JBI Systematic Review Protocol


Reviewers
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Review Objective
The purpose of this systematic review is to establish the best available evidence on strategies to promote intermittent urethral self-catheterisation in adults with neurogenic / neuropathic bladders.

More specifically, the review questions are:
- What are the extrinsic and/or intrinsic factors that influence the suitability of individuals to perform self intermittent [urethral] catheterisation (SIMC)?
- What strategies promote long term compliance with SIMC?
- What are the advantages and disadvantages of using SIMC?
- Does SIMC improve the quality of life for people using this bladder management strategy?

Background
Urinary catheterisation refers to the act of passing a catheter into the bladder via the urethra or a surgically created channel to drain urine. Regular emptying of the bladder prevents over distension, aims to maintain urological function and urinary continence, and avoids complications\(^1\). Although indwelling catheters remain in-situ, intermittent catheters are removed after drainage of urine and are advocated as the method of choice in the management of neurogenic bladder dysfunction\(^1, 3\). The term neurogenic bladder refers to dysfunction of the urinary bladder due to interference in the central nervous system or peripheral nerves controlling micturition. The term neuropathic refers to a disease or disorder, especially a degenerative one that affects the nervous system. While neurogenic and neuropathic causes are associated with bladder dysfunction, to enhance readability the term neurogenic will be used throughout the remainder of this document.

Clinical presentations of neurogenic bladders vary according to the aetiology and severity of the neurological impairment. A bladder may be atonic when the detrusor muscle of the bladder does not contract. Or a bladder may be reflexic when the detrusor muscle is overactive, contracting reflexively at low volumes. This may result in incontinence, as the cerebral cortex is unable to suppress this action as a result of the neurological injury. In addition, high bladder pressures may result if the sphincter remains closed while the detrusor contracts, resulting in a phenomenon called
Detrusor-Sphincter Dyssynergia. Figure 1 outlines disorders that cause long-term neurogenic and neuropathic bladder dysfunction⁴.

**Figure 1 Disorders that Cause Long-Term Neurogenic / Neuropathic Bladder Dysfunction**

At or Above the Brain Stem
- Multiple Sclerosis
- Cerebrovascular Disease
- Brain Tumour/Abcess
- Parkinson's Disease
- Dementia
- Cerebral Palsy
- Infection eg Encephalitis
- Acquired Brain Injury

Spinal Lesions
- Spinal Cord Injury
- Multiple Sclerosis
- Spina Bifida
- Transverse Myelitis
- Poliomyelitis
- Vascular Lesions
- Spinal Tumours
- Congential Abnormalities

Cauda Equina / Peripheral Neuropathies
- Cauda Equina Syndrome
- Diabetes
- Alcoholic Neuropathy
- Sacral Cord Tumour
- Congential Abnormalities

Self–catheterisation has been promoted since Lapides and his colleagues pioneered clean catheterisation techniques in the early 1970s⁵-⁸. Lapides claimed that urinary tract infections (UTI) did not result from bacteria introduced in the process of catheterisation, but from decreased resistance to bacteria. He identified that high bladder pressure decreased blood flow to the bladder, which as a consequence increased susceptibility to UTI⁵. Subsequent monitoring of patients who were taught to self-catheterise observed them beginning to take control of their lives⁹ as well as alleviating symptoms and associated complications. Self-catheterisation promoted independence and could be taught to children, adults, care providers and people with physical disabilities², 10-12.

The ramifications of intermittent self-catheterisation can be seen by observing changes in the morbidity and mortality relating to urological dysfunction of people
with Spinal Cord Injuries (SCI). Morbidity and mortality in the SCI patient usually occurs due to secondary complications of the SCI rather than damage to the cord, with the most common and debilitating sequelae being complications of the renal system\textsuperscript{[13]}. During World War 1, approximately 80% of SCI patients died from pyelonephritis\textsuperscript{[14]}. In the 1960s all SCI patients had a UTI within forty-eight hours of admission, often resulting in renal damage, and eventual renal failure leading to death or the loss of a kidney. It was reported in 1969 that 75% of deaths in long-term paraplegics were due to renal failure caused by a mixture of chronic pyelonephritis, calculosis, amyloidosis and secondary hypertension\textsuperscript{[13]}. Following the introduction of self-intermittent catheterisation in the 1970s, and with the current emphasis on scrupulous catheterisation techniques and patient education, the morbidity and mortality rates of those with SCI have decreased markedly. By 2006, the mortality rate related to diseases of the genito-urinary system in SCI persons had decreased to 3.6\%\textsuperscript{[15]}.

