

## CHAPTER 4

### Committee 22

# Management with Continence Products

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# Management with Continence Products

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## A. PATIENT ASSESSMENT AND PRODUCT EVALUATION

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### I. INTRODUCTION

Not all incontinence can be cured completely and even those who are successfully treated may have to live with incontinence for a time while, for example, they wait for surgery or for pelvic floor muscle training to yield its benefits. Still others – depending on their frailty, severity of incontinence and personal priorities – may not be candidates for treatment or may choose management over attempted cure. For all such people, the challenge is to discover how to deal with their incontinence so as to minimise its impact on their quality of life. This usually involves using some kind of continence product(s) to control or contain leakage of urine and / or faeces, and /or to manage urinary retention. Managing incontinence successfully with products is often referred to as *contained incontinence*, *managed incontinence* or *social continence*, in recognition of the substantial benefits it can bring to quality of life even though cure has not been achieved (See Chapter 18 for a more comprehensive discussion of these and related terms).

This chapter is aimed primarily at healthcare professionals seeking to make informed decisions as they choose between continence product categories and select a specific product within a chosen category. The chapter includes a section for each of the major product categories, each section reviewing published data and – where possible - identifying evidence-based recommendations for product selection and use. Products designed to deal with skin and odour problems caused by incontinence are also addressed.

The product sections are preceded by two others: the first provides overall guidelines for product selection, while the second reviews the methodological challenges of conducting continence product evaluations and interpreting the results.

### II. PATIENT ASSESSMENT AND OVERALL GUIDELINES FOR SELECTING CONTINENCE PRODUCTS

Selecting suitable continence products is critical for patient well-being. Ability to contain and conceal incontinence enables individuals to protect their public identity as a continent person and avoid the stigma associated with incontinence. Failure to do so can result in limited social and professional opportunities, place relationships in jeopardy and detrimentally affect emotional and mental wellbeing (Mittness & Barker 1995); (Paterson 2000).

Fortunately there are diverse ranges of different products to choose from; however, without comprehensive and current information on the range of products available this plethora of choice can be overwhelming and confusing (Paterson et al. 2003). Accessibility, affordability and supply of continence products are also complex and these issues are often compounded by the lack of knowledge and information readily available to incontinent people and their carers on how to choose a product that best meets needs (Paterson, Dunn, Kowanko, van, Stein & Pretty 2003).

Choice of appropriate products for an individual with incontinence is influenced by resources and care available and client / carer preference as well as assessment of specific client characteristics and needs (Gibb & Wong 1994); (Proudfoot, Farmer & McIntosh 1994); (Paterson, Dunn, Kowanko, van, Stein & Pretty 2003).

## 1. PRODUCT CATEGORIES

The continence products considered here may be divided into two broad types (**Fig II-1**): products to prevent incontinence by assisting toileting; and products to manage urinary retention or to contain / control incontinence (urinary and / or faecal).

All toileting products can be useful for urinary and / or faecal incontinence except for handheld urinals which are just for urinary incontinence. Containment / control products are subdivided into three overlapping categories: those for urinary incontinence, urinary retention and faecal incontinence. So, for example, someone with urinary retention is most likely to benefit from one of the products in the red ellipse, while someone with urinary incontinence will most likely benefit from one in the blue ellipse. A patient suffering from both problems will need two products (one from each ellipse) or one product from the intersection of the two ellipses.

## 2. CHOOSING BETWEEN PRODUCT CATEGORIES

The algorithms below (**Figs II-2 and II-3**) are designed to provide guidance for determining broadly which type (prevention or containment / control) and which category of products are likely to be of benefit. Three main questions determine which types of products are likely to be suitable:

- Is there urinary incontinence or faecal incontinence or both?

- Is there urinary retention with or without incontinence?
- Are there problems with toilet access (eg proximity or design of the toilet; mobility or urgency problems for the patient)?

Answers to these questions will determine which one (or more) of the algorithms is most appropriate for an individual and guide the pathway in the algorithm to be followed in finding the most appropriate category of product(s).

## 3. PATIENT ASSESSMENT FACTORS

Many factors are known to influence the suitability of a particular product category or individual product for a patient and these are listed in **Table II-1**.

## 4. SUMMARY

In conclusion, continence products find an important role in enhancing the quality of life and reducing stigma of incontinence of those who: are awaiting treatment; are waiting for treatment to take effect; elect not to pursue cure options; are unable to be fully cured and are living with an ongoing bladder / bowel problem. How effective they are in this role is determined by the correct choice and application of the product (Level of Evidence 4).

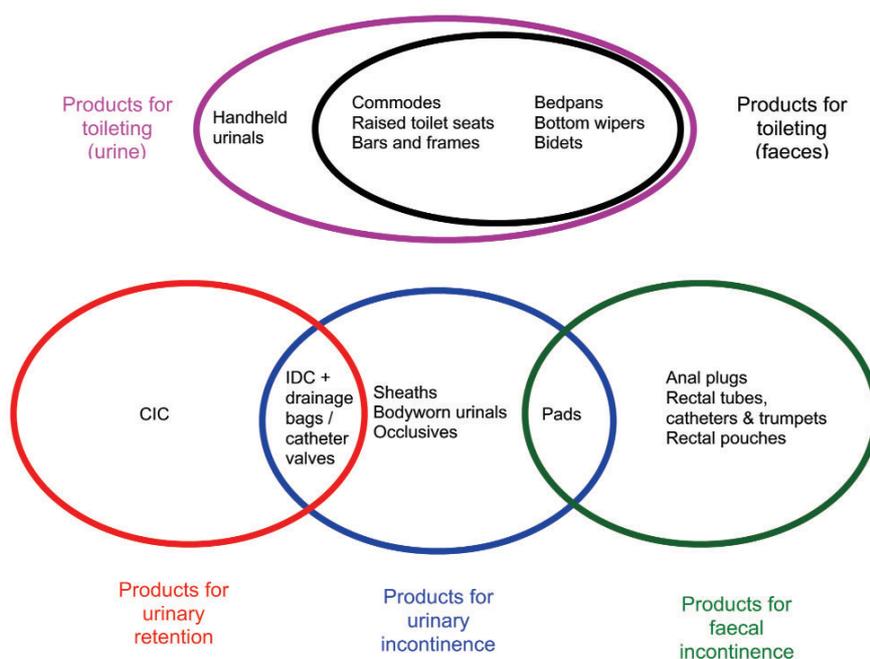


Figure II-1. Categories of continence products.

*Table II-1. Key elements of patient assessment*

<b>Element</b>	<b>Rationale</b>
<b>Independence / assistance</b>	If a carer is required to apply or change the product then it may be important to involve them in the selection of the product and to establish their willingness and ability to use it.
<b>Nature of incontinence</b>	The frequency, volume and flow rate of the incontinence influences product suitability. Generally smaller, more discrete products should be tried before larger bulkier products.
<b>Mental acuity</b>	Mental impairment can affect the person's ability to manage the product. Products that resemble usual underwear (e.g. some absorbents) may be easiest to manage. Products which have health implications if used incorrectly (e.g. occlusives or catheter valves) should be avoided if mental impairment is present
<b>Mobility</b>	Impaired mobility may make some product choices impractical or require toilet or clothing modification to allow effective use of the product.
<b>Dexterity</b>	Problems with hand or finger movement can make it difficult to use some products, eg taps on leg bags, straps with buttons.
<b>Eyesight</b>	Impaired eyesight limits effective application and management of some products.
<b>Physical characteristics</b>	Anthropometrics (e.g. height and waist, thigh, penile circumference) will influence the comfort and effectiveness of a product
<b>Leg abduction problems</b>	Difficulty with abduction can make the use of some products impractical or ineffective.
<b>Lifestyle</b>	Daily activities can influence the choice of product and a mixture of products may provide optimum management. Different products may be most satisfactory for day time and going out (when discreteness may be a priority) and night-time or staying in (when comfort may be a priority) or for holidays (when large quantities of disposables may be a problem).
<b>Laundry facilities</b>	Reusable continence products and bed linen may be very heavy when wet and take a long time to dry. It is important to check that the person doing the laundry has the ability and facilities to cope.
<b>Disposal facilities</b>	Ability to appropriately, safely and discreetly dispose of the selected products need to be considered
<b>Personal preferences</b>	Different people like different products and where possible patients should be given a choice of products with which to experiment to determine the most satisfactory product.
<b>Personal priorities</b>	Everyone wants to avoid leakage but other factors such as discreteness may be more or less important to individuals.

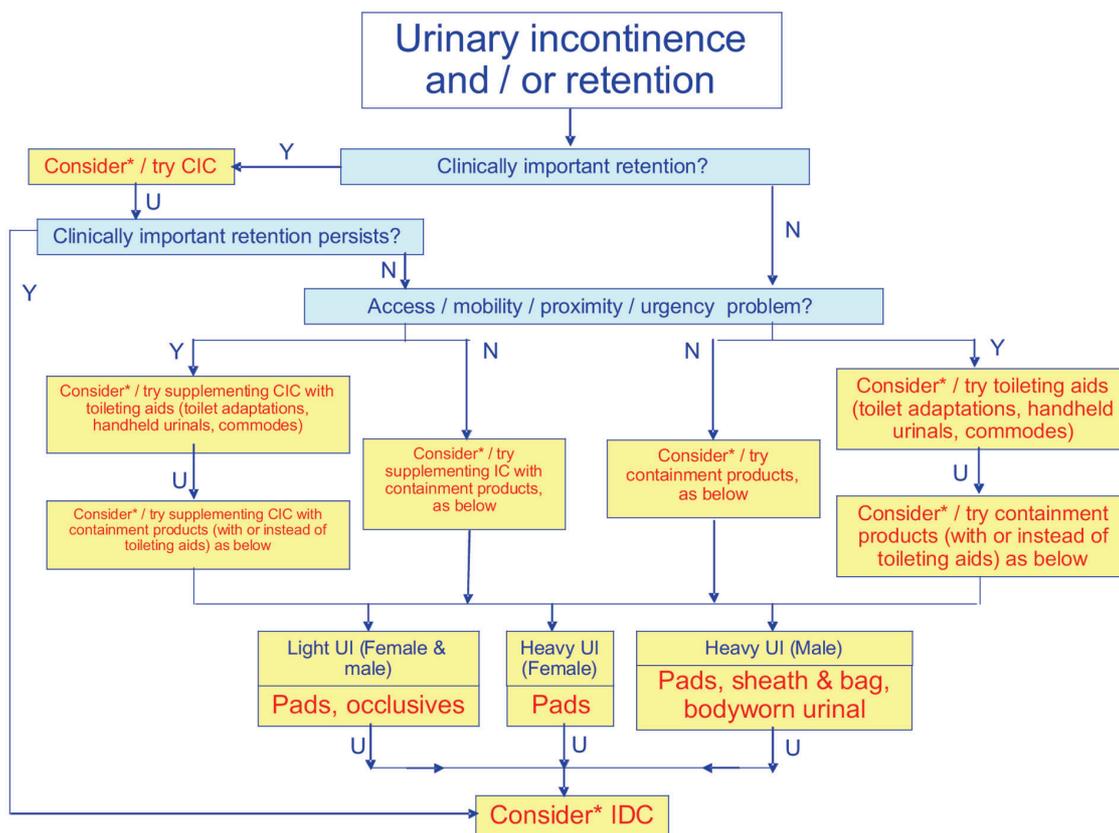


Figure II-2. Algorithm to guide choosing between categories of toileting and containment products for urinary incontinence and / or retention. (Y = Yes; N = No; U = unsatisfactory ie considered and deemed unsuitable or tried and found not to work satisfactorily). \* Consideration should be based on assessment of the patient's physical characteristics, cognitive ability and personal preferences, as well as the nature of their incontinence.

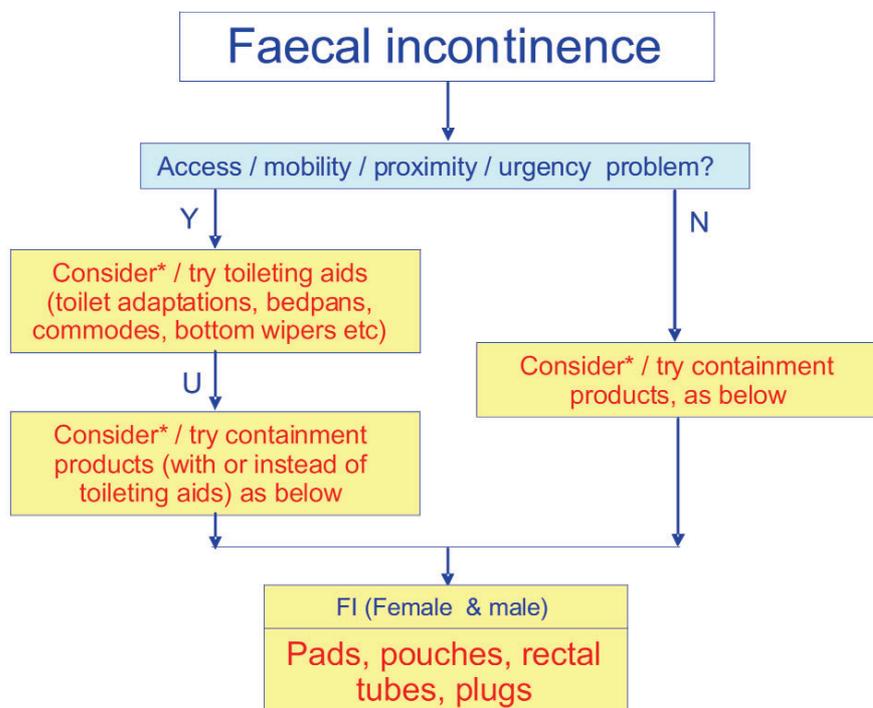


Figure II-3. Algorithm to guide choosing between categories of toileting and containment products for faecal incontinence. (Y = Yes; N = No; U = unsatisfactory ie considered and deemed inappropriate or tried and found not to work satisfactorily). \* Consideration should be based on assessment of the patient's physical characteristics, cognitive ability and personal preferences, as well as the nature of their incontinence.

## 5. RECOMMENDATIONS

- Incontinence should be actively managed with products to minimise the impact of incontinence on quality of life (Grade of Recommendation C).
- Patients should be carefully assessed (and reassessed) to select the most appropriate products (Grade of Recommendation C).

## III. PRODUCT EVALUATION METHODOLOGY

Measuring the performance of continence products is methodologically challenging. Manufacturers modify and change their products regularly, both in terms of materials and designs and this limits the long-term validity of research results. There are also complex issues regarding research questions, study design, product representation, blinding and sample size (Fader, Cottenden & Brooks 2001) which are discussed below.

### 1. RESEARCH QUESTIONS

#### a) Comparisons

Part of the complexity of product evaluations is the sheer number and type of products which means that many different comparisons can be made and at different levels. **Table III-1** shows a hierarchy of different questions regarding product choice.

**Table III-1. Levels of questions Which type of product (eg catheter, sheath, absorbent pad)?**

1. Which design of product type (eg pull-up or diaper)?
2. Which material type (eg reusable or disposable)?
3. Which design/material feature (eg with / without elastic gathers; with/without superabsorbent polymer)?
4. Which product brand?

For example, in the field of absorbents the practitioner wishes to know whether to use an underpad or a bodyworn product, a reusable or a disposable, a diaper or an insert (if they select a bodyworn), a diaper with standing gathers or without and, finally, which of the many diaper brands is likely to be most effective. Attempting to answer this final question is the most pertinent question for the practitioner (who may already have made decisions about questions 1-

4) but is particularly problematic because of the high rate of product change. By the time the results of a clinical trial of product brands are known many of the test products will have been modified and the results will have limited value for product selection. However, these 'single group' studies do have value in demonstrating the range of performance within the group of product brands, and where objective measurements can be made (for example, of leakage performance) can allow for comparisons between groups of products. Single group studies are also helpful in promoting product improvement by revealing common problems experienced by patients and exposing particularly poor products or poor product features which are amenable to change by manufacturers.

Basic product designs, features and materials change much less frequently and attempting to answer questions 1-4 is therefore likely to lead to more long-lasting results. Such studies have been attempted by many researchers, but these have frequently been confounded by problems with product representation.

#### b) Product representation

The single greatest (and most frequently overlooked) threat to the validity of clinical trials of products is the selection of the products entered into the study. Studies of single groups of similar product brands have shown that patient 'overall opinion' scores vary by as much as 70 percentage points (Fader et al. 1999c) and the selection of products to represent the group of interest is therefore crucial. Studies that have purported to compare different designs or materials have often included a small number (or more frequently a single) arbitrarily selected product(s). Generalizing the results of such studies to whole product groups (e.g reusable underpads, or disposable bodyworns) is meaningless and misleading. It is perfectly possible to select (either by accident or design) a particularly 'good' product from one group and a particularly 'poor' product from another. A well-designed study will therefore be seriously flawed if there is no clear process or pilot study to determine and justify the choice of particular products chosen to represent the product group. Even with a systematic process of product selection (or preferably a pilot study) it is unwise to select a single product to represent a whole group of products and selection of a small group of products (e.g. three) is preferable. This allows for any 'within group' differences to be detected and helps to demonstrate the 'representativeness' of the products selected.

The most controlled method of testing different designs, materials or features of products is to make up experimental batches which differ only in the aspect of interest (e.g. the material or the feature) and a small number of studies have attempted this (Clancy & Malone-Lee 1991); (Thornburn et al. 1997). However, experimentally made products are not usually identical to those available on the market, which impairs the validity of such studies.

## 2. RESEARCH DESIGN

A randomized controlled trial is not possible for clinical trials of products simply because a ‘control’ product does not exist. Nor is there a ‘standard or reference’ product to act as a control and comparisons with ‘standard practice’ (i.e. the product currently in use) is prone to bias.

Although it is methodologically simpler (and more robust) to compare only two different product groups, it is more clinically relevant to compare several competing groups, using a multiple cross-over design, where there are valid comparisons. For example, there are four main design groups of disposable bodyworn pads for moderate/heavy incontinence (inserts, diapers, pull-ups and T-shaped). Evaluation of all four groups together is much faster (and therefore gives more long-lasting results) and more cost-effective than several serial studies. Cross-over trials are vulnerable to order effects and randomization of the order of testing should be carried out using Latin squares (Armitage & Berry 1994) to ensure balance.

It is important that clinical trials of single groups of products (which aim to enable selection of particular product brands) are comprehensive (i.e. cover all the available products) because otherwise manufacturers can justifiably claim that although their product may be similar to one of those tested even subtle differences may lead to clinically important differences.

A further problem with research design is the blinding of products. Different products have different appearances and it is impossible to blind subjects or staff to the product in use. Products can be repackaged to assist anonymising but this may have unwanted effects on the products and is expensive.

Previous product experience can also affect study results, particularly if a substantial proportion of subjects are currently using a product included in the study. It is therefore important to record which pro-

ducts are in current use in order to add this data to the model used in the analysis.

### a) Sample size and study power

Studies that include more than two products (or two small groups of products) will need to be powered so that multiple comparisons can be made. As the number of products included in the study increases the number of possible comparisons of pairs of products rises. This requires a corresponding reduction in the significance level (e.g. by using the Bonferroni method) for each pair-wise comparison to retain the overall level of significance (usually  $p < 0.05$ ).

Thus as the total number of pair-wise comparisons increases the likelihood of a type 2 error (accepting the null hypothesis when it is false) also increases.

Sample sizes therefore need to be calculated to allow for each pair-wise comparison. Sample size requirements rise rapidly if each subject does not test each product and the number of products entered into a study must therefore be limited by subject fatigue. As an example, a clinical trial of four product groups where the primary outcome variable will be binarised (e.g. satisfactory / unsatisfactory) will require a sample size of approximately 80 subjects with an alpha of  $< 0.05$  and  $d$  (difference) of 20%.

### b) Outcome variables

Studies of product performance have most frequently used self-report questionnaires at the end of the product test period to assess subject ratings of product performance. Diaries of product related events such as leakage, laundry generation and product consumption are also commonly included.

Subjects in some studies have been asked to identify and prioritise items of product performance (Clarke-O’Neill et al. 2002b); (Clarke-O’Neill et al. 2004); (Macaulay et al. 2004a) to inform questionnaires and **Table III-2** shows the most common items of high priority to subjects.

**Table III-2. Most common items of high priority to subjects**

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Absorbency / leakage
Comfort
Discreteness
Fit
Smell

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Questionnaire items vary depending on the products being tested and, for product groups where few studies have been carried out, it is particularly important to tailor questionnaires to patient needs by asking study subjects to prioritise items and to assess final questionnaires for content and face validity. One study (Fader et al. 2001b) has measured the test re-test reliability of a questionnaire to assess sheath performance and found moderately good Kappa scores when assessing the same sheath twice with four weeks between measurement periods.

Skin health and pain or discomfort are the main physical health consequences of containment products and skin health (which can be rated by self-report or by skin inspection) has sometimes been used as the primary outcome variable (e.g. (Brown 1994a)). Urinary tract infection is an important outcome for invasive devices such as catheters.

Although leakage performance is most frequently rated as the top priority for users, good leakage performance is not adequate as a sole measure of patient satisfaction with performance. A single (or multiple) fatal flaw such as poor comfort, bulkiness, or poor fit may cause a product that performs well for leakage to be unacceptable to the patient. For this reason aggregate measures - which assumes that the overall performance of a product can be calculated using a weighted sum of the scores for specific aspects of performance (like comfort and freedom from leakage) - are ill-advised. Patient overall opinion or satisfaction with the product should therefore be used as the primary outcome variable (Fader, Cottenden & Brooks 2001).

There are no quality of life measurement tools specifically designed for clinical trials of products, but there is a need for such tools to measure the impact that good or bad product performance has on people's lives. Existing incontinence-specific quality of life tools are designed to measure change after interventions to improve incontinence and include urinary symptoms. These tools are therefore likely to be insensitive to changes in quality of life brought about by products.

### 3. SUMMARY AND RECOMMENDATIONS

- There is little published evidence on which to base summary and recommendations regarding methodology and so the following summary points / recommendations are all Level of Evidence 3 / Grade of Recommendation C.

- Evaluation of continence products is methodologically complex and many attempts at providing robust evidence for product selection have been hampered by methodological weaknesses.
- Product representation is critical to providing robust and generalisable data. Selection of products for inclusion in a study needs to be transparent and systematic and several products should preferably be included to represent a product group.
- Multiple crossover designs are likely to be more efficient than randomised controlled trials and therefore sample sizes estimation needs to take into account the multiple comparisons that will be made.
- Outcome variables should include patient (or carer) questionnaire including items that have been established as important to patient users.
- Diary data should be included to determine leakage performance, skin health, laundry and product consumption.
- The primary outcome variable should be patient overall opinion/satisfaction

## 4. RESEARCH PRIORITIES

The development of a Quality of Life tool for users of continence products.

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## B. PRODUCTS FOR PREVENTING OR CONTAINING URINARY INCONTINENCE

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### I. HANDHELD URINALS

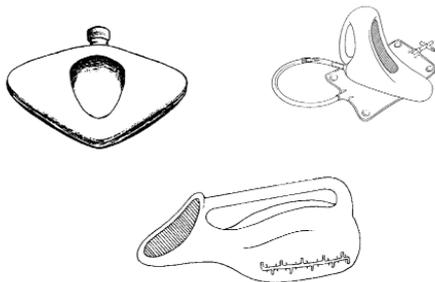
Handheld urinals are portable devices designed to allow a person to empty their bladder when access to a toilet is not possible or convenient, often due to limited mobility, hip abduction or flexibility. They can be especially helpful for those suffering from frequency and/or urgency.

An effective hand held urinal must enable its user to empty his / her bladder in comfort and confident of no spillage. It should not require excessive physical effort on their part and should be easy to empty without spillage.

## 1. FEMALE HANDHELD URINALS

Female handheld urinals come in a variety of shapes and sizes (**Fig I-1**). Most are moulded in plastic but they may be made from metal or (for single use items) cardboard. Some are designed for use in particular postures, like standing, sitting or lying down – but see below. Some have handles to facilitate grip and positioning. Some are intended to empty into a drainage bag during or after use.

Although female handheld urinals are often described and discussed in general nursing articles on continence products they have only been the subject of one published (cross-over) evaluation. Fader et al. (Fader et al. 1999b) carried out a multi-centre study in which each of 37 community-based women (age range 33-89y; mean age 61y) was invited to evaluate all 13 products on the UK market in 1997. No product suited everybody but each was successful for at least some subjects. The key requirements for success were that the user should be able to position the urinal easily and feel confident that it would catch urine without spilling (Level of Evidence 2). Many products were successful when used in the standing / crouching position or when sitting on the edge of a chair / bed / wheelchair. Fewer worked well for users sitting in a chair / wheelchair. Only one worked even reasonably well when users were lying / semi-lying. In general, subjects with higher levels of dependency found fewer urinals to be suitable for their needs.



*Figure I-1. A variety of female handheld urinals.*

### a) Recommendations

Since the ability of female users to position a urinal depends on many factors – especially the postures they can adopt, their ability to abduct their hips, and their manual dexterity, as well as the geometry of the urinal – if possible, users should experiment with a range of products before making a selection. Where possible a library of products for short-term loan to facilitate experimentation should be established (Grade of Recommendation B).

### b) Priorities for research

Female handheld urinals which are effective for supine users and those unable to move to the edge of a chair should be developed.

## 2. MALE HANDHELD URINALS

Most handheld urinals for men are somewhat similar, involving a narrowed neck opening into which the penis is placed. Some products come with a detachable non-spill adaptor containing a flutter valve to impede back-flow of urine from the urinal. There are no published trials of such products but they appear to perform their task adequately.

Disposable hand-held urinals are available for both men and women and may be helpful for travel and ‘emergency’ purposes; however, their efficacy has not yet been assessed.

## II. COMMODES AND BEDPANS

Toilets can be difficult to use by people with mobility problems and other disabilities. Toilet adaptations such as raised toilet seats, padded seats, and grab rails can be very helpful in enabling individuals to access the toilet easily and comfortably. However if access to the toilet is impossible commodes and other toileting receptacles should be considered.

Commodes are devices that comprise a frame supporting a toilet seat with a pan (disposable or washable) beneath to receive urine and faeces. They are used independently of a toilet and may be static or mobile. Mostly, they are used by people with reduced mobility who find it difficult to access a conventional toilet. Bedpans are portable receptacles that may be used for passing urine or faeces while in bed or chair. Some female urinals (see section 4) may also be used to collect faeces.

### 1. RESULTS

Fader (Fader 2002) has reviewed the little work that has been done to evaluate existing commodes and bedpans and to identify the needs of users. An investigation of commode design by Nazarko (Nazarko 1995) highlighted the problem of commodes providing poor trunk support for elderly and disabled people. Prolonged periods of sitting alone (for privacy) to enable defecation resulted in a risk of falls. Nazarko worked with a manufacturer to produce a

design specification for a commode. Consultation with patients indicated that many would prefer to use a toilet. As a consequence, attention was focused in designing a shower chair which could also be used as a commode or could be wheeled over a toilet.

An evaluation of the four main types of commodes (standard; with adjustable height; with removable / drop-down arm; with adjustable height and removable / drop-down arm combination) was published by the UK Medical Devices Agency (Medical Devices Agency 1993). One third of the 150 commodes on the UK market at the time were found to have backwards instability, and most of them scored poorly for aesthetics and comfort. A discussion of the results of this evaluation and its application to nursing was subsequently published by Ballinger et al. (Ballinger et al. 1996).

The maintenance of hospital commodes can be a problem and Gillan (Gillan 1999) complained about the poor condition of commodes in wards for elderly people.

Naylor & Mulley (Naylor & Mulley 1993) investigated the use of commodes in community-dwelling patients and the attitude of carers and users towards them (115 subjects and 105 carers). The main reasons for commode use were impaired mobility, difficulty climbing stairs and urinary incontinence. Main concerns were lack of privacy and embarrassment about using the commode, unpleasant smells and the poor physical appearance of the commode. Carers tended to view them negatively, particularly with regard to cleaning. Where commodes were used for defecation in a living area the authors highlighted the problem of odour and recommended the use of a chemical toilet.

Nelson and colleagues (Nelson et al. 1993) surveyed 147 spinal cord injured patients regarding their satisfaction and safety with the shower chairs (used for bowel care) used in the home. They found that around a half of patients were dissatisfied with their chairs and concerns expressed related to lack of hand access to the perianal area, difficulty in turning and rolling the chair and problems with keeping the chair clean. One third of patients experienced chair-related falls and nearly a quarter reported chair-related pressure ulcers. Two-thirds of subjects felt that their safety was compromised.

The same group of researchers evaluated three shower chairs using video-taping, photography and questionnaires and produced performance criteria

for the design of an optimal shower chair (Malassigne et al. 1993). Pressure mapping devices were used to measure seat pressures on three subjects who tested all three bowel/shower chairs to inform seat design (Nelson, Malassigne & Murray 1994).

These researchers (Malassigne et al. 1995) then set about designing a more advanced commode-shower chair. This chair had lockable, swing-away armrests and lever activated brakes to facilitate transfers. To prevent pressure ulcers a chair frame and padding combination was designed to facilitate a seating position that distributed body weight and reduced pressure on pressure points. Cupped edgeless footrests were designed to reduce the risk of heel ulcers. An adapted version of this chair is now commercially available in the USA.

Bedpans and other portable receptacles are not well described in the literature. Generally bedpans are considered to be unsuitable for defecation for safety and acceptability reasons. However, for individuals with specific needs (eg frequency and urgency of defecation) a portable receptacle may be beneficial. Although many portable urinals are now available for both men and women (Fader, Pettersson, Dean, Brooks & Cottenden 1999b), very few are recommended for defecation (MacIntosh 1998) and they have yet to be formally evaluated.

Privacy and dignity need to be given high priority when patients need to use a bedpan or commode, in particular in institutional settings. Care needs to be taken when transporting patients on a shower chair to maintain dignity and avoid revealing the patient's bottom.

Bottom wiping and cleaning can be difficult for people with disabilities, particularly manual dexterity problems. Simple moist wipes may be helpful and are widely available. Devices designed to assist with bottom wiping problems are on the market and portable bidets are also available, however there are no published trials of these products.

## 2. SUMMARY

- There are major defects in most of the current designs of commodes, especially: poor aesthetics; poor trunk support; instability (i.e. a tendency to tip over easily); poor comfort; difficult to clean, poor pressure relief (Level of Evidence 3).

- If direct transfer to a toilet is impossible or unsafe a sani-chair / shower chair is usually preferable to a commode (Level of Evidence 3).
- The main concerns of users about commodes are: lack of privacy; embarrassment over use; odour; poor aesthetics (Level of Evidence 2).
- Defecation on a bedpan or other portable receptacle presents problems of safety and unacceptability to users (Level of Evidence 2).

### 3. RECOMMENDATIONS

- If at all possible, access to a toilet should be made available for defecation (Grade of Recommendation C).
- If direct transfer to a toilet is impossible or unsafe, a sani-chair / shower chair should be offered in preference to a commode wherever possible (Grade of Recommendation C).
- If a commode is used, care should be taken to ensure good trunk support; that the chair is stable; and that methods of reducing noise and odour are offered (Grade of Recommendation C).
- With commodes and sani-chairs / shower chairs, the users' bottom should never be visible to others and transportation to the toilet and use of the toilet or commode should be carried out with due regard to privacy and dignity (Grade of Recommendation C).
- Bedpans and other portable receptacles should be avoided for defecation purposes (Grade of Recommendation C).
- Patients vulnerable to pressure ulcers should not sit on a commode / sani-chair / shower chair for prolonged periods (Grade of Recommendation C).
- The person should be given a direct method of calling for assistance when left on the toilet / commode / sani-chair / shower chair (Grade of Recommendation C).

### 4. RESEARCH PRIORITIES

- Studies are needed to determine how to make toilets accessible to as many users as possible. These may lead to improved designs for toilets and associated equipment and / or strategies for toileting.
- Studies are needed to determine which commode / sani-chair / shower chair designs best meet performance and safety requirements.
- Development of better commodes designed to overcome the limitations identified.

## III. ABSORBENT PRODUCTS

### 1. INTRODUCTION

Absorbent products are available in a wide range of sizes and absorbencies encompassing light through to very heavy incontinence. Broadly speaking, absorbent products can be divided into two main sub-groups: those suitable for light incontinence (usually smaller products) and those suitable for moderate-heavy incontinence (usually larger products). Manufacturers generally indicate the severity of incontinence that each product is designed to accommodate.

Although absorbent pads are most commonly used for urinary incontinence they are also used by individuals for both faecal and urine / faecal incontinence; however, there have been no published studies which specifically address this issue.

Incidental findings from evaluations of products indicate that absorption capacity alone does not determine whether a user will choose to use a product. Some users may have frequent, low flow rate loss of small amounts of urine, whilst others may be dry for days but then have a high volume, high flow rate incontinence incident. Both may prefer to use pads for light incontinence. Mobile and independent community dwelling women of all levels of incontinence are reported to generally prefer small pads and are often willing to change them frequently rather than use larger products and change them less often (Fader et al. 1987). Conversely, dependent, immobile individuals may prefer the security of larger products despite relatively low urine volumes due to their dependence on others for pad changing.

Studies that have collected and weighed used pads to

measure urine volume have found overlap between the volumes contained in each sub-group; thus in a study of insert pads for moderate-heavy incontinence used by older people in residential care (Cottenden et al. 1998) around a third of insert pads for moderate-heavy incontinence contained less than 100g of urine and in a study of older women with light incontinence living in the community (Medical Devices Agency 2002) about 10% of insert pads for light incontinence were found to contain more than 100g of urine.

It is possible that a proportion of patients are simply provided with inappropriate products that exceed or fall short of the absorption capacity they require. One study investigated this issue (Hellstrom et al. 1993) and found that patients were more satisfied with their products once their urine loss had been determined by pad weighing and appropriately absorbent products were provided. But many of these patients were using inadequate products to start with (such as tissue paper) and firm conclusions could not be drawn. In practice, it is probably hard to justify the need for pad weighing to determine which absorbents should be provided and if there is doubt about which group a patient falls into then the patient should be offered small pads for light incontinence in the first instance and the size of pad titrated upwards as necessary.

**a) Absorbent product categories**

Absorbent products may be classified into two broad categories - disposable (single-use) and reusable (washable) - with each category dividing into two sub-categories: bodyworn products (worn on the person) or underpads (placed under the person). Within each sub-category are different design groups such as diapers and pull-ups which are sub-divided (usual-

ly by size) according to the severity of incontinence. Some designs are further subdivided into those intended for men, women or children. This classification is shown in **Table III-1**.

**Bodyworn** absorbent products can be divided into four main design groups:

**Inserts** (sometimes called liners or, in the case of small pads, shields) are held in place by close-fitting underwear or stretch mesh briefs (**Fig III-1**). Disposable inserts (**Fig III-2 and Fig III-3**) usually have an adhesive strip on the back to help secure them and may have an indicator that changes colour when wet to signal the need for a pad change. They may have longitudinal, elasticated standing gathers of hydrophobic material intended to impede lateral leakage of urine and faeces. They are sometimes rectangular but are often shaped to fit the body more snugly. Elastication at the legs may also be used to enhance fit. Reusable inserts (**Fig III-4**) are usually more simply designed than disposable inserts, with no elastication and are either shaped or a simple rectangle. Inserts are made in a wide range of sizes suitable for light through to very heavy incontinence.

• **Diapers** are adult-size versions of babies' diapers. Disposable diapers (**Figs III-5**) usually have elasticated waist and legs and self-adhesive tabs (usually resealable), and often a wetness indicator and standing gathers. More recently modified diapers have been introduced that fasten round the waist before the front is pulled into position and secured, to enable users to apply the diaper whilst standing (**Fig III-6**). Reusable diapers are usually elasticated at the waist and legs and are fixed with Velcro or press-studs (**Fig III-7**). Diapers are intended for moderate to very-heavy incontinence.

**Table III-1. Classification of absorbent continence products**

<b>Categories:</b>	<b>Disposable (single use)</b>		<b>Reusable (washable)</b>	
Sub-categories:	Bodyworns	Underpads	Bodyworns	Underpads
Design groups*	Inserts Diapers Pull-ups Pouches	Bedpads Chairpads	Inserts Diapers Pull-ups Pouches	Bedpads Chairpads
Sub-groups	Groups sub-divide according to the severity of incontinence (light or moderate/heavy) and the sex of the intended users (M, F or unisex).			

\* The products within a given design group may vary considerably in their features and the materials they are made from.

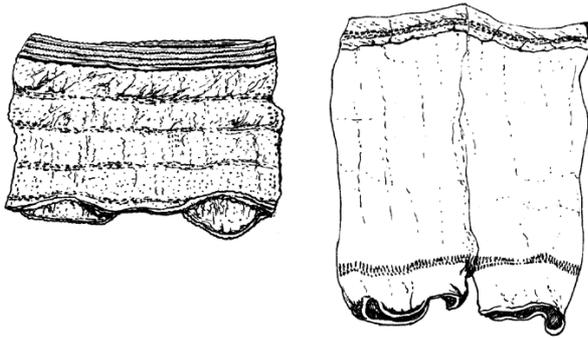


Figure III-1. Mesh pants with (right) and without (left) legs, for securing incontinence pads in position.

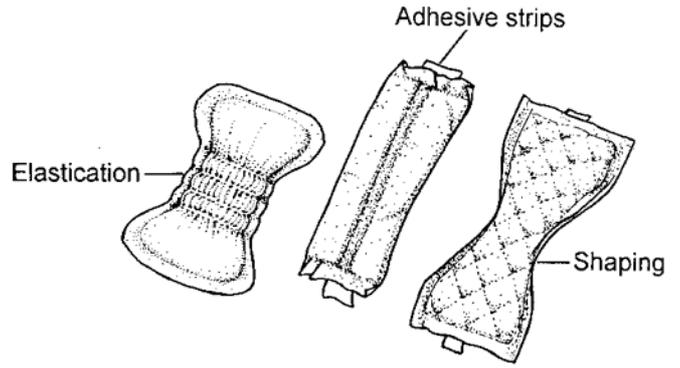


Figure III-2. Disposable inserts for light incontinence.

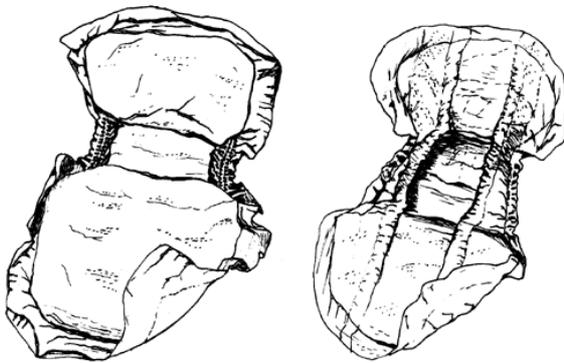


Figure III-3. Disposable inserts with (right) and without (left) standing gathers, for moderate / heavy incontinence.

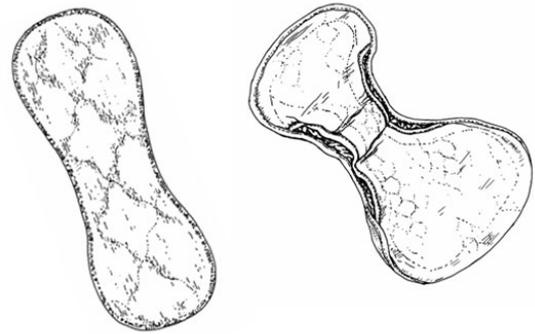


Figure III-4. Reusable inserts for light (left) and moderate / heavy (right) incontinence.

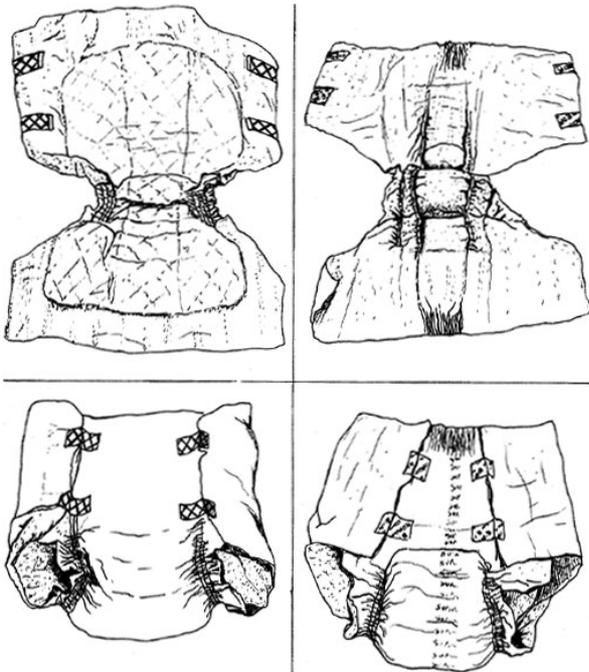


Figure III-5. Disposable diapers with (right) and without (left) standing gathers, for moderate / heavy incontinence. Diapers are shown open (top) and with the tabs secured (bottom).

