INTERNATIONAL SPINAL CORD INJURY URINARY TRACT INFECTION BASIC DATA SET – Version 1.0

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Collection of data on urinary tract infection is universal when individuals with spinal cord lesions consult doctors with knowledge regarding spinal cord lesions. Interpretation of the data, however, is less standardized, as urinary tract infection in patients with spinal cord injury is not unambiguously defined.
The purpose of the International Spinal Cord Injury (SCI) Urinary Tract Infection (UTI) Basic Data Set for individuals with SCI is to standardize the collection and reporting of a minimal amount of information related to a possible UTI 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 data in the International SCI UTI Basic Data Set generally will be used in connection 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 neurological status. In addition, the International SCI UTI Basic Data Set can be used in relation to the International SCI Lower Urinary Tract Function Basic Data Set (Biering-Sørensen et al., 2008) which, among other variables, contains information on the bladder emptying method(s), involuntary urine leakage (incontinence), and drugs for the urinary tract within the last year including antibiotics/antiseptics for treatment of UTI or for prophylactic reasons.

A spinal cord lesion may be traumatic or non-traumatic in aetiology. 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) (www.iscos.org.uk), the National Institute of Neurological Disorders and Stroke (NINDS), and the Common Data Elements (CDE) Project website (www.CommonDataElements.ninds.nih.gov) (Biering-Sørensen et al., 2010).

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VARIABLE NAME: Date of data collection

DESCRIPTION: This variable documents the date of data collection

CODES: YYYYMMDD

COMMENTS: This collection of data on urinary tract infection may be carried out at any time after the spinal cord lesion. Therefore, the date of data collection is imperative to be able to identify the data collected in relation to other data collected on the same individual at various time points.

VARIABLE NAME: Length of time of onset of new symptom/symptoms

DESCRIPTION: This variable documents the new onset or increase in subjective symptom(s) which may present in individuals with spinal cord lesions who have a urinary tract infection (UTI).

CODES:
less than 1 day
1 to 3 days
>3 days-1 week
>1 week-2 weeks
>2 weeks-1 month
>1 month-3 months
> 3 months

COMMENTS: With respect to UTI, individuals with spinal cord lesions may have many signs and symptoms due to their spinal cord lesion or other problems. Therefore, it is important to determine that an individual's signs and symptoms are of a new onset or have increased and are not chronic in nature from a preexisting or intercurrent problem.

A UTI is characterized by the new onset of sign(s)/symptom(s) (see below) accompanied by laboratory findings of a UTI, (bacteriuria, leukocyturia and positive urine culture) (National Institute on Disability and Rehabilitation Research (NIDDR) criteria for UTI, 1992). The individual would be expected to have an onset of symptoms within 2 weeks. However, it is possible that a person's UTI could develop into a chronic condition such as chronic testicular pain from epididymitis. It is important to note that individuals with a spinal cord lesion may have many other signs and symptoms (see below) in addition to traditional signs and symptoms of a UTI in able-bodied individuals. Because of alterations in sensation, some symptoms may be absent in individuals with spinal cord lesions. Other problems, such as autonomic dysreflexia, may develop or worsen due to a UTI.

VARIABLE NAME: Signs and Symptoms of urinary tract infection in individuals with spinal cord lesions.

DESCRIPTION: This variable documents the new onset or increase in signs and symptoms, which may be experienced by individuals with spinal cord injury who have a urinary tract infection.