Self-catheterisation is now recognised as the mainstay in the management of neurogenic bladder disorders\textsuperscript{[12]}. Teaching patients to self-catheterise promotes their quality of life, enabling individuals to take control of their bladder by liberating them from constraints imposed by the bladder dysfunction\textsuperscript{[16]}. However, it is essential that people who opt to self-catheterise comply with the recommended techniques and regimes, and are provided with appropriate resources to maintain a healthy bladder. Having determined that intermittent catheterisation is the gold standard in the management for the neurogenic bladder, it should be advocated for all patients. Nevertheless, limited resources and funding are factors which may prevent the implementation of this method of bladder management for people with neurogenic bladder dysfunction.

Multiple issues arise for people requiring urinary catheterisation. One issue is the variation in the practice of catheterisation and another is the need for the patient to be compliant long-term. Techniques of self-catheterisation vary and include ‘clean’ and ‘sterile’ methods. In addition, the type of catheter, how it is packaged, and the frequency of catheterisation and catheter coatings differ. Furthermore, although recognised as the ideal bladder management for patients with neurogenic bladders, and advocated for more than three decades, the actual practice of self-catheterisation varies. These inconsistencies introduce uncertainties and complexities into the rehabilitation process.
Rehabilitation has been defined as ‘a dynamic process in which a disabled person is aided in achieving optimum physical, emotional, psychological, social, or vocational potential to maintain dignity and self respect in a life that is as independent and self-fulfilling as possible’[17]. If the disability includes bladder dysfunction, learning to live independently may involve learning to self-catheterise. The ability to comply long-term with the recommended techniques and regimes of self-catheterisation inevitably influences the health and independence of people using this method of bladder management.

Given these issues, the development of an evidence base for catheterisation practice is essential. Published reviews related to urinary catheterisation have addressed discrete aspects of bladder management. The first of these reviews - ‘Management of short-term indwelling urethral catheters to prevent urinary tract infections’ - was published by the Joanna Briggs Institute in 2000 and reviewed in 2004[18]. As indicated by the title, this review synthesised data on interventions related to preventing catheter related UTI. Aspects of technique, equipment and frequency of bag change were explored. In 2007, Getliffe, Fader, Allen, Pinar and Moore published a systematic review titled ‘Current evidence on intermittent catheterisation: Single-use catheters or clean reused catheters and the incidence of UTI’[10]. This material was also published on The Cochrane Database of Systematic Reviews[11] titled Long term bladder management by intermittent catheterisation in adults and children’. One objective of this systematic review was to explore the effectiveness of clean versus sterile techniques in the prevention of UTI. Another objective was to establish the incidence of urethral irritation and trauma, with coated and uncoated catheters. Collectively these systematic reviews address long-and short-term bladder management using indwelling and intermittent catheterisation. The focus has been on preventing complications related to technique or equipment. Unique issues such as the advantages and disadvantages of self-catheterisation, long-term compliance, independence and a criterion of suitability for self-catheterising have not yet been addressed within a systematic review. In addition, quality of life issues have not been addressed using designs other than randomised control trials. Therefore the purpose of this review is to address this gap by presenting the best available evidence on strategies that facilitate successful intermittent self-catheterisation. This will enhance worldwide practice by providing a best practice guideline for nurses caring for adults with neurogenic bladder disorders requiring intermittent self-catheterisation.
Criteria for considering studies for this review

Types of Studies
This review will incorporate the best available evidence for each of the sub-topics identified by the objectives and specific questions asked in this systematic review.