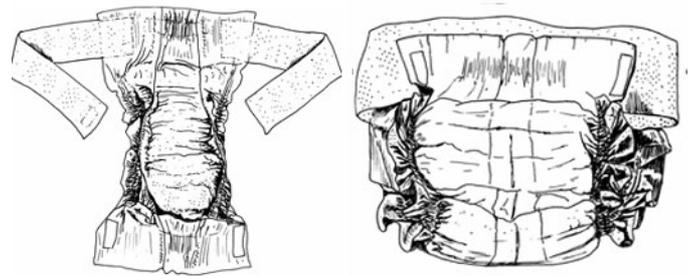


Figure III-6: A modified (T-shaped) diaper. The waist band (left) is secured first and then the front pulled up and secured in position (right).

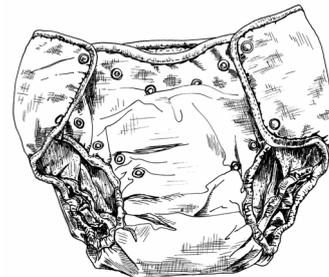


Figure III-7. A reusable diaper.

**Pull-ups** are similar in construction to trainer pants for toddlers. The absorbent material is built into a pull-up pant and is either limited to the crotch area or distributed throughout the pants (Figs III-8 to III-10). Disposable pull-ups (Fig III-8) are usually elasticated throughout the pants to give a close fit. Both disposable and reusable pull-ups have versions for different levels of incontinence. Reusable pull-ups for light incontinence are often known as pants with integral pad (Fig III-10).

**Male pouches** (sometimes called shields, guards or leaves) are for lightly incontinent men and are designed to fit around the penis and sometimes the scrotum too (Figs III-11 and III-12). All are worn with close-fitting underwear or stretch mesh briefs. An adhesive strip is often provided on the disposable versions to help hold them in place.

**Underpad** absorbent products are usually simple rectangles of different sizes to be used on the bed or chair (Fig III-13). Reusable underpads (Fig III-14) may have a high friction backing or have ‘wings’ for tucking beneath the mattress of single beds to help keep them in place. Underpads vary widely in absorbency with less absorbent products being used as ‘back-up’ with bodyworn absorbents and more absorbent products being used as sole protection on the bed at night.

**b) Absorbent product materials**

Absorbent products – disposable or reusable – usually comprise three main layers: an absorbent core sandwiched between a water-proof backing beneath and a water-permeable coverstock (or topsheet) next to the wearer’s skin.

The main component in disposable absorbent cores is invariably some kind of fluffed wood pulp fibres but most also contain some powdered superabsorber (sometimes referred to as SAP (superabsorbent polymer) or AGM (absorbent gelling material)), which is often concentrated in the crotch region. Superabsorbers hold much more urine – weight for weight – than fluff pulp and retain it far more tenaciously under pressure. They are usually based on cross-lin-

ked salts of polyacrylic acid whose chemistry can be varied according to the balance of properties such as absorption capacity and absorption speed desired. Some thermoplastic fibres are also sometimes included in absorbent cores to reduce core break up and the collapse of the structure when wet. It is increasingly common for absorbent cores to comprise two or more layers, each designed to perform a different function. For example, an upper layer might comprise low absorbency fibres selected to receive and distribute urine efficiently and maintain a dry layer next to the skin, while lower layers provide absorption capacity. Some disposable products have ‘breathable’ plastic backings designed to reduce skin occlusion.

Reusable absorbent cores are usually made from a needlefelt or knitted fabric comprising rayon and/or polyester fibres. A variety of polymers are used for the water-proofing. In general, the thicker, stiffer materials are more durable (the durability of the plastic backing often determines the lifetime of the product) but less comfortable. Topsheets are usually made from either cotton – which is hydrophilic and said to have good dry comfort – or polyester – which is hydrophobic and said to have good wet comfort.

**2. ABSORBENT PRODUCTS FOR WOMEN WITH LIGHT INCONTINENCE**

There are four main product designs for women with light incontinence (Table III-2). The disposable pull-up group are relatively expensive, single-use items and are seldom used for light incontinence except as ‘emergency’ items. Underpads are not commonly used for light incontinence.

**a) Quality of data**

A small number of robust comparative evaluations of absorbent pads for lightly incontinent women have been published. One study has compared a range of disposable inserts and menstrual pads and there have been comprehensive single group studies of disposable inserts and washable pants with integral pads. There have been no published studies of reusable inserts for light incontinence. Nor have there been

**Table III-2. Bodyworn absorbent products for lightly incontinent women**

	<b>Disposable</b>	<b>Reusable</b>
Design groups	Inserts (Fig III.2)	Inserts (Fig III.4)
	Pull-ups: pants with integral pad (Fig III.8)	Pull-ups: pants with integral pad (Fig III.10)

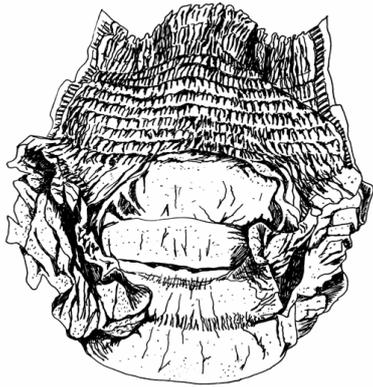


Figure III-8. A disposable pull-up.

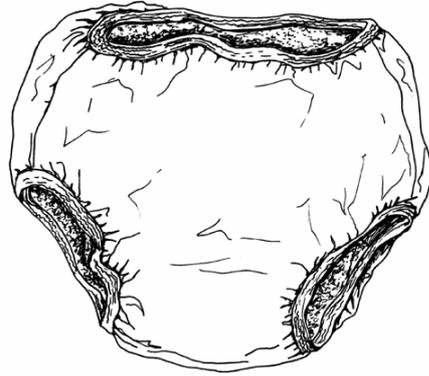


Figure III-9. A reusable pull-up for heavy incontinence.

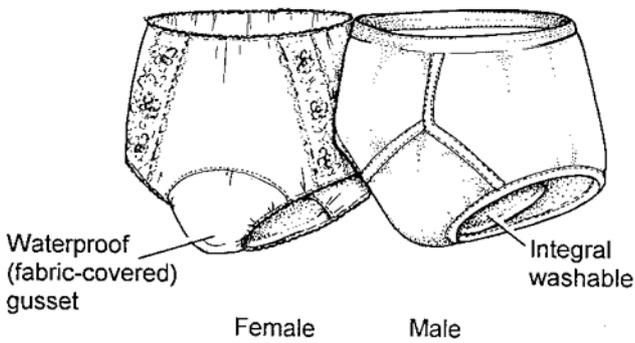


Figure III-10. Reusable pull-up pant (also known as pants with integral pad) for lightly incontinent men (right) and women (left).

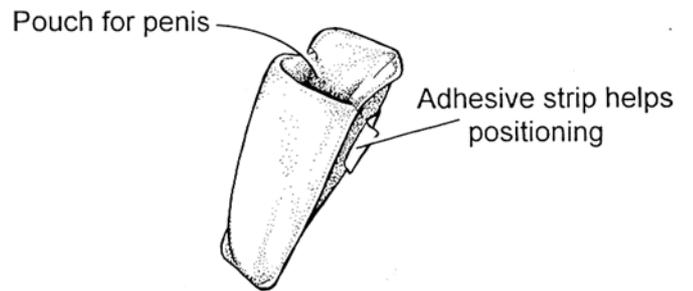


Figure III-11. A disposable pouch for men.

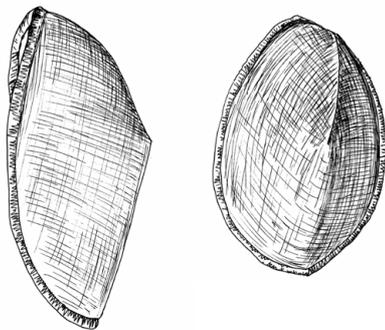


Figure III-12. Reusable pouches for men: side view (left) and front view (right).

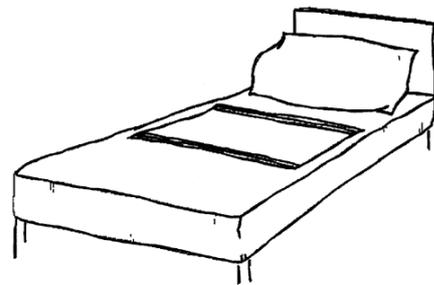


Figure III-13. A disposable underpad.

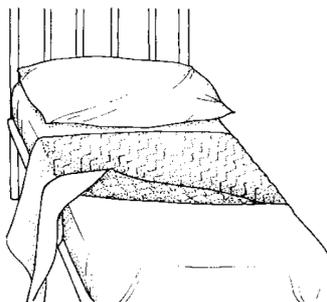


Figure III-14. A reusable underpad.

any studies directly comparing different design groups to determine which designs are most effective, and no cost-effectiveness data has been published. However, taking all these studies together it is possible to draw cautious broad conclusions about the effectiveness of different product designs. A further study has compared specially made experimental products that have differed from one another in carefully controlled ways enabling more specific questions about product materials and design to be addressed.

**b) Results**

Using a multiple crossover design, Clarke-O'Neill et al. (Clarke-O'Neill, Pettersson, Fader, Cottenden & Brooks 2004) compared the range (12 products) of disposable inserts for lightly incontinent women available in the UK in 2000. Products were tested by 60 community-based women aged 50 years or older who currently used products similar to those to be evaluated. Products were evaluated using a pad performance questionnaire and a pad leakage diary. As a group, the products performed well in terms of their ability to hold urine without leakage. Pad leakage diary results from 5761 saved pads showed that although the mode urine weight was 8g, the range was wide (0-180g). The frequency distribution showed a long tail with around a third of pads having a urine weight of more than 40g. The best performing product showed a leakage performance of 95% (CI 81-99) of pads not leaking at all with 10g of urine and 92% (CI 78-98) with 20g of urine. By comparison, 81% (CI 67-89) of the worst performing product did not leak at all with 10g of urine and 76% (CI 63-86) with 20g of urine. However, the 'overall opinion' scores of the testers showed much greater differences between products with 88% of subjects scoring the most successful insert as Good or OK compared with 51% for the least successful product (p<0.001). (Level of Evidence 2)

A similar study by the same research group (Clarke-

O'Neill, Pettersson, Fader, Dean, Brooks & Cottenden 2002b) compared all the 10 reusable pants with integral pad for lightly incontinent women available in the UK in 1999. Seventy-two community-based women who usually used absorbent products for light incontinence tested each product for one week each. Leakage performance was found to be disappointing with 69% (CI 59-78) of the best performing product not leaking at all with 10g of urine, compared to 40% (CI 29-51) for the least successful product. Again subjects' 'overall opinion' scores showed wide differences with the best performing product scoring 85% Good or OK compared with 34% for the least successful product. (Level of Evidence 2)

A comparison between the results of these two studies (**Table III-3**) shows that - for community-based women with light incontinence - disposable insert pads are more effective at preventing leakage than reusable pants with integral pad, but the best products in the two groups had similar scores for 'overall opinion'.

However, comparisons between these data must be made cautiously because these were two separate studies undertaken with two different - albeit similar - populations. It is likely that reusable pants are cheaper in the long-term than disposable inserts, assuming that they have a reasonably long life (in excess of 50 washes), but economic comparisons have not been studied. Reusable pants have a more 'normal' appearance than disposable inserts and are likely to be particularly useful for occasional incontinence when often disposable pads would still be dry when discarded.

Baker and Norton (Baker & Norton 1996) evaluated six small disposable inserts and two menstrual pads (available in the USA in 1991) with 65 community dwelling women. The products were rated using an evaluation questionnaire and daily diary of pad use. The two menstrual pads (which were the least expensive pads in the study) scored significantly higher

**Table III-3. Comparison between findings from two studies: (1) disposable inserts (2) reusable pants with integral pad**

		Most successful disposable insert	Most successful reusable pants with integral pad
Overall opinion:	Good:	57%	58%
	OK:	31%	27%
	Poor:	12%	15%
% of pads not leaking at all for:	10g of urine:	96% (CI 86-99)	69% (CI 59-78)
	20g of urine:	89% (CI 76-95)	44% (CI 32-57)

than many of the incontinence products although neither was the most popular pad. The authors concluded that women should try a ‘maxi’ menstrual pad first and then move onto a higher capacity (incontinence) pad if this is inadequate. However, products have changed considerably since this study was carried out and the current relative performance of menstrual pads compared to disposable inserts for incontinence is not known (Level of Evidence 2)

Thornburn et al (Thornburn, Fader, Dean, Brooks & Cottenden 1997) compared three variants of a small, shaped disposable pad by asking twenty lightly incontinent women living in the community (age range 37-89) to evaluate each in turn for a week in random order. Women then blind tested a random sequence of 42 pads (14 of each variant) scoring the performance of each individual pad. One variant was engineered to have high absorbency and good wetback (resistance to allowing fluid to escape back on to the wearer’s skin) by using a hydrophobic coverstock and including a substantial quantity of superabsorber in the core. A second variant had a hydrophilic coverstock and no superabsorber, chosen to give low absorbency and poor wetback. The third variant had intermediate properties. Whenever differences in wet comfort, absorbency or overall performance were found they were in the expected order but differences were small and few reached statistical significance. The clinical value of including technically superior materials was not strongly supported. However this was a small study and may have had insufficient power to detect significant differences (Level of Evidence 2).

**c) Summary**

As a design group, disposable inserts are more effective at containing leakage than reusable pants with integral pad (Level of Evidence 3). However, the individual products within both design groups exhibit a wide range of performance and acceptability for individuals, and it cannot therefore be assumed that a single brand of product will be as acceptable or effective in terms of leakage performance as another (Level of Evidence 2). Some reusable pants with integral pad were well-liked by patients and may be (an acceptable alternative to

disposable inserts for those who prefer a more ‘normal’ appearance or for women with very light incontinence (Level of Evidence 3). Menstrual pads may be as effective as some disposable inserts (Level of Evidence 3).

**d) Recommendations**

- Most disposable inserts for light incontinence are likely to be satisfactory for patients in terms of leakage, but patients may have individual preferences and should be offered a selection to try where possible (Grade of Recommendation B).
- Menstrual pads may be sufficient for some patients with very light incontinence (Grade of Recommendation C).
- Reusable pants are an acceptable and probably cost-effective alternative to disposable inserts for women with very light incontinence, but are more likely to leak than disposable inserts and are not recommended for heavier urine loss. (Grade of Recommendation B).

**e) Research priorities**

Reusable pants need to be compared directly with disposable inserts and current menstrual pads, including an economic analysis.

**3. ABSORBENT PRODUCTS FOR MEN WITH LIGHT INCONTINENCE**

There are five main product designs for men with light incontinence (Table III-4). However, disposable and reusable insert pads are often unappealing to men as they are often marketed specifically at women and bear a strong resemblance to menstrual pads. Anatomical differences are also likely to mean that they are less effective for men. Pouch, shield and leaf products (Figs III-11 and III-12) are designed to be more suitable for men by containing the penis or penis and scrotum.

Only one study has been published which has evaluated absorbent products for men with light incontinence (Medical Devices Agency, 2005)

**Table VI-4. Bodyworn absorbent products for lightly incontinent men**

	<b>Disposable</b>	<b>Reusable</b>
Design groups	Inserts (Fig VI-2)	Inserts (Fig VI-4)
	Pouch (Fig VI-11)	Pouch (Fig VI-12)
		Pull-ups: pants with integral pad (Fig VI-10)

This study compared the four main absorbent designs of products available in the UK in 2003; disposable insert pads, pouches and leafs and washable pants with integral pad. Six leaf (five disposable and one washable) and six pouch (all disposable) products were studied (representing all pouches and leaf brands available in the UK) together with a selected disposable insert pad and a selected washable pant with integral pouch (chosen to represent their respective designs). 70 men with light incontinence completed the 14 week study and completed product performance questionnaires at the end of testing each product for a week. Products were supplied in random order within their design group and the design group order was also randomised. Pad leakage diaries were used to record weight and leakage performance of products. At the end of testing each design a design performance questionnaire was completed. ‘Overall opinion’ was used as the primary outcome variable. Results showed that the pouch design performed significantly worse than the leaf and the insert design. The most common problems with the pouch were staying in place and difficulties re-inserting the penis in the pouch once the pouch was wet. The leaf designs had the best leakage scores, although the disposable insert was also very effective for leakage prevention and was substantially cheaper than the leaf designs. The washable leaf was the least successful of the leaf designs. The washable pants with integral pad received polarised overall opinion scores (loved or hated) and scored well for staying in place but poorly for leakage.

### c) Recommendations

Disposable leafs appear to be the most acceptable and effective design for men with light incontinence, but simple insert pads may also be effective and may be cheaper. Washable pants with integral pad are likely to be most suitable for men with *very* light incontinence who have difficulties keeping a product in place.

## 4. ABSORBENT PRODUCTS FOR MEN AND WOMEN WITH MODERATE-HEAVY INCONTINENCE

There are 12 absorbent product designs for men and women with moderate-heavy incontinence (Table III-5). The most commonly used products are disposable bodyworn inserts and diapers (Figs III-3 and III-5). More recently, modified diapers (T-shaped diapers, Fig III-6) have been introduced which can be applied by the wearer whilst standing. Pull-ups are also a relatively new innovation and comprise an absorbent pad integrated into a disposable elasticated pant (Fig III-8). Reusable counterparts are available to most disposable bodyworn designs, but they have a much smaller market. They are made from a variety of natural and synthetic materials. Disposable and reusable bedpads are used on the bed at night with or without the support of a bodyworn product. Disposable and reusable chairpads are used either without a bodyworn product (in which case the individual must sit directly on the pad with no underpants on) or in combination with bodyworn products to protect chairs from leakage. Both practices place an underpad on display and mark the individual as being incontinent and are therefore to be discouraged.

Table III-5. Absorbent products for moderate-heavy adult incontinence

Type	Disposable (single use)		Reusable (washable)	
	Bodyworns	Underpads	Bodyworns	Underpads
Design groups	Inserts (Fig. III-3)	Bedpads (Fig. III-14)	Inserts (Fig. III-4)	Bedpads (Fig. III-14)
	Diapers (Fig. III-5)	Chairpads	Diapers (Fig. III-7)	Chairpads
	T shaped diapers (Fig. III-6)		T shaped diapers	
	Pull-ups (Fig. III-8)		Pull-ups(Fig. III-9)	

### *a) Quality of data*

A large number of comparative studies of absorbent products for moderate-heavy incontinence have been made but most include products that are no longer available. Furthermore, changes in materials and design features mean that it is impossible to generalise any particular findings to products of today. Brink (Brink 1990) identified 30 studies of absorbent products published between 1965-1990. A Cochrane review (Brazzelli, Shirran & Vale 2004) found only six studies that met the review criteria and no firm conclusions could be drawn. However, this review only considered (arbitrarily) four types of product comparisons and did not include, for example, single group studies. The reviewers commented on the methodological weaknesses of the studies but did not address the essential issue of lack of systematic product selection which affected the selected studies. One robust multi-centre international study (Cottenden & Ledger 1993) examined the correlation between laboratory testing and the leakage performance of products clinically.

### *b) Disposable bodyworn absorbent products*

#### **1. RESULTS**

In a double-blind cross-over study involving 45 heavily incontinent older adults (38 women, 7 men) Clancy and Malone-Lee (Clancy & Malone-Lee 1991) compared the leakage performance of four different variants (each available in three sizes) of a large, shaped, bodyworn pad. Each variant had been manufactured specifically for the study; that is, none of the products was available commercially. The results were complex but, in general, the variant with two layers of fluff pulp leaked significantly less than the one with one layer, while adding some superabsorber to the lower pulp layer produced a further significant improvement. Increasing the quantity of superabsorber yielded no clear advantage. It was also found that pads were more likely to leak if they were not held in place by pants ( $p < 0.0001$ ) and that, if there any leakage from a pad, this tended to be less severe if the supplied mesh pants were worn than if normal pants were worn ( $p < 0.05$ ) (Level of Evidence 2). The mesh pants probably held pads more firmly to the body.

There have been two single design group studies of bodyworn products for moderate-heavy incontinence, both carried out in nursing homes. A study of shaped insert pads included 228 subjects from 33 nursing/residential homes who tested 20 ranges of insert pads (74 products in total) (Medical Devices

Agency 1998). A similar study of diapers involved 192 subjects from 37 nursing/residential homes who tested 36 products (Medical Devices Agency 1999). These studies showed the wide range of product performance within single product groups. For example, the least successful diaper (based on 'overall opinion') was found to be unacceptable to 100% of the test subjects while the most successful was unacceptable to only 6% (Level of Evidence 2).

In addition, there have been a number of studies on the impact of wet pads on skin health and these are reviewed in section D.I.

Because clinical evaluations are expensive and time-consuming, laboratory evaluation procedures are in widespread use. Few have been clinically validated but there are some clinically-validated International Standards relating to leakage performance. ISO 11948-1 (International Standards Organisation 1996) concerns large pads for heavy incontinence. It describes a simple method for measuring the absorption capacity of pads in the laboratory that was shown to correlate well with the leakage performance of 18 different products evaluated in an international multi-centre clinical study involving 112 heavily incontinent adults (Cottenden & Ledger 1993) The strength of the correlation between technical and clinical data data depended on the exact parameters being compared, but typically  $r = 0.9$ . (Level of Evidence 2). This laboratory test (the Rothwell method) is now in common use in the UK and provides a basis for selecting similar products with which to make direct comparisons (for cost purposes) or to select promising pads for inclusion in clinical trials.

The ability of the ISO 11948-1 to predict the leakage performance of more recent bodyworn pads (138 diapers and inserts) for heavy incontinence was investigated by Cottenden et al. (Cottenden et al. 2003). Correlations were poorer than in the original 1993 study ( $r < 0.87$  compared with  $r < 0.95$ ) but still strong enough to make the method useful. For a given Rothwell capacity, the leakage performance of diapers was far superior to inserts, but no evidence was found for any other design feature of the test products (inserts and diapers) having a significant impact on their leakage performance (Level of Evidence 2).

The repeatability and reproducibility of the ISO 11948-1 was investigated by Cottenden and co-workers (Cottenden et al. 2002) in three laboratories (UK, Spain and Sweden). Repeatability (precision between repeats in the same laboratory) was found to

be very good with the co-efficient of variation for five repeats rarely exceeding 5%. However, the reproducibility (precision between laboratories) was poorer, revealing systematic differences: results from the Swedish and Spanish laboratories typically exceeded those from the English laboratory by 13% and 8%, respectively. Efforts to identify the source(s) of this poor reproducibility have so far been unsuccessful but it seems likely that minor variations in interpretation of the standard when constructing the apparatus and / or executing the test are to blame (Level of Evidence 2).

## 2. SUMMARY

Although numerous studies have demonstrated significant differences in various aspects of performance between nominally similar products, none of the products evaluated is still on the market. Furthermore, compared products almost always differed from one another in too many ways for the efficacy of particular design features or materials to be established.

Insert pads leak significantly less if they are held in place by mesh pants than by ordinary pants, and using no pants at all is associated with significantly more leakage than if either kind of pant is worn (Level of Evidence 3). There is evidence that pads containing superabsorber leak less, are more comfortable, and keep the skin drier than those without (Level of Evidence 2). The leakage performance of inserts and diapers for heavy incontinence can be predicted with reasonable precision using international standard laboratory tests (Level of Evidence 2). These tests have been shown to have very good repeatability but more variable reproducibility (Level of Evidence 2). The leakage performance of diapers is significantly better than that of inserts of similar absorption capacity (Level of Evidence 2)

## 3. RECOMMENDATIONS

Although published studies provide virtually no direct information on current commercial products they do consistently identify certain aspects of pad performance which should be considered in selecting products. They are summarized in an ISO guidance document - and below - along with guidelines where possible. These recommendations apply generally to bodyworn pads both for moderate to heavy and light incontinence.

- *Individuality*: No study has ever identified one product that worked best for all testers: needs

and priorities vary. Accordingly, users are advised to try a variety of products when possible (Grade of Recommendation B).

- *Freedom from leakage*: Where possible, international standard laboratory tests should be used to rank the likely leakage performance of different pads for heavy and light incontinence (Grade of Recommendation B). In general, pads containing superabsorber should be selected in preference to those without (Grade of Recommendation B) and diapers should be selected in preference to inserts to minimise leakage (Grade of Recommendation B). Nobody wants their pad to leak but compromises have to be made: the pad needed to contain a person's most severe accident may be substantially more bulky and expensive than is needed most of the time. Some users choose to tolerate a higher risk of pad leakage in exchange for being able to use cheaper, smaller (more discrete) pads. The balance of priorities for a given user should be investigated in making product selections (Grade of Recommendation C).
- *Comfort and skin health*: In general, pads containing superabsorber should be selected in preference to those without (Grade of Recommendation B). Shaped pads should usually be selected in preference to unshaped (Grade of Recommendation C).
- *Staying in place*: No product is effective if it slips from position. Inserts should be used with pants, preferably mesh pants (Grade of Recommendation B). Shaped pads are preferable to rectangular (Grade of Recommendation C).
- *Ease of putting on and taking off*: The ease of putting pads on and taking them off should be considered, especially for caregivers and for incontinent users with reduced mobility or dexterity (Grade of Recommendation C).
- *Aesthetics and discretion*: A possible preference for small, more discrete pads (even if they are more likely to leak) should be considered, especially for those wishing to wear close fitting clothing (Grade of Recommendation C). The possibility of plastic backing materials rustling noisily should be considered (Grade of Recommendation C).

- *Independence and lifestyle:* The ability of a user to change his/her own pad should be considered (Grade of Recommendation C): those able to change their own pad can often manage with a smaller (less absorbent) one than those reliant on a caregiver. Users who travel should consider in their choice of product(s) the practicalities of carrying a supply of pads, disposing of used ones, and dealing with laundry (Grade of Recommendation C).
- *Costs:* Cost issues should be approached with caution (Grade of Recommendation C). Expensive pads do not necessarily work better than cheaper ones. Cheaper pads do not necessarily save money. If pads leak more they may have to be changed more frequently and/or lead to higher laundry costs. More pad changes will mean increased caregiver workload. However, more absorbent pads will not necessarily reduce pad consumption rates: pads are often changed according to ward or personal routine.

### ***c) Reusable bodyworn absorbent products***

There have been no robust clinical evaluations of reusable absorbent bodyworn products for moderate-heavy adult incontinence. Macaulay et al. (Macaulay, Clarke-ONeill, Fader, Pettersson & Cottenden 2004a) recently carried out a pilot study of 19 products with 14 community dwelling subjects. The products included a mixture of reusable insert and brief designs and two disposable bodyworn products. Product performances varied widely: the most popular was rated as good (for overall performance) by 78% of testers, while the least popular scored 22%. Although most of the reusable products performed poorly for leakage, one reusable product made of cotton towelling, scored better than both the other reusable and other disposable products (Level of Evidence 3)

## **1. RECOMMENDATIONS**

Reusable products for moderate- heavy incontinence should be considered with caution since, on balance, the literature suggests that they will not usually be as effective as disposables (Grade of Recommendation C).

### ***d) Comparisons between disposable and reusable bodyworn products.***

Seven trials have compared disposable with reusable bodyworn products for moderate-heavy incontinence

(Beber 1980); (Grant 1982); (Haeker 1986); (Dolman 1988); (Hu, Kaltreider & Igou 1990); (Harper et al. 1995). The trials varied in size and design from a large controlled trial with 276 subjects (Beber 1980) to a small trial of eleven subjects (Dolman 1988). In addition some trials have compared disposable and reusable bedpads and body-worn. Brown (Brown 1994a) (Brown 1994b) undertook a large trial of this kind. As before no systematic methods of product selection were used for these studies which limit the utility of the results since particularly good or poor products may have been selected to represent the disposable or reusable groups.

Skin condition was used as an outcome measure in five of the above trials. However, only three used an experimental design and statistical methods of analysis. Beber (Beber 1980) and Grant (Grant 1982) both reported that they did not find statistically significant differences between the reusable and disposable products in terms of an adverse change in skin condition. But Hu et al. (Hu, Kaltreider & Igou 1989) reported a statistically significant improvement in the skin condition of the disposable users as compared to the reusable users.

Other parameters frequently investigated in these studies were staff preference, leakage and laundry. Overall, the disposables in the studies were considered to have performed better than the reusable products in terms of preventing leakage (often measured by quantity of laundry) and staff preference

Four studies attempted to measure costs (Haeker 1986); (Grant 1982); (Hu, Kaltreider & Igou 1988); and (Brown 1994b). Of these, three used statistical methods of analysis. Hu et al. (Hu, Kaltreider & Igou 1988) and Brown (Brown 1994b) reported that although there were *no* statistically significant differences in terms of per-day product costs of reusable and disposable products, the laundry costs associated with the disposable product (ie for laundering soiled bed linen and clothes) were significantly lower than those associated with the reusable product (ie for laundering the products as well as soiled bed linen and clothes). Brown (Brown 1994b) found no significant differences between daily costs of the reusable or disposable products. But statistically significant differences were found between the groups in terms of incontinence-related laundry, with the disposable group producing less laundry than the reusable group. Grant (Grant 1982) reported that the cost of reusable products was significantly lower than for disposables, however laundry costs were not taken into account.

In addition, Merret et al. carried out a small trial of two new disposable products compared to an undescribed reusable product that was in established use (it is not clear whether this product was a body-worn or a bedpad). The results favoured the disposable product. Staff morale improved with the disposable product and they reported a decrease in unpleasantness associated with changing pads.

## 1. SUMMARY

The literature indicates that disposable bodyworn products generally perform better than reusables in terms of skin condition and leakage. However, it is clear that there are more and less effective products in each category and that local needs, priorities, motivations, laundry facilities and cost structures can be as important as product performance in determining the optimal solution in a given situation (Level of Evidence 2). The key issues are summarized below.

## 2. RECOMMENDATIONS

- *Laundry issues:* Access to good, reliable washing and drying facilities should be checked before reusable products are introduced (Grade of Recommendation B). Laundry – especially of bedpads – can be heavy work, beyond the capability of frail incontinent people or their caregivers. The number of reusable products needed per user depends on laundry turn-around times. Drying times for reusables can be long and expensive, especially for bodyworn for heavy incontinence and for bedpads.
- *Personal preferences:* Personal preferences (of both users and caregivers) with regard to choosing between reusable and disposable products should be taken into account carefully (Grade of Recommendation C). Some users prefer the chore of laundering reusables to anxiety over whether their next consignment of disposables will be delivered on time. Reusables generally require less storage space than disposables. Discreet disposal of disposables can be a challenge. The possibility of using a mix of disposable and reusable products should be considered (Grade of Recommendation C). Some users who choose disposables when at home prefer reusables when traveling because of the space that disposables occupy in luggage and the possible inconvenience of disposal. Others use

reusables at home and disposables when away as they see the balance of disadvantages and advantages differently.

- *Personalisation of products:* In institutions, the chore of personalizing reusable products and sorting them after each laundry cycle should be considered before they are introduced (Grade of Recommendation C). Reusable bodyworn are often personalised to particular users. In institutions this means marking products with users' names and sorting them after laundry, an extra task for caregivers. Reusable bedpads are not usually personalised.
- *Staining:* Reusable products should not usually be used by those with faecal incontinence – beyond occasional light smearing – because of staining (Grade of Recommendation C). Skin sprays and ointments may stain reusables too.
- *Costs:* Cost comparisons between reusable and disposable products should be made with caution (Grade of Recommendation C). Key factors are: local arrangements (mostly laundry and transport costs); the durability of the products (which depends on how carefully they are used and the criteria for deciding when they should be replaced); the costs of ordering, transporting and disposing of disposables; and product purchase costs. Much of the cost of reusables is encountered with the initial capital outlay for stock. This also represents a commitment to use the products for an extended period and so expensive mistakes can be made if it transpires that a better product was/has become available. It will usually be wise to experiment with samples of a variety of alternative products before committing to major purchases.

### e) Disposable underpads

Published trials comparing different disposable bedpads are few (Henderson & Rogers 1971); (Thornburn, Cottenden & Ledger 1992); (Brown 1994a) and it is not possible to draw firm conclusions from them on the effectiveness of different product design features and materials. Some useful work has been done to highlight the risks of infection from disposable bedpads and to validate clinically some laboratory tests to assist with product selection by predicting pad leakage performance.

Bedpads are generally supplied as non-sterile items and Bradbury (Bradbury 1985) has drawn attention

to the risk of infection, particularly from products containing recycled paper. Leigh and Petch (Leigh & Petch 1987) and Spratt et al. (Spratt, Kearns & Keenlyside 1988) have conducted microbiological tests on a range of products. Both studies identified low levels of bacterial contamination but concluded that the risk to patients was minimal unless they were immunocompromised in some way. More recently, Stansfield and Caudle (Stansfield & Caudle 1997) reported an outbreak of wound colonization on a surgical orthopaedic hospital ward which they attributed to the use of disposable underpads containing virgin wood pulp.

Due to the paucity of published clinical data many technical tests have been devised to evaluate products in the laboratory. The only tests with published clinical validations are described by Cottenden et al. (Cottenden et al. 1998) who subjected six different bedpads to a variety of laboratory tests and to a multi-centre clinical evaluation in which 95 incontinent subjects tested each product in turn for a week, in random order. A combination of two laboratory tests (one to measure the absorption capacity and the other the absorption time of bedpads) gave a strong correlation with the percentage of subjects finding the leakage performance of a product acceptable when used as their sole protection ( $r = 0.94$ ) and predicted the acceptability scores of all six products accurate to within  $\pm$  eight percentage points. A different absorption capacity test produced a strong correlation for the leakage performance of bedpads used as back-up to bodyworn products ( $r = 0.96$ ) and predicted the acceptability scores of all six products to within  $\pm$  five percentage points.

### 1. SUMMARY

No robust data are available on the effectiveness of current disposable bedpads or of their various design features or constituent materials. There is a risk of infection from bedpads made from recycled paper for immunocompromised users (Level of evidence 2). The leakage performance of bedpads (used alone or as back up to bodyworn pads) can be predicted with reasonable precision using clinically-validated laboratory tests (Level of Evidence 2).

### 2. RECOMMENDATIONS

Immunocompromised people should not use bedpads made from recycled paper because of the risk of infection (Grade of Recommendation B). Where possible, clinically-validated laboratory tests should be used to rank the likely leakage performance of different products (Grade of Recommendation B).

### f) Reusable underpads

Cottenden (Cottenden 1992) has reviewed comparative evaluations of different reusable bedpads up to about 1990. Leiby and Shanahan (Leiby & Shanahan 1994) have since published a study. Some evaluations have found significant differences between products relating, for example, to leakage performance and impact on skin health but none of the products evaluated is still available in the variant tested. In addition, compared products always differed from one another in many respects making it impossible to draw reliable generic conclusions relating to the products now available. However, the choice of topsheet material and the presence or absence of features like tuck-in flaps and integral water-proofing appear to be, primarily, matters of personal preference.

In institutional settings reusable bedpads are commonly used by multiple patients and questions are often asked about the risk of cross-infection. Cottenden et al. (Cottenden et al. 1999) assessed the risk by determining the microbial content of 145 bedpads of five different designs after a night's use by incontinent adults, followed by laundering using a standard foul wash procedure which included heat disinfection at 71°C for three minutes. Laundering destroyed all known pathogenic organisms, although some commensal flora were isolated in small numbers. It was concluded that foul wash laundry had left bedpads safe for multiple patient reuse with no demonstrable risk of cross-infection.

### 1. SUMMARY

The literature contains insufficient robust data on which to base guidelines for choosing between reusable bedpads. Choice of topsheet material and the presence/absence of design features like tuck-in flaps and integral/separate water-proof backing appear to be, primarily, matters of personal preference (Level of evidence 3). Provided an approved foul wash procedure is used, the risk of cross-infection between different users of a bedpads is very low (Level of Evidence 2).

### 2. RECOMMENDATIONS

Personal preferences of users with regard to topsheet material, tuck-in flaps and integral water-proof backing should be considered in making product selections (Grade of Recommendation C). Provided an adequate foul laundry wash cycle is used, the risk of cross-infection between successive users of reusable bedpads is low and not a contra-indication for their use (Grade of Recommendation B).

## 5. ABSORBENT PADS FOR CHILDREN

Most children are expected to achieve daytime dryness by the age of three (Lukeman 1997). However, some children take longer to become dry and some e.g. children with learning and physical disabilities may never reach this goal. These children usually require absorbent products to contain leakage.

To date there has been only one study of absorbent products for children and this has compared the diaper design with the newer pull-up design (Macaulay et al. 2004b). 61 children with physical and / or learning disabilities tested five diaper products and five pull-up products with each product tested for one week each. The children were randomised to receive either the pull-up or diaper group first and individual products were tested in random order. Parents completed a product performance questionnaire and a pad leakage diary to record wet weights and severity of leakage. Parents were asked to state their preference for a design for day and night use.

Findings indicated that the diapers and pull-ups performed similarly when compared with the other products within their design group, although there were some statistically significant differences between products. Overall, diapers were preferred for nighttime use by the majority of parents. 40% of parents preferred pull-ups for daytime use and these were found to be particularly appropriate for older children and those who were attempting independent toileting, provided they did not have faecal incontinence and did not wear callipers or adapted footwear. Diapers were more suitable for children who were dependent on carers, had faecal incontinence, and wore callipers or adapted footwear. The authors recommended that both diapers and pull-ups be supplied for children, with pull-ups (which are about 50% more expensive than diapers) being provided for selected children during the daytime.

### *Summary and recommendations*

Diapers and pull-ups meet different needs of children and both should be made available to children with disabilities, dependent on assessment. (Level of Evidence 3 / Grade of Recommendation C).

## IV. SHEATHS

Close-fitting penile sheaths (sometimes called condoms, uridomes or external catheters) are the

most commonly used male incontinence devices and they are used in combination with a urine drainage bag. They may be considered provided a man has no obstructive bladder emptying problems, leaving little or no post void residual (Ouslander, Greengold & Chen 1987). However, those with neurogenic bladder emptying problems, may use sheaths in combination with clean intermittent catheterisation (CIC). Sheaths are often unsuitable for elderly men due to inadequate penile length and / or diameter for secure sheath attachment.

An effective sheath is one that stays securely in place for an acceptable period of time, is leak-free, comfortable to wear, easy to apply and remove, avoids skin damage and channels the urine effectively into a urinary drainage bag

### 1. PRODUCT CATEGORIES

Sheaths come with a variety of features (Fig IV-1) of which the following are the most important to consider in making selections:

- **Material:** sheaths may be made from latex, silicone rubber or other synthetic polymers. Some men will be allergic to latex.
- **Size:** most sheaths are supplied in a range of lengths and sizes. Most companies supply them with diameters in the range of about 20 – 40 mm, in 5-10 mm increments.
- **Adhesive:** the adhesive may be integral to the sheath (one-piece systems) or come as a separate strip or spray (two-piece systems). Some men will be allergic to some adhesives.
- **Applicator:** some sheaths come with an applicator intended to help users and carers to put the sheath on.
- **Anti-kinking / twisting features:** some sheaths come with features intended to improve drainage by reducing kinking and twisting at the distal end, near the connection to the drainage bag tube.
- **Anti-blow-off features:** some sheaths come with features intended to reduce the likelihood of the sheath blowing off at high urine flow rates; for example, at the beginning of a void (eg the distal end of the sheath may be thickened and bulbous to stop the internal walls sticking to one another between voids).
- **Connection to the drainage bag:** some sheaths come with features intended to increase the ease and security of connection to the drainage tube (eg a push ring or ridge at the end of the outlet tubing)

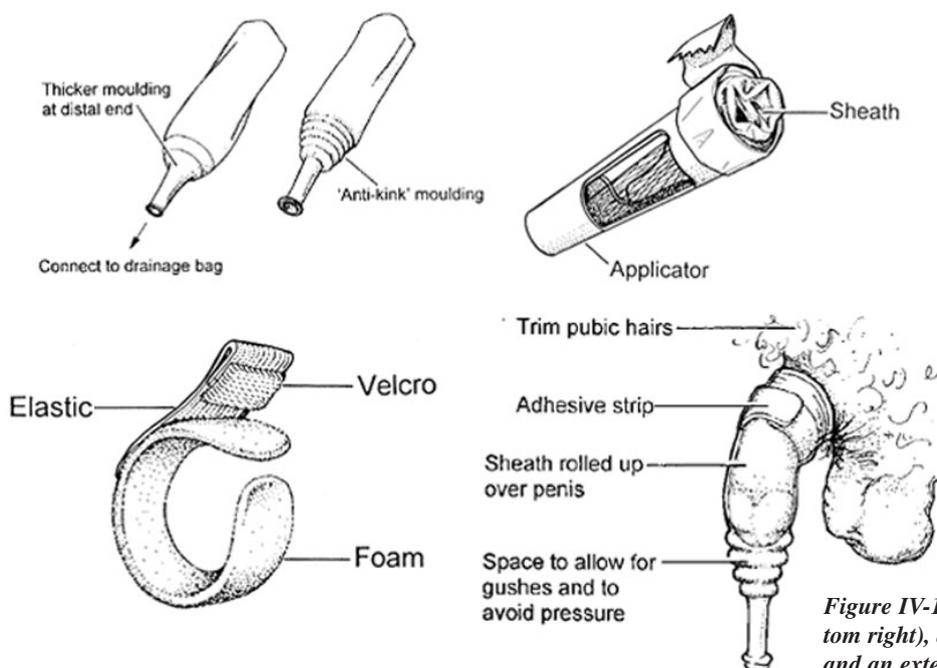


Figure IV-1. A variety of sheaths (top left and bottom right), a sheath applicator (top right) and an external fixation strip (bottom left).