CODES:
Fever
New onset or increase in incontinence, including leaking around catheter
Increased spasticity
Malaise, lethargy or sense of unease
Cloudy urine with increased urine odor
Pyuria/Leukocyturia
Discomfort or pain over the kidney (costovertebral angle) or bladder or during micturition (dysuria)
Autonomic dysreflexia
Other, specify

COMMENTS: Symptoms are subjective reports given to the examiner. Signs are objective physical findings of the examiner. Individuals with spinal cord lesions may have many of the above signs and symptoms due to their spinal cord lesion or other problems. Therefore, it is important to determine that an individual's symptoms are of a new onset or have increased and are not chronic in nature from a preexisting or intercurrent problem. Many signs and symptoms do not constitute justification for treatment. A UTI is characterized by the new onset of symptoms accompanied with laboratory findings (bacteriuria, leukocyturia and positive urine culture) of a UTI (National Institute on Disability and Rehabilitation Research criteria for UTI, 1992). For the purposes of the International SCI UTI Basic Data Set only the signs and symptoms indicated above were chosen. Massa and colleagues (2009) found that cloudy urine had the highest accuracy (83.1%), and leukocytes in the urine had the highest sensitivity (82.8%) for the presence of UTI. Fever had very high specificity (99%) but very low sensitivity (6.9%). Autonomic dysreflexia data had low numbers and should be interpreted with caution. Kidney/bladder discomfort, increased spasticity, feeling sick, sense of unease, increased need to perform catheterization, feeling tired, incontinence, and foul smelling urine all had high sensitivity (77-95%) but very low specificity (less than 50%).

Fever: Elevated body temperature. In the presence of a fever one should check for signs of sepsis. Spinal cord injured people prone to poikilothermia (particularly Cervical and high-thoracic lesions) need ambient temperature levels to be taken into consideration when assessing fever (Guttmann, 1958). Additional research is necessary to better standardize temperature measurement and provide normative values for SCI.

Table: Thresholds for Elevated body Temperature (Fever) and Normal ranges for temperature variation in Non-Spinal Cord Injured Adults. (Sund-Levander et al, 2002)

Elevated body temperature	Observed normal ranges*

Oral at or above 38.2°C (101° F)	33.2-38.2°C (92-101°F)
Axillary at or above 37°C (99° F)	35.5-37.0°C (96-99°F)
Rectal at or above 37.8°C (100° F)	34.4-37.8°C (94-100°F)
Tympanic at or above 37.8°C (100°F)	35.4-37.8°C (96-100°F)

Note: Individuals with SCI who are prone to poikilothermia may need the above normal ranges to be adjusted for their normal temperature range within a given environmental temperature. The above temperature ranges are for non-SCI adults. Sund-Levander etal (2002) also provide adult temperature values stratified by sex within their article. The significant temperature ranges in children and infants has been previously published by El-Radhi (2006). The potential clinical significance of lower temperature thresholds (than those given above) in children should be recognised.

Urinary incontinence /failure of control or leaking around the catheter: The report of any involuntary leakage of urine. This may or may not be associated with urgency and need for increased catheterizations.

Spasticity: report of new or increased muscular hypertonicity compared to the patient's usual self assessed baseline, or on examination with increased resistance to stretch.

Malaise, lethargy or sense of unease: feeling tired or unwell, different from the person's usual state of health.

Cloudy urine: report that the urine is not clear. There may be report of mucus or sediment.

Malodorous urine: A distinct change in urine odor with a strong foul smell which persists on change of catheter equipment.

Pyuria/Leukocyturia: presence of white blood cells generated by the mucosal lining and seen on urinalysis.

Back pain: Pain in the lower back below the rib cage – complaints of pain located on one or other side of the back just below the ribs (costovertebral angle region corresponding to the location of the kidney). Pain is elicited by palpation or percussion of the space over the kidneys. The costovertebral angle is formed by the lateral and downward curve of the lowest rib and the vertical column of the spine. This pain is frequently observed due to inflammation of a kidney.

Bladder pain: report of pain felt in the suprapubic or retropubic region (midline lower abdomen above the pubic symphysis, or with palpation. Usually increases with bladder filling, and may persist after voiding.

Dysuria: pain and discomfort when voiding. Usually associated with localized inflammation but may be referred pain from the bladder, prostate or sphincter.

Autonomic dysreflexia: In individuals with spinal cord lesions at T6 and above – patient complains of feelings related to a sudden onset of elevated blood pressure, and other symptoms such as headache, sweating, flushing brought on by a noxious stimuli such as bladder distention/ bladder infection) (PVA Clinical Practice Guideline).