Quantitative
This component of the review will consider any randomised controlled trials (RCT) that examine the effectiveness of strategies to promote long term compliance with self-intermittent catheterisation. In the absence of RCT other quantitative research designs such as non-randomised experimental and quasi experimental, before and after studies, cohort studies and case series/case reports will be considered for inclusion in a narrative summary. For the remaining three sub-topics, i.e. quality of life, advantages and disadvantages of SIMC, and factors influencing suitability of individuals to perform SIMC, all quantitative research designs will be considered for inclusion.

Qualitative
This component of the review will consider any interpretive studies that draw on the experiences of intermittent self-catheterisation by adults for each of the sub-topics. This will include, but not be limited to, designs such as phenomenology, grounded theory and ethnography.

Studies excluded from this review include:
- Those involving children and adolescents, i.e. > 18 years of age,
- Catheterisation performed by a carer or health professional,
- Catheterisation of a surgically created stoma,
- Indwelling catheters,
- Comparison of catheter types,
- Strategies to specifically reduce infection.
Types of participants

The review will include adults who are 18 years or older, who undertake urethral self-catheterisation for management of their neurogenic bladder dysfunction.

Types of interventions/phenomena of interest

The interventions, programs and strategies of primary interest are those that prepare adults to self-catheterise as a bladder management strategy. These include the following:

- Education and preparation to self-catheterise,
- Specific self-catheterisation techniques,
- Factors considered to identify suitability for self-catheterisation,
- Interventions that promote compliance and continuity with self-catheterisation.

Types of outcome measures/anticipated outcomes

The outcomes that are of interest include, but are not confined to the following:

- Quality of life in people self-catheterising,
- Incidence of depression in people self-catheterising,
- Long-term compliance with self-catheterisation,
- Advantages and disadvantages of urethral self-catheterisation,
- Identified limitations to intermittent self-catheterisation.

Search Strategy for identification of studies

The search strategy aims to find both published and unpublished studies and papers. The search will not be limited to English language studies although an English abstract will be required for the article to be assessed. Translation of non-English articles will be undertaken for eligible studies for which translation resources are available: Danish, Cantonese, German, French, Italian, Mandarin and Spanish. A three-step search strategy will be utilised. An initial limited search of MEDLINE and CINAHL will be undertaken followed by an analysis of the text words contained in the title, abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken. Thirdly, the reference list of all identified reports and articles will be searched for additional studies.

The databases to be searched include:

- AustHealth
- Cochrane Library
- Current Contents
- EMBASE
Bibliographies of articles will be checked and key articles will be cross-checked in citation indexes. Databases covering the nursing, medical, education and behavioural science literature will be searched. Journals relevant to the topic accessible in local educational and health libraries or on-line will be ‘hand’ searched for the period 2007 to mid-2008 to ensure studies which have not been listed in the major indexing services are retrieved.

The search for unpublished studies will include grey literature and unpublished material such as conference papers, research reports and dissertations will be sourced wherever possible. The sources searched to locate unpublished studies include:

- ProQuest Dissertations and Theses
- Index to Theses
- Grey Literature Report
- PsycEXTRA
- Conference papers
- Research registers
- WWW sites of relevant associations
- Internet search engines
- Direct communication with researchers and relevant professional organisations

The search strategy will be limited to the years 1970 to mid-2008. The rationale for commencing the search from 1970 is that it is when Lapides and his colleagues published their seminal work, which pioneered clean catheterisation and paved the way for self-catheterisation [5-8, 19-21].
The search terms used to locate studies for the review will be drawn from the natural language terms of the topic and the controlled language indexing terms used by different databases, as applicable. Individual search strategies will be developed for each index, adopting the different terminology of index thesauri. Initial keywords to be used will be: catheterisation/catheterization, self-catheterisation/self-catheterization, intermittent catheterisation/catheterization, bladder management outcomes and compliance, intermittent catheter and self, and will be used alone and as combined terms. Truncated versions of terms such as self-catheter*; catheter*; bladder manag*; and the abbreviation SIMC will be used.