- **Retracted penis features:** with or without specific features intended to accommodate a retracted penis (eg a shorter sheath or a wider adhesive seal).
- **Durability:** some sheaths are intended for use over a limited time period (eg 24 h) while other (generally, more robust) designs are intended for extended wear.

## 2. QUALITY OF DATA

Some controlled comparative evaluations of different sheaths have been performed; one extensive market survey to identify the needs and priorities of sheath users; and one study to compare a sheath with an indwelling urethral catheter. Other studies report on the problems encountered by various groups of sheath users

## 3. RESULTS

Although many men use sheaths successfully problems have been reported in the literature. In a study on (an unspecified number of) spinal cord injured men, Golji (Golji 1981) found that 15% experienced side effects or complications when using sheaths. These were irritative, allergic or compressive in nature. Jayachandran et al. (Jayachandran, Moopan & Kim 1985) reported similar experiences with six incontinent men of widely varying aetiology and highlighted the importance of ensuring that the sheath does not become twisted near the distal end to avoid stagnation of urine and the risk of UTI. They also stressed the importance of good genital hygiene

to avoid problems with infections.

In a study of 94 men on medical/ surgical wards, Hirsh et al. (Hirsh, Fainstein & Musher 1979) found that none of the 79 who were judged as co-operative and able to manage their sheaths properly developed UTI (mean period of use, 21.2 days). By contrast, eight of 15 patients who tended to tug and kink the drainage tube attached to their sheath developed UTI within a mean of 9.6 days. In a retrospective study, Johnson et al. (Johnson et al. 1990) compared the frequency of UTI in users (mean period of use, 35 months) and non-users of sheaths amongst 64 elderly men on an extended care unit. He found that 63% of users but only 14% of non-users developed UTI. No difference was found between men who did and did not tug and kink their tubing. Ouslander et al. (Ouslander, Greengold & Chen 1987) reported that 40% of 30 nursing home sheath users (mean period of use, 35.9 months) developed at least one UTI.

Nichols and Balis (Nichols & Balis 2000) reported the results of a survey undertaken for marketing purposes of an international cohort of 216 men who had used sheaths for at least three years, and their carers. Their responses to 19 brands of sheath were gathered using a questionnaire in the form of a Likert scale. It was found that catheter security (presumed to mean staying in place and freedom from leakage) was the most important issue for both wearers and carers, followed by comfort and ease of application and removal.

There have been a number of comparative evaluations of different sheaths. Peifer and Hanover (Peifer

& Hanover 1997) reported on an evaluation in which 20 men compared a new branded sheath system, that consists of three parts: a tubular sheath impervious to urine with a drainage tube connection at one end and a ring at the other, an undergarment with a frontal opening through which the penis is extended, and a ring like collar which is used to keep the sheath and penis in the correct position, with the variety of external sheaths they had previously been using. The participants were a convenience sample identified through Pharmacy medication files. They were all experienced users of urinary sheaths. In all 32 men were approached and 20 consented. A questionnaire was developed to test the participants pre and post intervention. Each used the new sheath for at least one week. The new sheath proved more popular with the participants: it was judged as providing superior security (13/20 experienced increased dryness by day; 10/20 by night), and was considered easier to apply (19/20) and remove (20/20).

In a multi-centre study involving 35 men (age range 22-87y; mean age, 54y; 34 living in their own homes), the UK Medical Devices Agency (Medical Devices Agency 1995) compared four latex sheaths: two with integral adhesive; and two in which the adhesive was supplied as a separate strip. They found the products with integral adhesive to be more successful in both overall performance and ease of application. Fader et al. (Fader, Pettersson, Dean, Brooks, Cottenden & Malone-Lee 2001b) conducted a multi-centre study to compare all six sheaths with integral adhesive on the UK market in 1998. Five were made from latex, one from silicone rubber. Four were supplied with an applicator, two without.

Fifty-eight men (age range 26-88y; mean age 53y) were given the opportunity to try each sheath in turn for one week. The silicone rubber sheath was found to be significantly better than four of the other sheaths in overall performance ( $p < 0.01$ ). The ease with which a sheath could be put on was found to be the best predictor of overall performance. Surprisingly, sheaths with an applicator were found to be unacceptable to a significantly higher proportion of subjects than sheaths without an applicator ( $p < 0.0001$ ). Subjects found that the silicone sheath fell off/blew off significantly less frequently than two of the other products ( $p < 0.01$ ).

Watson & Kuhn (Watson & Kuhn 1990) describe a crossover study with six male participants they found the choice of leg bags may influence the performance of penile sheaths. Goldyn, Buck and Chenelly

(Goldyn, Buck & Chenelly 1992) conducted an exploratory study on 10 patients in an extended care hospital to consider the efficacy of a brand name external sheath and a hospital constructed sheath. The brand name sheath was found to be more secure and the preferred nursing choice but it was recognised that the hospital-constructed sheath was useful for patients with fragile skin and limited mobility. A study by Saint et al. (Saint et al. 1999) provided further evidence (although low level) to support the importance of security and comfort to sheath users. Using questionnaires, they interviewed a convenience sample of 104 older men (response rate = 90%) and surveyed 99 nurses (response rate = 92%) about the relative merits and problems of sheaths and indwelling catheters.

The study population was drawn from a university-affiliated Veterans Affairs Medical Centre in the USA. The patients using the sheaths were more likely to believe their product was comfortable ( $p = 0.04$ ) and less likely to believe it was restrictive ( $p = 0.002$ ) or painful ( $p = 0.008$ ) than those using an indwelling catheter. This viewpoint was supported by the nurses surveyed, the majority of whom (no numbers given) believed that sheaths were more comfortable and less restrictive than indwelling urinary catheters for male users, but required more care time because they fell off or leaked.

#### 4. SUMMARY

For incontinent males who do not have a significant post void residual (or are carrying out CIC) sheath drainage can provide a good alternative to pads. However, the increased risk for complications such as local skin breakdown, bacteriuria and infection - especially in the frail elderly male - should be borne in mind. Also, there is the risk of urinary retention if the condom twists or the external band is too tight, leading to poor drainage to the urine bag (Level of Evidence 3). Sheaths with integral adhesive are more popular with users and easier to apply than those with separate adhesive strip (Level of Evidence 3). Security and the ease with which a sheath can be put on are the best indicators of its overall performance (Level of Evidence 2).

Sheath applicators are often ineffective and unpopular (Level of Evidence 2). There can be considerable differences in performance between products with somewhat similar designs (Level of Evidence 2).

## 5. RECOMMENDATIONS

- Since there can be considerable differences in performance between products of similar design, men should be given the opportunity to experiment with different products before making a final selection (Grade of Recommendation B).
- The key performance characteristics which should be considered are: security (ie ability to keep a leak-proof seal and channel urine to the drainage bag without leakage) and ease of putting the sheath on and taking it off (Grade of Recommendation B).
- In general, sheaths with integral adhesive (one-piece systems) should be selected rather than those in which the adhesive is supplied separately (two-piece systems) (Grade of Recommendation C).
- It should not be assumed that a sheath applicator will make sheath application easier: often it does not (Grade of Recommendation B).
- Potential sheath users should be asked if they have an allergy history and regular users should be routinely checked as their latex allergy status can change over time and with continued use. (Some health settings are moving to reduce or eliminate latex usage whenever possible and some manufacturers have moved to offer non-latex sheaths) (Grade of Recommendation C)
- Sheath users should be monitored for skin health, tissue damage and UTI (Grade of Recommendation C)

## 6. RESEARCH PRIORITIES

- Although products are continually being developed, changed, withdrawn and released, comparison studies that are controlled and use multiple sites to achieve larger numbers are recommended to further evaluate the effectiveness of the variety of sheaths available as well as the risk of complications.
- Since leg bag features may influence the performance of the sheath, further evaluation of design features claimed to reduce twisting and kinking at the drainage bag connection site and increase ease and security of connection to drainage bags is required.
- Well designed studies to generate and validate procedures to help identify the type of sheath most likely to suit an individual are needed.

## V. URINE DRAINAGE BAGS AND ACCESSORIES

Urinary drainage bags are attached to an indwelling catheter or penile sheath to collect and store urine. Features of effective drainage bag systems include ease of operation of all components (connectors, taps, and support devices), comfort and discreteness.

### 1. PRODUCT CATEGORIES

Urine drainage bags fall into two major categories: leg / body worn bags for day-time usage; and large capacity body-free bags for night-time use (night drainage bag) which are suspended from a stand or bed hook.

Leg / body worn bags come with a variety of features of which the following are the most important to consider in making selections:

- **Volume:** most bags have a volume in the range of 350-750 ml, but some are bigger.
- **Material:** most bags are made from transparent PVC (polyvinyl chloride) but PVDF (polyvinylidene fluoride) (less noise from rustling), polyethylene or rubber / latex may be used.
- **Sterility:** bags may or may not be supplied sterile.
- **Wear position:** bags may be designed for wearing over the knee, across or down the thigh, down the calf, or against the abdomen.
- **Attachment / suspension system:** most bags are attached to the leg with straps, which are usually made from latex or a (usually elasticated) fabric. A variety of hooks, loops, buttons / button holes and *Velcro* may be used to secure straps and to attach bags to straps. Some bags are designed for suspension from a waist belt. Some straps and suspension devices can be bought separately from bags, but they are generally not suitable for use with all bags (**Fig V-1**).
- **Connecting tube:** bags come with a variety of connecting tube lengths (eg the length required for wearing a bag on the calf will be greater than that for the thigh). With some products the tube can be cut to the preferred length.
- **Drainage tap:** Drainable bags come with a variety of drainage tap designs (**Fig V-2**).
- **Sampling port:** bags may or may not have a sampling port for taking urine specimens.
- **Comfort features:** some bags come with features intended to increase comfort – most commonly, a fabric backing against the skin to reduce sweating.

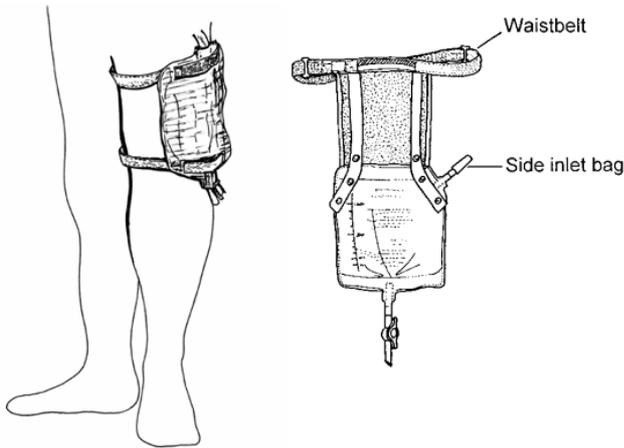


Figure V-1. Body worn urine drainage bags held in place using leg straps (left) and a waist band suspension system (right).

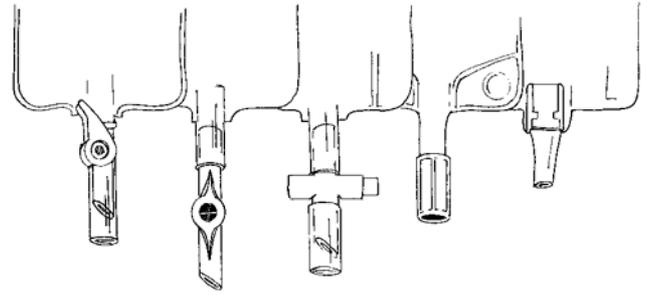


Figure V-2. A variety of urine drainage bag tap designs.

- **Discretion features:** some bags come with features intended to increase discretion – most commonly, internal welds between the front and back faces to reduce bulging and / or sounds caused by a large volume of liquid moving about as the user mobilises.
- **Anti-kinking / twisting features:** some bags come with features intended to improve drainage by reducing kinking and twisting in the connecting tube.
- **Infection reduction features:** some bags come with features intended to reduce the risk of cross infection between bag users by care givers. Such features may include a non return flap valve, a sampling port and / or a tap with an outlet sleeve which allows the overnight bag to be connected to the body worn bag. This linkage provides a mechanism to maintain a closed catheter system designed to minimise the risk of cross-infection by reducing the handling of the catheter. Having connected the night bag to the leg bag sleeve, the leg bag tap is opened and urine flows freely from the sheath or catheter through the leg bag into the night drainage bag.

Night drainage bags are usually held on a suspension system away from the body. They may be connected directly to the catheter or sheath or they may be connected to the drainage tap of the leg / body worn bag to avoid the need for repeated connections and disconnections with the catheter or sheath (Fig V-3). They usually have a capacity of 2000-4000 ml and come with a variety of design features similar to

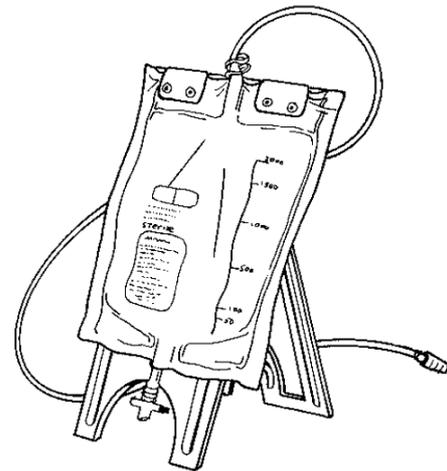


Figure V-3. A night urine drainage bag on a stand.

those for leg / body worn bags. Night drainage bags are available without a tap for single use as well as with a variety of drainage tap designs for emptying and reuse. Glass bottles are also available for high volume or overnight urine drainage.

## 2. QUALITY OF DATA

Several controlled comparative evaluations of urine drainage bags and suspension systems have been performed, as well as a small number of studies addressing infection and cross-infection issues. There is also one case controlled study which has investigated the *purple urinary bag syndrome*.

### 3. RESULTS

Kennedy et al. (Kennedy, Brocklehurst & Lye 1983) tested the performance of ten different drainage bags in a simulation study involving 40 subjects (mostly health-care staff) which focused particularly on taps. Significant differences ( $p < 0.05$ ) were found between many pairs of bags with regard to each of the performance aspects studied: ease of tap opening and closing, ability to empty the bag without urine wetting fingers; and how easy the tap mechanism was to understand. Taps comprising caps or bungs were found to be particularly fiddly and messy to use.

In a study which focused primarily on the cross-infection risks associated with leg bags, Wilson and Coates (Wilson & Coates 1996) evaluated four leg bags. Each of ten long-term catheterised patients was invited to try each bag for a week in turn. The authors concluded that no one bag suited every patient; rather, each was liked by some users. The popularity (or otherwise) of many features was a matter of personal preference. Adverse comments mostly related to the tap (difficult to operate; opened accidentally, causing leakage) and the straps.

The UK Medical Devices Agency (Medical Devices Agency 1996) evaluated all 14 sterile 500 ml leg bags on the UK market in 1995 in a multi-centre study involving 83 test subjects (58 men, 25 women). About half (44) lived in their own homes and almost all the rest in nursing/residential homes. Subjects were divided into pairs matched for sex, mobility, manual dexterity and dependency and each pair was offered each of the 14 bags (seven each) to try for a week in turn. Preferences varied but the main concerns of users consistently focused on taps (many subjects found many taps difficult to operate), straps (discomfort was common) and the minimisation of leakage (through faults in bags and/or connectors; onto the fingers when emptying; or by the tap accidentally opening in use). The most popular bags tended to perform well in these three respects.

In a multi-centre study involving 34 men (age range 27-84y; mean age 55y; all sheath users) Fader et al. (Medical Devices Agency 1999) evaluated all seven non-sterile 500-700 ml leg bags on the UK market in 1997. Twenty-five of the men lived in their own homes and the rest in residential/nursing homes or long stay wards. Conclusions were substantially similar to those for the earlier MDA study.

Thelwell et al. (Thelwell et al. 1995a) conducted a cross-over study in which 52 subjects (20 men, 32

women) compared four suspension systems for fastening leg bags with the leg straps they had used prior to the study. Each subject evaluated each product for a week in turn and recorded their findings on a weekly questionnaire. Only one of the alternative systems was considered to be as effective as the leg straps. Again, difficulty of application, comfort, discreteness and cost were key issues.

The cross-infection risks of leg bags (particularly via the tap or sampling port) have been studied by Glenister (Glenister 1987) and by Wilson and Coates (Wilson & Coates 1996). Cross-infection is an important concern in hospitals and residential settings, particularly where indwelling catheters are in use. In community settings where patients manage their own leg bag the risks are considerably reduced. In her study Glenister (Glenister 1987) concluded that designs in which the tap and outlet spouts were most widely separated were most effective at preventing contamination of the hands with urine. Wilson and Coates (Wilson & Coates 1996) studied sampling ports and contamination of leg bag spouts. They suggested that the night connector tubing attached to the taps on the four leg bags in their study made decontamination difficult.

Rooney (Rooney 1994) measured the incidence of urinary tract infection in 14 people with neurogenic bladders before and after they changed from using sterile to non-sterile urinary leg drainage bags. Ten participants were on Foley catheter drainage and four were using sheaths. Prior to the introduction of the new leg bag at least two urine specimens were collected for culture and then following the introduction of the new bag random urine specimens were collected for culture and sensitivity during the three month study period. Bedside urine collection bags were used by all participants at night and there was no change made to the standard practice of rinsing the overnight bag with water each morning and recapping the drainage tubing. The non-sterile leg bags were cleaned after each use with a dilute mixture of 8oz of chlorine bleach to 1 gallon of tap water. There were no infections found during the study period and the authors claimed that their statistical analysis of the findings demonstrated no increase in incidence of UTI attributable to use of reusable urinary bags.

There is little research to support the common practice of changing drainage bags every five to seven days. The practice appears to be based upon expert opinion, anecdotal evidence and manufacturers' recommendations. However, Keerasuntonpong et al. (Keerasuntonpong et al. 2003) undertook a randomi-

zed controlled study that compared the incidence of catheter-related urinary tract infections in a group of 79 hospitalised patients whose catheter bag was changed every three days with that for a group of 74 patients who had their bag changed at the time of the catheter change or if the bag became faulty. A urine sample for culture was obtained for each participant every seven days, on the day the catheter was removed or on the day the participant was suspected of having an infection. The findings suggest that urinary drainage bags could be left for longer than three days but the authors were reluctant to define how long as the sample size was considered too small to rule out a false-negative result. They recommended additional study.

There are occasional reports in the literature of purple discolouration in urine drainage bags – termed, *purple urine bag syndrome* (PUBS) – and there is considerable debate and diversity of opinion over the cause and significance of the phenomenon. Mantani et al (Mantani et al. 2003) conducted a case controlled study on 26 patients in three long-term wards. Fourteen (two men and 12 women) had exhibited PUBS while 12 (four men and eight women) had not. The clinical, microbiological and bacteriological backgrounds of the subjects in the two groups were compared to identify possible causes of PUBS. The findings suggest that women with urine that is alkaline and has a high bacterial yield are most likely to exhibit PUBS.

Some international standards have been developed which provide general advice on bag performance and test methods (International Standards Organisation 1988 & 1998). These standards can be useful to laboratories asked to advise on bulk buying choices. Studies which have compared leg bags and catheter valves are reviewed in section VIII.

#### 4. SUMMARY

Taken together, published studies agree that the main factors to consider in selecting leg bags are the ease of tap operation, the comfort of the straps and the minimisation of leakage (Level of Evidence 2). Bags in which the tap and outlet spout are widely separated are most likely to be effective at preventing contamination of the hands with urine and cross-infection (Level of Evidence 3). There is no evidence that non-sterile leg bags that are washed out daily with a dilute chlorine solution pose any greater risk to catheter-induced infection than sterile bags (Level of Evidence 3).

## 5. RECOMMENDATIONS

In making urine drainage bag selections particular attention should be focused on: the ability of the user to operate the tap; comfort (especially of the straps); freedom from leakage (especially from the welds and the tap); and discretion (especially visibility beneath clothing) (Grade of Recommendation C).

## 6. RESEARCH PRIORITIES

- Studies are required to determine whether or not non-sterile bags for catheter use increase the risk of infection in acute, nursing home and own home settings.
- Studies are required to establish whether the incidence of UTI is increased if bags are changed at the time of catheter change rather than weekly.
- Further studies are required to confirm that bags in which tap and outlet spout are widely spaced reduce risk of cross-infection.

## VI. BODYWORN URINALS

### 1. FEMALE BODYWORN URINALS

Pieper et al. (Pieper et al. 1989) has reviewed the many attempts to design bodyworn urine collection devices for women. The major challenge is in achieving a comfortable and aesthetically acceptable leak-proof seal with the body. Various designs have sought to achieve this by holding a collection device over the urethral meatus with the help of suction, straps, adhesive or close-fitting underwear. While none have found widespread success and usage they are available commercially in some countries.

### 2. MALE BODYWORN URINALS

The urine collection devices most commonly used by men are sheaths (see Section IV) but a variety of other products such as pubic pressure urinals are available. They comprise a ring-shaped opening or cone-shaped component which is worn around the penis (and held firmly against the pubis by means of a belt and straps) and channels urine to an integral collection bag (**Fig VI-1**). Such devices are not widely used but they can be effective for individuals whose penis is too retracted for a sheath to be suitable. There are no published evaluations of these products.

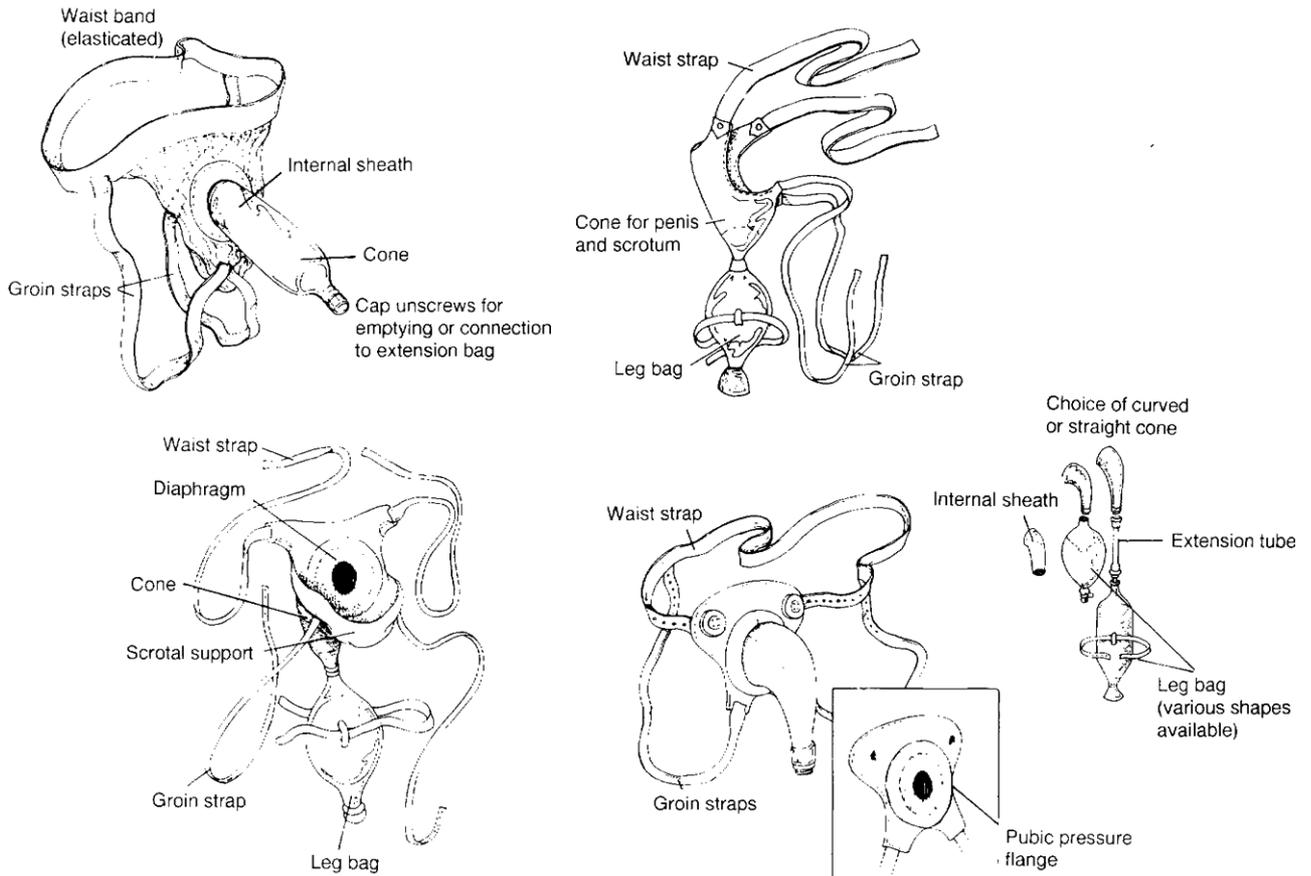


Figure VI-1. A variety of pubic pressure bodyworn urinals for men

### 3. RESEARCH PRIORITIES

There is a need for leak-free, comfortable and aesthetically acceptable body-worn urine collection devices for women and improved (in these respects) products for men.

## VII. OCCLUSIVE DEVICES FOR URINARY INCONTINENCE

### 1. FEMALE OCCLUSIVE DEVICES

Female occlusive devices fall into three categories, occluding: at the external meatus; in the urethra (intraurethral devices) or via the vagina (intravaginal devices).

#### a) Devices that occlude at the external meatus

Urethral occlusion devices have been developed to block urinary leakage at the external urethral meatus (Fig VII-1). Several devices have utilized either

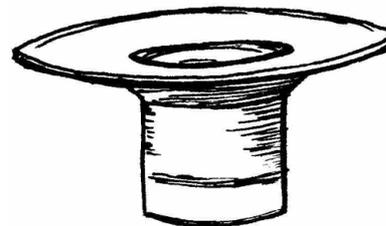


Figure VII-1. A female occlusive device that occludes at the external meatus.

adhesive or mild suction to occlude urinary loss at the urethral meatus. In addition to the simple barrier effect, compression of the wall of the distal urethra has been hypothesized to contribute to continence.

Miniguard (Uromed Inc., but no longer available) is an angularly shaped foam device which utilizes an adhesive hydrogel to adhere to the peri-meatal area. The device is single use, removed prior to voiding, and disposable. FemAssist (Insight™ Medical Corp., but no longer available) is a hat-shaped silicone device, which adheres by applying an adhesive

gel to the edge of the device, squeezing the central dome and creating a vacuum. The device is then placed over the urethral meatus and, upon release, the meatal mucosa is drawn up into the device and the urethral lumen is occluded. It may be worn for up to four hours or until voiding, after which the device is washed in hot soapy water and reapplied. The device is reusable for one week. CapSure (CR Bard Inc., now available only in USA) is applied and retained by suction. A petroleum based lubricant is applied prior to device use. The device is removed for voiding and re-utilized for up to two weeks.

## 1. QUALITY OF DATA AND RESULTS

Urinary diaries and pad weight tests were employed in all studies for objective efficacy measurements on Miniguard, FemAssist and CapSure. Incontinence input questionnaires (IIQ), visual analogue score (VAS), Quality of Life (QoL) and / or urogenital distress inventory (UDI) were also employed. Study lengths differed between centres from four weeks to three months. There have been no randomized control trials. Study designs have been open and longitudinal.

**Miniguard:** Eckford et al. (Eckford et al. 1996) studied the efficacy of a single application of this device during a one hour pad test and reported that 25% of patients were continent, 50% were improved, but 25% had worse incontinence. Brubaker et al. (Brubaker et al. 1999) recruited 648 women for a study of whom 411 enrolled, 390 used the device, and 346 completed the study. Of the 65 who enrolled but did not start the trial, 21 withdrew before device use, 17 were lost to follow-up, 12 withdrew for device-related reasons, and there were six protocol violations. Symptoms of vulvar irritation or lower urinary tract discomfort occurred in a small percentage of subjects but was generally transient, and only three women discontinued using the device for this reason. Also noted was a persistence of efficacy ( $p < 0.001$ ) four weeks following device discontinuation (Level of Evidence 3)

**FemAssist:** Versi & Harvey (Versi & Harvey 1998) studied 155 women with stress or mixed incontinence, of whom 133 attempted to use FemAssist and 96 enrolled in a four-week study. Their mean pad test loss fell from 27 g to 9.4 g ( $p < 0.001$ ) and 49% were dry. Symptomatic cure was more likely in those with mild incontinence. Of the nine women who had a positive pad test ( $> 2$  g) without the device, five were dry ( $< 2$  g) with the device ( $p < 0.05$ ). VAS scores showed a significant improvement for the symptom of stress incontinence ( $p < 0.05$ ). QoL scores improved

significantly by 38% ( $p < 0.05$ ) for the IIQ and 29% ( $p < 0.01$ ) for UDI (Level of Evidence 3).

Moore et al. (Moore et al. 1999b) reported on 57/100 recruited women who completed a one-month trial. Reduction of incontinence was statistically significant for pad testing, which revealed that 47% of the patients became continent and 33% had more than 50% benefit compared to baseline, while 9% had worse leakage. Those with severe baseline leakage were equally likely to respond as those with mild or moderate pad test loss. Women with stress urge or mixed incontinence appeared to respond equally well. Dropouts included 13% who were unwilling to utilize the device (Level of Evidence 3).

Tincello et al. (Tincello, Bolderson & Richmond 1997) in a 3-month prospective study involving 27 women with urodynamic stress incontinence found the median (range) loss with and without the device was 4.9 (0-65) ml and 21 (1-94), respectively ( $p < 0.01$ ); and 20 patients were less wet when using the device. Discomfort was greater among the women with a greater loss. The acceptability correlated negatively with discomfort ( $r = -0.53$ ) and negatively with embarrassment ( $r = -0.39$ ); 15 patients (56%) reported that they would use the device in the long-term (Level of Evidence 3). Tincello et al. (2000) later reported on 41 women recruited to use the device over a 3 month period, but 10 declined to participate, 6 withdrew before 2 weeks, 10 failed to attend 2 week follow-up and 11 did not attend 3 month follow-up. Only 2 completed the study. There was no difference in pad test or voiding diary grades. The authors concluded that the device had low acceptability and was ineffective, and could not be recommended for nonsurgical management of stress incontinence (Level of Evidence 3).

**CapSure:** Bellin et al. (Bellin et al. 1998) reported on 88/100 completers after 12 weeks, with 82% elimination of leakage on pad test, 91% continent on provocative stress test (single cough assessment of leakage), and 48% dry and 40% improved on urinary diaries. Pad test leakage decreased from 6.67 g (range 0.55-25.95 g) to 0.19 g (range, 0-2.5 g) by week 12. Five patients withdrew secondary to vaginal irritation and three due to poor device fit (Level of Evidence 3).

Shinopoulos et al. (Shinopoulos, Dann & Smith, III 1999) carried out a multi-centre study enrolling 100 women with stress incontinence who wore the device for 12 weeks. 84 women completed the study. Mean pad weights reduced from 6.7g at baseline to 0.19 by week 12. Complications affected 7 patients including urethral/vaginal swelling and vulval abra-

sion, but none of the affected patients withdrew from the study. The IQOL tool showed significant mean improvement from 62.3 to 90.4.

## 2. SUMMARY

Since the publication of the second edition of *Incontinence* (2002), there has not been a single clinical trial or any publication related to the use of external urethral occlusive devices. The only FDA-approved devices - Miniguard, FemAssist and CapSure - are no longer being distributed to the public.

External urethral occlusive devices were found to be of varying efficacy, with minimal morbidity. Efficacy of the combined studies reveals a continence rate of approximately 50% dry and 2/3 of patients improved. Devices achieve occlusion either by blocking at the meatus or compressing the distal urethral lumen and adherence to the peri-meatal area is essential to success. However, the method and degree of adherence is also the determining factor for the type and severity of local irritation. Patient selection based on motivation, appropriate anatomy, and manual dexterity, in combination with efficacy and morbidity will determine overall satisfaction. There is no data which compares one extra-urethral device to another, or to other categories of products. Cost comparisons for disposable versus short-term reusable devices are not available. Efficacy for different grades of incontinence has not been established. The objective degree of continence improvement in the clinical laboratory (pad and stress tests) is greater than in community use (diaries).

## 3. RECOMMENDATIONS

Although these devices have proved effective for some women, it appears that they have failed to find popularity with users and clinicians. They are no longer commercially available and so no recommendation on their use can be made.

## 4. RESEARCH PRIORITIES

Further research on the development and role of devices which block urinary leakage at the external urinary meatus, with a focus on improving patient acceptability are recommended. One half of patients utilizing these devices in monitored studies were dry and 2/3 of the patients were improved with minimal morbidity. These devices may have a future role in the algorithm of conservative treatment based on patient acceptance, availability and cost, especially in those patients with mild or moderate stress; incontinence who prefer to avoid pads or surgery.

## b) Intraurethral devices

Urethral inserts are silicone cylinders that are self-inserted or removed at the patient's discretion. They are intended for day-time use, especially during vigorous physical exercise. While some women manage exercise incontinence by limiting fluid intake before or during exercise, by choosing sports that allow frequent bathroom access, or wearing absorbent pads, 20% to 40% of women cope with leakage by ceasing exercise (Dunn, Brandt & Nygaard 2002). These devices present external retainers or flanges to prevent intravesical migration and proximal balloons to hold the device in place. They act by causing occlusion either in the urethra itself or at the external urethral meatus Balmforth & Cardozo (Balmforth & Cardozo 2003). (**Fig VII-2**)

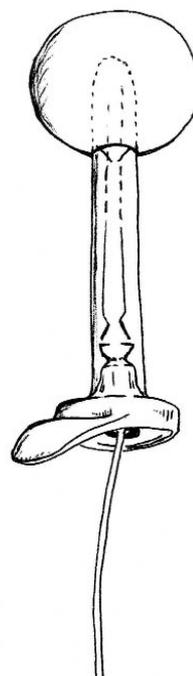


Figure VII-2. A female intraurethral occlusive device.

The FemSoft (Rochester Medical Corporation) is the only urethral insert currently distributed. It has a soft, compressible, mineral oil-filled silicone layer with an insertion probe. Before insertion, the fluid distends the proximal end of the cylinder, as the user pushes the device (guided by the insertion probe) into the urethra, fluid transfers automatically to the distal end, allowing the device to pass through the urethra. Once in place, fluid flows back to the proximal end to hold the device in place. None of these devices are recommended for reuse after removal.

The FemSoft Insert is currently packaged in a box of 28 inserts and each box is priced at \$49.95. The Viva (Nielsen et al. 1993) and Reliance devices, other intraurethral devices also mentioned in this sub-section, are not currently marketed.

### 1. QUALITY OF DATA AND RESULTS

The objective efficacy measurements utilized were the one-hour pad test, voiding diary and quality of life questionnaires. There have been no randomized control trials.

Nielsen et al. (Nielsen, Walter, Maegaard & Kromann-Andersen 1993) and Peschers et al. (Peschers et al. 1996) studied the Viva device. Peschers screened 53 patients with USI and 21 patients accepting treatment with the two sphere device. During a four month study, the investigators analyzed subjective improvement and performed pad-weight and cough tests. Nielsen et al. (Nielsen, Walter, Maegaard & Kromann-Andersen 1993) demonstrated 94% improvement on leakage and Peschers 67% improvement.

Staskin reported on a four month study of 135 of 215 patients who utilized a disposable balloon tipped urethral insert made from thermoplastic elastomer, inflated with an applicator on insertion and deflated by pulling a string at the meatal plate for removal during voiding (Reliance) (Uromed Corp., but no longer available). 80 subjects discontinued the device prematurely, the main reasons being discomfort and inability or unwillingness to use the device. Miller et al. (Miller & Bavendam 1996) and Sand et al. (Sand et al. 1999) then reported on 63 of the 135 patients from the above cohort who utilized the device for one year.

The Reliance device provided 72% complete dryness with 17% improvement on diary, and 80% complete dryness and 15% improvement on pad weight testing for Staskin et al. (Staskin et al. 1996) 79% complete dryness and 16% significant improvement on objective pad weight studies consistent with the improvement in subjective diaries ( $p < .0001$ ) for Miller & Bavendam (Miller & Bavendam 1996). The patients reported improved comfort and ease of use over time, with sensation of device presence decreasing from 35% at week one to 7% at 12 months for. The volume of urine lost during exercise decreased from a median of 20 gram (range 4.9-80.2 grams) without the insert to 2.6 grams (1.3-6.8) when the insert was worn ( $p = .03$ ). On a 5-point scale in which 1 represented very comfortable and 5 very uncomfortable, subjects rated the mean comfort for the sessions performed with the insert in place as 2.1.

Treatment for positive urine cultures was undertaken in 20% of symptomatic and 11% of asymptomatic patients, 39% of patients had positive cultures which were not treated and 30% had negative cultures at all monthly intervals for the four month study. The main reason for drop-out was discomfort (Staskin, Bavendam, Miller, Davila, Diokno, Knapp, Rappaport, Sand, Sant & Tutrone 1996). One or more episodes of gross hematuria (24%), cystoscopic findings of mucosal irritation at 4 or at 12 months (9%) and asymptomatic bacteruria (30%) on monthly cultures were also documented (Miller & Bavendam 1996).

Boos et al. (Boos et al. 1998) reported in an abstract, a randomized prospective parallel group trial comparing the Reliance intra-urethral insert with the FemAssist external meatal occlusive device. Assessments at baseline, one month, and three months included subjective efficacy, seven day diary, and pad test (1 hour). Fifty-three females were randomized to FemAssist and 49 to Reliance device. There were some initial problems with sizing the Reliance. Once this was corrected, 40.8% (20) of women were subjectively dry and the remainder improved on completing the trial. Of women using the FemAssist, 28.3% (15) were dry, 60.4% (32) were improved, 9.4% (5) were no better and only one subject was made worse with device use. Problems experienced were few and minor with no serious adverse events. The conclusion was that both devices are efficacious, the FemAssist was more comfortable, but required a greater degree of user skill to achieve control of leakage (Level of Evidence 2).

Recent studies have investigated the efficacy of the FemSoft which is the only intra-urethral device which is currently available. Dunn et al. (Dunn, Brandt & Nygaard 2002) measured pad weights during four standardized aerobics sessions during which six subjects were randomly assigned to exercise twice with the insert and without it. The medians of the averaged pad weights for the two different types of sessions were compared. Median urine loss during standardized exercise sessions decreased from 20g (range, 4.9 to 80.2g) without the device to 2.6g (range, 1.3 to 6.8g) with the device ( $P = 0.03$ ). Five women used the device at home during unsupervised exercise; one subject had urinary tract infection. At the end of 3 months, satisfaction and comfort were rated high on a 5-point scale. The conclusion was that the FemSoft urethral device is an effective, safe, and comfortable treatment for exercise incontinence in women (Level of Evidence 3).

Results from a prospective three-year study, (FDA

post-approval device safety data submitted by Rochester Medical Corporation, 2002 unpublished), for evaluation of the long term effect of the device involved 41 subjects. Of the group, nine women were 65 years or older (22%, 9/41); 80% were post-menopausal with 24 women (59%) being on hormone replacement. Thirty-eight, (93%) used absorbent products to contain urine leakage prior to enrolment. A total of 66 follow-up visits took place with an average participation period of 4.2 years. Seven patients withdrew in the third year, three due to non-study related health problems and one because of dissatisfaction due to urge symptoms. Two were lost to follow up. There was a significant difference in the rates of incontinence at the three-year follow-up between users and non-users of the device: 0.83 vs 2.64 episodes per day, according to voiding diaries. The difference in urine loss during pad weighing tests was also significant. There were 24 reported adverse events in the 41 subjects enrolled. None of these events required medical intervention except for antibiotic prescription in cases of urinary tract infection. The 24 events included: bacteriuria (11); symptomatic UTI (3); urinary symptoms (3); device performance problems (2); irritation (2); and migration (1).

In 33 women a total of 38 cystoscopies were performed at three years. Only one patient was reported to have an abnormal finding, but this was due to mucosal irritation produced by an indwelling Foley catheter during one hospitalization for a problem unrelated to the device. Patient satisfaction had not changed over the follow-up time interval. The Quality of Life questionnaire (I-QoL) scores at three years were compared to those at 12 months and there was improvement from the baseline of 60.6 to 74.0. No safety concerns concerning urethral integrity were identified after the three years of continuous use. The incidence of urinary tract infections, given the high number of insertions and removals, was considered low risk (Level of Evidence 3).

## 2. SUMMARY

Intraurethral devices have demonstrated high efficacy, but have been associated with urinary tract infection, hematuria and discomfort. Bacteriuria, without symptomatic infection, was similar to extraurethral device use, which approaches screening urinalysis data (Brubaker, Harris, Gleason, Newman & North 1999), or may be similar to the rates seen with self catheterization. Device migration into the bladder, which requires endoscopic removal is the most serious reported problem.