VARIABLE NAME: Urine dipstick test for nitrite and leukocyte esterase

DESCRIPTION: This variable documents the result of a urine dipstick test for nitrite and leukocyte esterase.

CODES: Nitrite:

Negative Positive Unknown

Leukocyte esterase:

Negative Positive Unknown

COMMENTS: The results can be recorded as negative, positive or unknown. An unknown result could occur from the test being unreadable, unusable, or not done.

According to a meta-analysis of urine dipstick test accuracy, it was concluded that the dipstick test alone seems to be useful in all populations to *exclude* the presence of infection if the results of both nitrites and leukocyte esterase are negative. The usefulness of the dipstick test alone to *rule in* infection is uncertain (Devillé et al., 2004). The only study with SCI individuals included in this analysis showed sensitivity of 0.79, specificity of 0.99 and positive and negative predictive values of 0.96 and 0.95 when the combined nitrites and leukocyte esterase test was measured against culture (Tuel et al., 1990). In a later study in a SCI population there was found a positive predictive value at 1.00 to detect significant bacteriuria when both nitrites and leukocyte esterase were positive (Hoffman et al., 2004). When using the National Institute on Disability and Rehabilitation Research (NIDDR) criteria for UTI (1992) it was found that the reliance on dipstick testing could result in high rates of overtreatment and lower rates of undertreatment as compared to positive bacteriuria (Hoffman et al., 2004). It should also be considered that *Enterococcus* and some other bacteria are not able to reduce nitrates to nitrite and can thus not be found with the dipstick test. Therefore dipstick for nitrites and leukocyte esterase may be an initial indication, but should be followed by culture if there is an intention to treat an UTI in SCI individuals.

One study compared the urine dipstick test and urine microscopy examination in SCI individuals and found these equally valuable (Faarvang et al., 2000). Microscopic analysis of urine, or urinalysis, is not part of routine clinical practice in many settings throughout the world. However, for sites where this is utilized,

the microscopic analysis, particularly the bacteria and white blood cells, is very helpful at evaluating the presence of bacteriuria and quantitatively evaluating the degree of pyuria.

VARIABLE NAME: Culture of urine and sensitivity

DESCRIPTION: This variable documents the result of culture of urine for bacteria and yeasts.

CODES:

Culture:		Negative	Positive	Unknown	
1)	species,	CFU/ cm^3.	Normal	or	Multiresistant
2)	species,	CFU/ cm^3.	Normal	or	Multiresistant
3)	species,	CFU/ cm^3.	Normal	or	Multiresistant
4)	species,	CFU/ cm^3.	Normal	or	Multiresistant
5)	species,	CFU/ cm^3.	Normal	or	Multiresistant

COMMENTS: The results can be recorded as negative, positive or unknown. An unknown result could occur from the test being unreadable, unusable, or not done.

Culture of urine is one of three major criteria in diagnosing UTIs, together with symptoms and immune response (Stamm, 1992; Massa et al., 2009). Urine for culture should be collected as a clean catch midstream technique, from an immediately installed urine catheter or as a suprapubic aspiration from an installed catheter (Stamm, 1992). It is not acceptable to collect a urine culture from a pre-existing catheter, from a collection bag, or from a container. It is preferred that the sample is sent to the Clinical Microbiological Laboratory (CML) in a cool container to prevent growth of microorganisms. Alternatively, the freshly voided urine can be transferred to a ”dipslide” and then sent to the CML. UTIs in people with spinal cord lesions are per definition complicated UTIs (Cardenas et al., 1995). All cultured microorganisms should be identified to the species level and quantified as colony forming units per mL (CFU/mL) (Cardenas et al., 1995). Any positive culture should be reported. This also includes information as to whether or not more than one microorganism is present. Persons with SCI commonly have more than one organism present in their urine culture (Linsenmeyer (2003). A value as low as 10 CFU/mL can, in some cases, be regarded as a significant finding (Stamm, 1992; Warren et al., 1999). However, for the CML 10^3 CFU/mL is a more reliable finding with standardized inoculation with 10 microL urine (Frimodt-Møller & Espersen 2000). A negative urine culture would indicate that there is no growth of any organism (bacteria or yeast.). A positive culture could mean that there is growth of bacterial species, yeast species, or both. Some CMLs may reject a specimen with more than 2 organisms as “contaminated”. If there is certainty that the specimen has been collected correctly, it may be necessarily to advocate with the CML for culture and speciation of all organisms.
In addition, an antibiogram providing a sensitivity pattern of relevant antimicrobials is mandatory. If the microorganism(s) cultured is/are resistant to three or more