**Methods of review**

**Critical Appraisal**

**Quantitative**

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review, using the standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI, Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion with a third reviewer.

**Qualitative**

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using the standardised critical appraisal instruments from the Joanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI, Appendix II). Any disagreements that arise between the reviewers will be resolved through discussion with a third reviewer.

A record of all included articles will be maintained identifying the title, author, source, location and the database they were sourced from.

**Data Extraction**

**Quantitative**

Data will be extracted from papers included in the review using standardised data extraction tools from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI, Appendix III). Any disagreements...
that arise between the reviewers will be resolved through discussion with a third reviewer.

**Qualitative**
Data will be extracted from papers included in the review using standardised data extraction tools from the Joanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI, Appendix IV). Any disagreements that arise between the reviewers will be resolved through discussion with a third reviewer.

**Data Synthesis**

**Quantitative**
Where possible, quantitative research study results will be pooled in statistical meta-analysis using Review manager software from the Cochrane Collaboration (Review manager V5). All results will be double entered. Odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed using the standard Chi-square. Where statistical pooling is not possible the findings will be presented in narrative form.

**Qualitative**
Where meta-synthesis is possible, qualitative research findings will be pooled using the Qualitative Assessment and Review Instrument (QARI). This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings (Level 1 findings) rated according to their quality, and categorising these findings on the basis of similarity in meaning (Level 2 findings). These categories are then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesised findings (Level 3 findings) that can be used as a basis for evidence-based practice. Where textual pooling is not possible the findings will be presented in narrative form.

**Conflicts of Interest**
None

**Acknowledgements**
Funding from the Foundation for Nursing Research at Royal Perth Hospital to assist in undertaking this systematic review is acknowledged with thanks.
References

# Appendix I

## JBI Critical Appraisal Checklist for Experimental Studies

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<th>Question</th>
<th>Yes</th>
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<td>1. Was the assignment to treatment groups truly random?</td>
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<td>2. Were participants blinded to treatment allocation?</td>
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<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6. Were the control and treatment groups comparable at entry?</td>
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Reviewer ___________________ Date __________
Author _____________________ Year __________ Record Number ______
7. Were groups treated identically other than for the named interventions?  

8. Were outcomes measured in the same way for all groups?  

9. Were outcomes measured in a reliable way?  

10. Was appropriate statistical analysis used?  

Overall appraisal: Include  Exclude  Seek further info.  

Comments (Including reasons for exclusion)
Appendix II

JBI QARI Critical Appraisal Checklist for Interpretive & Critical Research

Reviewer ___________________ Date __________
Author _____________________ Year __________ Record Number ______

1. Is there congruity between the stated philosophical perspective and the research methodology?
   Yes ☐ No ☐ Unclear ☐

2. Is there congruity between the research methodology and the research question or objectives?
   Yes ☐ No ☐ Unclear ☐

3. Is there congruity between the research methodology and the methods used to collect data?
   Yes ☐ No ☐ Unclear ☐

4. Is there congruity between the research methodology and the representation and analysis of data?
   Yes ☐ No ☐ Unclear ☐

5. Is there congruity between the research methodology and the interpretation of results?
   Yes ☐ No ☐ Unclear ☐

6. Is there a statement locating the researcher culturally or theoretically?
   Yes ☐ No ☐ Unclear ☐

7. Is the influence of the researcher on the research, and vice-versa, addressed?
   Yes ☐ No ☐ Unclear ☐

8. Are participants, and their voices, adequately represented?
   Yes ☐ No ☐ Unclear ☐
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?

10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reasons for exclusion)
Appendix III

JBI Data Extraction Form for Experimental/Observational Studies

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### Study results

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Appendix IV

JBI QARI Data Extraction Form
for Interpretive & Critical Research

Reviewer _____________________________ Date ________________
Author _____________________________ Year __________
Journal _____________________________ Record Number _______

Study Description
Methodology ________________________________________________________________

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Intervention ______________________________________________________________

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Participants ______________________________________________________________

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Data analysis ______________________________________________________________
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Extraction of findings complete   YES   ☐