Long-term results are limited. Patient and physician acceptance of this form of therapy has also been limited. The patient needs to have good hand dexterity in order to use the device and the cost is also a factor that precludes more widespread use (Level of Evidence 3).

## 3. RECOMMENDATIONS

Intraurethral occlusive devices may be considered for women with stress incontinence but they are invasive devices with high cost and have had limited evaluation. They may be most appropriate for intermittent and occasional use (such as during vigorous exercise) (Grade of Recommendation C).

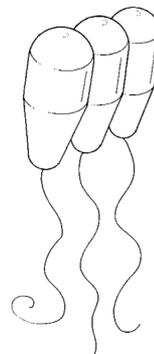
## 4. RESEARCH PRIORITIES

It is important that new devices and in particular invasive ones, be evaluated by randomized trials and comparing to control approved devices. Long-term follow-up results are needed to demonstrate the effects of such devices on the urethra and/or bladder and will determine the real value and safety of devices that initially have been adopted enthusiastically.

Further development and study of the use of intraurethral devices for the treatment of urinary incontinence is recommended. The role of intraurethral devices in patients who do not achieve the desired efficacy with other forms of conservative therapy, and to avoid surgery, requires further study.

### c) Intravaginal devices

Support of the bladder neck to correct urinary stress incontinence has been achieved, with varying success utilizing traditional i) tampons, ii) pessaries and contraceptive diaphragms, and iii) intravaginal devices specifically designed to support the bladder neck (**Fig. VII-3**).



*Figure VII-3. A female intravaginal occlusive device.*

## 1. QUALITY OF DATA AND RESULTS

### Tampons/pessaries:

Nygaard, I. (Nygaard 1995) performed a prospective, randomized, single blind, and laboratory based study testing 18 patients (age 33-73) with three 40 minute standardized aerobics sessions, utilizing a Hodge pessary, a super tampon, or no device. Urine loss was determined by a change in the weight of the pad worn while exercising. Statistical analysis of the log of urine loss revealed that women lost significantly less urine when exercising with either the pessary or the tampon than when exercising with no device. Continence rates were 6/14 cured and 2/14 improved with tampons, 4/10 improved with a diaphragm (Level of Evidence 2).

### Diaphragms / Pessaries

Realini & Walters (Realini & Walters 1990) analyzed the benefit for one week, in 10 selected patients of a coil-type diaphragm ring, which was softer than a pessary, utilizing diaries and a two hour pad test. They also gave an overall subjective evaluation of their experience. Urodynamic findings were essentially unchanged by wearing diaphragm rings. Four of the 10 women experienced clinically significant improvement in amount of urine lost during pad tests, number of leaks per week, and overall assessment response.(Level of Evidence 3).

Suarez, et al. (Suarez, Baum & Jacobs 1991) included urodynamic testing in his evaluation of a contraceptive diaphragm in 12 patients. Complete resolution of SUI was achieved in eleven of twelve patients (91%); two of the twelve achieved continence but withdrew from the study because of associated discomfort from the diaphragm, therefore, complete resolution of SUI was achieved in 9/12 patients (75%) (Level of Evidence 3).

Bhatia et al (Bhatia & Bergman 1985) reported on the urodynamic effects of the Hodge pessary on 30 women aged 29 to 71 with a history of UI. With the pessary, 24 of the 30 patients became continent when tested in supine position with a full bladder, 3 of the 24 patients lost urine with coughing in the standing position and demonstrated a positive cough profile despite the presence of the vaginal pessary. Uroflowmetry data show that the vaginal pessary did not produce any obstruction to the free flow of urine and suggested this is a modality to predict the outcome for bladder neck support surgery.

### Intra-vaginal devices designed specifically to support the bladder neck:

Included in this category are:

1. Removable reusable intra-vaginal ring, composed of silastic, and constructed with two prongs which are placed behind the symphysis to support the bladder neck (Introl, no current distributor).

2. Three different single use disposable devices:

A clam-type device composed of polyurethane foam, which is folded up upon its long axis and placed into the sagittal plane in the vagina, and when moistened, its dimensions expand by 30% and create a supportive cushion under the urethrovaginal junction (Conveen Continence Guard, Coloplast, Denmark). A newer version of the expanding polyurethane design, with similarities to a tampon, (Conveen Continence Tampon, Coloplast, Denmark). An expanding polyvinyl alcohol sponge (Ladycon, Home Care Engros, Norway),

### Reusable intra-vaginal ring (Introl)

A pilot laboratory study was carried out by Biswas, (Biswas 1988), the developer of the device, employed a straining cystogram. 86% of the patients were continent with the device in place on cystogram. Following this study, the number of device sizes was increased from 8 to 25. Evaluation studies followed examining efficacy, safety and satisfaction. Davila (Davila 1996) initially demonstrated that 83% of patients were dry on pad weight test. Later (Davila et al. 1999) the researchers enrolled seventy women (53 completed) ages 24-76, 29 with stress, and 24 with mixed incontinence in a 1-month study. A statistically significant reduction in incontinence was noted on pad testing (stress mean 46.6-16.6g; mixed, mean 31.9-6.8 g) and in bladder diary (stress, mean 28.6-7.8 losses per week; mixed, mean 30.2-15 losses per week) QoL scores (I-QoL) improved in both groups. With the device in place, urodynamic testing indicated normalization of urethral function without evidence of outflow obstruction. Subjects found the device comfortable, easy to use and convenient. Side effects include five urinary tract infections and 23 cases of vaginal soreness or mild irritation (Level of Evidence 3).

Moore (Moore et al. 1999a) detailed problems with both sizing and efficacy. Of the 80 recruits, four could not be fitted, and 11 did not satisfy all entry criteria. Of the 65 participants, 39 (60%) withdrew; 20 for distorted vaginal anatomy which made fitting difficult, five for lack of efficacy, four for constipation, and ten for unrelated patient events. In the remaining 26 patients, pad test weights decreased from a baseline median of 19 g to 2 g ( $p < 0.001$ ), 62% were continent, and 15% were >50% improved,

and wished no further therapy. Moore commented that the device was difficult to fit in women who have had multiple vaginal surgeries or were oestrogen deficient. Long-term follow-up showed that 18 of 26 (from the original 65) continued to wear the device at six months (interim dropouts being due to concurrent illness in half, the remainder had declining efficacy). Of these, 78% continued to wear the device for a minimum follow-up of two years (Level of Evidence 3).

In a separate study of patients with mixed incontinence by Moore et al. (Moore, Simons, Dowell, Bryant & Prashar 1999b), five of 21 recruits never wore the device home, leaving 16 participants. A further two did not reach week four, because of poor efficacy or inability to fit the device. In the 14 who reached week four, the median number of leaks/day declined from 4.3 to 1.0 ( $p = 0.002$ ). Median pad weight loss fell from 53 to 7g. ( $p = 0.012$ ). Cystometry showed an increase in maximum bladder capacity ( $p < 0.05$ ) and a modest reduction in severity of detrusor overactivity, with no evidence of outflow obstruction. Three women discontinued because of poor efficacy or a poorly fitting device, leaving 11 of 16 participants (69%) at week eight, when median pad weight decreased to 2ml (Level of Evidence 3).

Kondo et al. (Kondo et al. 1997) found no urinary flow obstruction with the device in place. Urine loss decreased from 20.6 to 4.8 gm. per hour ( $p < 0.001$ ) on the 60-minute pad weight test. Twenty two patients (29%), reported complete continence, and 39 (51 %) had decreased severity of incontinence by more than 50%. Minor adverse effects occurred in 26% of the patients. According to the global usefulness rating which was employed, 62 patients (81%) had some or maximum benefit (Level of Evidence 3).

### **Disposable intra-vaginal devices**

Thyssen & Lose (Thyssen & Lose 1996), tested the Contience Guard in 26 women with stress incontinence before and after one month's use: four women discontinued the treatment because of discomfort or difficulties in using the device 9 (41%) were subjectively cured of incontinence, 10 (45%) improved while three (14%) claimed unchanged incontinence. With the device in place all had decreased leakage at the 24-hour pad weighing test and unchanged urodynamic tests. No vaginal or urinary infections were found (Level of Evidence 3).

Thyssen et al. (Thyssen, Sander & Lose 1999) reported on 19/22 women with stress incontinence, sub-

jectively and objectively cured or improved in a short-term study, and who then continued the treatment with the device for one year. All 19 completed the study, 13 (68%) were subjectively dry, (26%) were improved and one (5%) reported unchanged incontinence. All but one had decreased leakage at the 24h pad test, and 67% a greater than 50% decrease. Subjectively cure was 41%, and 36% were dry on 24 hour pad test. Overall reduced leakage was statistically significant ( $p < 0.0005$ ) No significant changes were found in the other urodynamic measurements, specifically, urinary flow rate.

Sander et al. (Sander et al. 1999) found subjective cure in 11/55 women (20%) and improvement in 27/55 (49%) was reported. Results of the 24-hour pad test and mean leakage and episodes in the voiding diary significantly decreased. After three months, 58% of the 55 patients desired to continue device usage. There was a highly significant improvement in QoL scores using the IIQ, as well as two additional incontinence-related quality of life questionnaires. Responses to the SF-36 general health questionnaire showed no significant changes

Hahn & Milsom (Hahn & Milsom 1996) reported on 121 women, in a four week study. Patients dropped out because of vaginal irritation (25%), other product related reasons (6%), lack of time (6%), or failure to complete a user questionnaire. Of the remaining 90 (mean age 47.5), 85 performed a 24 hour pad test, which showed that baseline leakage of 42 ml/ 24h decreased to 14 ml/ 24h ( $p < 0.001$ ). Of these, 39 (46%) were continent. The device was considered unpleasant by 8%, and caused some local discomfort in 62% on direct questioning: 75% of these wished to continue using the device. The authors noted that older women (age 56-65) tolerated the device and appeared more motivated to continue. Coexistent atrophic vaginitis and the use of topical oestrogen was not discussed

Thyssen et al. (Thyssen et al. 2001) reported on 94 women recruited in a cross-over study, which compared two versions of the same device; the Conveen Contience Guard (CCG) and the Contrelle Contience Tampon CCT. 62 women (66%) completed the study with withdrawals mainly due to discomfort or for unknown reasons. Both devices reduced leakage significantly but the CCT was significantly better than the CCG. Few side-effects were reported. Thirty-two women continued the treatment for one year or more with 63% preferring the "tampon" type design for its ease of use.

The report on the polyvinyl sponge by Glavind (Glavind 1997) was an acute laboratory study of only six women utilizing a pad test measurement during 30 minutes of aerobic exercise. Without the vaginal sponge the patients had a mean loss of 7 g (range 2-18 g) during exercise. With the vaginal sponge in situ there was no leakage.

## 2. SUMMARY

Support of the bladder neck resulting in improved continence is possible with intravaginal devices without evidence that they cause significant lower urinary tract obstruction or morbidity (Level of Evidence 3).

The reusable Intrl device was shown to be an effective device for selected patients but there were problems with sizing especially in patients with prior vaginal surgery or with vaginal atrophy. However the device is not currently marketed.

Efficacy with the Conveen polyurethane expanding “clam” device was demonstrated with selected patients and difficulties with insertion appear to have been improved by the introduction of the ‘tampon’ type device. The device is currently marketed (Coloplast - [www.coloplast.com](http://www.coloplast.com)).

Studies performed in the acute setting, regardless of the device type, demonstrate better performance than diary based studies performed over time. Efficacy is also higher in patients with minimal to moderate urinary leakage.

Relatively high drop-out rates in monitored studies, during which patient support is provided, indicates the need for proper patient selection and patient and provider education (Level of Evidence 3).

## 3. RECOMMENDATIONS

Vaginal support devices should be included in the treatment option when managing women with stress urinary incontinence, dependent upon the availability of product, patient ability to manage the product (particularly manual dexterity) patient acceptance and cost (Grade of Recommendation C).

## 4. RESEARCH PRIORITIES

Long-term results are not available and studies comparing these therapies to other forms of conservative therapy or surgery are needed

## 2. MALE OCCLUSIVE DEVICES

Male occlusive devices aim to prevent urine leakage by compressing the penis. A variety of designs are available but occlusion is usually achieved with either a clamp or a peri-penile strap (Fig VII-4). Such devices have the potential advantages of low cost and simplicity compared with a sheath and drainage bag.

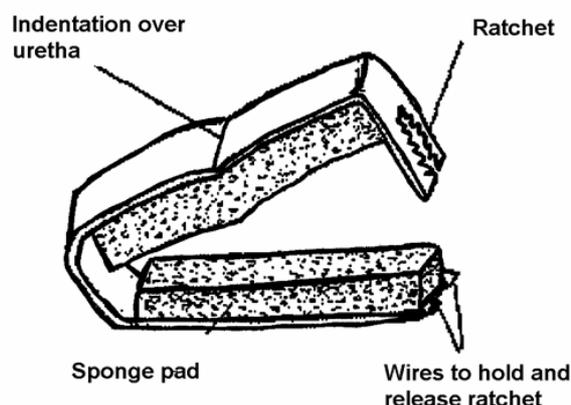


Figure VII-4. A penile clamp.

### a) Quality of data

The use of penile compression devices is described only rarely in the literature (Chye 1990); (Fantl, Newman & Colling 1996) and is usually referred to as a last resort where other forms of management have failed or been judged inappropriate. There has only been one published evaluation (Moore et al. 2004).

### b) Results

Moore et al. (Moore, Schieman, Ackerman, Dzus, Metcalfe & Voaklander 2004) evaluated three different devices (Timms C3 penile compression device; Cunningham clamp; and U-Text male adjustable tension band) in a cross-over study in which twelve men with stress urinary incontinence following radical prostatectomy tried each device in turn. Each of the devices significantly ( $p < 0.05$ ) reduced mean urine loss (measured using a 4h pad tests) compared with baseline measurements. There was some objective or subjective improvement in continence for each of the 12 men with at least one of the devices, although none completely eliminated urine loss when applied at a comfortable pressure. Ten of the 12 men rated the Cunningham clamp positively; two, the C3; and

none, the U-TEX. However, the C3 and U-TEX allowed good cavernosal artery blood flow while the Cunningham clamp significantly reduced it. Overall they concluded that, used correctly, the Cunningham clamp can be an effective method of controlling urinary incontinence in men with stress urinary incontinence who are cognitively intact and aware of bladder filling, and have normal genital sensation, intact penile skin and sufficient manual dexterity to open and close the device.

#### c) Summary

Male occlusive devices can be effective at preventing urinary leakage but is likely to lead to reduced cavernosal artery blood flow and therefore care must be taken to ensure regular removal or release. (Level of Evidence 2).

#### d) Recommendations

Male occlusive devices should be considered for selected men with stress urinary incontinence who are cognitively intact and aware of bladder filling, and have normal genital sensation, intact penile skin and sufficient manual dexterity to open and close the device (Grade of Recommendation C).

#### e) Priorities for research

There is a need for occlusive devices for men which are discrete, easy to use and which prevent leakage without risk of tissue damage.

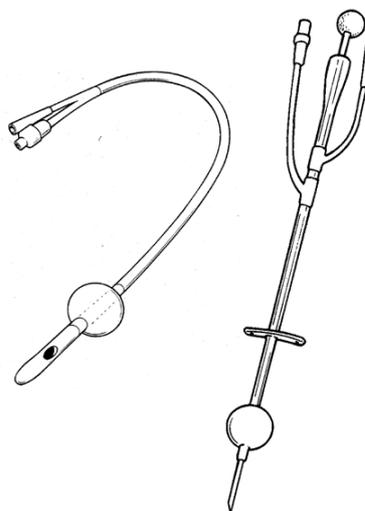
## VIII. CATHETERS

Urinary catheters can provide an effective way of draining the bladder in either the short-term or long-term, by intermittent or indwelling catheterisation. However they are rarely completely trouble-free and alternative strategies should be considered where possible. This section examines the characteristics of urinary catheters, and provides a critical review of existing evidence to guide choice of catheter material, and catheter management strategies to minimise associated risks. This sub-section deals with generic issues while (Subsequent) sub-sections focus on the specific evidence base relating to indwelling catheterisation (urethral and suprapubic) and intermittent catheterisation (CIC), respectively.

### 1. INDWELLING CATHETERS

Indwelling catheters (**Fig VIII-1**) may be inserted into the bladder urethrally (UC) or suprapubically (SPC) through an incision in the abdominal wall.

Short-term catheterisation is commonly considered to be up to 14 days (Brosnahan, Jull and Tracy, 2004) and long-term catheterisation more than 14 days (Niel-Weise and van den Broek, 2004).



*Figure VIII-1.A Foley catheter (left) and a suprapubic catheter with a sharp trocar for introducing the catheter (right).*

#### **Short-term catheterisation is most commonly used:**

- During surgical procedures and post-operative care.
- For accurate monitoring of urine output in acute illness.
- Instillation of medication directly into the bladder.
- For relief of acute or chronic urinary retention.

#### **Long-term catheterisation may be necessary in the management of patients with:**

- Bladder outlet obstruction, who are unsuitable for surgical relief of BOO.
- Chronic retention, often as a result of neurological injury or disease (where intermittent catheterisation is not possible).
- Debilitated, paralysed or comatose patients (in presence of skin breakdown and infected pressure ulcers).

- Intractable urinary incontinence where catheterisation enhances the patient's quality of life (only as a last resort when alternative non-invasive approaches are unsatisfactory or unsuccessful).

Indwelling catheters should be promptly removed if no longer needed since their use is associated with a number of risks / complications.

***a) An effective indwelling catheter should have the following characteristics:***

***Material:***

- Soft for comfort.
- Causing minimal tissue reaction or friction.
- Sufficiently firm for easy insertion and maintenance of lumen patency in situ.
- Elastic recoil so that an inflated balloon can deflate to almost its original size.
- Resistant to colonisation by micro-organisms and to encrustation by mineral deposits.

***Design:***

- Retained in the bladder effectively, yet easily removable without trauma to tissue.
- Soft 'tip' within bladder to avoid pressure damage to mucosa.
- Effective drainage while minimising risk of bladder mucosa being 'sucked' into drainage channel.
- Conforms to shape of urethra.

***b) Benefits versus catheter-associated risks and long-term complications***

Decisions on the management of bladder dysfunction by catheterisation need to consider both quality of life of patients / clients and the potential benefits of catheterisation compared to well-recognised catheter-associated risks and possible long-term complications, which include:

- Catheter-associated infection with potential to lead to life-threatening bacteraemia. Possible urethritis, epididymitis, prostatitis, pyelonephritis.
- Tissue damage (including meatal erosion, urethral stricture formation) arising from trauma, pressure and/or inflammatory reactions.
- Long-term inflammatory/ neoplastic changes in bladder tissue.
- Bladder calculi.
- Frequent bladder spasm which may result in leakage and / or the catheter being expelled.

- Catheter encrustation (linked to infection), leading to recurrent blockage.

The major risk associated with short-term, indwelling catheters used in acute care, is nosocomial (healthcare acquired) urinary tract infection, with a catheter being present in around 80% of such infections (Stamm 1998). Long-term catheters are also subject to further risks (indicated above) and are rarely completely trouble-free. Although for some patients a catheter can provide satisfactory management of bladder problems and greater independence, others experience pain and discomfort with a catheter in situ and / or are distressed by the impact of a catheter on their body image and sexuality. Overall, long-term indwelling catheters should be avoided where effective alternatives are possible, to minimise hazards to patients and detrimental impact on patients' and carers' quality of life.

Intermittent catheterisation is generally associated with fewer risks.

***c) Catheter materials – tissue reaction***

Catheters are made of a variety of materials including polyvinyl chloride (PVC or plastic), latex rubber with or without a coating, silicone rubber or metal. Plastic catheters are relatively cheap to manufacture, have a thin wall and relatively large lumen, and are designed for short-term use (in situ up to 14 days). Plastic catheters without a balloon are generally used for CIC. Some of these are coated with hydrophilic polymers that absorb water leading to a softer and more flexible catheter with a slippery surface with a low coefficient of friction. Latex catheters are restricted to short-term indwelling use (and commonly avoided where possible) because of potential discomfort due to high surface friction, vulnerability to rapid encrustation and the implication of latex allergic reactions in the development of urethritis and urethral stricture (Cox et al. 1989); (Ruutu et al. 1982), (Ruutu et al. 1984); (Nacey, Tulloch & Ferguson 1985); (Pariante et al. 200)). Ruutu et al. (Ruutu, Alfthan, Heikkinen, Jarvinen, Lehtonen, Merikallio & Standertskjold-Nordenstam 1982) reported an epidemic of urethral strictures following cardiac surgery and further studies (Graham, Mark & Pomeroy 1983) confirmed latex catheter materials contained substances toxic to cells in culture. Silicone catheters were not associated with toxicity and stricture formation (Ruutu et al. 1985); (Nacey & Delahunt 1991). Current catheter materials are required to conform to designated standards which include toxicity testing.

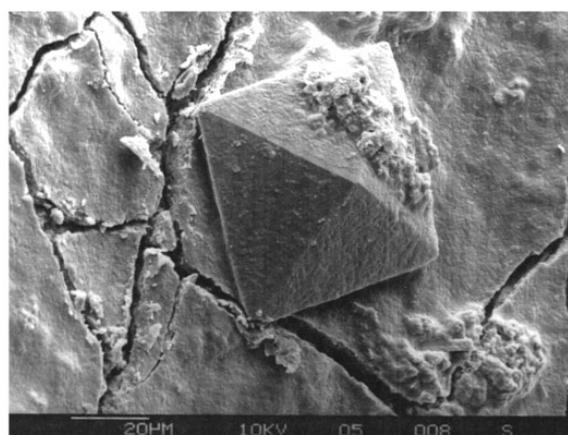
Attempts to minimise friction during catheterisation and to reduce tissue reactions have led to the coating of latex catheters with tightly bonded materials designed to provide a smoother, less irritant surface which also minimizes absorption of water by the latex (and subsequent changes in internal and external catheter diameters). Polytetrafluoroethylene (PTFE or teflon) coated latex catheters are sometimes used for medium-term use (catheter can remain in situ up to 28 days) but the current materials known to cause minimal friction and tissue reaction are silicone elastomer and hydrophilic polymer-coated catheters or all-silicone catheters (Talja, Korpela & Jarvi 1990) (**Table VIII-1**). These materials are therefore recommended for long-term use (each catheter expected to remain in situ for more than 14 days prior to replacement as part of a strategy for long-term case).

**d) Catheter material – microbial colonisation and biofilm formation**

The risk of bacteriuria (presence of bacteria in the urine) increases by 5-8% per day of indwelling catheterisation (Garibaldi et al. 1974); (Mulhall, Chapman & Crow 1988); (Stamm 1991); (Nicolle 2001) and therefore all long-term catheterised patients are likely to be bacteriuric within 4 weeks. A majority of microorganisms derive from the patient's own colonic and perineal flora or from the hands of health-care personnel during catheter insertion or management (Maki & Tambyah 2001). Access is gained in two ways: (1) extraluminally during catheter insertion or via the periurethral space; and (2) intraluminally following breaks in the closed system or contamination of urine in the drainage bag. The comparative importance of these routes is difficult to

determine, but animal models have demonstrated rapid colonisation via the intraluminal route following a break in the closed system, compared to the extraluminal route (32-48 hours v 72-168 hours respectively) (Nickel, Grant & Costerton 1985). However, clinical studies have shown that colonisation will occur even when strict infection control practices are adhered to (Garibaldi, Burke, Dickman & Smith 1974).

Electron microscopy of catheter surfaces has shown that indwelling catheters rapidly become colonised by a thick layer of infecting micro-organisms embedded in a matrix of host proteins and microbial exopolysaccharides, forming a strongly adherent biofilm (Nickel et al. 1994) (**Fig VIII-2**). Microorganisms growing as a biofilm are less susceptible to antimicrobial therapies than free-living organisms (Stickler et al. 1989) and most catheters removed after 7 days or more will be colonized by a bacterial biofilm, comprising a mixed community of organisms.



**Figure VIII-2.** Scanning electron micrograph of a section through a catheter luminal surface showing a thick biofilm layer (and a crystal of calcium oxalate).

**Table VIII-1.** Catheter materials

Duration of catheterisation		Catheter material
Intermittent	Removed immediately after urine drainage -	- plastic: with or without hydrophilic polymer coating - metal
Indwelling, short term use	Catheter expected to be in situ for up to 14 days	- latex or plastic - PTFE-coated latex - silver-alloy coated (catheter materials recommended for long-term use may also be selected)
Indwelling, long-term use	Catheter expected to be in situ for more than 14 days than (recommended time between catheter changes depends on local catheter policy - may be up to 12 weeks if trouble free)	- silicone elastomer-coated latex - hydrophilic polymer-coated latex - all-silicone

Efforts to reduce the risk of catheter-associated infection have included development of catheters with antimicrobial surfaces, such as silver. Silver ions are bactericidal (Fox & Modak 1974), are non-toxic to humans when applied topically, and have been used successfully in other areas of infection control such as burn wounds. Silver ions are purported to have broad spectrum activity against Gram-positive, Gram-negative, aerobic and anaerobic organisms. Early silver-coatings incorporated silver oxide onto the external surface of the catheter material only. Subsequently, silver-alloy coatings were developed to provide an integral coating of both internal and external surfaces and promote a slow release of silver ions. Other attempts to produce an antimicrobial coating have been directed towards impregnation with antibiotic or antiseptic agents. Urinary catheters have been coated with polymixin (Butler & Kunin 1968), cephalothin (Lazarus et al. 1971), kanamycin (Cheng 1988), dibekacin (Platt et al. 1983), nitrofurazone (Johnson, Delavari & Azar 1999); (Leclair et al. 2000), rifampicin and minocycline (Darouiche et al. 1999), chlorhexidine, silver sulfadiazine and triclosan (Gaonkar, Sampath & Modak 2003), ciprofluoxacin (Pugach et al. 1999) and gentamicin sulphate (Cho et al. 2001). Key studies are summarised in section VIII-2. Antiseptic agents are generally considered more likely to confer resistance to surface colonization than antibiotics and not to select for infection with antimicrobial drug resistant bacteria. Newer approaches to inhibiting biofilm development include inflation of the balloon with an antiseptic solution which then diffuses throughout the catheter material and into the surrounding area (Stickler, Jones & Russell 2003) or efforts to disrupt matrix or glycocalyx components (Tenke et al. 2004).

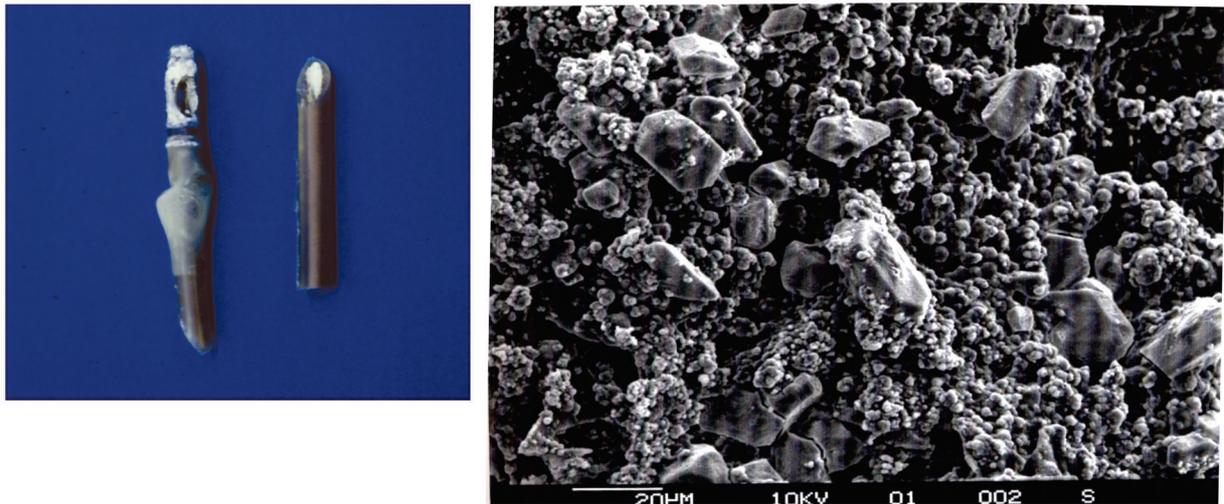
#### *e) Catheter materials – encrustation by mineral deposits*

Recurrent catheter encrustation by mineral deposits leading to catheter blockage occurs in up to 50% of long-term catheterised patients, with resultant increased costs to services and patients (Kunin, Chin & Chambers 1987a); (Getliffe 2003; Getliffe 1994b). Heavy encrustation on external surfaces of the catheter tip and balloon can also cause painful tissue trauma on catheter removal. The major components of encrustation are calcium phosphates and magnesium ammonium phosphate (struvite) (**Fig VIII-3**). Precipitation is influenced by ionic concentrations and pH but the urinary pH at which crystallisation occurs varies between individuals, ionic species (ie Ca<sup>++</sup>,

Mg<sup>++</sup>, phosphates) and at different times. Catheterised patients can usually be classified into ‘blockers’ or ‘non-blockers’ (Kunin, Chin & Chambers 1987a); (Getliffe 1994a) where ‘blockers’ are those individuals who experience recurrent catheter blockage within a few days to a few weeks. Urine from recurrent blockers tends to have a very narrow ‘safety margin’ between ‘voided’ urinary pH and the pH at which crystallisation occurs. This margin is much wider in non-blockers (Choong et al. 1999). Precipitates occur most commonly under alkaline conditions caused by the presence of urea-splitting microorganisms such as *Proteus mirabilis*, in the catheter biofilm (Cox et al. 1987); (Getliffe 1994a); (Stickler & Zimakoff 1994); (Choong, Hallson, Whitfield & Fry 1999) (**Fig VIII-3**). Encrustation may sometimes take place in the absence of infection (Choong & Whitfield 2000) and is also influenced by catheter surface properties, including roughness and irregularity, hydrophobicity and wettability, charge, polymer chemistry and coatings. None of the currently available long-term catheter materials is resistant to biofilm formation and encrustation.

#### *f) Catheter size – catheter gauge, length and balloon size*

Indwelling catheters are formed either by building up layers through dipping and coating on a shaped ‘former’ or by a process of extrusion of a single material. Catheter size (Charrière - Ch) or gauge (French gauge - Fr) is the circumference of the catheter shaft in millimetres. Internal diameter varies depending on the manufacturing method, with the extrusion process resulting in a catheter with relatively thinner walls and a larger lumen for the same Charriere size. A size 12Ch catheter made by dipping and coating will have an external diameter of around 4mm and an internal diameter of around 2mm or less. Urinary flow rate is proportional to the internal diameter of the catheter but 12 -16 Ch catheters (usual sizes for adults) easily drain normal quantities of urine including larger volumes produced by diuresis (Ebner et al. 1985). Larger sizes may be necessary where blood clots and other debris is a problem but large catheters are usually reserved for use following urological procedures, since they have been associated with increased bladder irritability and spasm in a descriptive study by Kennedy et al. (Kennedy, Brocklehurst & Lye 1983), and with potential blockage of para-urethral glands and tissue damage, including urethral strictures. Small balloons sizes are generally recommended for all patients (10ml for adults and 2.5-5ml for children) to minimise the risk



**Figure VIII-3.** An encrusted catheter (left) and a scanning electron micrograph of encrusting material containing struvite (large crystals) and calcium phosphates (small crystals)

of discomfort, bladder irritation and spasm, resulting in tissue damage caused by possible expulsion of the catheter with a fully inflated balloon.

The standard male length catheter (41-45cm) is available to males and females but a shorter female length (25cm) can be more comfortable and discrete for some women. The female length catheter should not be used for males as inflation of the balloon within the urethra can result in severe trauma. Paediatric catheters are usually approximately 30cm long.

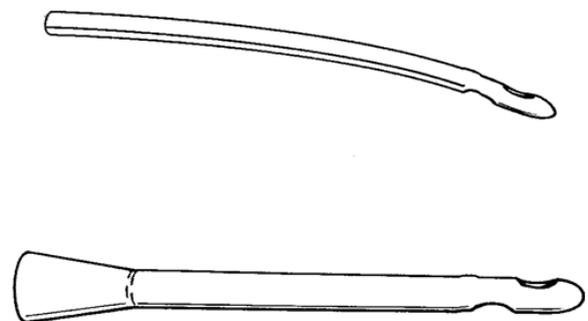
Drainage bag designs are dealt with in section V but patients who manage their own catheter drainage devices should have the opportunity to try a range of designs to ensure they are able to open/close the tap with confidence.

## 2. INTERMITTENT CATHETERS

Intermittent catheterisation can provide greater independence for patients and minimises or avoids many of the problems associated with indwelling catheters (**Fig VIII-4**). CIC can also be very effective in reducing incontinence, thus enabling some patients to be dry between catheterisations. The technique of clean intermittent self-catheterisation (CISC) can be taught to people of all ages, including the very elderly and children as young as four years old, with parental supervision (Eckstein 1979).

**Intermittent catheterisation can be appropriate for:**

- Patients with neurological disorders that result in urinary retention problems, including failure to empty the bladder, incomplete emptying, detrusor sphincter dyssynergia.



**Figure VIII-4.** Examples of catheters for intermittent catheterisation: Scott (top) and Nelaton (bottom).

- Patients with difficulty emptying the bladder after surgical procedures, if outflow obstruction occurs either in the short or long-term.
- Periodic emptying of a build up of residual urine in patients with detrusor overactivity.
- Acute urinary retention (most commonly in men).
- Management of urethral stricture.
- Emptying the bladder following continent urinary diversions such as a Mitrofanoff diversion.

CISC may be a practical option for patients who are:

- Sufficiently motivated to manage their own regular bladder drainage by this technique.
- Sufficiently dexterous to perform the technique. An appropriate level of manual dexterity is essential but generally if people can write and feed

themselves they have sufficient dexterity (Fowler 1998).

- Sufficiently cognitively aware to adhere to a regime and empty the bladder at appropriate time intervals to prevent bladder over-distension and preserve upper urinary tract function.

#### a) Catheter materials

Intermittent catheters for single use are sterile and have either a hydrophilic coating which requires immersion in water for a brief period to activate (e.g.30s), or a gel coating which does not require pre-preparation. Reusable catheters are made of latex, plastic (PVC), silicon, glass or stainless steel and are non-coated. They can be washed and reused following drying and careful storage. Metal catheters can be sterilized by heat or chemicals and may be used repeatedly for longer periods than other reusable materials. Some health care professionals make a distinction between 'single-use' (i.e disposed of after insertion) and 'single patient use' (cleaned and re-used by the same patient for a defined period of time, such as one week).

Most men require some form of lubrication to aid catheterisation, which can be on the catheter surface or instilled into the urethra (Burgdorfer, Heidler & Madersbacher 1997, Level of Evidence 3). In developing countries, where resources are limited, patients sometimes use plain water (Orikasa et al. 1976), (Level of Evidence 4) as lubricant. For those with preserved urethral sensation, a local anaesthetic gel may be needed. Many female patients do not use catheter lubrication but some prefer use of an anaesthetic gel.

#### b) Size and design

Intermittent catheters range in size from 6-20 Ch with most common sizes being 10-12 for females and 12-14 for males. Intermittent catheters are generally more rigid than indwelling catheters to aid insertion and a variety of aids to assist catheterisation are available (**Fig VIII-5**). Some women find a more rigid catheter easier to handle and some designs are slightly curved and made only in female length to accommodate this requirement. Some manufacturers produce conveniently packaged 'catheter-sets' where the catheter is already attached to a urine containment pouch inside the pack and a non-touch, clean technique is facilitated by holding the catheter inside the bag and gradually advancing it from the bag during insertion. Patients should have the opportunity to try different catheters and choose which best suits their needs and lifestyle.

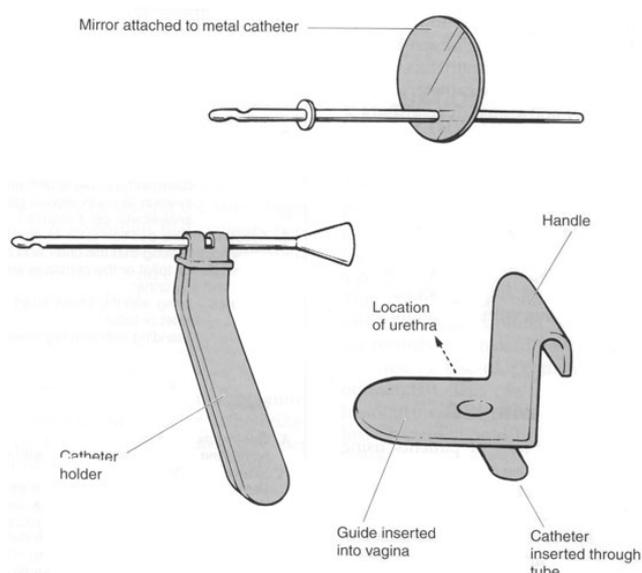


Figure VIII-5. Example aids to self catheterisation.

### 3. INDWELLING CATHETERISATION

#### a) Catheter-associated risks and complications

##### Symptomatic and asymptomatic catheter-associated urinary tract infection

##### 1. DEFINITIONS AND OUTCOME MEASURES

The urinary tract is recognised as the commonest site for nosocomial infection in hospitals and nursing homes, accounting for between 21% and 45% of all healthcare-associated infections (Plowman, Graves & Griffin 1999); (Stamm 1998); (EPINE 1992); (Emmerson 1996); (Sartor et al. 1995). The presence of a catheter is a key risk factor in around 80% of nosocomial UTIs, with the risk of bacteriuria increasing by 5-8% per day of catheterisation (Garibaldi, Burke, Dickman & Smith 1974); (Mulhall, Chapman & Crow 1988); (Stamm 1991); (Nicolle 2001). Bacteriuria is commonly used as a surrogate outcome measure for the clinically more important outcomes of symptomatic UTI and catheter-related bacteraemia.

Although symptomatic infection is far less common than asymptomatic catheter-associated bacteriuria, the frequency of catheter use produces substantial overall morbidity for patients and costs to healthcare services (Tambyah & Maki 2000b), often including unnecessary antibiotic drug therapy which may then

become a major source of antibiotic resistant pathogens. Asymptomatic infection (bacteriuria) can lead on to symptomatic infection, but the significance of long-term asymptomatic infection in its own right (e.g. effects of chronic tissue inflammation) is currently unknown.

In non-catheterised patients the criterion for 'significant' bacteriuria is commonly accepted to be  $>10^5$  cfu/ml but since growth of micro-organisms in catheterised patients is rapid, many authorities consider  $>10^2$  or  $10^3$  cfu/ml in a urine sample collected from the sampling port of the catheter, to be indicative of true catheter-associated infection (Maki & Tambyah 2001). Commonly used criteria for symptomatic infection have been questioned by (Tambyah & Maki 2000a) in a prospective study of 1497 newly catheterised patients. No significant difference in reported symptoms of pain, urgency, dysuria and fever was found between patients with a catheter-associated infection and those without, nor was there statistical evidence that peripheral leukocytosis is predictive of infection ( $p=0.14$ ) (Level of evidence 2). The criterion for bacteriuria (catheter-associated infection) in this study was  $\geq 10^3$  colony forming units (cfu)/ml urine) (Level of Evidence 2). This finding raises further questions over the selection of the most appropriate outcome measures in studies of catheter-associated infection.

## 2. QUALITY OF DATA

A majority of studies have addressed short-term catheter use in acute care. Comparisons between studies have often been limited by variable or unclear criteria used to define catheter-associated infection and the implications for long-term catheterised patients are uncertain. Few studies are sufficiently powered to detect symptomatic infection as an outcome measure and there is clearly a need to examine and agree the most appropriate criteria and measures for use in future research. The prevalence of catheter-associated infection in long-term catheterised patients, who are likely to be cared for predominantly in community settings, is largely unknown and there is a need for further epidemiological studies of prevalence and incidence of bacteriuria and symptomatic catheter-associated infection during long-term catheterisation in different populations and different care settings (NICE 2003).

There have been three published Cochrane reviews (Brosnahan, Jull & Tracy 2004); (Niel-Weise, Arend & van den Broek 2002); (Jamison, Maguire & McCann 2004)). Inclusion criteria adopted in these

reviews exhibited a degree of variability ranging from very strict criteria from which robust conclusions on available evidence could be drawn, to a broader acceptability in acknowledgement of the fact that in many areas there is very little evidence to guide practice. There were a further three systematic reviews, one meta-analysis and four papers presenting economic evaluations or models. Other studies included randomised trials RCTs, case series and retrospective reviews of patient groups.