different antimicrobial agents to which the microorganism would normally be susceptible, it is defined as being multiresistant (Jung et al., 2010; Moyo et al., 2010). A multiresistant microorganism, therefore, is not susceptible to more than three of the following eight antimicrobial agents: ampicillin/sulbactam, aztreonam, ceftazidime, ciprofloxacin, gentamicin, imipenem, piperacillin, and trimethoprim/sulfamethoxazole. Multiresistant organism colonization in individuals with spinal cord lesions has been associated with neuropathic bladder, bladder management method (particularly indwelling catheterization), high rates of antibiotic use, mechanical ventilation and pressure ulcers (Girard et al., 2006; Jung et al., 2010; Mylotte et al., 2006; Thom et al., 1999; Waites et al., 2000).
Precise identification is important to interpret the significance of the culture result, but also for interpretation of relapse or chronic /biofilm infection (Stamm, 1992, Rosen et al., 2007). The antibiogram can also be used in revealing reinfection, relapse or chronic/biofilm infection (Stamm, 1992). The latter can be supplemented with a measurement of specific antibody response to the pathogen (Moser, 1998). Finding of a chronic/biofilm infection can justify prolonged antibiotic treatment, but may also initiate examinations for urolithiasis, and focus on bladder emptying techniques (Cardenas et al., 1995).

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INTERNATIONAL SPINAL CORD INJURY DATA SETS
URINARY TRACT INFECTION BASIC DATA SET (Version 1.0) - FORM

Date of data collection: YYYYMMDD

Length of time of sign(s)/symptom(s) (tick one only)**:**

□ Less than 1 day □ 1 to 3 days □ 4 days-1 week □ >1week-2 weeks
□ >2weeks-1 month □ >1month-3 months □ > 3 months

Signs/symptoms (tick all that apply)**:**

□ Fever
□ Incontinence, onset or increase in episodes, including leaking around catheter
□ Spasticity, increased
□ Malaise, lethargy or sense of unease
□ Cloudy urine (with or without mucus or sediment) with increased odor
□ Pyuria
□ Discomfort or pain over the kidney or bladder or during micturition
□ Autonomic dysreflexia
□ Other _____

Urine dipstick test for nitrite (tick one only)**:**

□ Negative □ Positive □ Unknown

Urine dipstick test for leukocyte esterase (tick one only)**:**

□ Negative □ Positive □ Unknown

Urine culture (tick one only)**:**

□ Negative □ Positive □ Unknown

If positive, give species and amount of colony forming units (CFU)/mL (10^1-10^5CFU/mL), and the resistance pattern:

1) _____ species, _____CFU/mL
   Resistance pattern (tick one only): □ Normal □ Multi-drug resistant (agents from 3 or more different drug classes)
2) _____ species, _____CFU/mL
   Resistance pattern (tick one only): □ Normal □ Multi-drug resistant (agents from 3 or more different drug classes)
3) _____ species, _____CFU/mL
   Resistance pattern (tick one only): □ Normal □ Multi-drug resistant (agents from 3 or more different drug classes)
4) _____ species, _____CFU/mL
   Resistance pattern (tick one only): □ Normal □ Multi-drug resistant (agents from 3 or more different drug classes)
5) _____ species, _____CFU/mL
   Resistance pattern (tick one only): □ Normal □ Multi-drug resistant (agents from 3 or more different drug classes)