INTERNATIONAL SPINAL CORD INJURY DATA SETS

ENDOCRINE AND METABOLIC FUNCTION BASIC DATA SET (Version 1.2.1) – COMMENTS

The working-group consists of:

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The purpose of the International SCI Endocrine and Metabolic Function Basic Data Set for individuals with spinal cord lesion 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 (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 International SCI Endocrine and Metabolic Function Basic Data Set is anticipated to 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 International SCI 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 crucial 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 they could be used in individual studies or by agreement of the collaborating investigators.

This document was produced under the auspices of ISCoS and ASIA.
VARIABLE NAME: Date of data collection:

DESCRIPTION: This variable documents the date of data collection.

CODE

YYYY/MM/DD
Unknown

COMMENTS: 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.

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
Total cholesterol
High density lipoprotein (HDL) cholesterol
Low density lipoprotein (LDL) cholesterol
Triglycerides
Lipid disorders
Osteoporosis: Method: DXA or Other (e.g. CT, radiograph)
Thyroid disease
Other, specify
Unknown
If information was obtained other than from the medical record, please specify source

COMMENTS: These codes include endocrine and metabolic conditions diagnosed prior to the spinal cord lesion that may negatively impact health and function after spinal cord lesion.

At time of spinal cord lesion, a patient may present with a history of type 1 or type 2 diabetes mellitus (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003), which may be more difficult to manage after acute spinal cord injury (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 (i.e., the primary insulin responsive tissue responsible for glucose deposition). The designation of type 1 or type 2 diabetes mellitus is usually determined on clinical judgement. Juvenile-onset
patients should be classified as type 1, and all others, as type 2. Appreciated: the patient with type 2 diabetes may have features distinctive of a patient with type 1 diabetes, including a tendency for ketosis, but such patients are classified clinically as insulin-requiring type 2 diabetes. Therefore, the clinician must decide if a patient has type 1 or a type 2 diabetes mellitus.

Dyslipidemias may be worsened by a reduction in the serum HDL cholesterol value in those with acute or chronic SCI. Therefore, to have the ability to determine the effect of SCI per se on the lipid profile, this information, if available, should be provided (if several lipid profiles are available, the most recent values prior to SCI should be provided), along with the date obtained. The units of measurement to be used in this data set are mg/dL.

Osteoporosis present prior to the spinal cord lesion 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; NIH Consensus Development Panel, 2001; National Osteoporosis Foundation, 2008). The WHO diagnostic classification of osteoporosis cannot be applied to T-scores from measurements other than dual energy x-ray absorptiometry (DXA) at standard measurement sites (i.e., at the femoral neck, total femur, lumbar spine, or one-third radius). If DXA is not performed, the diagnosis of osteoporosis may be suggested if assessed by other diagnostic methods (i.e., x-ray, quantitative computerized tomography (qCT) or peripheral qCT, in conjunction with clinical risk factors (Baim et al. 2008). Therefore, if osteoporosis is to be diagnosed according to accepted guidelines, DXA must be the method used, or if presumptively diagnosed from methods that are not validated to make the diagnosis of osteoporosis, or performed by qualitative methods, this would be designated as Other method (e.g., CT, radiograph).

Having a spinal cord lesion 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 a spinal cord lesion, and they may to be exacerbated by spinal cord lesion (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 sustained antecedent to the spinal cord lesion. 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.