## 3. CATHETER MATERIALS AND ANTIMICROBIAL COATINGS

Most studies have focused on short-term catheterisation up to 14 days and longer-term effects are largely unknown. There is one Cochrane review on types of urethral catheters for management of short-term voiding problems in hospitalised patients (Brosnahan, Jull & Tracy 2004). The primary objective of this review was to determine the effect of type of indwelling urethral catheter on the risk of urinary tract infection in adults who undergo short-term urinary catheterisation (up to 14 days). Eighteen trials met the inclusion criteria and included 4237 hospitalised adults in 17 parallel group trials and 27,878 adults in one large cluster-randomised cross-over trial. Three comparisons were addressed in these trials: antiseptic impregnated catheters (silver oxide or silver alloy) versus standard catheters (11 trials); antibiotic impregnated catheters versus standard catheters (1 trial); and comparison of different standard catheters (6 trials). Niel-Weise et al. (Niel-Weise, Arend & van den Broek 2002) undertook a review of publications between 1966 and 2001, on the effectiveness of silver-coated versus uncoated catheters. They identified seven randomized trials and one meta-analysis but concluded that only one study (Thibon et al. 2000) was of sufficient quality with regard to method of randomization and blinding for valid interpretation. A smaller number of studies have examined antiseptic and / or antibiotic impregnation of catheter materials but no systematic reviews were identified. One RCT comparing an antibiotic (minocycline and rifampin) impregnated catheter with a standard catheter (Darouiche, Smith, Hanna, Dhabuwala, Steiner, Babaian, Boone, Scardino, Thornby & Raad 1999) was identified.

## 4. COST-BENEFIT ANALYSIS.

There have been few trials which have incorporated an economic evaluation and none which investigate the hypothesis that patients catheterised with antiseptic impregnated catheters may develop antimicrobial resistance. Three studies have specifically exa-

mined the economic benefits of silver-alloy catheters in preventing UTI in the short-term (Karchmer et al. 2000); (Plowman et al. 2001); and (Saint et al. 2000).

## 5. ANTIBIOTIC USE

There are a small number of RCTs and three Cochrane reviews relating to antibiotic use. Most studies have addressed short-term catheterisation or longer term intermittent catheterisation. Only one RCT testing antibiotic prophylaxis versus placebo in long-term catheterised patients was identified (Rutschmann & Zwahlen 1995).

A recently updated Cochrane review on 'Urinary catheter policies for long-term management of voiding in adults and children' (Niel-Weise & van den Broek 2004) examined seven trials, including 328 patients, in four cross-over and three parallel group RCTs. Trials comparing catheter policies (route of insertion and use of antibiotics) in long-term catheterisation (more than 14 days) were included. Comparisons were made between: (i) antibiotic prophylaxis versus antibiotics when clinically indicated (n=3 trials); and (ii) antibiotic prophylaxis versus antibiotics when microbiologically indicated (n=4 trials). There was insufficient data available to make comparisons between urethral, suprapubic and intermittent catheterisations.

## 6. BLADDER CANCER, BLADDER CALCULI AND URETHRAL STRICTURE

Complications of long-term catheter use include bladder cancer, bladder calculi and urethral strictures. Most published studies are retrospective cohort or case series and relate to spinal cord injured patients (Stonehill et al. 1996); (Donnellan & Bolton 1999); (West et al. 1999); (Chen, Devivo & Lloyd 2001); (Groah et al. 2002); (Ord, Lunn & Reynard 2003). The role and timing of screening remains a controversial topic with limited evidence to guide practitioners. Ruutu et al. (Ruutu, Alftan, Talja & Andersson 1985) reported on the association between latex catheters used in cardiac patients and subsequent occurrence of urethral stricture.

## 7. CATHETER ENCRUSTATION AND RECURRENT BLOCKAGE

Urinary catheter blockage is most commonly associated with high urinary pH and ammonia production. Recurrent catheter encrustation by mineral deposits occurs in up to 50% of long-term catheterised patients, leading to catheter blockage and either urinary retention or leakage caused by urine bypassing the catheter (Kunin, Chin & Chambers 1987b); (Getliffe 1994a), (Getliffe 2003). In the majority of

cases a catheter biofilm contains microorganisms which produce the enzyme urease and are capable of splitting urinary urea to release ammonia, causing the urinary pH to rise. One of the most common is *Proteus mirabilis* (Fig VIII-6). Under the resulting alkaline conditions minerals are precipitated from the urine on to the catheter surface. These become firmly bound as the biofilm continues to grow.

The majority of research on catheter encrustation comprises experimental, laboratory-based studies addressing current and / or potential catheter material surface properties in relation to bacterial adhesion and encrustation. A number of studies have employed *in vitro* models of the catheterised bladder to examine the influence of urinary composition on bacteria growth and encrustation, and the ability of acidic irrigations to reduce encrustation build up. There is relatively little clinical evidence to draw on in this area. Only two RCTs were identified: a double-blind trial of a urease inhibitor (acetohydroxamic acid) (Griffith & Gleeson 1991); and a small-scale comparative trial of Suby G, Solution R and with saline catheter 'washouts' in 14 older female patients (Kennedy et al. 1992) (see catheter management strategies below). Most other clinical studies were small-scale and descriptive although both Getliffe (Getliffe 1994a) and Kunin (Kunin, Chin & Chambers 1987a) compared groups of 'blockers' and non-blockers' to identify characteristics of recurrent 'blockers'.

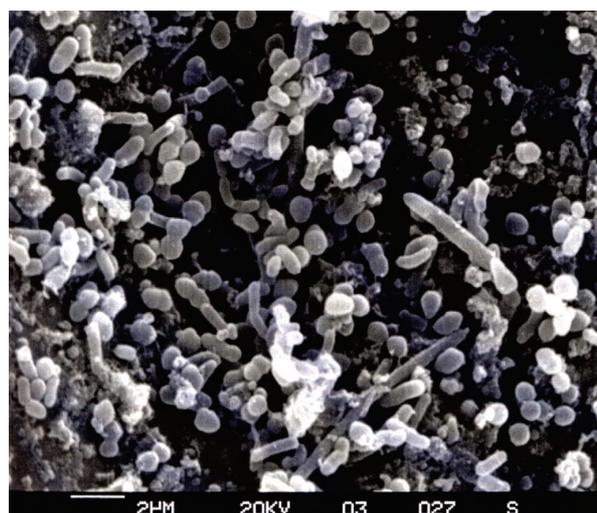


Figure VIII-6. Scanning electron micrograph of bacteria colonising an catheter surface (*Proteus mirabilis*, *Enterococcus faecalis* and *Lactobacillus* sp.).

## 4. RESULTS

### a) Risk factors: symptomatic and asymptomatic catheter-associated infection

Catheter-related bacteriuria has been shown to carry a 2.8 fold risk of death in hospitalized patients independent of other co-morbid conditions or disease severity (Platt et al. 1982); (Platt, Polk, Murdock & Rosner 1983) and Jepsen et al. (Jepsen et al. 1982) have also reported a bacteraemia rate in hospitalised, catheterised patients which was three times that of non catheterised patients (Level of Evidence 3). In a study of a large nursing home population by Kunin et al. (Kunin et al. 1992) associated risks of morbidity and mortality were also higher, with catheterized patients three times more likely to be hospitalized and three times more likely to be dead by the end of the year than non-catheterised patients (Level of Evidence 3).

Bacteraemia resulting from catheter-associated bacteriuria invariably represents a serious complication which may occur in approximately 4% of catheterised patients with bacteriuria (Saint, Veenstra & Lipsky 2000); (Saint, Veenstra, Sullivan, Chenoweth & Fendrick 2000); (Tambyah & Maki 2000a). Saint et al. (Saint, Veenstra & Lipsky 2000) statistically pooled results from several prospective studies on short-term indwelling catheterisation and estimated that:

- 26% of patients (not receiving systemic antibiotics) with a short-term, standard non-coated indwelling catheter in situ for between two and 10 days will develop bacteriuria.
- 24% of those developing bacteriuria will develop a symptomatic UTI without bacteraemia.
- 72% of patients developing bacteriuria will remain asymptomatic and not require treatment.
- 4% with bacteriuria will develop bacteraemia.

The definition of bacteriuria varied between studies, ranging from  $\geq 10^3$  cfu/ml to  $\geq 10^5$  cfu/ml (Level of Evidence 2/3)

In a review by Stamm (Stamm 1991), increased risk of bacteriuria was associated with duration of catheterisation, female gender, absence of systemic antibiotics and catheter care practices. Risk factors which are independently predictive of increased risk for catheter-associated infection have been identified in a number of large prospective studies of catheterised patients (Maki & Tambyah 2001) (Table VIII-2). There is evidence that females have a substantially higher risk than males (relative risk: RR 2.5-3.7)

*Table VIII-2. Risk factors for catheter-associated infection based on prospective studies and use of multivariate statistical modelling (adapted from Maki & Tambyah 2001).*

Risk factor	Relative risk
Prolonged catheterisation >6 days	5.1-6.8
Female	2.5-3.7
Catheter insertion outside the operating room	2.0-5.3
Other active sites of infection	2.3-2.4
Diabetes	2.2-2.3
Malnutrition	2.4
Ureteral stent	2.5
Renal insufficiency (creatinine > 2.0mg/dL)	2.1-2.6
Using a catheter to measure urine output	2.0
Improper position of drainage tube (above bladder or sagging below drainage bag)	1.9

but the greatest risk is associated with prolonged catheterisation > 6 days (RR 5.1-6.8) and by 30 days bacteriuria is almost universal. In earlier studies heavy cutaneous periurethral colonisation has also been identified as an important risk factor for catheter-associated infection in both males and females (Daifuku & Stamm 1984); (Garibaldi et al. 1980) (Level of Evidence 2).

### 1. CATHETER MATERIALS AND ANTIMICROBIAL COATINGS

Saint et al. (Saint et al. 1998) conducted a meta-analysis of publications between 1966 and Jan 1997 on silver coated-catheters. Eight trials met the inclusion criteria, (four studies on silver alloy and four on silver oxide-coated catheters). In most studies the sample populations were urology, medical or surgical patients, with one study including intensive care and neurology patients and one including spinal cord injury or neurosurgery patients. The results indicated a significant benefit from all silver catheters for women only. Overall silver-alloy catheters were significantly more protective against bacteriuria (OR 0.24, 95% CI 0.11-0.52) than silver oxide catheters (OR 0.79, 95% CI 0.56-1.10). The meta-analysis concluded that silver alloy catheters significantly reduced catheter-associated infection by three-fold compared to standard non-coated catheters, however, the authors noted that the results of the meta-analysis should be treated with some caution due to the diversity of study populations and interventions (eg antibiotic use); variable definitions of bacteriuria employed ( $10^2$  –  $10^5$  cfu/ml); and possible

influences due to all four studies on silver-alloy catheters being performed in the same institution, although with different patient groups.

More recent studies have reported mixed results with several demonstrating significant benefit of silver-alloy catheters but with smaller relative risk reduction compared to studies in the meta-analysis (Karchmer, Giannetta, Muto, Strain & Farr 2000); (Bologna et al. 1999); (Maki et al. 1998). One study failed to find significant benefit associated with silver alloy catheters (Thibon, Le Coutour, Leroyer & Fabry 2000) (Level of Evidence 1) and another reported benefit from silver-alloy catheters used for 5 days but not when used for 14 days (Verleyen et al. 1999) (Level of Evidence 1). Niel-Weise (Niel-Weise, Arend & van den Broek 2002) recommended that any meta-analysis should be based only on clinically homogeneous studies of high methodological quality and concluded there was insufficient evidence to recommend silver-coated urinary catheters. Nevertheless there is a large body of data which does indicate benefit, although differences in methodological detail and outcome criteria limit direct comparison or meta-analysis.

In short-term catheterized hospitalized subjects, the recent Cochrane analysis by Brosnahan et al. (Brosnahan, Jull & Tracy 2004) found that silver oxide catheters were not associated with a statistically significant reduction in bacteriuria but the confidence intervals were wide (RR 0.89, 95% CI 0.68-1.15). Silver alloy catheters were found to significantly reduce incidence of asymptomatic bacteriuria (RR 0.36, 95% CI 0.24 to 0.52) in hospitalized adults catheterised for less than a week. At greater than one week the risk of asymptomatic bacteriuria was still reduced (RR 0.67, 95% CI 0.50-0.90). The authors claimed the risk of symptomatic urinary tract infection was also found to be reduced with silver-alloy catheters (RR 0.60, 95% CI 0.50-0.73). However, this has not been well substantiated as Brosnahan et al. do not provide clear criteria for symptomatic infection in their review and simply define UTI as symptomatic bacteriuria  $> 10^5$  or  $10^6$  cfu/ml.

It is not yet known if silver alloy catheters confer any benefit for patients who use long-term catheters (catheters which are expected to remain in place for 14 days or more before changing), since it is unclear how long the silver alloy coating is effective.

Some attempts have been made to release silver into the urine from a catheter-associated device rather than impregnation into the catheter material. Reiche

et al. (Reiche et al. 2000) performed an RCT with 243 catheterized patients randomized to a system releasing silver ions into the urine or a control group and also subdivided into a urine meter system with a sampling port or a closed urine bag system. Patients with pre-existing bacteriuria or developing bacteriuria within 48 hours of catheterisation were excluded. 170 patients were available for analysis. 45 % of patients remained catheterized at six days and 7% at 10 days. Dipstick analysis was performed daily and the urine cultured if abnormal. No significant difference was detected between groups or during a sub-analysis for male or female sex (Level of Evidence 1).

The impact of antibiotic impregnated catheters has been examined, both in vitro (Johnson, Delavari & Azar 1999); (Gaonkar, Sampath & Modak 2003) and in vivo with animal models (Pugach, DiTizio, Mittelman, Bruce, DiCosmo & Khoury 1999); (Cho, Lee, Lee, Kim, Kwon, Chung & Yoon 2001) using different strains of bacteria and in clinical studies (Darouiche, Smith, Hanna, Dhabuwala, Steiner, Babaian, Boone, Scardino, Thornby & Raad 1999); (Leclair, Cysan, Munster, Neste, Murphy, 2000). Both in vitro and in vivo animal studies have demonstrated significantly superior antibacterial activity and delays in onset of bacteriuria compared to uncoated catheters. However, any potential benefits need to be balanced against the risk of developing antimicrobial resistance and this may limit the clinical use of catheters coated with these agents. Catheters impregnated with a combination of minocycline and rifampin (n=56) were compared with silicone catheters (n=68) in an RCT by Darouiche et al., (Darouiche, Smith, Hanna, Dhabuwala, Steiner, Babaian, Boone, Scardino, Thornby & Raad 1999). This multi-centre, prospective RCT showed that patients catheterised for a median of 14 days took longer to develop bacteriuria with anti-microbial-impregnated catheters than control catheters. Patients with minocycline and rifampin impregnated catheters had significantly lower rates of gram positive bacteriuria than controls but rates of gram negative bacteriuria and candiduria were similar. Bacteriuria was defined as  $>10^4$  cfu/ml and results from 124/141 patients were available for analysis. Symptomatic UTI was identified in 1.8% of the antibiotic impregnated catheter group compared to 8.8% of the control group, but this did not reach statistical significance ( $p=0.13$ ). Patients in both groups received preoperative antibiotic prophylaxis with a single dose of parenteral cephalosporin and this raises ques-

tions about the potential impact of antibiotic use on the study outcomes and conclusions. Since Gram negative bacteria tend to predominate in catheter biofilms isolated from long-term catheter users, there is no evidence that antibiotic impregnated catheters are likely to confer notable benefit in long-term catheterisation. (Level of Evidence 2)

In another non-randomised study an evaluation of the potential benefit of a nitrofurazone-impregnated catheter was carried out on 74 burns patients in a burns ICU during a six month surveillance period of catheter-associated infection (Leclair, Cysan, Munster, Neste, Murphy, 2000). A statistically significant difference was detected in the incidence of bacteriuria (defined as  $\geq 10^5$  cfu/ml) with 13 catheter-associated infections identified in 533 catheter days (44 patients) in the surveillance period compared to four catheter-associated infections in 550 catheter days (30 patients) in the nitrofurazone group ( $p=0.021$ ). However, the authors note that it was unclear what effect re-catheterisation in a sterile environment had. (Level of Evidence 3).

An alternative approach to generating an antimicrobial environment within and around an indwelling catheter is to fill the balloon with an antiseptic agent. Stickler et al. (Stickler et al. 2003) have demonstrated in vitro, that when the antiseptic Triclosan is used to fill the balloon of a silicone catheter it diffuses from the balloon into the surrounding medium and throughout the silicone material, inhibiting bacterial growth and biofilm development. If this effect is supported in clinical trials this could provide a novel and useful approach.

## 2. COST BENEFIT ANALYSIS

This subject is also addressed in the chapter on economics (See chapter 3), but there are relatively few studies which include analyses of cost benefits of different catheters and these tend to rely heavily on certain assumptions. The major assumptions used in economic modelling need to be considered carefully in the interpretation of any economic analysis. One common assumption is that a certain proportion of patients with bacteriuria will develop the clinically important outcomes of symptomatic UTI or bacteraemia. The studies reported here have focused on silver-coated catheters used in short-term catheterisation. Any potential benefits for long-term catheterisations remain unknown.

Karchmer et al. (Karchmer, Giannetta, Muto, Strain & Farr 2000) included a cost-analysis based on cost estimates of treating a UTI in 1992 and adjusted for

inflation. Wards were categorised into three strata according to baseline infection rates (high, medium and low) and cost estimates used both a high and a low approximation of costs. The authors calculated a catheter-related cost reduction of between 3.3 and 35.5%, despite the fact that silver-alloy catheters were significantly more expensive than standard catheters (close to twice the unit price). However, the study is limited by the randomisation to wards or units rather than individual patients and by the crossover design which may have led to contamination between groups (Level of Evidence 2). Lai and Fontecchio (Lai & Fontecchio 2002) compared the rate of catheter-associated UTIs following the introduction of silver-alloy coated urinary catheters (Bardex IC Foley catheter) into the hospital in October 1997, with projected baseline historical rates associated with uncoated catheters. The cost of catheter-associated UTI was estimated from reviewing files of all patients who had a UTI in the month of January 1997 and who were using uncoated catheters. Data was collected over five months of silver coated catheter use and 45,545 patient days. The baseline catheter related UTI of 4.9 per 1000 patient-days decreased to 2.7 per 1000 patient days with the use of the silver catheter. Despite a 45% reduction this did not reach statistical significance ( $p=0.1$ ). However, it was estimated that 216 fewer infections occurred per year with the use of silver catheters. The mean cost of a UTI (calculated with hospital charges) was estimated to be \$1214US with a median cost of \$614. The estimated net cost saving per year (based on the average cost of a UTI) was \$142,315. When the median cost was used there was a saving of \$12,564. The authors conclude the use of the silver-alloy catheter resulted in a non-significant reduction in catheter-associated UTIs and a modest cost saving (Level of Evidence 3).

Both Saint (Saint, Veenstra, Sullivan, Chenoweth & Fendrick 2000) and Plowman (Plowman, Graves, Esquivel & Roberts 2001) developed economic models based on published evidence. Saint et al. generated a decision-analysis model from the meta-analysis (reported in 1998). The model, which was based on a simulated cohort of 1000 hospitalized patients on general medical, surgical, urological and intensive care services requiring short-term urethral catheterisation (defined as 2-10 days), suggested that silver-alloy catheters are likely to produce clinical and economic benefits compared to standard non-coated catheters. Assuming a relative risk reduction of 25%, they calculated silver-alloy catheters could

lead to a 47% relative decrease in the incidence of symptomatic UTI and a relative decrease in resultant bacteraemia of 44% and could lead to savings in up to 84% of cases. However, they also recommended further work to examine long-term benefits. Plowman et al. (Plowman, Graves, Esquivel & Roberts 2001) developed a cost / benefits model to examine the economic benefits of using silver-alloy catheters to reduce UTI in catheterised hospitalised patients in England. Using an illustrative example where the median incidence of catheter-associated infection in catheterised patients was estimated as 7.3% (from published literature) and the average number of additional days in hospital estimated as 3.6 days, the model predicts that a reduction in the incidence of UTI of 14.6% in catheterised medical patients and 11.4% in catheterised surgical patients would provide a 'break even' status. Any further reduction in incidence of UTI would then result in cost savings.

### 3. ANTIBIOTIC USE

It is generally accepted that use of antibiotics in asymptomatic catheterised patients will significantly delay the onset of bacteriuria. This benefit is transient and only effective in the initial days of catheterisation. Garibaldi et al. (Garibaldi, Burke, Dickman & Smith 1974) noted that antibiotics reduced the rate of bacteriuria independent of sex, age or underlying illness, but were of no benefit and predisposed to resistant bacteriuria in patients catheterized for longer than four days (Garibaldi, Burke, Dickman & Smith 1974). Moreover prophylactic use of antibiotics is unlikely to prevent symptomatic urinary tract infection and is associated with an increase in adverse events (Maynard & Diokno 1984); (Nicolle, Mayhew & Bryan 1987); (Schlager et al. 1998). Catheter specimens of urine ( CSUs) taken prior to the removal of urinary catheters are considered to be of limited value given the rapid development of bacteriuria (Davies & Shroff 1983) and in the absence of symptoms suggesting an acute urinary tract infection, routine urine cultures should not be performed in catheterized patients (Wong 1983).

At present prophylactic antibiotic use in long-term catheterised patients is not recommended. Warren et al. (Warren et al. 1982) recruited 35 adult patients from chronic care hospitals with urethral catheters in place for more than one week. Weekly urine specimens were collected by needle aspiration of the distal catheter. Bacteriuria was defined as  $\geq 10^5$  cfu/ml. Patients were randomized to control group or study group to receive cephalexin for documented bacteriuria sensitive to cephalexin (Warren, Tenney,

Hoopes, Muncie & Anthony 1982). Bacteriuria was observed in over 98% of weekly urine specimen groups. The cephalexin group (17) were observed for a mean of 32.1 weeks and received cephalexin on 42% of study days. The control group (18) were observed for a mean of 26.5 weeks. In the treatment group - excluding first urine specimens - only 36% of organisms isolated were sensitive to cephalexin, compared to 75% in the control group. There was no difference in prevalence of bacteriuria, duration of bacteriuric episodes, number of bacterial strains present each week, febrile days or catheter obstructions. The control group were more likely to receive non-protocol antibiotics. The conclusions of the study were that routine use of cephalexin in catheterised patients is not warranted.

Studies of long-term catheterised patients are difficult given the frail nature of many elderly patients with catheters. Rutschmann and Zwahlen (Rutschmann & Zwahlen 1995) lost 30% of their sample during a double-blind, cross-over study of 34 elderly nursing home patients with urethral catheters. Patients were randomised to receive antibiotic prophylaxis (200mg/day norfloxacin ) or placebo for three months, followed by cross-over. Urine cultures were obtained once monthly. Episodes of UTI, catheter-related complications (obstruction, encrustation, leakage, suprapubic pain, inflammation of meatus, haematuria and side effects of treatment were monitored weekly. Symptomatic UTI was defined as bacteriuria  $\geq 10^5$  cfu/ml and (i) a temp  $>38.5^{\circ}\text{C}$  for two days in the absence of other clinical sources of infection or (ii) flank pain or unexplained mental disturbance or abdominal discomfort. Twenty-three patients completed the study and results showed that norfloxacin was associated with a persistent decrease in gram-negative isolates ( $p < 0.005$ ). Although norfloxacin failed to reduce asymptomatic bacteriuria, there was a significant reduction in symptomatic UTIs (1 v 12,  $p < 0.02$ ), a decrease in catheter-associated complications of obstruction and leakage ( $p < 0.05$ ) and an improvement in patients' general condition ( $p < 0.001$ ) as ranked by nursing staff. Of the 11 patients who did not complete the study, six died (of non-infectious causes), one died of septic shock and four were withdrawn. However, norfloxacin treatment was also strongly associated with the acquisition of gram-positive norfloxacin resistant flora (RR 4.66, 95% CI 2.47-8.80), and there was a rapid recolonisation by norfloxacin sensitive gram negative bacteria on cessation of treatment. Overall the study concluded that norfloxacin failed to pre-

vent bacteriuria in long-term catheterised patients and favoured the emergence of quinolone-resistant organisms, although there were some clinically observable benefits in some patients.

Similarly there is little strong evidence of benefit in prophylactic antibiotics prior to re-catheterisation. An RCT conducted by Firestein et al. (Firestein et al. 2001) randomly allocated 70 residents in a long-term care home to a treatment group (1gm IV meropenem given 30 minutes before re-catheterisation or control group (no antibiotics). Subjects had not received antibiotics during the two weeks prior to the trial and were followed for 28 days. No significant differences were identified in urine cultures at three, seven, 14 or 28 days.

Raz et al. (Raz, Schiller & Nicolle 2000) also examined nursing home residents in an RCT of 54 residents managed by long-term catheterisation. Subjects were randomised to undergo catheter replacement or no catheter replacement before antibiotic intervention for clinical diagnosis of UTI. Clinical outcomes (reduction in polymicrobial counts, time to achieve afebrile status and clinical status at 72 hours) were significantly better among subjects randomised to catheter change immediately before institution of antibiotics.

Certain bacterial strains may be particularly difficult to eradicate. In a prospective study of infection in catheterised nursing home patients Sabbuba et al. (Sabbuba, Mahenthiralingam & Stickler 2003) showed that a single genotype of *P. mirabilis* can persist in the urinary tract despite many changes of catheter, periods of non-catheterisation and antibiotic therapy.

Some studies have suggested a benefit of methenamine in preventing bacteriuria in women undergoing gynaecological surgery and requiring short term catheterisation (Ladehoff et al. 1984); (Knoff 1985); (Tyreman et al. 1986). In a more recent double-blind RCT (Schiotz & Guttu 2002), prophylactic methenamine in women requiring a transurethral catheter after gynaecological surgery was shown to reduce the risk of asymptomatic bacteriuria by 40% ( $p=0.02$ ) and symptomatic UTI by 80% ( $p=0.03$ ). However, a Cochrane review (Lee et al. 2004) concluded there is not enough reliable evidence to conclusively support the use of methenamine hippurate for urinary prophylaxis and identified methodological issues in existing studies.

Harding et al. (Harding et al. 1991) examined the persistence of bacteriuria after catheter removal. These authors undertook two RCTs on female hospi-

talized patients, catheterized for a short period (< 30 days), and one uncontrolled trial. Those with persisting bacteriuria 48 hours after catheter removal (defined as  $\geq 10^5$  cfu/ml) were eligible for inclusion. Exclusion criteria were: underlying urinary pathology; concurrent antimicrobial therapy; allergy to trimethoprim or sulfamethoxazole or combination; pregnancy; and creatinine concentration > 200  $\mu\text{mol/l}$ . Patients were grouped as asymptomatic ( $n=124$ ), symptoms of lower urinary tract ( $n=32$ ) or symptoms of upper tract infection ( $n=10$ ). In one RCT 112/124 asymptomatic patients were randomized to receive i) no therapy; ( $n= 42$ ) ii) a single dose of trimethoprim-sulfamethoxazole 320-1600 mg orally ( $n=37$ ); or iii) 10 days of oral therapy 160-180 mg twice daily ( $n=33$ ). Urine samples were collected after randomization on days two, seven and 14 and at 28 days for patients receiving antibiotics. Symptoms were monitored regularly and results showed:

- 15/42 (36%) asymptomatic patients had spontaneous resolution of bacteriuria within 14 days. Of these 14/19 (74%) were younger than 65 and 1/23 (4%) were older than 65 ( $p<0.001$ ).
- 7/42 developed symptoms of lower urinary tract within 14 days and were treated with antibiotics. The remaining 20 patients had persisting bacteriuria though asymptomatic and were treated with antibiotics after 14 days. Patients treated with antibiotics – single dose had resolution rate 81% (30/37) or 10 day course resolution rate was 79% (26/33). This was significantly better than spontaneous resolution ( $p<0.001$ ).

In the second RCT 30/32 patients with symptomatic UTI were randomized to one day of therapy ( $n=14$ ) or 10 days of therapy ( $n=17$ ). All 10 women with symptoms or signs of upper tract infection received 10 days of oral therapy. In symptomatic women the resolution rate for single or 10 day therapy was similar: 79% (11/15) and 81% (13/17) respectively.

When analysis included stratification by age (<65 or  $\geq 65$  yrs) single dose therapy resolved infection in 94% younger patients (31/33) (CI 0.86 – 1.02) and 56% older patients (10/18)(CI 0.32- 0.79:  $p=0.002$ ).

10 days of therapy resolved infection in 27/32 (84% CI 71%-97%) younger patients and 12/17 (71%; CI 49% to 93%) older patients  $p=0.17$ .

The authors concluded that resolution of bacteriuria 48 hours after catheter removal seldom occurred (4%). 26% with asymptomatic bacteriuria developed urinary symptoms within 14 days of catheter remo-

val. Older women rarely had bacterial clearance without therapy. Further work needs to be done to determine optimal course of antibiotic in the older patient.

#### 4. BLADDER CANCER

A number of case reports have linked carcinoma of the bladder with recurrent UTIs, renal calculi, spinal injury, long-term catheterisation and intermittent catheterisation (Kaufman et al. 1977); (Delnay et al. 1999). The incidence of bladder cancer in the spinal cord injury (SCI) population has been reported as 2.3%. This is approximately 460 times more common than in the general population (Bejany, Lockhart & Rhamy 1987). The reported incidence of squamous cell carcinoma associated with a chronic indwelling catheter is between 2.3% and 10%. Bladder stones have been identified as an independent risk factor for bladder cancer by some authors (Stonehill, Dmochowski, Patterson & Cox 1996).

Stonehill et al. (Stonehill, Dmochowski, Patterson & Cox 1996) undertook a case-controlled retrospective review of SCI patients with bladder tumours in a Memphis Veteran's Administration Hospital between 1988 and 1995. A case-control population of 27 randomly (alphabetically) chosen SCI patients, with duration of injury longer than 20 years, was compared to the tumour population. They also looked at new patients presenting with bladder neoplasia without SCI injury in the same period. Nineteen patients with bladder tumours were identified (two with benign leiomyoma and 17 with bladder malignancy: 10/17 (59%) patients had squamous cell carcinoma (SCC) and 5/17 (29%) had transitional cell carcinoma (TCC)). Indwelling catheters had been used for more than eight years in 15/17 patients, of whom nine used urethral catheters and six used suprapubic catheters. Only 10/27 used long term catheters in the case control group who did not develop bladder cancer. Stonehill et al. reported RR 12.8 for bladder cancer in patients using indwelling catheters. The relationship between cancer and duration of catheterisation did not reach statistical significance. Presence of bladder stones was significantly associated with bladder cancer ( $p=0.001$ ). None of the patients were asymptomatic at presentation, although two patients were identified on surveillance cytology alone, and the authors question the value of asymptomatic biopsy. 12/17 patients were identified on cytology (71% sensitivity, 97% specificity). Stonehill et al. recommended that SCI patients with an indwelling catheter for longer than five years or bladder stones should have yearly urinalysis for

microscopic haematuria, plus three cytology specimens in three days and, if cytology is suspicious, cystoscopy and bladder biopsy should be undertaken (Level of Evidence 3).

In another retrospective review West et al. (West, Cummings, Longo, Virgo, Johnson & Parra 1999) undertook a SCI population-based analysis of invasive treatments for carcinoma of the bladder in all US Department of Veterans Affairs Hospitals from 1988 to 1992. A chart review was undertaken regarding method of bladder management and tumour histologic findings. From a pool of 33,565 SCI patients, West et al. identified 130 (129 men and 1 woman) with bladder malignancy (0.39%). In 42/130 patients (32%) adequate data was available for further evaluation. The mean age at diagnosis was 57.3 years (range 36 to 84). TCC was reported in 55% and SCC in 33%. The groups were divided into a chronic indwelling catheter group (urethral, 18; suprapubic, 8) and a non-catheterized group (CIC, 8; condom drainage, 6; and spontaneous voiding, 2). There was an equal incidence of TCC and SCC in patients with indwelling catheters whereas in the non-catheter group SCC was present in only 3 /16. The mean duration of SCI was 23.9 years in the catheterized group compared to 20 years in the non-catheter group. In the latter group, patients were diagnosed with bladder cancer a mean of 18.1 years after SCI compared to 26.5 years in the catheter group. ( $p=0.054$ ). Based on their results the authors concluded long-term catheters in SCI should be avoided and suggested yearly cystoscopy after 10 years would be reasonable (Level of Evidence 3).

Groah et al. (Groah, Weitzenkamp, Lammertse, Whitenek, Lezotte & Hamman 2002) undertook a retrospective cohort study of the SCI population of a large treatment centre in Denver between 1950 and 1997 identified from a database developed in 1979. Patients were included if they were known to have survived at least one year and initial screening cystoscopy performed post-SCI documented presence or absence of bladder cancer. Of 9112 patients, 3670 subjects were included for follow-up after initial negative screening cystoscopy. Patients were grouped by bladder management into an indwelling catheter group - including urethral or suprapubic (IDC); non-indwelling catheter - including intermittent catheterisation (NIDC); and a mixed group (MULTI). Cases of bladder cancer occurring between 1979 and 1998 were identified. Data from the National Cancer Institute was used to ascertain general population incidence of bladder cancer of 2-20 per 100,000. Twenty-one cases of bladder cancers

were available for analysis. 15/21 occurred in the IDC group and 3/21 in each of the NIDC and MULTI groups. Age adjusted analyses revealed an association of bladder cancer with IDC use in SCI. The IDC group had an age-adjusted rate of 77 per 100,000 person-years compared with 56.1 and 18.6 per 100,000 person-years in the MULTI and NIDC groups, respectively. After age and gender adjustment, patients with SCI were 15.2 (95% CI, 9.2-23.3) times more likely to develop bladder cancer than the general population. There was no increased risk in the first 10 years of catheter use but between 10 and 19 years the risk increased to 86.8 per 100,000 person-years and in those with an IDC for more than 20 years the risk increased to 398.1 per 100,000 person-years. For those using IDC there was a 25-fold greater risk of bladder cancer than the general population. There was no relation between bladder calculi and bladder cancer in this group. The authors did not comment on the histological types of bladder cancer identified (Level of Evidence 3).

Although the available data is indicative of increased risk of bladder cancer in patients using an indwelling catheter for many years the relative risk of bladder cancer remains unclear. The precise role of screening - although advocated by many - also remains uncertain (Subramonian & Harrison 1999); (Yang & Clowers 1999). Razdan et al. (Razdan et al. 2003) investigated North American current practice in urologic surveillance and management in spinal cord injury. They sent a faxed 14 point questionnaire to 269 American members of the Society of Urodynamics and Female Urology. From a 60% response rate, Razdan reported that 25% of urologists perform annual cystoscopies in stable spinal cord injury patients and the overwhelming majority of urologists surveyed performed cystoscopy in the presence of long-term indwelling catheters. However, the authors noted the lack of any defined protocol for the surveillance of patients with SCI.

## 5. BLADDER CALCULI

Risk of bladder calculi formation in spinal cord injured patients was examined by Ord et al. (Ord, Lunn & Reynard 2003) in a retrospective cohort study of 457 patients, controlled for variable follow up by regression analysis. Indwelling catheters (urethral and suprapubic insertion) were significantly associated with increased risk of bladder calculi formation compared to intermittent catheterisation (hazard ratio 10.5;  $p < 0.0005$  and 12.8;  $p < 0.0005$ ), respectively. This increased risk was independent of age, sex, level and degree of injury.

Donnellan and Bolton (Donnellan & Bolton 1999) retrospectively reviewed 1359 presentations to a spinal unit between 1982 and 1996. During this period 3.5% of patients were treated for upper tract struvite calculi. At two years after injury the incidence was 0.9%. Patients were more likely to have complete and cervical spinal cord lesions. 53% developed their first stone more than 10 years after the injury; 49% had indwelling catheters; 52% previous bladder stones; and 28% vesicoureteric reflux. Only 2% of stones occurred with patients performing CIC.

Chen et al. (Chen, Devivo & Lloyd 2001) undertook a review of bladder stone incidence in spinal cord injury patients from 1973-1996. They documented a significant decline in incidence of bladder stones over 3 decades. Compared to those who were catheter-free, users of indwelling urethral or suprapubic catheters had an approximate nine-fold increased risk, and persons using intermittent or condom catheters a four-fold increased risk of a bladder stone in the first year. In patients presenting between 1985-1996, risk ratio for bladder stone was 2.7 (95% CI 0.5 -14.9) for intermittent catheter; 2.1 (95% CI 0.4-11.8) for condom catheter; and 6.6 for indwelling catheter (95% CI 1.1-37.6) (Chen, Devivo & Lloyd 2001).

## 6. URETHRAL STRICTURES

The uncoated latex catheter has been associated with an unacceptably high incidence of urethral stricture, in studies of patients catheterised during cardiac bypass surgery (Ruutu, Alfthan, Talja & Andersson 1985). This has been a driving factor in establishing stricter standards on catheter materials.

## 7. CATHETER ENCRUSTATION AND RECURRENT BLOCKAGE – EXPERIMENTAL STUDIES

All currently available catheter materials are subject to biofilm formation and encrustation. In a series of laboratory studies by Morris et al. (Morris, Stickler & Winters 1997); (Morris & Stickler 1998a), none of 18 types of catheter material resisted biofilm formation by a clinical strain of *P. mirabilis*. All catheter materials blocked when tested in a model of the catheterised bladder. Relative times to blockage were: silver-coated latex 17.7h; hydrogel-coated latex 34h; silicone-coated latex 38h; all silicone 47h. However, the authors note that the internal diameter of the coated latex catheters was much smaller than the silicone catheters (1.5mm compared to 2.5mm).

It is not possible to examine the effects of polymer surface properties on microbial adhesion and formation of catheter encrustation in detail here but recent

studies by Downer et al. (Downer et al. 2003) have shown that strongly electron donating surfaces are less prone to adherence by *P.mirabilis* than more hydrophobic materials. Park et al. (Park et al. 2002) have also shown that some copolymer polyurethane blends are associated with less microbial adherence and improved resistance to encrustation in an artificial bladder model. Another potentially promising innovation is the use of the antiseptic agent triclosan in the catheter balloon (Stickler, Jones & Russell 2003). In a laboratory model of the catheterised bladder infected with *P.mirabilis* silicone catheters with balloons inflated with triclosan (10g/l) drained freely for seven days compared to 24h for controls inflated with water. Triclosan became impregnated throughout the silicone catheter material and strongly inhibited the formation of the crystalline biofilm. Further work on clinical trials with triclosan and potential long-term benefits is awaited.

Cranberry juice has frequently been advocated to reduce UTIs, microbial adherence and biofilm development but a Cochrane review of five trials (Jepson, Mihaljevic & Craig 2004) concluded that the small number and poor quality of most trials (conducted on non-catheterised patients) gave no reliable evidence of the effectiveness of cranberry products. The large numbers of drop-outs also raises doubts over long-term acceptability of cranberry juice for many patients. In an *in vitro* study by Morris and Stickler (Morris & Stickler 2001) drinking cranberry juice did not produce urine which was inhibitory to the development of *P.mirabilis* biofilms and catheter blockage but increased fluid intake was beneficial. Although some studies have claimed drinking cranberry juice can decrease urinary pH in healthy volunteers (Kessler, Jansen & Hesse 2002), Bibby et al.'s experimental work (Bibby, Cox & Hukins 1995) clearly demonstrated the extreme difficulty in accomplishing reduction in urinary pH in the presence of urease.

Urease inhibitors - including acetohydroxamic acid (1.0mg/ml) and fluorofamide (1.0microg/ml) - have been shown to restrict the increase in urinary pH of *P.mirabilis* infected urine from 9.1 to 7.6, in a simple physical model of the catheterised bladder (Morris & Stickler 1998b). Significant reductions in precipitation of calcium and magnesium salts were also noted but potential for clinical use and the impact of possible side-effects are unclear, although the outcomes support the small amount of clinical work reported in the literature (see section on clinical studies below).

## ***b) Catheter management strategies***

### **1. QUALITY OF DATA**

A number of strategies and protocols for catheter-care practices have been recommended but relatively few practices are supported by evidence from randomized controlled trials. For example, in the 'Guidelines for prevention of healthcare associated infections in primary and community care' commissioned by the UK's National Institute for Clinical Excellence (NICE 2003), of 29 recommendations relating to urinary catheterisation only six were Grade A (directly based on Level 1 evidence); with one each at Grades B and C. The remaining 21 were all grade D, being based on evidence from expert groups or clinical opinion. A systematic review on the management of short-term indwelling catheters (1-14 days) to prevent urinary tract infections was conducted by Dunn et al., (Dunn et al. 2002). The review addressed interventions including catheterisation technique; meatal care; catheter composition; drainage systems; care delivery and education. Eighteen RCTs were included in the analysis but the authors noted that a number of the included RCTs had methodological problems including small sample sizes and high dropout rates. It is difficult to draw clear recommendations from this review due to reliance on results of individual small-scale studies. This serves to highlight the relative lack of robust evidence to support catheter care.

### **2. CATHETER COMFORT**

Indwelling catheters can cause substantial patient discomfort but only one study which addressed this subject in any detail, was identified (Saint, Lipsky, Baker, McDonald & Ossenkop 1999).

### **3. CATHETER INSERTION AND REMOVAL**

A small number of RCTs have been published on this topic, particularly on timing of catheter removal post-surgery (mainly prostatectomy). A recent review by Fernandez et al. (Fernandez, Griffiths & Murie 2003) has examined policies for removal of indwelling urethral catheters for short-term management of voiding in adults and children.

