention to reduce progression of coronary heart disease in persons with spinal cord lesions (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults 2001). The units of measurement to be used in this data set are mg/dL.

**INTERNATIONAL SPINAL CORD INJURY ENDOCRINOLOGY & METABOLISM
BASIC DATA SET - FORM (Version 1.0)**

Date performed: YYYY/MM/DD Unknown

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

- None
- Diabetes mellitus Type 1: _____ Type 2: _____
- Lipid disorder Specify diagnosis: _____
- Osteoporosis
- Thyroid disease Specify diagnosis: _____
- Adrenal disease Specify diagnosis: _____
- Gonadal disease Specify diagnosis: _____
- Pituitary disease Specify diagnosis: _____
- Other, specify _____
- Unknown

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
- Thyroid disease Specify diagnosis: _____
- Adrenal disease Specify diagnosis: _____
- Gonadal disease Specify diagnosis: _____
- Pituitary disease Specify diagnosis: _____
- Other, specify _____
- Unknown

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

Gonadal status (check appropriate stage):

Prepubertal: _____ Pubertal: _____ Adult: _____
Menopausal: _____ Postmenopausal: _____ (female only)

Body mass index:

Test performed Yes: _____ No: _____
Height (or length) _____ m Weight _____ kg BMI: _____ kg/m²

Serum lipid profile within the last year:

Test performed Yes: _____ No: _____
Total cholesterol _____ mg/dL Triglycerides _____ mg/dL
HDL cholesterol _____ mg/dL LDL cholesterol _____ mg/dL
(HDL or LDL cholesterol: mmol/L x 39 = mg/dL; Triglycerides: mmol/L x 89 = mg/dL)