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

**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 Method: DXA, Other (e.g. CT, radiograph)
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, 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; The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003; 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 spinal cord lesion due to inactivity and adverse body composition changes. The designation of type 1 or type 2 diabetes mellitus is usually determined by clinical criteria. Juvenile-onset patients should be classified as type 1, and all others, as type 2 diabetes. It may be appreciated that the patient with type 2 diabetes may have features that are distinctive of a patient with type 1 diabetes, including a tendency for ketosis, but such patients are classified clinically as insulin-requiring type 2 diabetics. Thus, it remains a clinical judgement to decide if the patient has a type 1 or a type 2 diabetes mellitus. 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; NIH Consensus Development Panel, 2001; Eser et al 2004; National Osteoporosis Foundation, 2008). Thus, it is important to record this information in detail, whenever possible. The diagnosis of osteoporosis may be made by routine x-ray, but this is a relatively insensitive method; at present, the method of choice to
diagnose osteoporosis is DXA, but qCT may also be employed; as such, the method used to make the diagnosis of osteoporosis should be specified. According to the recommendations of the International Society of Clinical Densitometry, osteoporosis is defined from the DXA scan (Baim et al. 2008). CT/qCT and radiograph are not accepted methods to make a diagnosis of osteoporosis, although it may certainly provide interesting and suggestive information on the patient. Therefore, if osteoporosis is diagnosed according to accepted guidelines, the method used must be DXA, or if presumptively diagnosed, Other methods (e.g., CT, radiograph) (Baim et al. 2008).

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 SCI 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).

If information was obtained other than from the medical record, the source should be specified.

**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 a spinal cord lesion. Postmenopausal osteoporosis may worsen the bone loss of immobilization, although not documented. Female gonadal status is usually a clinical diagnosis, which may or may not be confirmed with laboratory studies (e.g., serum gonadotropins and/or estrogen, in the case of menopause). In the female, puberty is defined as coincident with the initiation of breast development and/or with the appearance of axillary or pubic hair and before the start of menstruation; the term “adult” should be applied if post-pubertal (i.e., after the onset of menses) and not yet menopausal. Male gonadal status should be primarily a laboratory diagnosis (e.g., low serum testosterone) reinforced by clinical symptoms/ findings (small testes, decreased muscle mass/tone, weakness, fatigue, reduction in libido, depressive mood, loss of energy and motivation, difficulty concentrating, memory impairment, and decreased sense of well being); these symptoms and signs are nonspecific manifestations and, thus, it is often difficult to
know with any degree of certainty if the complaint is secondary to androgen deficiency or other conditions/factors. However, in the present data set, it is sufficient to make diagnoses of gonadal status as a clinical judgement if laboratory studies are not available to confirm the clinical impression.

**VARIABLE NAME:** Height (or length) and Weight:

**DESCRIPTION:** This variable will provide the measurements necessary to calculate the body mass index (BMI), a surrogate measure of total body adiposity.

**CODES:**
- Height (or length) in m
- Weight in kg

**COMMENTS:** There are adverse body composition changes that result from spinal cord lesion 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). Obtaining the height and weight will permit the computation BMI (kg/m²), which is easy to perform and useful 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 a surrogate index of adiposity in persons with spinal cord lesions as well, albeit lower cut-off values have been proposed as more appropriate to define overweight and obesity (Spungen et al. 2003; Weaver et al. 2007; Laughton et al. 2009.).

**VARIABLE NAME:** Fasting serum lipid profile performed within the past year:

**DESCRIPTION:** This variable will document the fasting serum lipid profile measured within the past year.

**CODES:**
- During administration of anti-lipid therapy:
  - Yes
  - No
- Total cholesterol
- High density lipoprotein (HDL) cholesterol
- Low density lipoprotein (LDL) cholesterol
- Triglycerides

**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). There is value in obtaining a fasting lipid profile, whether or not it is performed while on therapy with an anti-lipid medication. The units of measurement to be used in this data set are mg/dL.
References:


Acknowledgements:
We are thankful for the comments and suggestions received from Susan Charlifue, Lawrence Vogel, Vanessa Noonan, Marcalee Sipski Alexander, Inge Eriks-Hoogland, and Michael DeVivo. The authors wish to thank the Department of Veterans Affairs Rehabilitation Research and Development Service for their support (grant B4162C).
INTERNATIONAL SPINAL CORD INJURY ENDOCRINOLOGY AND METABOLISM
FUNCTION BASIC DATA SET - FORM (Version 1.2.1)

Date performed: YYYY/MM/DD

Endocrine & metabolic conditions diagnosed before spinal cord lesion (collected once):
☐ None
Diabetes mellitus ☐ Type 1 ☐ Type 2
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
(TC, HDL or LDL cholesterol: mmol/L x 39 = mg/dL; TG: mmol/L x 89 = 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 ☐ Adult ☐ 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)