### **4. PERI-URETHRAL AND MEATAL CARE**

Peri-urethral and meatal care strategies in prevention of catheter-associated infection at catheterisation and/or during subsequent catheter care have been studied in RCTs by a number of groups (Burke et al. 1981); (Burke et al. 1983); (Classen et al. 1991a; Classen et al. 1991b); (Huth et al. 1992); (Schiotz

1996); (Webster et al. 2001); (Ibrahim & Rashid 2002). Systematic reviews involving these studies have been published by Saint & Lipsky (Saint & Lipsky 1999) and by Pratt et al. (Pratt et al. 2001) who examined six studies which met the inclusion criteria and compared meatal cleansing with a variety of antiseptic/ antimicrobial agents to cleansing with soap and water.

## 5. DRAINAGE BAG CARE

The potential for reduction of risks of catheter-associated infection by irrigation of the drainage bag and or bladder with agents such as hydrogen peroxide has been investigated by a number of groups, including Maizels and Schaeffer (Maizels & Schaeffer 1980), Holliman et al. (Holliman et al. 1987), Thompson et al. (Thompson et al. 1984). Other investigators have looked at chlorhexidine (Gillespie et al. 1983); (Davies et al. 1987) and povidone iodine (van den Broek, Daha & Mouton 1985); (Schneeberger et al. 1992).

Dudley and Barriere (Dudley & Barriere 1981) reviewed published evidence on a range of antimicrobial irrigations (acetic acid, amphotericin B, chlorhexidine digluconate, nitrofurazone, neomycin, polymixin B, and silver nitrate) in the prevention and treatment of catheter related urinary tract infections. Stickler and Chawla (Stickler & Chawla 1987) reviewed the use of antiseptics in management of patients with long-term indwelling catheters.

Two RCTs have examined strategies to reduce risks of catheter-associated infection through minimising catheter / bag disconnection by providing a sealed junction (Platt, Polk, Murdock & Rosner 1983); (Huth, Burke, Larsen, Classen & Stevens 1992).

## 6. MAINTAINING EFFECTIVE CATHETER DRAINAGE

Catheter drainage can be compromised by a variety of factors from simple causes such as kinked tubing or the position of the drainage bag, to bladder spasm, pressure of a constipated bowel on the adjacent urethra, suction of bladder mucosa into the catheter eye, or blockage by blood clots, mucous or encrustations formed by deposits of mineral salts. The algorithms in **Figs VIII-7 to VIII-9** provide some guidance on troubleshooting drainage problems.

Use of urinary catheters is rarely completely trouble-free. These algorithms combine current evidence-based knowledge and expert opinion to provide a guide to trouble-shooting problems.

The day to day management of recurrent catheter

encrustation and blockage is largely a nursing responsibility but there are few options available. In a majority of patients a characteristic pattern of 'catheter life' can be identified with careful record-keeping (Getliffe 1994a); (Kunin, Chin & Chambers 1987b); (Norberg, Norberg & Parkhede 1983). This may allow pro-active strategies of care designed to change the catheter before likely blockage. However, very frequent catheter changes can be unsuccessful or unacceptable for some patients as well as being costly in terms of health service resources (Kohler-Ockmore & Feneley 1996). An alternative strategy is the regular prophylactic instillation or irrigation of the catheter with an acidic 'catheter maintenance' solution to dissolve mineral deposits. In older literature the term 'bladder washout' appears but as the aim is to wash the catheter, rather than the bladder, 'catheter maintenance solution' is a more appropriate. However, the term used in the original research will be used here to avoid confusion.

A range of commercially available catheter-maintenance solutions is indicated in **Table VIII-3**, although these are not necessarily available worldwide.

Research on prevention and / or reduction of encrustation has been largely directed towards development of new catheter materials and catheter designs; efforts to acidify urine; and interventions to promote dissolution of existing encrustations. Although the most desirable outcome would be prevention of encrustation it may be more realistic to develop effective interventions which prolong 'catheter life' ie increase the length of time a catheter remains patent in situ alongside efforts to find a material which remains completely free of encrustation.

A small number of studies have examined the efficacy of acidic catheter maintenance solutions under laboratory-based experimental conditions. One small-scale comparative trial of Suby G, Solution R and saline catheter 'washouts' has been reported (Kennedy, Brocklehurst, Robinson & Faragher 1992). Most other clinical studies were small scale and descriptive and therefore more evidence is needed to guide practitioners.

## Results

### 1. CATHETER COMFORT

Although anecdotal information on the discomfort experienced by many catheterised patients is readily available, there is a general lack of published evidence from research studies. In one study at a Vete-

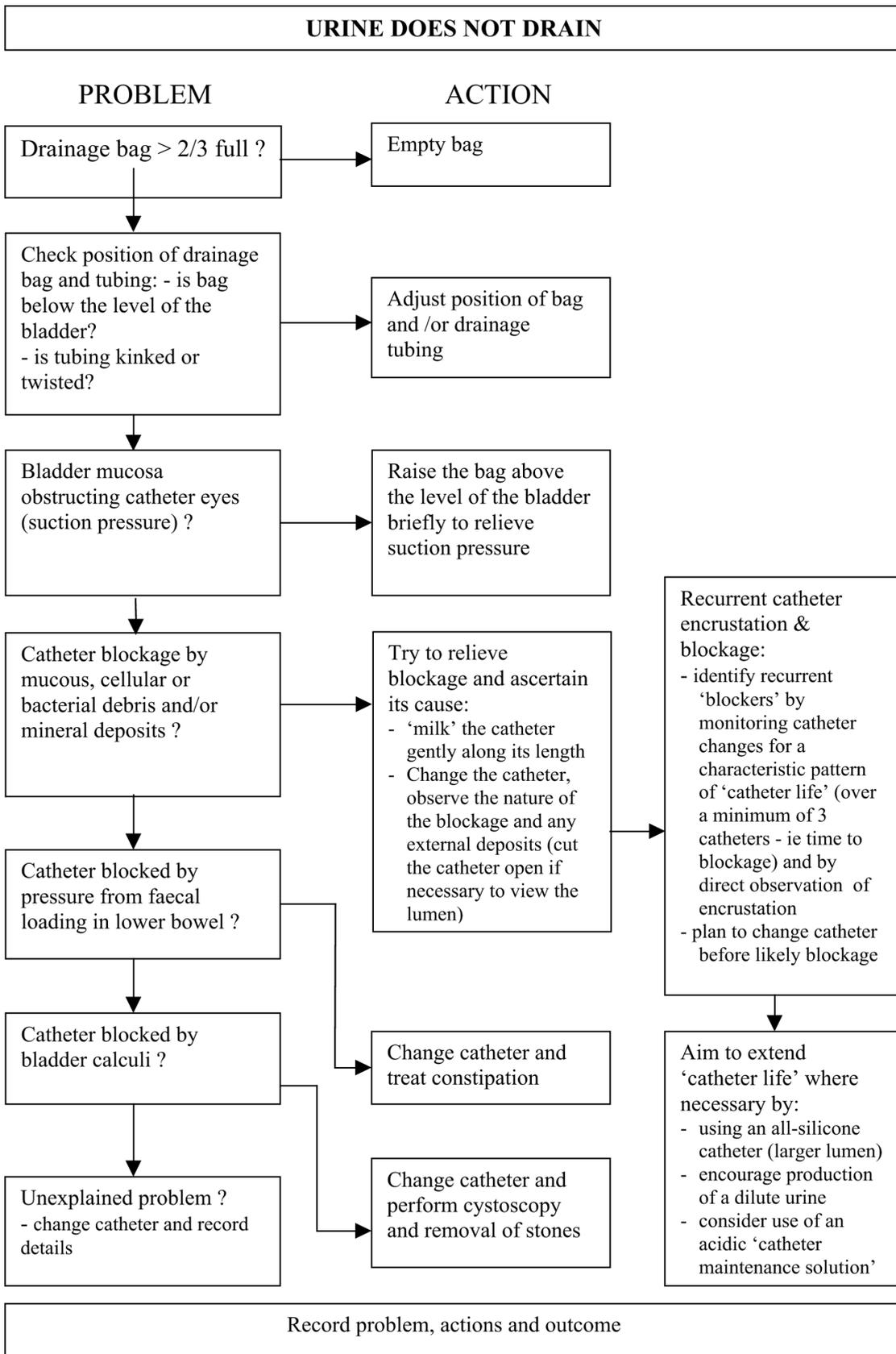
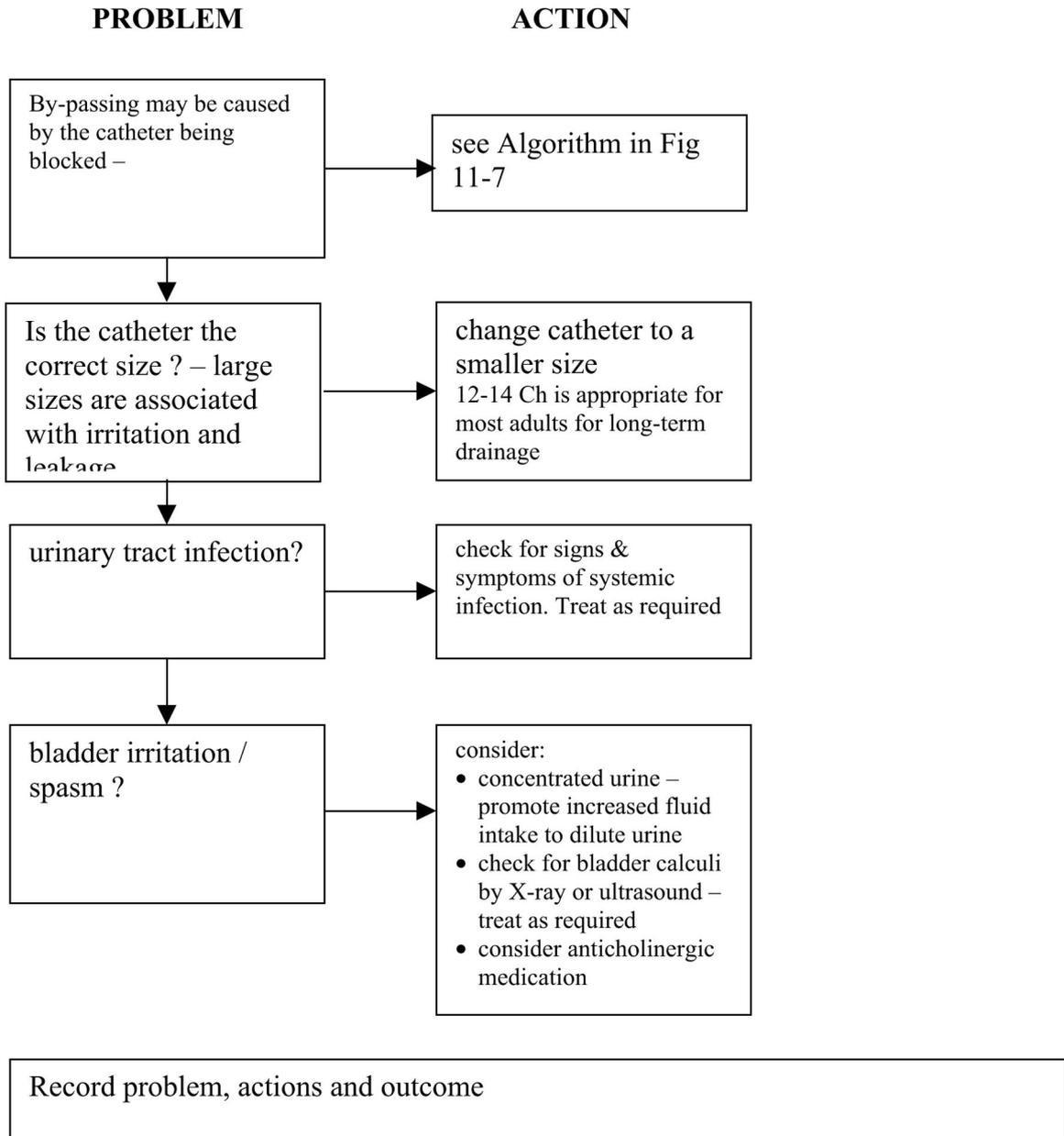


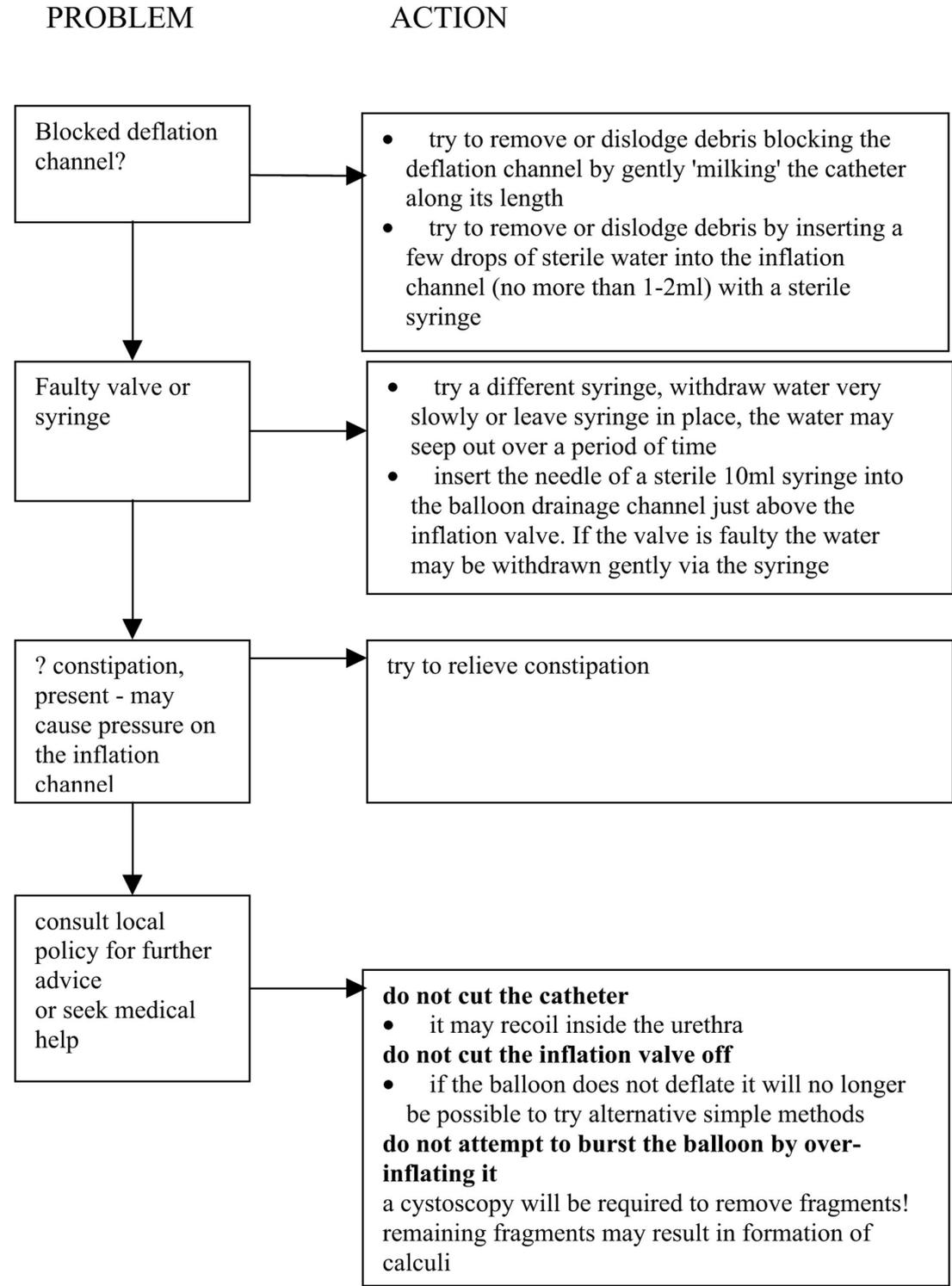
Figure VIII-7. Troubleshooting long-term catheter problems: urine does not drain.

## URINARY BY-PASSING



*Figure VIII-8. Troubleshooting long-term catheter problems: urinary by-passing*

**THE INFLATION BALLOON DOES NOT DEFLATE**



*Figure VIII-9. Troubleshooting long-term catheter problems: the inflation balloon does not deflate.*

**Table VIII-3. Catheter maintenance solutions.**

<b>Suby G or Solution G<sup>1</sup></b>	3.23% citric acid solution, pH 4, containing magnesium oxide to minimise tissue irritation, aimed at reducing encrustation. Used where routine catheter maintenance is required to reduce build up of encrustations.
<b>Solution R<sup>1</sup></b>	6% citric acid solution, pH 2, containing magnesium carbonate, aimed at dissolving encrustations. A stronger acid than Suby G and therefore not recommended for frequent, regular use.
<b>RenacidinR<sup>2</sup></b>	A citric acid solution, pH 3.5-4.2, containing glucono-delta-lactone to minimise tissue irritation and magnesium carbonate, aimed at reducing encrustation.
<b>Mandelic acid 1%<sup>1</sup></b>	An acidic solution, pH 2, aimed at inhibiting the growth of urease-producers. A stronger acid which is not commonly used to reduce catheter encrustations
<b>Saline 0.9%<sup>1,3</sup></b>	A neutral solution, pH 7, recommended for flushing of debris and small blood clots. Neutral pH solutions will not dissolve catheter encrustations.
<b>Chlorhexidine 0.02%<sup>1</sup></b>	An antiseptic solution aimed at preventing or reducing bacterial growth, in particular E. coli and Klebsiella species (but will not prevent biofilm formation on long-term catheters)

*1 available in UK pre-packed in a sterile delivery devices designed for instillation into a urinary catheter.*

*2 RenacidinR is available in USA but is not pre-packed in a delivery device. Not widely used*

*3 saline is widely available*

rans Affairs Medical Centre by Saint et al. (Saint, Lipsky, Baker, McDonald & Ossenkop 1999) 30% of catheterised patients surveyed found the indwelling catheter embarrassing, 42% reported it was uncomfortable with 48% complaining it was painful, and 61% stated it restricted their activities of daily living. Some discomfort can be reduced by careful selection of catheter and balloon size, and by the use of devices designed to secure the catheter and/or support the weight of the drainage bag to prevent dragging on the catheter.

## **2. CATHETER INSERTION AND REMOVAL**

Catheterisation is generally accepted to be a sterile procedure but the degree of rigour applied may vary in different circumstances. Pickard and Grundy (Pickard & Grundy 1996) compared two insertion techniques in 46 patients with SCI. Technique I employed a 3-minute handwash from fingers to elbows, followed by application of a sterile gown and gloves. Technique II was a shorter method requiring a 30-second handwash followed by double gloving (two sets of sterile gloves). Results showed no difference in incidence of UTI between methods and the authors' institution abandoned the more rigid technique I in favour of the shorter technique II (Level of Evidence 2).

The optimal time of short-term catheter removal is unclear but should be as soon as possible, depending on clinical need rather than at a specified time. A review by Fernandez et al. (Fernandez, Griffiths & Murie 2003) examined policies for removal of ind-

welling urethral catheters for short-term management of voiding in adults and children. Eight eligible randomized controlled trials comparing effectiveness of early morning versus late night removal of urethral catheters were reviewed. The results supported a significant reduction in length of hospitalization following midnight removal particularly following surgery.

Kelleher (Kelleher 2002) recruited 160 urology patients requiring catheterisation. Patients were randomized using computer generated numbers prior to surgery to have their urethral catheter removed at either midnight or 6am (80 in each group). Rounds were done at 0800 and 1700 to establish which patients could have catheter removed the following day and also to establish if patients were ready for discharge. The mean time to first void was 219 minutes in the midnight group compared to 178 minutes in the 0600 group. ( $p=0.02$ ). The volume of first and second voids were significantly higher in the midnight group (268 ml and 322 ml) than the 6am group (177 ml ( $p<0.0001$ ) and 195 ml ( $p<0.0001$ ). 64% of patients in the midnight group compared to 23% in the 6am group were discharged on the same day ( $p<0.0001$ ). Four patients developing retention in the midnight group were recatheterized within 12 hours compared to four patients in the 6am group recatheterized between 24-30 hours post catheter removal. Key studies are summarised in **Table VIII-4**.

It is difficult to interpret the results of these trial void

Table VIII-4. Studies on timing of short-term catheter removal

Study	Study design	Number of subjects	Nature of subjects	Results
Crowe et al 1994	Randomised study – method not stated. Removal at midnight v 6am. First void volume measured. Residual at 10h measured	242 patients midnight removal n=115, 6am removal n=127	Urology patients requiring catheterisation	Mean vol 1 <sup>st</sup> void 245ml (midnight) v 145 ml (6am) (p<0.001). Discharge on same day 27% (midnight) v 9% (6am)(Level of Evidence 2)
Lyth, Braslis, & Iacovou 1997	Randomised prospective trial. Midnight trial of micturition (TOM), 6am TOM and infusion TOM (up to 500ml saline rapidly infused prior to catheter removal	118 consecutive patients	Urology patients following TURP or BNI	Mean vol 1 <sup>st</sup> void 178ml (midnight) v 385ml (6am) v 343 ml (infusion TOM). Infusion of saline resulted in a mean of 13h earlier discharge compared to midnight or 6am TOM. Authors comment this was statistically significant but no p value given (Level of Evidence 2)
Wilson, Sandhu, & Kaisary 1997)	Randomised trial of micturition at 6am with or without saline infusion prior to catheter removal. Randomised by sealed envelopes. Trial of micturition on day 2 post-op.	75 consecutive patients. Randomised on 1 <sup>st</sup> day after TURP. Stratified by elective TURP (52); acute retention (14); acute and chronic retention (9)	Urology patients undergoing TURP. Readiness for discharge defined as good control of voiding and passing >200ml at each void.	Assessed as ready for discharge on same day as TOM: 62% infusion group v 37% standard group (p<0.05. Actual numbers going home on Day 1 or Day 2 was not significantly different (Level of Evidence 2)
Kelleher 2002	Randomised trial of micturition midnight or 6am	160 patients 80 in each group	Urology patients. 0800 and 1700 rounds to establish if catheter could be removed and if patient ready for discharge.	Time to first void 219 minutes (midnight) compared to 178 min (0600) p=0.02. Higher volumes for first 2 voids if midnight removal 268 and 322 mls versus 177 and 195mls. (p<0.0001). 64% midnight group discharged on same day v 23% (p<0.0001). (Level of Evidence 21)

studies despite indications of improved voiding associated with midnight removal. The decision regarding discharge and timing of discharge can be subjective and relate to timing of ward rounds and other factors. As in Wilson's study future studies perhaps should define discharge criteria in addition to time of discharge. Clearly the later in the day this assessment is performed the less likely the patient will be discharged that day. The assessment of readiness for discharge should be performed by someone blinded to the timing and / or use of infusions at catheter removal.

### 3. PERIURETHRAL AND MEATAL CARE

Meatal cleansing by simple washing with soap and water during routine bathing or showering is recommended (Level of Evidence 1) (Burke, Garibaldi, Britt, Jacobson, Conti & Alling 1981). No consistent reduction in bacteriuria has been demonstrated by meatal cleansing regimes using povidone-iodine solution or cream, chlorhexidine, polymicrobial creams, 1% silver sulfadiazine or antiseptic lubricating gels, compared to routine bathing or showering (Saint & Lipsky 1999); (Pratt, Pellowe, Loveday, Robinson, Smith, Barrett, Davey, Harper, Loveday, McDougall, Mulhall, Privett, Smales, Taylor & Wel-ler, 2001).

### 4. DRAINAGE BAG CARE

There is little evidence to support the addition of antimicrobial agents to drainage bags to prevent catheter-associated infection (see below) (Level of Evidence 1). This is perhaps unsurprising given current knowledge of the behaviour of microbial biofilms colonising catheter and drainage bag surfaces, including decreased susceptibility to antimicrobial therapies.

A review of the use of antimicrobial irrigations (acetic acid, amphotericin B, chlorhexidine digluconate, nitrofurazone, neomycin 40, Polymixin B 200,000 units, silver nitrate) by Dudley and Barriere (Dudley & Barriere 1981) concluded that none of these agents was able to decrease incidence of bacteriuria below that commonly present in a closed drainage system. They recommended that prophylactic irrigation in closed catheter systems was unnecessary. Although two studies have indicated that hydrogen peroxide may be beneficial in reducing catheter-associated infection in patients catheterized short-term (Maizels & Schaeffer 1980); (Holliman, Seal, Archer & Doman 1987) others have found no benefit (Thompson, Haley, Searcy, Guenther, Kaiser, Groschel, Gillenwater & Wenzel 1984). Results need to be

treated with caution where no randomization, no power calculations and / or small sample size limit the research quality of reported studies.

Stickler and Chawla (Stickler & Chawla 1987) reviewed the use of antiseptics in management of patients with long-term indwelling catheters, and recommended that special antiseptic policies needed to be developed for patients undergoing long-term catheterisation. They raised concerns that antiseptic procedures recommended for short-term catheterisation could be detrimental to the long-term catheterised population. This conclusion was at least partially based on reports from a number of studies suggesting that frequent chlorhexidine application prior to intermittent catheterisation changed the urethral flora, decreasing the predominantly Gram positive flora and resulting in increasing colonization with Gram negative flora. Stickler and Chawla reported an increase in the incidence of chlorhexidine resistant, multi-drug resistant Gram negative organisms in spinal units that use chlorhexidine extensively.

Stickler et al. (Stickler, Clayton & Chawla 1987) used a model of the catheterized bladder to study effects of various antiseptics against a variety of urinary pathogens isolated from spinal cord injury patients. They studied povidone-iodine, phenoxylethanol, chlorhexidine, chlorhexidine + EDTA + Tris, noxythiolin and neomycin. With the exception of phenoxylethanol against *Providencia stuartii* and *Pseudomonas aeruginosa*, the antibacterial agents were not effective in sterilizing bladder urine and only had a temporary bactericidal impact on the urinary organisms.

Other efforts to reduce catheter-associated infection have been directed at reducing breaks in the sealed drainage system. Huth et al. (Huth, Burke, Larsen, Classen & Stevens 1992) examined the effect of a tape seal at the catheter / drainage bag junction. They compared newly catheterized patients who were randomised (unblinded) to receive a tape seal (n=903) or no tape seal (n=837, control group). Urine specimens were collected daily through aseptic needle puncture from a sampling port in the drainage tubing. Bacteriuria was defined as  $\geq 10^3$  cfu /ml. Power calculations suggested a sample size of 686 into each group and results were available from 1740 subjects. Catheter care violations and antibiotic use were monitored. The tape seal reduced catheter junction disconnection by 14.9%, although this was not statistically significant. There was no significant association with catheter care violations including

disconnection of the catheter-drainage tubing junction and bacteriuria. Overall there was no significant difference between the tape seal group and the control group in relation to: bacteriuria (13.7% v 14.9%;  $p=0.52$ ); daily incidence of bacteriuria (5.0% v 5.5%); or onset of bacteriuria (4.6 days v 4.3 days). These results contrast with the findings of Platt et al. (Platt, Polk, Murdock & Rosner 1983) who found that catheters without seals were disconnected significantly more than sealed catheters ( $p=0.04$ ). Of those patients who were not receiving antibiotics, mortality was higher in the unsealed group ( $p=0.03$ ). However, it is notable that the overall junction disconnection rate in Huth et al's was 8.7% compared to 25.8% in Platt et al's study. This may be indicative of improved adherence to good practice over time, at least in Huth's study, but cannot be generalised further. Huth et al. concluded that use of a tape seal applied after catheterisation did not reduce bacteriuria or mortality (Level of Evidence 1).

#### 5. MAINTAINING EFFECTIVE CATHETER DRAINAGE

The reduction of encrustation and corresponding extension of 'catheter life' by regular instillation of an acidic catheter maintenance solution into the catheter has been advocated by some researchers, particularly where frequent catheter changes for blockage are difficult and / or unacceptable to patients. Solution G (Suby G) and Solution R have been shown to be effective in *in vitro* models of the catheterised bladder (Getliffe 1996); (Getliffe, Hughes & Le 2000); (Hesse et al. 1992) and *in vitro* models of struvite stone chemolysis (Jacobs, Heimbach & Hesse 2001). In response to concerns over potential damage to the bladder mucosa from acidic catheter maintenance solutions, Getliffe et al. (Getliffe, Hughes & Le 2000) attempted to provide supporting evidence to guide the use of catheter maintenance solutions. These authors advocate the use of small volumes of solution so that less enters the bladder and have demonstrated that under controlled laboratory conditions smaller volumes of acidic solutions (Suby G) (50mL) are as effective as the commonly available standard of 100ml, retained in the catheter for 15 minutes. Getliffe et al. have also shown that two sequential washouts with 50ml are more effective than a single washout but the outcomes remain to be tested in well controlled clinical trials.

Clinical studies on the prevention or management of catheter encrustation are extremely limited (Getliffe 1994a); (Pomfret 1995) with only two relevant RCTs

identified. In one, a randomised double-blind trial of a urease inhibitor (acetohydroxamic acid) in the palliative treatment of infection-induced urinary calculi, the study demonstrated effectiveness in lowering urinary pH in urine infected with *P.mirabilis* but the side effects were unacceptable to patients (Gleeson, Cunnane & Grainger 1991) (Level of Evidence 1). Earlier clinical work reported by Burns and Gauthier (Burns & Gauthier 1984) also examined oral administration of acetohydroxamic acid to five patients with chronic indwelling catheters requiring frequent changes ( $\geq 1$  every 2 weeks) due to encrustation and blockage. The dose was based on body weight (eg. 250mg three times daily for patients between 50-70kg). The degree of encrustation before and during acetohydroxamic acid therapy was compared in each patient by drying and weighing the proximal 6cm of the catheter. Encrusting material was eluted by alternate soaking in strong acid and strong alkali solutions before drying and weighing again. The degree of encrustation decreased significantly during therapy ( $p<0.05$ ) and the authors reported minimal adverse side effects experienced by patients but acknowledged the potential for more severe side effects to occur (Level of Evidence 3).

The second RCT was a randomized cross-over study which compared citric acid catheter instillations (Suby G and Solution R) with saline in 14 older female catheterised patients (Kennedy, Brocklehurst, Robinson & Faragher 1992). Methodological issues make it difficult to draw robust conclusions on the effectiveness of acidic solutions in managing catheter blockage but there was a higher incidence of red-cells in the retrieved washout fluid with Suby G compared to saline (mean incidence of 28% and 14%, respectively). However, increased shedding of uroepithelial cells was present in the retrieved washout from all three solutions which suggests that mucosal trauma is at least partially related to the physical process of administration. This issue was previously raised by Elliot et al. (Elliot et al. 1989) who also demonstrated increased uroepithelial shedding following washouts with up to 60ml saline 0.9%; chlorhexidine 0.02% or noxythiolin 2.5%.

A number of other clinical studies have focused on chemolysis of infection stones (principally composed of struvite). Stronger acidic solutions such as Solution R have been shown to dissolve fragments of struvite renal calculi following lithotripsy (Holden & Rao 1991) but potential benefits may be outweighed by the greater risk of inflammatory tissue reactions when used as a catheter maintenance solution.

### c) Summary

Most published studies of patients with indwelling catheters have focussed on short-term catheters (< 14 days) in hospitalised patients and relatively few have compared different modes of catheterisation (urethral, suprapubic, intermittent). The main subject of research on catheter use has been the risk of catheter-associated infection and the surrogate outcome measure of bacteriuria is commonly employed. However, there are important questions over the appropriateness of this as an outcome measure and the clinical importance of asymptomatic urinary tract infection. Although there is clear evidence to support a small proportion of catheter care procedures (indicated below) the majority of procedures are based on clinical experience and expert opinion. Long-term studies are difficult to carry out for a variety of reasons (not least the frailty of many long-term catheterised patients) and RCTs may not be the most appropriate or pragmatic design. Although there are now a number of Cochrane reviews it is clear that the quality of studies available frequently precludes drawing robust conclusions.

In summary, there are nine Cochrane reviews recently completed or in progress (Appendix VIII-1), and a small number of meta-analyses, mainly confined to catheter materials/coatings and associated infection (catheter-associated infection). There is limited availability of data from well-controlled, randomised trials and the majority of studies are based on short-term catheterisation in acute care facilities. There are relatively fewer studies based on community dwelling patients and a notable lack of robust studies on many catheter care procedures. Most studies which exist are small scale.

#### ***Catheter associated risks/complications***

- Silver alloy catheters are associated with statistically significant reduction in incidence of asymptomatic bacteriuria in short-term catheterised, hospitalized adults (studies of varying quality included) (Level of Evidence 1). There is less robust data to show that silver-alloy catheters reduce symptomatic bacteriuria.
- Silver oxide coated catheters are not associated with a statistically significant reduction in bacteriuria (Level of Evidence 2).

- Antibiotic coated catheters may have a role in delaying the onset of bacteriuria in short-term catheterisation in selected patients. Clinical importance is not well-established. The effectiveness of specific antibiotic preparations may be limited to specific groups of microorganisms. Potential toxicity and antibiotic resistance is unknown. (Level of Evidence 2)
- Long term indwelling catheter usage in spinal cord injury patients has been associated with an increased risk of bladder cancer (Level of Evidence 3).
- Recurrent urinary catheter blockage caused by encrustation occurs in 40-50% of all long-term catheterised patients (Level of Evidence 2). In the majority a characteristic pattern of 'catheter life' can be identified (Level of Evidence 3).
- All currently available catheter materials are subject to biofilm formation and encrustation (Level of Evidence 1).
- Evidence from in vitro models indicates that acidic 'catheter maintenance' solutions may have a role in dissolving encrustations (Level of Evidence 2)

### d) Recommendations

- Indwelling catheters should only be used after alternative management strategies have been considered (Grade of Recommendation A)
- Silver-alloy catheters should be considered for short-term catheterised patients to reduce the risk of catheter-associated infection (Grade of Recommendation A).
- All-silicone or hydrogel-coated catheters are preferable to other materials for long-term use (Grade of Recommendation B)
- Maintain closed drainage system to reduce risk of catheter-associated infection (Grade of Recommendation A).
- Meatal cleansing with plain soap and water (antiseptic agents no advantage) is recommended (Grade of Recommendation A).
- Bladder irrigation and antibiotic prophylaxis are NOT recommended as routine infection-control measure (Grade of Recommendation B).

- Addition of disinfectants to drainage bags is NOT recommended as an infection control strategy (Grade of Recommendation A).
- Asymptomatic bacteriuria should NOT be treated with antibiotics (unless urological instrumentation is planned) (Grade of Recommendation B).
- Mid-night catheter removal improves time and volume of first void and may lead to earlier discharge post surgery than early morning removal post-prostatectomy (Grade of Recommendation B).
- Identification of a characteristic pattern of 'catheter life' can facilitate pre-emptive catheter changes in patients with recurrent catheter encrustation and blockage (Grade of Recommendation C).
- Bladder cancer is a significant risk in long-term catheterized patients. Investigations should be case-finding rather than routine screening (Grade of Recommendation D).

#### 4. INDWELLING SUPRAPUBIC CATHETERISATION

##### a) Background

For some patients the insertion of an indwelling catheter suprapubically into the bladder through the abdominal wall offers advantages over the urethral route. This technique may be necessary following urethral or pelvic trauma but also offers advantages in acute and long-term care:

- Minimized risk of urethra trauma to men and women during catheter insertion and withdrawal.
- Minimized risk of urethral destruction/necrosis from pressure caused by the weight of poorly supported catheter bags, expulsion of the catheter, particularly in neurologically impaired women, or sitting on the catheter in wheelchair bound women.
- Ease of access to entry site in patients with reduced mobility, who are wheelchair bound, have restricted hip mobility or experience urethral pain.
- Facilitation of post-surgical trial of voiding (by temporarily clamping the drainage tubing).
- Greater freedom for expression of sexuality, although this may be counteracted by perceptions of altered body image

- Suprapubic catheter (SPC) insertion is generally contra-indicated in patients with haematuria of unknown origin, bladder tumour, or small contracted and fibrotic bladders which may have resulted from long-term urethral catheterisation on free drainage. In obese or immobile patients the traditional stoma site may become concealed by an apron of excess anterior abdominal wall fatty tissue which can lead to sub-optimal care by both patient and carer (Lilas, Andrews & Hanbury 1999). The use of SPC in neuropathic bladders remains a controversial topic. It has been reported to be associated with accelerated renal deterioration in the spinal injury group (Hackler 1982) and risk of autonomic dysreflexia at catheter change (Jannings & Kelly 2001), but there is evidence of successful use in specialist centres with a high degree of patient satisfaction (Sheriff et al. 1998). (See also chapter XXXX on neuropathic bladder). In frail elderly men, an SPC can be preferable to a urethral insertion to avoid urethritis, orchidopididimitis and prostatitis.

Although SPC is gaining wide acceptance for bladder drainage and many regard SPC insertion as a simple procedure, it is not without risks. The initial insertion of the SPC requires a minor surgical procedure which presents a potential risk of injury to adjacent structures to the bladder, especially the small and large intestines with resultant peritonitis (Heit 1997); (Sheriff, Foley, McFarlane, Nauth-Misir, Craggs & Shah 1998); (Simpson 2001). Other complications of initial SPC insertion include misplacement (Hamid, Peters & Shah 2002); (Goldblum & Brugger 1999) and incisional hernia (Mehta et al. 1999); (Lobel & Sand 1997).

##### SPC catheters and catheter material

Indwelling urethral catheters can be used suprapubically and retained in place by inflating the balloon, but not all urethral catheters are licensed for suprapubic use. Short-term catheters may be made of plastic (PVC) but all-silicone or coated-latex (with silicone or hydrophilic polymer) catheters are the materials of choice in Foley catheters used for long-term catheterization. Some suprapubic catheterisation kits provide a catheter; others allow the insertion of any catheter. Some specialised suprapubic catheters - mostly used for post-operative drainage - are stitched or stuck into position on the abdominal wall. Suprapubic catheter removal is sometimes associated with trauma of tracts or stoma site where overgranulation has occurred, with bleeding and patient discomfort

(Jannings & Kelly 2001); (Anderson et al. 2002). This is a particular problem with catheter materials - such as all-silicone - which are prone to hysteresis leading to balloon cuffing on deflation. This problem may also occur with hydrophilic coated catheters but is less common (Parkin et al. 2002); (Gonzalzo & Walsh 2003).

### **Insertion and management**

There are a number of techniques for insertion described in the literature. The preferred technique varies from region to region and there is no clear evidence that there is a single 'best way'. However, where patients are at high risk of bowel injury (eg previous abdominal surgery or small fibrotic bladders which do not expand well at cystoscopy), many authorities recommend introduction of the SPC under direct visualisation of the bladder by small formal dissection (Sheriff, Foley, McFarlane, Nauth-Misir, Craggs & Shah 1998) or by percutaneous technique using intraoperative ultrasonography combined with flexible cystoscopy (Lawrentschuk et al. 2003); (Aguilera & Choi 2004). In low risk patients nurse specialists may undertake first insertion of an SPC, according to agreed policy and protocols and Gujral et al., (Gujral, Kirkwood & Hinchliffe 1999) reported on 164 patients who had their first SPC inserted by a continence advisor / urology nurse specialist with no evidence of serious consequences.

Subsequent catheter changes can be competently managed by skilled nurses (Anderson, Walsh, Louey, Meade & Fairbrother 2002) - often in the patient's own home - but the new catheter should be inserted as quickly as possible whilst the track is still easy to follow. A delay of only a few minutes can result in partial obliteration of the tract (Iacovou 1994). It is also possible to insert the new catheter too far through the bladder so it enters the urethra with resultant trauma when attempts to inflate the balloon are made. Careful observation of the length of catheter external to the abdomen and the angle of protrusion prior to catheter change can help to ensure correct positioning of the new catheter. Dressings around the stoma site are not normally required unless there is discharge.

Protocols on catheter change frequency vary widely from monthly to up to three months if the catheter is trouble-free. In the absence of clear supporting evidence this remains an area of controversy amongst clinicians with advocates of early change believing this to reduce the incidence of complications while others argue that frequent changes increase the risk

of infection, trauma and long-term histological changes.

Overall the risks associated with short and long-term use of indwelling catheters are common to both urethral and SPC insertions, including catheter-associated infection, tissue trauma, catheter encrustation leading to blockage, formation of bladder calculi and histological changes (Delnay, Stonehill, Goldman, Jukkola & Dmochowski 1999); (Schaafsma, Delaere & Theunissen 1999). Evidence of urethral destruction and bladder cancer occurs most commonly beyond 5-10 years. In some patients - especially women - there may be a risk of continued urethral leakage with SPC, which may require closure of the urethra. A number of studies have indicated a reduced risk of infection associated with SPC in the short-term compared to urethral catheterisation and this is examined further below.

### **b) Quality of data**

The published literature on suprapubic catheterization is still relatively small, with much of it based on single centre cohort or case studies, or on short-term post-operative care following surgical procedures (not necessarily related to lower urinary tract symptoms). The majority of reports on SPC for long-term bladder drainage focus on the management of neurogenic bladder. Robust conclusions are often difficult to reach given the relatively short follow-up time frame of many studies and the lack of precise definitions of key outcome measures such as measurement of infection. The papers reviewed included one review of five previously published RCTs (Branagan & Moran 2002) and two RCTs (Theofrastous & Cobb 2002); (Baan et al. 2003). Other studies were cohort or case series.

### **c) Results**

#### **Catheter-associated risks/complications**

Sheriff et al. (Sheriff, Foley, McFarlane, Nauth-Misir, Craggs & Shah 1998) reviewed the records of 185 neurological patients who had a SPC inserted between early 1988 and late 1995 and were followed up for 3-68 months. Results demonstrated that the policy for SPC management (including a regime of catheter clamping and anticholinergic medication) was associated with preservation of renal function and it was concluded that SPC is an effective and well-tolerated method of management in selected patients with neuropathic bladder dysfunction for whom only major surgery would otherwise provide a solution to incontinence. There was a 2.7% inciden-

ce of small bowel injury including one fatality from silent peritonitis. The overall incidence of complaints was 30%, with 48% of these associated with bladder calculi requiring intervention. The most common complaints were recurrent catheter blockage (18% of cases), persistent urinary leakage (8%); and recurrent symptomatic UTI (4%). The overall incidence of asymptomatic infection was 98%. The general level of satisfaction was very high with 70 % of patients awarding a score of 9/10 and 95% awarding 7/10. It is of interest to note that in, 18% of cases, a SPC was inserted following the request of the patient having heard about this form of bladder management from others. The incidence of recurrent catheter blockage was notably less than the 40% or more commonly reported for long-term urethral catheterisation (Kunin 1989); (Getliffe 1994a) but studies which compare this outcome directly are needed to draw robust conclusions.

### **Catheter-associated infection**

Branagan & Moran (Branagan & Moran 2002) reviewed five previously published RCTs comparing SPC with urethral catheters following colorectal surgery (Rasmussen et al. 1977); (Sethia et al. 1987); (Perrin, Penfold & McLeish 1997); (Ratnaval et al. 1996); (O'Kelly et al. 1995). Most studies had small numbers, catheters were used short-term and there was no apparent difference in the duration of catheterisation between the two techniques. Significant UTI was defined in different papers as bacteriuria with either  $\geq 10^4$  or  $10^5$  organisms or cfu/ml. Frequency of UTI was less in the SPC group in three of the studies, with no significant difference in the other two. The SPC groups reported less pain and discomfort than the urethral groups and SPC was preferred by those patients who experienced both. The authors conclude that the results reported favour SPC over urethral catheterization as UTIs are reduced, particularly in females, and the ability to attempt normal voiding is facilitated, particularly in males (Level of Evidence 2).

Theofrastous & Cobb (Theofrastous & Cobb 2002) randomised 57 women with genuine stress incontinence to suprapubic versus transurethral catheterization for bladder drainage after open Burch retropubic urethropexy. Outcome measures consisted of the return of voiding function, patient comfort, length of hospitalization, and the development of lower urinary tract infection. The authors found no difference in the return of bladder function, hospital duration, or rate of cystitis between transurethral and suprapubic catheterization after retropubic urethropexy. (Level of Evidence 2)

More recently, Baan et al. (Baan, Vermeulen, van der, Bossuyt, Olszyna & Gouma 2003) carried out a prospective RCT on the incidence of UTI within six weeks of surgery, in patients undergoing laparotomy. UTI was defined as one or more clinical symptoms (fever, increased micturition frequency, burning during voiding, pain in lower abdomen, raised leucocyte count) and a positive urine culture of  $10^5$ cfu/ml and  $< 3$  bacterial species. 146 patients were randomised by computer programme on the day before surgery to urethral catheterisation or SPC. There was no significant difference in incidence of UTI (UC: 8/71 [11%] versus SPC:9/75 [12%]). The analysis was per protocol but all patients who required recatheterisation for any reason received UC and this may have masked any real differences between the two insertion techniques (Level of Evidence 2). Horgan et al. (Horgan et al. 1992) compared urethral and SPC in elderly nursing home patients with acute retention of urine and identified a significantly reduced risk of UTI and urethral stricture in the SPC group (Level of Evidence 2).

### **Bladder cancer and bladder calculi**

A number of case study reports have drawn attention to long-term risks of carcinoma involving squamous cells or urothelial cells within the cystostomy tract with or without extension further into the bladder (Schaafsma, Delaere & Theunissen 1999); (Berge et al. 1999); (Blake et al. 1996); (Stokes, Wheeler & Reyes 1995). However, in a retrospective analysis of screening biopsies for bladder malignancy in 36 patients with SPC for more than 12 years, Hamid et al. (Hamid et al. 2003) found no tumours in the screened group although histological findings were frequently abnormal (Level of Evidence 2). The authors suggest that screening cystoscopy and biopsy may be invalid as a test in this group and it therefore important to distinguish between histological changes and confirmed cancers when interpreting study results. In West et al's retrospective cohort analysis of 33,565 SCI patients, 130 were identified with bladder cancer (0.39%). No distinction was made between incidences associated with urethral or SPC catheters (West, Cummings, Longo, Virgo, Johnson & Parra 1999) but significantly less were associated with non-catheter care (which included ie CIC) (see section VIII-2).

Longer-term cohort or case study follow up has been reported by some groups, most commonly for spinal cord injury patients (SCI). Where SPC has been compared to intermittent catheterisation (CIC) the main difference appears to be in a lower incidence of

bladder calculi in the CIC group. Mitsui et al. (Mitsui et al. 2000) have reported a prospective comparison of long-term outcomes between SPC and CIC management regimes for spinal cord injured patients. Thirty-four quadriplegic patients managed by SPC were followed up for a mean period of 8.6 years and 27 paraplegic patients managed by CIC followed up for a mean of 9.9 years. There was no significant difference between groups in respect of symptomatic UTI, renal stone, degree of bother and overall satisfaction. However, there was a significantly increased incidence of bladder stones in the SPC group (Level of Evidence 2).

In Nomura et al's case series of SPC in 118 patients with neurogenic bladders (Nomura et al. 2000b) common complications were bladder calculi (25%) particularly associated with high urinary pH – and urethral leakage (10%). Bladder calculi-free rates at five and 10 years were 77% and 64% respectively, falling to 50% at 20 years. Bladder management and risk of bladder stone formation was examined further by Ord et al. (Ord, Lunn & Reynard 2003) in a retrospective cohort study of 457 spinal cord injured patients, controlled for variable follow up by regression analysis. Both SPC and urethral catheterization were significantly associated with increased risk of bladder stone formation compared to intermittent catheterization (hazard ratio 10.5;  $p < 0.0005$  and 12.8;  $p < 0.0005$ ). This increased risk was independent of age, sex, level and degree of injury but stones were no more likely to form with SPC than urethral catheters (hazard ratio 1.2,  $p = 0.6$ ).

#### **d) SPC catheter management strategies**

Urinary catheter 'deflation cuff' formation can be a problem in both SPC and urethral catheterizations causing difficulty in removal and great discomfort to patients. Evidence suggests deflation cuff formation can be a particular problem for all-silicone SPCs and a retrospective study of 113 patients cared for by community nurses showed that 30% of nurses had experienced problems changing catheters in the previous 12 months (Evans & Feneley 2000). In vitro studies have confirmed increased retention force and resistance to withdrawal caused by cuff formation and although cuffs can form with other catheter materials (eg hydrogel coated-latex) the retention force is less than with all-silicone material (Parkin, Scanlan, Woolley, Grover, Evans & Feneley 2002). Gonzalgo and Walsh (Gonzalgo & Walsh 2003) have suggested that slow deflation may increase the probability of the silicone balloon returning to its pre-inflation shape. Alternatively, reinsertion of 0.5-1ml

water is sufficient to fill the catheter inflation lumen and eliminate the balloon cuff. Subsequent use of lubrication with gentle removal of the catheter was well-tolerated by patients and produced virtually no trauma.

#### **e) Cost-benefit**

Few studies have examined the relative cost-benefits of SPC and where this has been addressed it is commonly limited to direct costs, such as increased costs of surgical insertion with ultrasound guide for neuro-pathic bladders, compared to urethral insertion. However, this must be balanced by the high levels of satisfaction and improved quality of life reported by many patients (Sheriff, Foley, McFarlane, Nauth-Misir, Craggs & Shah 1998); (Nomura et al. 2000a). In a study comparing first and subsequent SPC change in relation to complications and costs (Anderson, Walsh, Louey, Meade & Fairbrother 2002), catheter change by skilled nurses at home or outpatient clinic was shown to be cost-effective, with no increased risk to patients.

#### **f) Summary**

- SPC is an appropriate alternative to urethral catheterization for many patients following appropriate risk assessment (Level of Evidence 1)
- SPC insertion is a skilled procedure, particularly for patients with small neuropathic bladders. (Level of Evidence 3)
- Evidence of reduced catheter-associated infection short-term SPC is inconclusive and there is no evidence of long-term benefit in relation to catheter-associated infection compared to urethral catheterisation. (Level of Evidence 2)
- Patient comfort, quality of life and satisfaction with SPC is generally good compared to urethral catheters (Level of Evidence 1)
- Evidence for preventing meatal trauma in males is good. (Level of Evidence 1)

#### **g) Recommendations**

- If indwelling catheterisation is being considered, SPC should be considered alongside UC, following appropriate risk assessment (Grade of Recommendation B).
- SPC insertion should be carried out only by appropriately trained and skilled practitioners (Grade of Recommendation C).

## 5. INTERMITTENT CATHETERISATION

### *a) Background*

Advantages of intermittent catheterisation over indwelling catheterisation

Intermittent catheterisation is the act of passing a catheter into the bladder to drain urine via the urethra, or catheterisable channel into the bladder by continent urinary diversions such as a Mitrofanoff diversion. The catheter is removed immediately after urine drainage. Urine can be drained directly into the toilet, into a urinal, a plastic bag or other reservoir. The catheter should be kept in place until urine flow stops and then be pulled out slowly (with or without Valsalva or bladder expression) in order to completely empty residual urine. Traditionally intermittent catheterisation was done using a sterile technique but this was time-consuming and expensive. The introduction of the clean technique (CIC) revolutionised the management of patients with neurogenic bladders, improving convenience without unacceptable increases in infection rate (Lapides et al. 1972). The procedure is widely advocated as an effective bladder management strategy which avoids many of the risks associated with indwelling catheter. Clean (non-sterile) intermittent, self catheterization of the bladder (CISC) has been particularly useful in the management of neurogenic and non-neurogenic dysfunction of the lower urinary tract and is nowadays considered as the methods of choice for the management of neurogenic bladder dysfunctions (see also the chapter on neurogenic bladder). The importance of regular bladder drainage has been emphasised by Lapides et al. (Lapides et al. 1974) who suggested that, as well as providing a reservoir for infection, the increased intravesical pressure caused by build up of residual urine could reduce the vascular supply to the bladder tissue rendering it more susceptible to bacterial invasion. Lapides et al. also recognised that raised intravesical pressure could also contribute to potential damage to the upper urinary tract by back pressure and urine reflux.

It is generally accepted that CIC may be an appropriate technique to teach suitable patients (or a carer if this is acceptable to both) if the residual urine is 100ml or more, although the optimal post-void residual indicating the need to start bladder catheterization in neurogenic patients remains to be clarified. However, Dromerick & Edwards (Dromerick & Edwards 2003) demonstrated, in a case series of stroke patients, that post-void residual greater than 150ml is an independent risk factor for the develop-

ment of UTI (Dromerick & Edwards 2003) (Level of Evidence 2). Clean intermittent self- catheterisation (CISC) can be taught to people of all ages, including the very elderly and children as young as four years old, with parental supervision (Eckstein 1979). Carers can also be taught a clean intermittent catheterisation procedure (CIC) where this is acceptable to both patient and carer. Disabilities such as blindness, lack of perineal sensation, tremor, mental disability and paraplegia do not necessarily preclude individuals from mastering the technique if they have sufficient manual dexterity. Lack of motivation is the most common reason for failure. Patients require individualised care plans to identify appropriate catheterisation frequency, based on assessment of their voiding problem through discussion, frequency- volume charts and ultrasound bladder scans for residual urine. Some need to catheterise several times per day, others less frequently. [XXXX cross ref to neurological chapter]. Children at school need a multi-professional assessment which may include a continence advisor, paediatric community nurse or school nurses, the child's consultant, the child and parents. With adequate training, suitable facilities and supportive teaching staff many children are able to carry out CIC themselves either on a toilet or from a wheelchair. CIC has been shown to be a viable therapeutic option for children with a large post-void residual urine volume in the absence of any neurological abnormality (Pohl et al. 2002). A literature review conducted by Wyndaele (Wyndaele 2002) indicated a wide variety of materials and techniques used for intermittent catheterisation. The study concluded that there was no one best technique or material and that choice of both depend greatly on the patient's individual anatomic, social and economic status. **Table VIII-5** provides some guidance on patient education and troubleshooting for CIC.

### **Advantages of intermittent over indwelling catheterisation**

- Greater opportunity to reach own potential in terms of self-care and independence..
- Less risk of common catheter-associated complications.
- Better protection of upper urinary tract from reflux.
- Reduced need for equipment and appliances eg drainage bags.
- Greater freedom for expression of sexuality.
- Improved continence is possible between catheterisations.

**Table VIII-5. Intermittent catheterisation**

Patient education & support	Guidance for common problems
<ul style="list-style-type: none"> <li>• Discussion of individual bladder dysfunction and reasons for CIC</li> <li>• Personal anatomy and identification of urethral orifice</li> <li>• CIC technique – comfortable position, frequency, observation</li> <li>• Hygiene</li> <li>• Discussion of any psycho-sexual anxieties (body image, sexual function etc)</li> <li>• Single use v reusable catheters (cleaning, storing, re-use, disposal)</li> <li>• Difficulties and what to do</li> <li>• Dietary advice and avoidance of constipation</li> <li>• Obtaining supplies</li> <li>• Follow-up visits and consultations</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Catheter will not go in at first attempt</b> – relax for a while and try again a bit later; lubricate catheter (eg dipping in water); if necessary seek professional guidance</li> <li>• <b>Catheter inserted into vagina by mistake</b> – with draw, wash and re-insert</li> <li>• <b>Catheter will not come out</b> – leave for a few minutes, of patient’s technique relax and try to ‘let go’, cough gently and withdraw catheter</li> <li>• <b>UTI</b> – report changes in urine (eg blood, sediment, smell). Know how to recognise signs of symptomatic infection and seek treatment and review of CIC technique</li> </ul>

*An effective intermittent catheter has the following characteristics:*

**MATERIAL:**

- Soft for comfort.
- Minimal friction on insertion or removal.
- Sufficiently firm for easy insertion and maintenance of lumen patency.

**DESIGN:**

- Smooth surface and edges to catheter eyes to avoid tissue trauma on frequent catheterisation.
- Shaped for easy passage through urethral contours.
- Easy to hold and manipulate for those with limited dexterity.
- Easy to identify correct end for insertion and for drainage, for those with visual impairment.
- Packaged to facilitate quick and efficient use and disposal, to limit the impact of frequent catheterisation on quality of life and time spent on bladder care and the impact of temptations to compromise on associated hygiene and infection control.

**CATHETER MATERIALS AND SIZES**

Background information on catheter materials, sizes and aids to assist catheterisation has been presented

in the introductory section on catheters (see section VIII.1). There is a continuing debate over whether catheters designated for single use by manufacturers should only be used once or whether ‘single use’ can be interpreted as use by a ‘single patient’. Further research on the appropriateness of washing and reusing these catheters for a limited period of time is required in order to be able to give clearer guidance to patients and practitioners.

**b) Quality of data**

The majority of data on intermittent catheterisation relates to catheter-associated infection and catheter materials/.coatings. The following sources of data were identified: one Cochrane review on ‘catheter management policies for management of long-term voiding problems in patients with neurogenic bladder’ (Jamison, Maguire & McCann 2004); five RCTs on catheter materials/coatings; a variety of (largely) cohort or case series studies on clinical effectiveness / complications. The majority of studies on catheter coating focus on hydrophilic coated catheters and have been conducted on products from one particular manufacturer.

**c) Results**

**1. CATHETER-ASSOCIATED RISKS AND COMPLICATIONS**

Wyndaele (Wyndaele 2002) examined complications of intermittent catheterisation in a recent literature

review (82 studies). Urinary tract infection was the most frequent complication and catheterisation frequency and the avoidance of bladder over-filling were recognised as important prevention measures. Prostatitis was an identified risk in men but epididymitis and urethritis were relatively rare. Trauma from catheterisation was noted to occur regularly but lasting effects were more limited. The prevalence of urethral strictures and false passages increased with longer use of CIC but the study concluded that the most important preventative measures are good education of all involved in CIC, good patient compliance, use of an appropriate catheter material and good catheterisation technique.

## 2. CATHETER MATERIALS AND TISSUE TRAUMA

Hydrophilic polymers which can bind lubricating liquids have been shown to reduce friction but any relationship to catheter-associated infection is less clear. Some hydrophilic-coated catheters are still reportedly subject to urethral 'sticking'. This may be due to the catheter drying out during catheterisation due to the osmotic gradient. Some manufacturers have added a salt layer to the catheter surface to enhance the osmolality and to equalize it with the osmolality of human urine (Waller, Telander & Sullivan 1997). In Waller et al's cross-over study of two different coated catheters it was necessary to use saline as a lubricator in place of water to reduce the risk of urethral adhesion by one of the catheters. Key studies are summarised in **Table VIII-6**. Catheter names are included where they are clearly identified in the original publications. No economic evaluations were identified but Sutherland et al. (Sutherland et al. 1996) noted that the Lofric hydrophilic-coated catheter was approximately twice as expensive as a standard PVC catheter and was only approved for single use. These authors questioned whether better patient satisfaction and decreased urethral irritation could justify the greater expense but acknowledged that for select individuals (particularly those with a history of urethral trauma or sphincteric spasm) a hydrophilic-coated catheter such as the Lofric catheter offered significant advantages. In a small scale (27 patients), randomised, cross-over study in two centres to compare two coated catheters (SpeediCath [Coloplast]) and Lofric [Astra Tech] there were no significant differences in performance of each catheter but catheter but the SpeediCath demonstrated statistically significant benefit to patients in terms of speed of use, ease of use and the concept of water as an integral part of the packaging of the catheter permitting easy lubrication (Pascoe & Clovis 2001).

It has been claimed that the risk of urethral stricture formation may be less when hydrophilic coated catheters are used. Vaidyanathan et al. (Vaidyanathan, Soni, Dundas & Krishnan 1994) studied the degree of urethral inflammation by urethral cytology in two groups on CIC: one using ordinary PVC catheters with lubricant; the other using hydrophilic coated catheters. The group using hydrophilic coated catheters had significantly less urethral inflammation. Waller et al. (Waller et al. 1995) found no extra stricture occurring in their patients using hydrophilic catheters after a mean follow-up of seven years. Although this data suggests some benefit in using hydrophilic catheters to minimise stricture formation in the long-term there is a need for further comparative evidence. Hedlund et al. (Hedlund et al. 2001) reviewed the literature on CIC (28 studies) and called for a prospective, randomized, long-term, multi-centre study to address cost-benefit and cost effectiveness. Data on patient characteristics should include age; gender; diagnosis of bladder dysfunction; reason for CIC; physical and mental handicap; manual dexterity; and previous treatments. Effect parameters should include number of catheterizations; urinary tract infection (symptomatic or asymptomatic); early and long-term urethral complications; patient satisfaction, preferences; and drop-out rates.

## 3. CATHETER-ASSOCIATED INFECTION

The prevalence of UTIs associated with intermittent catheterization varies widely in the literature. This is, at least partially, due to the various definitions of UTI based on bacteriuria alone (asymptomatic) or symptomatic UTI (with or without clearly defined criteria); evaluation methods used; different catheterization techniques; different frequencies of urine analysis; the administration or not of prophylactic antibiotics; the group of patients studied etc. Baake and Vollset (Bakke & Vollset 1993) followed 302 patients using CIC for a year and found three main predictive factors of infection: high mean catheterisation volume; low frequency of catheterisation; and urine leaking in men with neurogenic dysfunction. These authors also identified low age in both men and women and non-self catheterisation in men as predictive factors. Bacteriuria was a risk factor of future clinical infection. Bakke et al. (Bakke, Digranes & Hoisaeter 1997) re-surveyed 170 of these 302 previously studied patients who had been performing CIC since 1988. 91% were using the low-friction LoFric catheter. The survey included a questionnaire and urine culture over a two week period. 61% had bacteriuria defined as  $\geq 10^4$  cfu/ml and in the preceding two weeks 35% were identified

Table VIII-6. Studies comparing coated v non coated catheters for CIC

Study	Design	No subjects	Nature of subjects	Results
Lundgren et al., 2000	Animal model - comparison of hydrophilic coated catheters with and without salt layer (high osmolality and low osmolality), and with or without drainage eyes	15 rabbits randomized into 5 groups; I control – no catheter II salt-coated III uncoated IV & V as II & III but with no drainage eyes		Degree of urethral injury evaluated on a 4 point histological scale. High osmolality catheters gave less urethral trauma than low osmolality catheters. There was significantly lower removal friction for high osmolality catheters. No significant differences in urethral trauma or removal friction associated with presence or absence of drainage eyes. Conclusion: high osmolality catheters recommended.
(Wyndaele et al. 2000)	Case series. Patients changed from conventional catheters to low friction hydrophilic-coated catheter	N=39	Male patients using conventional catheters for CIC for a long time. Age range 19-74 yrs	Urethritis and urethral bleeding were less frequent with the low friction catheter. Patient satisfaction was significantly higher. Negative issues raised were mainly related to availability and use of water to lubricate the catheter, difficulty of manipulation and fear for cost. (Level of Evidence 3)
Pachler and Frimodt-Moller, 1999	Randomised cross-over trial of disposable, non-hydrophilic PVC catheter reused several times a day prior to discarding, compared to a Lofric single use sterile catheter. Patients used each catheter type for 3 wks.	N=32	Patients performing CIC for a short period.	No significant difference between groups for frequency of CIC, discomfort when used, opinion on handling the catheter, preference toward one catheter, or of infection. Conclusion: non-hydrophilic PVC catheters may be used safely, with no discomfort to patients using CIC for short time periods. Non-hydrophilic catheters may be more cost-effective. (Level of Evidence 2)

Table VIII-6. Studies comparing coated v non coated catheters for CIC

Study	Design	No subjects	Nature of subjects	Results
Vapnek, Maynard, & Kim 2003	Prospective RCT of Lofric hydrophilic coated catheter v standard plastic catheter for CIC	Multi-centre (3 sites) n= 62, 31 per group. 49 completed the 12 mth trial (8 lost from Lofric group and 5 from control group)	Males with neurogenic bladders who perform CIC	Lofric group: significantly less haematuria compared to controls (p=0.027). Significant decrease in UTI rate from baseline in Lofric group but not in controls (p=0.012 v p= 0.24). There were no significant differences between groups in microscopic pyuria, bacteriuria or clinical infection rate ( Level of Evidence 1)
Fader et al., 2001	Prospective randomised comparative study. Each subject tested each of 4 different hydrophilic-coated catheters in a random order	61 men	Community-based men who perform CIC	No significant differences in ratings of 'sticking' on removal between 'Lofric' and 'Easicath' (p>0.05). There were significant differences between these two and the 'Aquacath' and 'Silky' which were found to stick more (p<0.001). (Level of Evidence 2)
Pascoe and Clovis, 2001	Randomised, cross-over trial in two centres of SpeediCath [Coloplast] and Lofric [Asta Tech]. Each catheter tested for 1 week	N= 27	Males and females all performing CIC > twice a day for >3mths	No significant differences in performance but SpeediCath significant benefit in ease of use, speed of use, and concept of water as an integral part of the catheter packaging. (Level of Evidence 2)
Giannantoni et al., 2001	Cross-over comparison of the Nelaton catheter (standard plastic catheter with a solid tip and single eye) v pre-lubricated non hydrophilic catheter to determine patient satisfaction and overall incidence of complications. Non-randomised	N=16	14 male and 2 female spinal cord injured patients (SCI)	Patients opinion of pre-lubricated catheter (ease and comfort of use) was significantly higher (p=0.000013). There was also significantly less incidence of urinary tract infection (p=0.026), asymptomatic bacteriuria (p=0.008) and decreased urethral cell counts and haematuria suggesting a better safety profile. (Level of Evidence 3)

Table VIII-6. Studies comparing coated v non coated catheters for CIC

Study	Design	No subjects	Nature of subjects	Results
Sutherland, Kogan, & Baskin, & Mevorach 1996	RCT of Lofric hydrophilic coated catheter v standard plastic catheter. Weekly urinalysis for 8 weeks and questionnaire	N=33 Lofric group 17 Control group 16	Boys skilled performing CIC	Microhaematuria was significantly lower with Lofric (p<0.05). Lofric catheter was ranked significantly higher for convenience (p<0.05) and insertion comfort (p<0.05) (Level of Evidence 1)
Waller, Telander, & Sullivan 1997	Randomised cross-over to compare two commercial hydrophilic catheters for CIC. Maximal friction force during removal of catheter measured by dynamometer twice daily	N=14	Male SCI patients. Catheterisation was by nursing staff. Each catheter type was used for 10d	Maximal friction force during removal of catheter significantly lower for Lofric v EasiCath/Conveen (0.87/0.84 N v 1.38/1.27 N) Sticking to urethral epithelium reported 3 times (2 pts) v 42 times (9 pts) respectively. Osmolality of outer layer of Lofric was 10 x higher than EasiCath/Conveen (900mOsm/kg). Authors believe this may explain the results.(Level of Evidence 2)
Vaidyanath an et al., 1994	Comparison of PVC catheter (Group I) v Lofric (Group II) on urethral cytology	N=31	SCI patients performing CIC. No significant differences between groups on demography, diagnosis, frequency of catheterization. Lofric group had used CIC for significantly longer (median 24d v 151d)	Urethral inflammatory response to repeated urethral catheterization (polymorphs:epithelial cells in urethral smear) was significantly less with Lofric (p<0.0001) (Level of Evidence 3)

of having some sign of a clinical UTI. This was significantly higher in women (40%) than men (12.5%). Patients reporting a symptomatic infection had a higher mean residual volume of 432 ml compared to 353 ml in those without symptoms. The difference was significant only in women. Patients with a frequency of  $\leq 3$ /day catheters were less likely to have sterile urine but this only reached statistical significance in men (Level of Evidence 2).

Biering-Sorensen et al. (Biering-Sorensen et al. 1999) studied 77 SCI patients on CIC after five years and found that 81% had been treated for at least one UTI, 22% had two-three UTIs/year and 12% had four or more/year. The technique of IC used does not seem to be a risk factor and Penders et al. (Penders et al. 2003) have found that, despite different catheterization techniques used, the number of episodes of clinically significant nosocomial urinary infections is not different and the mean species turnover is the same (Level of Evidence 2).

#### 4. URETHRAL STRICTURES AND OTHER COMPLICATIONS

Long-term follow-ups have shown that complications associated with CIC can occur, the most common being recurrent UTIs and urethral trauma (Wyndaele & Maes 1990); (Perrouin-Verbe et al. 1995). Urethral bleeding is frequently seen in new patients and occurs regularly in one third on a long-term basis (Webb, Lawson & Neal 1990). Trauma of the urethra - especially in men - can cause false passage. In neurogenic patients on CIC, urethral trauma with false passages has been treated effectively with six weeks indwelling catheter use and five days antibiotics (Michielsen & Wyndaele 1999) (Level of Evidence 3). The false passages disappeared on cystoscopy and CIC could be restarted.

Perrouin-Verbe et al. (Perrouin-Verbe, Labat, Richard, Mauduyt de la Greve, Buzelin & Mathe 1995) evaluated the overall incidence of complications of CIC in a population of 159 SCI patients. The rate of lower urinary tract infection was 28% and bacteriuria was 60%. Chronic pyelonephritis was never observed but the rate of epididymitis was 10% and urethral stricture was 5.3%. These two complications increased with the number of years of performing CIC. The authors also showed that patients who developed strictures had a slightly higher catheterization rate than those who did not. The incidence of urethral strictures increases with a longer follow-up and is also increased in men who have previously used an indwelling urethral catheter. Wyndaele and Maes (Wyndaele & Maes 1990) followed 75 patients

on CIC for a mean period of 7 years with a maximum of 12 years, the majority using CIC for neurogenic bladder. They found 11 urethral complications in 15 patients - mostly male - some of which were recurrent. Most events occurred after five years of CIC. Günther & Clark (Günther & Clark 2000) presented results of a study of 230 men on CIC. In those who had also used an indwelling urethral catheter at some time there were urethral changes in 26.9% (3.7% strictures). In men using CIC who had no history of indwelling catheter the prevalence of urethral changes was 16.9% (no strictures).

Formation of bladder stones has also been found to be associated with long-term use of CIC (Chen, Devivo & Lloyd 2001) (Level of Evidence 2). Barroso et al. (Barroso et al. 2000) reported an increased risk of developing bladder calculi in children performing CIC based on the records of 403 children. Stones were diagnosed in 28 patients. The incidence was slightly higher in those with a Mitrofanoff conduit but was not influenced by bladder augmentation (Level of Evidence 3).

#### 5. CATHETER MANAGEMENT STRATEGY AND CATHETERISATION TECHNIQUE

Many studies have demonstrated the safety of CIC compared to sterile intermittent catheterisation for patients performing their own care. CIC in a hospital setting is less well established but has been proposed as an option worthy of consideration and further researched by King et al. (King et al. 1992) and Prieto-Fingerhut et al. (Prieto-Fingerhut, Banovac & Lynne 1997). King et al. studied 46 hospitalized SCI patients not receiving prophylactic antibiotics and undergoing intermittent catheterisation. Patients were randomized to either clean (use of sterile new catheter at the beginning of each day) or sterile groups of equal size. Catheterizations were performed at least six-hourly. Infection was defined as  $\geq 10^5$  cfu/ml, or  $\geq 10^4$  cfu/ml and fever  $\geq 100^\circ\text{F}$ . Overall results showed that 28 patients (60.9%) developed significant bacteriuria. The method of catheterization did not influence development of bacteriuria ( $p=0.55$ ) or symptomatic UTI ( $p=0.7$ ). King et al. concluded that the data support the use of clean intermittent catheterization under the conditions used in the study, including the use of a sterile catheter each day and careful monitoring of infection and technique (Level of Evidence 2). Prieto-Fingerhut et al. (Prieto-Fingerhut, Banovac & Lynne 1997) conducted a prospective RCT and cost-benefit analysis on the effect of sterile and non-sterile intermittent catheterisation on the incidence of urinary tract

infection (based on analysis of weekly urine samples) in 29 patients after SCI. They found a UTI incidence of 28.6% in the sterile intermittent catheterisation group compared to 42.4% incidence in the non-sterile group. This difference was not statistically significant although the study is limited by its sample size. The cost of antibiotic use for the sterile group was only 43 % of the cost for those in the non-sterile group. However the cost of the sterile IC kits was 371% of the cost of the kits used by the non sterile group bringing the total cost of the sterile program to 277% of the non-sterile program. The authors conclude that determination of more precise comparison of cost-effectiveness of sterile versus non-sterile intermittent catheterization should include consideration of other factors related to treating UTIs such as requirement for more intensive nursing care, and days lost from rehabilitative therapy, which are less easily measured (Level of Evidence 2).

Schlager et al. (Schlager, Clark & Anderson 2001) compared the use of a single-use sterile catheter for each void with reuse of a cleaned catheter for 5 voids prior to discarding. In a cross-over study with 10 children with neurogenic bladders in which each catheter regime was tested for a four month period the frequency of bacteriuria was no different and remained at 75%. Two patients in each group developed symptomatic UTIs (Level of Evidence 2).

An alternative design approach has used a urethral introducer tip that protects the catheter from contamination of the first 1.5cm of the urethra. This system (O'Neil catheter) includes a plastic sheath with prelubricated plastic sleeve. Bennett et al. compared the O'Neil catheter with introducer to one without and found a significant decrease in symptomatic urinary tract infection in SCI patients (Bennett et al. 1997). Retrospective reviews have suggested the O'Neil catheter results in a decrease in infection in hospitalized patients.

## 6. CATHETER CLEANING FOR RE-USE

Catheters are often reused many times, up to weeks and months. Methods of cleaning or re-sterilising include soaking in a variety of antiseptic solutions or boiling water or microwave sterilisation. Kurtz et al. (Kurtz, Van Zandt & Burns 1995) compared three home cleaning methods used by patients performing CIC and found all of the following to be effective: 0.6% hydrogen peroxide; bleach in a 1:4 solution with tap water; and betadine in a 1:2 solution with tap water. None of the cleaned catheters showed detectable bacterial growth for 48 hours after the cleaning procedure was performed (Level of Eviden-

ce 4). Lavalley et al. (Lavalley et al. 1995) also compared the effectiveness of hydrogen peroxide, vinegar, dishwashing detergent, and tap water alone to clean catheters contaminated with *Pseudomonas aeruginosa* and *Escherichia coli*. They also examined the effect of immediate rinsing and drying before cleaning. Results indicated that rinsing and drying immediately after use was the most effective at reducing bacteria to near zero (Level of Evidence 4). Microwave sterilization has been advocated by some, but has not been adequately evaluated.

A study by Sherbondy et al. (Sherbondy et al. 2002) showed that even where standardized instructions (both verbal and written) were provided, microwave sterilization techniques by patients performing CIC varied considerably. Many patients surveyed did not follow the study instructions recommending sterilizing used catheters on a daily basis, cleaning with soap and water and air drying before inserting into a microwave oven on a paper towel. Microwaving on high for six minutes on a rotation table was recommended together with a heat sink (one cup of water in a microwave safe container be placed in the microwave to absorb extra heat). Catheter melting was reported by 63% and was significantly associated with the absence of a rotation table.

## 7. COMPARISONS BETWEEN INTERMITTENT AND INDWELLING CATHETERISATION

A systematic review of risk factors for UTI in adults with spinal cord dysfunction was published by Shekelle et al. (Shekelle et al. 1999). Twenty two studies met the inclusion criteria for evaluation but the authors noted that many had important methodological deficiencies. They found two studies that provide evidence supporting increased bladder residual volume as a risk factor. Patients on intermittent catheterisation had fewer infections than those with indwelling catheters.

They found conflicting evidence over the value of sterile or "non touch" catheter techniques compared with CIC. Shekelle et al. reported there was insufficient evidence to assess risk due to psychological, behavioural and hygiene factors, sex, level of function and time since injury.

In the study by Gunther and Clark (Gunther & Clark 2000) (reported above) the results of 230 men on CIC were also compared with those of 311 men not using CIC. Of those with a history of using an indwelling catheter the prevalence of urethral changes was 25.4% (2.5% strictures). This was similar to the prevalence in those using CIC with a previous histo-

ry of indwelling catheter use. In those with no history of indwelling catheter the prevalence of urethral changes was 17.9% (1.5% strictures) and this was also similar to the CIC group with no history of indwelling catheter. This study suggests that an indwelling catheter has a greater influence on urethral changes and stricture than CIC (Level of Evidence 3).

Patel et al. (Patel, Watts & Grant 2001) examined the outcomes of different forms of urinary drainage for men with acute urinary retention. After a short period of indwelling urinary catheterization patients were taught to use CIC (34 men). Patients who failed this were re-catheterised and taught to manage a valve or failing this a leg bag (16 men) and then discharged home. The CIC group had a higher rate of spontaneous voiding (56% v 25%) and a lower incidence of UTI (32% v 75%). At TURP 20% in the CIC group had a UTI compared to 69% in the indwelling catheter group. Patients using CIC preferred it and had fewer complications. The authors concluded that CIC was well accepted by those patients who were able to manage the technique, resulted in fewer UTIs and should be considered in patients presenting with acute retention.

#### d) Summary

CIC is the optimum method of urinary drainage in patients with neurogenic bladder dysfunction and others with problems of bladder emptying. It can be taught to patients of all ages who have sufficient manual dexterity and motivation to manage the technique. The most common reason for failure is lack of motivation. Urinary tract infection is the most frequent complication and the most important preventative measures for all complications are good education of all involved in CIC management, good patient compliance, use of an appropriate catheter material and good catheterisation technique.

Hydrophilic-coated catheters confer benefits in terms of comfort and minimised tissue trauma compared to non-coated catheters (Level of Evidence 2/3) but evidence of benefit in relation to urinary tract infection is less clear. CIC has been shown to have benefits over indwelling catheterisation:

- Less urethral inflammation (measured by cytology) than urethral indwelling catheterisation. (Level of Evidence 2/3)
- Lower incidence of bladder stones than indwelling catheterisation. (Level of Evidence 2)

#### e) Recommendations

- Clean intermittent catheterisation (CIC) is a treatment of choice for those with ongoing bladder emptying problems and residual urine > 100ml (Grade of Recommendation A).
- Technique can be taught to all ages. Appropriate education and ongoing support are needed (Grade of Recommendation C/D).
- An external lubricant or lubricant-coated catheter is recommended to minimise urethral trauma (Grade of Recommendation B).
- Frequency of catheterisation needs to be based on individual need, to prevent over-filling of bladder (Grade of Recommendation C).

### 6. CATHETER VALVES

#### a) Background

Catheter valves can provide a discreet alternative to conventional urine drainage bags and offer potential for maintenance of bladder tone and capacity for appropriate patients. The valve is a small device connected to the catheter outlet in place of a bag. Closure and opening the valve allows bladder filling and intermittent drainage rather continuous drainage into a bag. Valves are available in a variety of designs (Fig VIII-10) ranging from simple inexpensive types (less than £2 each) used for up to a week, to more expensive, complex, forms which last longer and which may permit one handed action (around £19 each). Most valve designs can be attached to a drainage bag at night to allow free drainage while the patient sleeps. A spigot is not a suitable alternative to a valve since it must be removed from the catheter to allow drainage thereby breaking the 'closed system'. Patients must be able to manipulate the valve mecha-

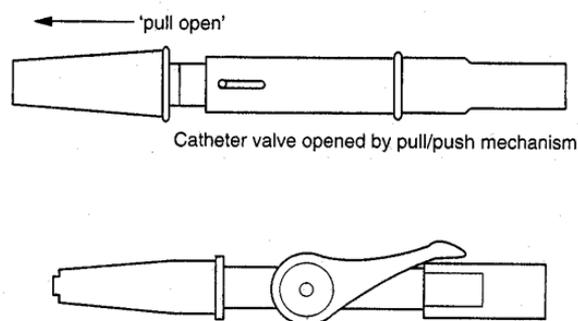


Figure VIII-10. Example catheter valves.

nism and empty the bladder regularly to avoid overfilling, with accompanying risks of back pressure on the upper urinary tract. Valves are generally inappropriate for patients with poor manual dexterity, poor bladder capacity, detrusor overactivity, ureteric reflux, renal impairment or cognitive impairment.

### ***b) Quality of data***

There is relatively little research-based literature on catheter valves with much of the evidence supporting beneficial effects derived from the level of expert opinion. Concerns over possible increased risk of infection associated with valves have not been realised although there is a paucity of research in this area. The flushing mechanism resulting from bladder filling and emptying may be expected to contribute to reduction in problems of encrustation and blockage but, again, research evidence is lacking. There is stronger evidence of benefits in terms of patient comfort and independence since this is a common finding in most studies. Five studies comparing a catheter valve with standard drainage (leg bag) were identified. Three (Woods, McCreanor & Aitchison 1999); (Rowley et al. 1995); (German et al. 1997) were cross-over designs (with 28, 16 and 18 subjects respectively) (Level of Evidence 3) and two (Lewington et al. 1989); (Wilson, Sandhu & Kaisary 1997) randomized their sample of 100 subjects to either catheter valve or standard drainage (Level of Evidence 2).

### ***c) Results***

None of the studies identified any significant difference in urinary tract infection and a majority found a high level of preference or acceptability of catheter valves (>72%). There were no differences in reported incidence of bladder spasms or discomfort; however, there was a higher incidence of nocturnal frequency and episodes of bypassing with valves. It was suggested that a combination of a valve during the day and free drainage at night through an open valve connected to a drainage bag could be an appropriate management strategy.

In Woods et al's small scale study (Woods, McCreanor & Aitchison 1999) 28 patients from two diagnostic groups (bladder outflow obstruction secondary to prostatic disease, n=16; or neurogenic dysfunction, n=12) completed eight weeks in the trial with conventional catheter drainage before being randomised to drainage with one of two different valves, either Uroflow (Simcare) or Flip-flo (Bard). Patients' ages ranged from 36-81 years with a mean of 73 years. There is no indication whether patients were on free-drainage overnight. There was a drop

out rate of close to 30% during the valve phase of the trial with 50% of these being neurogenic patients experiencing bypassing. There were no significant differences between patient preferences, quality of life (Nottingham Health Profile) or adverse-event scores. The authors concluded that the concept of a trial comparing valves with conventional drainage may be flawed since patients with catheters need to be considered as individuals and, instead of comparing drainage systems to find which is 'best', it will always be important to find what is most suitable for each individual.

Several studies have evaluated a single valve design (Doherty 1999); (Addison 1999) but only one has compared a broad range of valve designs (Fader et al. 1997). Fader et al. undertook a comparative evaluation of the seven catheter valves available on the UK market in 1996. Each valve type was tested for one week by between 19 and 36 subjects, followed by completion of a product evaluation questionnaire. Performance scores (and costs) varied widely between products but critical characteristics were: being easy to manipulate, leak-free, and inconspicuous. The authors concluded that prescribers need to be aware of the strengths and limitations of different valves for appropriate product selection. (Level of Evidence 3).

### ***d) Summary***

- Catheter valves provide a well-accepted system of bladder emptying for suitable patients who are able to manipulate the valve mechanism and empty the bladder regularly to avoid overfilling (Level of Evidence 2).
- There is no evidence of increased risk of urinary tract infection with valves compared to conventional drainage systems (Level of Evidence 2).
- Valves may promote maintenance of bladder tone and capacity (Level of Evidence 4).

### ***e) Recommendations***

- A catheter valve can provide an effective means of catheter drainage following appropriate patient assessment (Grade of Recommendation B).
- A combination of a valve during the day and free drainage at night through an open valve connected to a drainage bag could be an appropriate management strategy (Grade of Recommendation D).

## 7. QUALITY OF LIFE FOR PEOPLE WITH INDWELLING CATHETERS

Incontinence in catheter users is often related to neurogenic bladder and urinary retention, and use of an indwelling catheter is often a last choice after having tried condom, intermittent self catheterization, and other voiding treatments. Quality of life for people with indwelling urinary catheters has not been adequately studied. Only one RCT and one Cochrane Review were found that relate to the topic; the other studies provided Level 4 evidence from case series reports. Most research was qualitative or descriptive, aimed at understanding the nature of catheter-related issues and patient concerns. There is an over-abundance of clinical articles with expert opinion being the dominant form; these were not reviewed.

### *a) Quality of data*

There is one RCT (Roe 1990b); Level of Evidence 1-2); one Cochrane review (Jamison, Maguire & McCann 2004) - Level of evidence 1); three case series reports focusing on people with indwelling catheters (Fraczyk, Godfrey & Feneley 2003); (Saint, Lipsky, Baker, McDonald & Ossenkop 1999); (Wilde 2002a; Wilde 2002b), (Wilde 2003a; Wilde 2003b)- Level of evidence 4); and five case series reports including people with catheters (Jakobsson, Hallberg & Loven 2000); (Pateman & Johnson 2000); (Roe & May 1999); (Seymour 1998); (Zommick et al. 2003)(Level of Evidence 4).

### *b) Results*

Only one Cochrane review was found that related to quality of life in people with neurogenic bladder. This review compared different forms of catheters (indwelling and external (ie sheath / condom device)) to alternative management approaches. Out of 400 studies reviewed, no trials met the inclusion criteria of either randomized or quasi-randomized controlled trials. (Jamison, Maguire & McCann 2004) (Level of Evidence 1).

In the only RCT, an older study by Roe (Roe 1990a) with 45 people showed that an educational booklet for catheter wearers significantly improved knowledge and acceptance of the catheter. Though the implications for this type of intervention are positive, the study has not been replicated, and the sample was small (Level of Evidence 1-2)

There are no instruments measuring quality of life in people with urinary catheters. Research reports in people with long-term catheters have identified issues related to sexuality, shame and stigma, embarrassment, loss of control of bodily function, reminders of illness/mortality, and the inconvenience and

worries of catheter-related problems. Yet catheter users also acknowledge its benefits of freedom from wetness, convenience, and its utility in promoting urine drainage. Some studies of incontinence include catheter wearers; most do not. Moreover, reports focused on incontinence that do include individuals with catheters may not adequately describe the sample with respect to the device, thus confounding interpretations.

The following topics were found addressing QoL in indirect or partial ways for populations with indwelling catheters: 1) drainage bag and impact on daily life (Fraczyk, Godfrey & Feneley 2003); 2) role of education on acceptance of the catheter (Roe 1990a); 3) men's and their nurses preferences for condom or indwelling catheters (Saint, Lipsky, Baker, McDonald & Ossenkop 1999); 4) lived experience of long-term urinary catheterization (Wilde 2002a ; Wilde 2002b;Wilde 2003a; Wilde 2003b). Studies which included some subjects with catheters and some without catheters were related to 1) prostate cancer (Jakobsson, Hallberg & Loven 2000); 2) prostatectomy for BPH (Pateman & Johnson 2000); 3) incontinence and sexuality (Roe & May 1999); 4) rehabilitation and incontinence (Seymour 1998); and 5) lower urinary tract reconstruction in cervical spinal cord injury patients (Zommick, Simoneau, Skinner & Ginsberg 2003) (Level of Evidence 4).

In a phenomenological study of the lived experience of 14 long-term catheter wearers, Wilde (Wilde 2002b) used the metaphor of flowing water to characterize the lived experience with a long-term urinary catheter. This study did not address QoL in a direct way, but study participants talked about issues that mattered to them in describing their experiences, many of which had a direct impact on QoL. People talked about the force of urine flow, the weight of the urine bag, and the sound of urine sloshing around in the bag. They spoke of how they learned to pay attention to urine flow to prevent urine accidents, and though feeling vulnerable because of disruptions that it could cause, they also acknowledged that keeping urine flowing was critical to their well being. Living with the catheter was described also as a swing back and forth between stigma when it contributed to embarrassment or shame and acceptance when it was working right and did not cause problems. The catheter became a source of embarrassment during catheter changes, bag emptying, and when it leaked or spilled in public (Wilde 2003a). People used planning and great care when going out (e.g., mapping out the toilets) to prevent urine accidents (Wilde 2002b). They were bothered also by their lack of bodily control, the monotonous care,

and how it was a reminder of their condition and mortality. Leaking, blocking, and urinary tract infection were persistent problems that interfered with daily activities. (Wilde 2002a), (Wilde 2003b) (Level of Evidence 4). Acceptance and non-acceptance of illness was also one of the major themes in a study by Jakobsson et al. (Jakobsson, Hallberg & Loven 2000) of experiences of men with prostate cancer, many of whom were treated with a urinary catheter. The study focused on issues of micturation, treatment with an indwelling catheter, and sexual life. The catheter contributed to feelings of shame, excess hospital visits for complications, and with other treatments for cancer, an end to sexual activity (Level of Evidence 4).

Issues related to sexuality were dominant in several studies. Using a catheter compounded changes in sexual life caused by illness or injury (Seymour 1998); (Wilde 2003a). Embarrassment was also a common experience stemming from exposure to the opposite sex, the visibility of the urine bag, and unpredictability of urine accidents (Pateman & Johnson 2000); (Seymour 1998); (Wilde 2002a) (Wilde 2003a). Male-female sensitivities during catheter insertion by a person of the opposite sex were noted also in men (Pateman & Johnson 2000) and in both sexes (Wilde 2003a). In addition, care providers did not seem to give enough information about sexuality and how to adapt to a catheter, and many catheter users said they needed this information (Wilde 2003a) (Level of Evidence 4).

Complications of autonomic dysreflexia (AD) for people with spinal cord injury had an impact on quality of life. In a qualitative study of incontinence and sexuality by Roe and May (Roe & May 1999), a man was traumatized by negative attitudes of others who thought he was perverted because he needed help disentangling twisted drainage tubing to try to prevent AD from blocked urine flow. In Wilde's study (2002b), several people complained that care providers did not know much about AD and often dismissed their anxiety and concerns (Wilde 2002a).

Studies have also examined quality of life issues related to practical aspects of living with the catheter. In a pilot study of patient preferences for urine bag placement using a mailed questionnaire (n=59), almost 25% said that wearing a bag had a negative affect on everyday living (Fraczyk, Godfrey & Feneley 2003). Concealing the bag was preferred by 89% and, surprisingly, some people wanted their bags placed differently than they currently were positioned (Level of Evidence 4).

Quality of life was addressed in a study of male patients (n=104) and their nurses (n=99) in which preferences were compared for indwelling catheters and sheaths. Among users, sheaths were considered less painful / more comfortable and they interfered less with activity. Nurses, though acknowledging that sheaths fell off more and took more of their time, also thought that condom catheters were easier for their patients and more comfortable (Saint, Lipsky, Baker, McDonald & Ossenkop 1999). One study suggested that surgery for people with cervical SCI may be an alternative for people with indwelling catheters, and it may improve their quality of life. In a study of long-term outcomes for people with cervical SCI who went through lower urinary tract reconstruction, satisfaction was reported as very positive postoperatively in 76% of the sample of 28 individuals, and 80% reported improved quality of life. Twenty of 21 were then able to manage with intermittent catheterization (self or a family member) (Zommick, Simoneau, Skinner & Ginsberg 2003) (Level of Evidence 4).

### *c) Summary*

Quality of life for people with urinary catheters has not been studied adequately (no RCTs or Cochrane reviews). Limited reports of descriptive and qualitative research (Level of Evidence 4) suggest that major QoL issues involve stigma related to exposure and urine accidents, sexuality, and acceptance / non-acceptance of the catheter. Other concerns include disruptions in daily activities because of catheter problems (e.g., blocking, leaking, UTI, dislodgement), catheter associated discomfort, and a lack of knowledge in caregivers (professional and lay) of autonomic dysreflexia in those with SCI.

### *d) Recommendations*

Quality of life measures need to be developed for this population of people who may have different needs than others with incontinence. Existing quality of life instruments for incontinence might be modified using findings from qualitative and descriptive research with catheter users. Studies of incontinent people that include catheter users should present data in ways that give the reader information about this sub-population. Roe's study (Roe 1990a) showing that education can enhance acceptance of the catheter may be a suitable project for replication.

## 8. RESEARCH PRIORITIES

### a) *General*

- Despite much published research, catheter studies have been hampered by methodological weaknesses. There is a need for agreement on key criteria to permit robust comparisons between studies: (i) criteria for symptomatic UTI, (ii) significant bacteriuria in a catheterised patient, (iii) standardised time frames for following patients in studies of catheter-associated infection eg 48h, 5 days, 7 days, 14 days 21 days etc (iv) documentation of the use of antibiotics prior to and during a study eg preoperatively in surgery or commencement of antibiotics for other conditions during the study, (v) patient follow-up to include bacteriuria post catheter removal.
- Better adherence to CONSORT guidelines (Altman et al. 2001) eg double blind randomization with appropriate power calculations, intention to treat analysis with inclusion of study drop-outs
- Need for clinical studies which are adequately powered to detect clinically and economically important endpoints in addition to more easily measured surrogate endpoints such as bacteriuria.
- Comparative studies of different patient groups eg. males and females, different age groups, patients at home and those in institutional care, including quality of life measures.
- Further research on development of biomaterials that resist microbial adherence and biofilm formation and /or prevent catheter-associated bacteriuria in the long-term as well as short-term

### b) *Indwelling catheters*

- To ascertain the significance of asymptomatic bacteriuria in short-term catheterised patients and the potential long-term effects in long-term catheterised patients.
- Studies comparing catheterisation techniques eg suprapubic and urethral catheters, on catheter-associated infection and other risks or potential benefits
- Better prospective data on long-term sequelae eg ongoing symptoms, strictures, calculi, bladder cancer.

- Epidemiological studies of catheter-associated infection in primary and community care.
- Frequency of catheter changes – does the frequency of regular re-catheterisation make a difference to UTI and other complications
- Catheter materials resistant to microbial biofilm formation
- New approaches to disruption of the biofilm
- Clinical evaluation of acidic ‘catheter maintenance’ in managing recurrent catheter encrustation and reducing build up of encrusting material

### c) *Intermittent catheters*

- Further studies on the risks/benefits of single use catheterisation (new catheter used at each insertion) versus single patient use (patients cleans, stores and re-uses the same catheter for several days) for patients whose long-term bladder management is by CISC or CIC.

### d) *Catheter valves*

- Investigation of effect of catheter valves on incidence and frequency of catheter encrustation and blockage
- Cost-effectiveness studies of disposable versus re-useable valves
- Studies designed to demonstrate if catheter valves promote maintenance of bladder tone and capacity
- Further examination of combination management strategies such as valve during the day and free drainage overnight

### e) *Quality of life*

- Identification of appropriate quality of life indicators/criteria and measures for catheterised patients.
- Development of a quality of life measurement instrument including both subjective measures and objective measures such as frequency of catheter blockage, catheter-associated infection, hospitalization, unplanned catheter changes. Adequacy of equipment, knowledge about self care, working with caregivers in catheter management and effects on sexual activity might also be included.

## APPENDIX VIII-1:

### Cochrane catheter-related reviews completed, undergoing revision or nearing completion

- Short term urinary catheter policies following urogenital surgery in adults (Phipps 2004).
- Policies for removal of indwelling urethral catheters for short-term management of voiding in adults and children (Fernandez & Griffiths 2004).
- Types of urethral catheters for management of short-term voiding problems in hospitalized adults (Brosnahan, Jull & Tracy 2004).
- Urinary catheter policies for short-term management of voiding in hospitalized adults. (Niel-Wiese et al., 2003 in progress).
- Urinary catheter policies for long-term management of voiding in adults (Niel-Weise & van den Broek 2004).
- Catheter policies for management of long-term voiding problems in patients with neurogenic bladder (Jamison, Maguire & McCann 2004).
- Methenamine hippurate for preventing urinary tract infections (Lee, Bhuta, Craig & Simpson 2004).
- Washout policies for management of long-term voiding problems in catheterised adults (Mooney et al., 2004 in progress).
- Indwelling bladder catheterisation as part of post-operative care for caesarean section (Page, Buntinx & Hanssens 2004).

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## C. PRODUCTS FOR PREVENTING OR CONTAINING FAECAL INCONTINENCE

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The broader issues of faecal incontinence are dealt with comprehensively in chapter XXXX while this chapter deals with products for preventing or managing faecal incontinence. They fall into three main categories:

- products that aim either to prevent or contain leaked stool.
- products that seek to prevent or mask the offensi-

ve odour that occurs from leaked stool or flatus.

- products for preventing or treating perianal skin damage associated with faecal incontinence (one of the primary complications of faecal incontinence and an important part of care).

Products dealing with skin health and odour are covered in sections DI and D2, respectively, while products for preventing or containing faecal incontinence are covered in this section (apart from absorbent pads, which are included in section BIII).

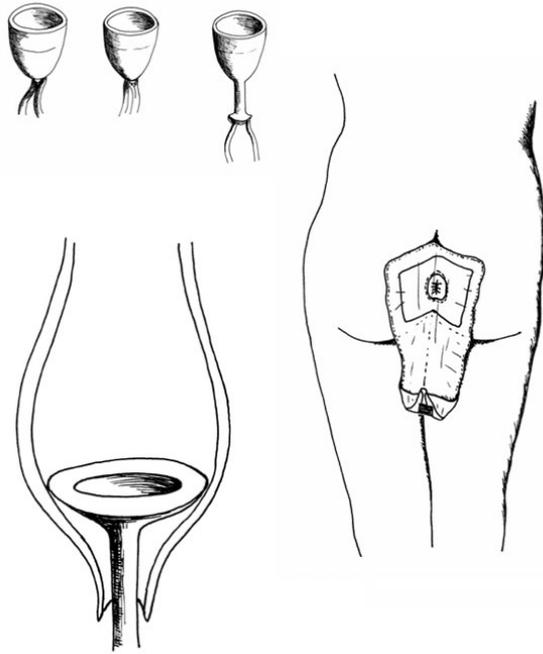
### I. PRODUCTS TO PREVENT OR CONTAIN LEAKED STOOL

- Products fall into three groups:
- Plugs to prevent leakage of faeces.
- Devices to channel faeces from the rectum into a storage container.
- Absorbent pads to contain leaked faeces (see section 3).

An anal plug (**Fig I-1**) consists of a foam, cup-shaped plug that is collapsed and held by a film for insertion; the plug opens when the film comes in contact with the moist rectal mucosa (Mortensen & Humphreys 1991); (Norton & Kamm 2001). It is inserted like a suppository using a lubricant gel. It has a string for removal or it can be expelled by raising intra-abdominal pressure and pushing like during normal defaecation. The anal plug has been used mainly by people who live in the community and are independent in managing faecal incontinence and toileting.

By contrast, devices for channelling faeces from the rectum to a storage container are used primarily by people who are acutely ill, critically ill, bedridden, or in long-term care institutions and receive assistance in incontinence management and toileting by caregivers (Kim et al. 2001); (Duso 1992); (Hanlon & Cofone 1996); (Ross 1993). These devices do not prevent faecal incontinence and are used primarily for preventing or treating skin damage associated with faecal incontinence. They include rectal tubes, catheters, trumpets, and pouches (**Fig I-1**).

Rectal tubes and catheters are inserted into the rectum and drain faeces through openings at their proximal end into a collection bag. Sometimes a balloon slightly distal to the proximal tip is inflated with the aim of preventing leakage of faeces around the catheter and to retard inadvertent expulsion of the



**Figure I-1.** Anal plugs (top left), a rectal trumpet in position in the rectum (bottom left) and a faecal pouch (right).

tube during defaecation (Kim, Shim, Choi, Ahn, Jang & Shin 2001). This arrangement works best with liquid stool which is most likely to be able to flow without blocking the drainage lumen (Freedman 1991); (Ross 1993). Cutting the tip of the catheter off at an angle to facilitate drainage of stool of thicker consistency has been reported (Bosley 1994). A rectal tube / catheter is contraindicated in patients who have intestinal mucosal disease, immunosuppression, gastrointestinal bleeding or bleeding tendencies, recent myocardial infarction or prostate surgery (Beitz 1997); (Bosley 1994). Use of a rectal tube with or without inflating the balloon is controversial because of concerns of perforating the rectum, damaging the anal sphincter or rectal mucosa, stimulating intestinal secretion worsening diarrhoea and thus incontinence (Freedman 1991); (Bosley 1994); (Rainville 1987). Critically ill patients, who often receive a rectal tube, may be at greater risk for intestinal ischemia and rectal damage because they experience shunting of blood from the gastrointestinal tract during shock or low perfusion states.

A rectal trumpet is a nasopharyngeal airway that is inserted into the rectum and connected to a collection bag at its distal end. The flange end of the trumpet is inserted into the rectum (Grogan & Kramer 2002). A possible advantage of the rectal trumpet over a rectal

tube is that it is shorter and has less contact with the rectal mucosa, so limiting the area of possible damage. Other limitations are similar to those for the rectal tube / catheter regarding risk of expulsion from forceful valsalva movements and dislodging during linen changes or from tugging on the collection bag (Grogan & Kramer 2002). Nasopharyngeal airways that can be used as a rectal trumpet are produced by several manufacturers.

A rectal pouch consists of a pliable wafer, which has an opening at its centre, an adhesive on the body side, and a collection bag on the other. The wafer adheres to the perianal skin. The bag has a resealable port at its distal end through which faeces can be drained without the need to remove the wafer from the skin. The port can also be connected to a larger, gravity drainage bag. Some pouches have a small folded flap that allows flatus to escape so that it doesn't inflate and rupture the bag. The pouch avoids the risks of rectal or sphincter damage associated with the rectal tube or trumpet. If used without the additional drainage bag, it can collect leaked stool of any consistency without clogging. A limitation of the rectal pouch is difficulty in applying it on people who have a small space or severe oedema between the anus and vagina or scrotum. Other reported disadvantages include difficulties in maintaining the seal (especially when the perianal skin is already damaged); break of the seal when repositioning the patient; and skin tears by traumatic removal of the adhesive (Grogan & Kramer 2002); (Hanlon & Cofone 1996).

## 1. QUALITY OF DATA

There have been three published evaluations of anal plugs for controlling faecal incontinence in adults and one in children. Two of the adult studies and the pediatric study had a single group, repeated measures design (Mortensen & Humphreys 1991); (Norton & Kamm 2001); (Pfrommer et al. 2000), and the third report in adults was a case series (Christiansen & Roed-Petersen 1993). All of the studies in adults evaluated plugs from the same manufacturer (Coloplast, Denmark). The study in children compared the Coloplast device with one by Med.SSE-System, Germany. The clinical evaluation of another brand of anal plug (Kim, US Patent 5 569 216, apparently not currently commercially available) with bedridden patients with diarrhoea, constipation or loose stools did not investigate faecal incontinence as an outcome (Kim, Shim, Choi, Ahn, Jang & Shin 2001). There has also been one published evaluation of a rectal

trumpet using a case series design (Grogan & Kramer 2002); no comparison group or pre-post measures were included.

## 2. RESULTS

The three evaluations of anal plugs by adults involved relatively small cohorts of adult ambulatory subjects, mostly women. One sample had 10 subjects (Mortensen & Humphreys 1991); the second had 14 (Christiansen & Roed-Petersen 1993); and the third had 34 subjects of whom 20 completed the study (Norton & Kamm 2001). In two studies, subjects were incontinent of both solid and liquid stool (Mortensen & Humphreys 1991); (Christiansen & Roed-Petersen 1993) while the nature of the subjects' incontinence in the third was not reported (Norton & Kamm 2001). The cause of faecal incontinence varied in all three studies and included spina bifida, spinal injury, post-surgical incontinence, sphincteric injury, and obstetric trauma. In the paediatric study, 61% of 38 children (ages 6 to 15 years), completed the study; eight children had overflow incontinence due to constipation (Pfrommer, Holschneider, Loffler, Schauff & Ure 2000). Faecal incontinence was measured by self-report using a daily stool diary before using the plug and during plug use for one (Mortensen & Humphreys 1991), two (Norton & Kamm 2001) or four weeks (Christiansen & Roed-Petersen 1993). A questionnaire was used in the paediatric study after use of the two anal plugs for three weeks each (Pfrommer, Holschneider, Loffler, Schauff & Ure 2000). The main reported outcome measures were: the number of episodes of faecal incontinence per number of anal plugs used due to self removal or need for defecation (Mortensen & Humphreys 1991); the number of patients experiencing no fecal incontinence (Christiansen & Roed-Petersen 1993); (Norton & Kamm 2001) or improved fecal incontinence (Norton & Kamm 2001) when using the plug; and the number of patients able to retain 150 ml of viscous fluid using the plug (Christiansen & Roed-Petersen 1993). The percentage of participants lost to follow-up was 10% (Mortensen and Humphreys), 39% (Pfrommer), 68% (Norton and Kamm), and 80% (Christiansen and Roed-Petersen).

Of the adults who tolerated wearing the plug, it prevented fecal incontinence in 83% (Christiansen & Roed-Petersen 1993); 50% (Mortensen & Humphreys 1991); and 64% (Norton & Kamm 2001) of cases (Level of Evidence = 3 for all three studies). In one study, a further 20% reported an improvement in

faecal incontinence but not complete prevention (Norton & Kamm 2001). Eighty-six percent of persons were able to retain 150 ml of viscous fluid while the plug was inserted (Christiansen & Roed-Petersen 1993). An associated problem reported in one study was that the string used to remove the plug became damp and soiled after four hours of use (Norton & Kamm 2001). The plug slipped out in 43% of patients in one study (Christiansen & Roed-Petersen 1993) and approximately 20% of plug uses in a second (Mortensen & Humphreys 1991). In children, the anal plug prevented faecal incontinence in 68%. One plug (polyurethane foam) was lost during wear by approximately one-third of children, and the other plug (polyvinyl alcohol) was lost by approximately two-thirds of them (Pfrommer, Holschneider, Loffler, Schauff & Ure 2000).

Discomfort was reported by 71% (Christiansen & Roed-Petersen 1993) and 70% (Norton & Kamm 2001) of adult subjects while the adults in the third study (Mortensen & Humphreys 1991) reported discomfort during 10-19% of plug uses. There was no association between comfort of the plug and anorectal sensitivity during anal-rectal physiology tests (Norton & Kamm 2001). Despite efficacy, 64% of the subjects in two of the studies (Christiansen & Roed-Petersen 1993); (Norton & Kamm 2001) said they would not continue to wear the plug. Two of the children who withdrew from the study had complained of discomfort (Pfrommer, Holschneider, Loffler, Schauff & Ure 2000). A "feeling of pressure" while wearing the plug was reported in 39% of children (Pfrommer, Holschneider, Loffler, Schauff & Ure 2000). It was not evident from the report whether the children were asked about "discomfort" or "pain" while wearing the anal plug. Adults rated all three anal plugs that were evaluated as relatively easy to insert. Two plugs were difficult to remove in only 5% to 6% of uses while the third was difficult to remove in 23% of uses (Mortensen & Humphreys 1991). Twenty percent of children reported that insertion of one plug was painful while twenty percent found removal of the other plug to be painful; one child experienced bleeding on removal of this second plug. Contrary to the majority of adults, children appeared to have greater tolerance of the anal plug.

One case series study evaluated the use of a rectal trumpet in 22 acutely or critically ill patients with faecal incontinence and perineal skin damage. For 90% of the subjects, the skin damage had been caused by wearing a rectal pouch immediately prior to

the study. Subjects used the trumpet for periods varying between 36 hours and 16 days (mean 6.5 days; sd 4.4 days). The reasons for any discontinuation of use were reported. Outcome was determined using a daily questionnaire completed by patients' nurses and the health of the perianal skin was noted by subjective assessment. No standardised definitions or criteria for restoration of skin integrity or healing of skin damage were reported. Two subjects were lost to follow up. Faeces were successfully diverted to and contained by the collection bag in all patients. Recovery from skin damage was reported in 7 (39%) patients and partial healing of skin in the remaining 11 (61%). Discomfort on insertion was noted for 41% of subjects (Level of Evidence 3).

A new rectal catheter and collection bag system specifically designed for extended use and diversion of faeces has been developed (Zassi Medical evolutions, Fernandina Beach, FL, USA). The retention cuff collapses to assist with insertion (US FDA approved for up to 29 days) and there is also a collapsible zone below the cuff that resides in the anus to allow normal anal sphincter function during use. The catheter is equipped with ports for irrigation and sampling. In a recent abstract, use of this catheter did not result in any complications and was associated with reductions in infections of the urinary tract (approximately 50% decrease), skin and soft tissue (~60%) and bloodstream (~2%) in burn unit patients compared to historical controls ((Echols & Freidman 2004)). Two months were required to train nursing staff to use the new catheter system (Level of Evidence 3).

### 3. SUMMARY

Anal plugs can successfully prevent faecal incontinence but they are associated with high levels of discomfort (Level of Evidence 3).

Rectal trumpets can successfully channel faeces to a collection bag and there is some evidence that they can thereby enable damaged perianal skin to recover but they are associated with high levels of discomfort (Level of Evidence 3).

### 4. RECOMMENDATIONS

- Anal plugs and rectal trumpets may be tried but many patients are likely to reject them due to discomfort (Grade of Recommendation C).
- The use of a rectal trumpet in patients with loose/liquid stool consistency offers an alternative to the rectal pouch when pouch adherence is a problem and may preserve perianal skin integrity or facilitate healing (Grade of Recommendation C). The rectal trumpet may be associated with fewer risks than a standard longer rectal tubes (Grade of Recommendation C).
- Use of standard rectal tubes with and without inflatable balloons for fecal diversion are indicated primarily for non-ambulatory patients with liquid stools (Grade of Recommendation C). However, the safety of prolonged use of these types of catheters requires further study.
- Use of a rectal pouch attached to a drainage catheter to divert liquid stool is recommended, but there is a risk of skin damage. For this reason it is not recommended in cases where the need for faecal diversion is less acute (e.g. where stool is more formed) (Grade of Recommendation C).

### 5. RESEARCH PRIORITIES

- Development of an anal plug that is more comfortable and tolerable.
- More rigorous evaluation of anal plugs using larger subject cohorts and more objective outcome measures over longer periods of use.
- More rigorous evaluation of rectal tubes / catheters and trumpets using larger subject cohorts and more objective outcome measures over longer periods of use.
- Development and evaluation of a rectal pouch that is easy to apply and remove, adheres to skin better and, perhaps, even promotes healing of damaged skin to which it would be applied.

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## D. OTHER CONTINENCE PRODUCT RELATED ISSUES

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### I. SKIN HEALTH AND CONTINENCE PRODUCTS

The skin of an incontinent individual will be regularly exposed to contact with urine and/or faeces and damage to the skin is the main physical health consequence of urinary and faecal incontinence. The majority of current knowledge about the effects of urine and faeces on skin has been obtained from studies with pads or pad materials on animals, healthy infants, and on body areas such as the forearm or back of adults. Where clinical trials have been conducted, they have usually been on infants and rarely on adults using pads. Skin irritation within the pad occlusion area is usually termed diaper dermatitis in infants and perineal dermatitis in adults.

#### 1. THE ROLE OF URINE AND FAECES IN SKIN IRRITATION

Prolonged exposure to water alone has been shown to cause hydration dermatitis (Kligman 1994); (Tsai & Maibach 1999) and prolonged occlusion of the skin (as within a continence product) has been demonstrated to reduce skin barrier function (Fluhr et al. 1999) and significantly raise microbial counts and pH (Faergemann et al. 1983); (Aly et al. 1978). Repeated wetting and drying makes the skin more vulnerable to substances that are usually innocuous, e.g., bile salts (Suskind & Ishihara 1965); (Berg, Buckingham & Stewart 1986).

A product that simply maintains wet and occluded skin (even without the additional constituents of urine and faeces) is therefore likely to cause skin irritation and increase skin permeability to other irritants.

Using a hairless mouse model Buckingham and Berg (Buckingham & Berg 1986) examined the role of faeces in the aetiology of diaper dermatitis. They identified proteases and lipases as the major irritants and noted that these faecal enzymes not only irritated the skin directly but also increased the susceptibility of the skin to other irritants such as bile salts. The irritant effect of faeces was virtually eliminated by heating, which destroys enzymes, and was restored by the replacement of specific enzymes (e.g., lipase

and protease). Skin damage appeared dependent on the concentration and length of exposure to enzymes in faeces (Andersen et al. 1994).

A similar mouse model was used by the same researchers (Berg, Buckingham & Stewart 1986) to examine the role of urine in the aetiology of diaper dermatitis. They found that the irritant potential of urine by itself was minimal over short periods (48 hours) but after continuous exposure (10 days), skin damage became apparent. The researchers also measured skin permeability and found that continuous exposure to urine greatly increased skin permeability (more than 15 fold) compared to occluded skin or skin exposed only to water.

However, the combination of urine and faeces caused significantly higher levels of irritation than urine or faeces alone. The authors concluded that the presence of faecal urease results in the break down of urinary urea causing an increase in pH, which increases the activities of faecal proteases and lipases leading to skin irritation. The role of microorganisms, which comprise approximately 50% of the solid component of faeces, in skin damage is unresolved. Microorganisms on the skin of infants with and without diaper dermatitis were similar (Leyden 1986). Zimmerer et al. (Zimmerer, Lawson & Calvert 1986) sampled the microflora of the skin after pre-loading with pre-wetted patches containing urine and found that the microbial counts were significantly higher for wet patches relative to the dry patch controls. It was nearly impossible to establish infection with the opportunistic organism, *Candida albicans*, on normal skin without complete occlusion of the site (Maibach & Kligman 1962). Therefore, it is thought that bacterial or fungal infection is secondary to alterations in the skin barrier that allow penetration of the microorganisms (Faria, Shwayder & Krull 1996).

Zimmerer et al. (Zimmerer, Lawson & Calvert 1986) examined the role of skin wetness in the development of diaper dermatitis by using the volar forearms of adult volunteers. They aimed to determine the effects of wet and dry diaper materials on skin health with respect to friction, abrasion damage, permeability and microbial growth. Pre-wetted patches of baby diapers were placed on the volar forearms of adults for two hours and then the skin was subjected to friction and abrasion. The coefficient of friction for the 'wet' skin was significantly higher than for 'dry' skin although increased fluid loading of wet patches did not further increase skin friction. Similarly, skin hydrated with a wet patch showed a signi-

ficant increase in skin abrasion damage relative to a dry patch. Again, variations in the fluid loading of the patch did not produce significant changes in abrasion damage.

Although the volar forearm is most commonly used for skin experimentation, it has not been shown to be a valid model for the skin exposed to an incontinence pad, i.e., buttocks and groins. Schnetz and colleagues (Schnetz et al. 1999) demonstrated that trans-epidermal water loss (TEWL) measurements (used to measure both skin barrier function and excess water in the skin) from the volar forearm did not correlate with those taken from the face, although the left and right side of the face showed good correlation. The researchers concluded that TEWL measurements for the study of facial cosmetics should be taken from the face rather than the forearm. Similarly, studies using the volar forearm may not be valid for the buttocks and groin. Skin in the perianal area was shown to be more sensitive to faecal irritation than that on the inner arm (Caplan 1966).

Berg (Berg 1987) analysed the aetiological factors contributing to infant diaper dermatitis and developed a model (**Fig I-1**) to show its development and resolution. However, the applicability of this model to adults with incontinence has not been tested, and other factors such as low mobility and prolonged pressure - which are common in frail, older adults - are not accounted for in this model. In addition, this model assumes the presence of urinary and faecal incontinence, which is much less common in adult populations than urinary incontinence alone.

#### **b) Prevalence of perineal dermatitis**

Perineal dermatitis (PD) is an inflammation of the skin characterized by redness, tissue breakdown or denudement, vesiculation, oozing, crusting, soreness, itching, and in its more severe form, pain and fungal patches (Brown & Sears 1993); (Gray 2004)

within the pad area. In a study of assessment records of more than 59,000 residents in 510 nursing homes located in 31 US states, Bliss et al. (Bliss et al. 2002) reported a prevalence of perineal dermatitis of 7%. In studies with smaller sample sizes, perineal dermatitis (**Table I-1**) has been shown to affect about a third to a half of patients wearing pads.

Most researchers have reported ratings of colour changes (degree of erythema) based on visual inspection, which may be confounded by the presence of reactive hyperaemia on areas subject to pressure (particularly the buttocks and sacrum). These proportions may therefore be overestimates. Bliss et al. (Bliss et al. 2003) prospectively investigated the development of PD using assessment data of 1,850 elders who were free of PD at admission to a nursing home. The preliminary report showed that at three months after admission, faecal incontinence alone and double incontinence were significant predictors of PD, but urinary incontinence alone was not a significant risk.

#### **c) Pressure ulcers and incontinence**

The role of urinary and faecal incontinence in the development of pressure ulcers is uncertain. Studies aiming to identify risk factors for the development of pressure ulcers have generally found that the presence of both urinary and faecal incontinence was a risk (Maklebust & Magnan 1994); (Watret 1999); (Brandeis et al. 1994); (Bergquist & Frantz 1999), but some studies have only found faecal rather than urinary incontinence to be a risk factor (Theaker et al. 2000); (Spector & Fortinsky 1998). Pressure ulcer risk assessment scales all have a sub-scale of incontinence or moisture-level, and the main mechanism for the development of pressure ulcers has been thought to be the increased friction and increased vulnerability to abrasion of wet skin.

Recently Fader et al. (Fader et al. 2003), examined the effects of absorbent continence pads on mattress

**Table I-1. Studies to determine the prevalence of perineal dermatitis**

<b>Authors</b>	<b>Sample</b>	<b>Prevalence of dermatitis</b>
Lyder in full	15 older people: psychogeriatric wards	33%
Keller, Sinkovic & Miles 1990)	95 older people: long stay	53%
Gray 2001	50 adults (ambulatory urodynamics)	42%
Brown 1994b	166 adults (acute medical wards)	35%

### Diaper environment

Increased skin wetness  
Increased skin permeability  
Higher skin friction coefficient  
Lower skin abrasion resistance  
Greater microbial load  
Increasing pH

### Caretaker intervention

Increased diaper changing  
Increased bathing  
Topical medication  
Improved diapers

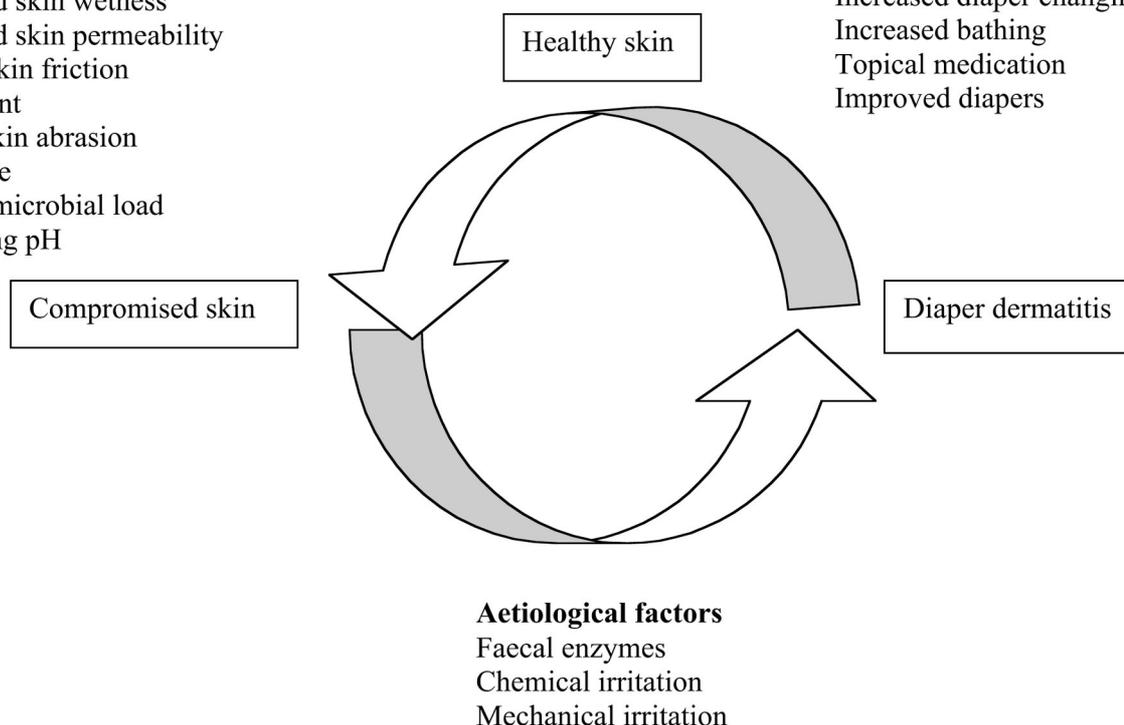


Figure I-1. Berg's model of diaper dermatitis (1987).

interface pressures using an articulated model or “phantom” as the subject and found that the presence of a pad significantly and substantially (around 20%) increased the peak pressures recorded between the buttocks and the pad. Peak pressures were frequently found at the locations of pad creases and it was considered that pad folding and compression may contribute to raised interface pressures. It is therefore possible that continence product use contributes to the formation of pressure ulcers by raising interface pressures.

## 2. CLINICAL STUDIES OF THE IMPACT OF PRODUCTS AND PRODUCT MATERIALS ON SKIN HEALTH

Product manufacturers introduced diapers with super-absorbent polymers (SAP) in the 1980s, which were designed to reduce skin wetness, buffer pH and reduce urine/faecal contact in order to help prevent diaper dermatitis. This led to clinical and laboratory studies to evaluate the efficacy of diapers with different materials, in particular, super-absorbent polymers (SAP) compared to those without, and compared to conventional washable diapers.

### a) Quality of data

There are three types of studies testing the effects of different products or product materials on skin health: (i) clinical trials of normal infants wearing diapers; (ii) laboratory wet patch testing of adult forearms with diaper or continence pad patches; and (iii) clinical trials of adult absorbent pads containing different materials. The infant diaper studies were randomised controlled trials with large samples and blind measurement of outcomes. It should be noted that these studies were carried out by industry employed staff. The infant and laboratory studies used a probe comprising two hygrosensors and thermistors (an evaporimeter) placed on the ‘wet’ skin to measure trans-epidermal water loss (TEWL), an indicator of skin hydration level. However, there is uncertainty about optimum procedures for measuring TEWL, and different procedures and outcomes were used in the studies, making it difficult to compare results. Probably the most important threat to the validity of these studies is the selection of products or materials used in the study. None of the studies adequately described the products used - in particular regarding their total absorbency. Thus it is possible that an alternative explanation for the fairly

consistent findings that disposable pads with SAP perform better on skin outcome measures may be that those with SAP simply had greater absorbency than those without.

## **b) Results**

### **1. CLINICAL STUDIES OF ADULT ABSORBENT PRODUCTS**

Campbell and colleagues (Campbell et al. 1987) conducted four clinical studies involving 1,614 infants randomly assigned to either disposable diapers with SAP, disposable diapers without SAP or washable cloth diapers. Disposable diapers with SAP were associated with significantly reduced skin wetness as measured by TEWL, lower pH and lower ratings of diaper dermatitis when compared to the two other diaper products (Level of Evidence 2).

Lane et al. (Lane, Rehder & Helm 1990) randomised disposable diapers without SAP and disposable diapers with SAP to 149 newborn infants and assessed their skin condition 7 times over a 14 week period. Skin rash ratings were significantly lower for infants wearing diapers with SAP at only one time period (14 weeks) (Level of Evidence 2).

Davis and colleagues (Davis et al. 1989) assessed 150 infants over 15 weeks in a cross-over study involving four different disposable diaper types, two with different levels of SAP and two with different levels of fluff pulp only. Both diapers containing SAP were associated with significantly less skin wetness and significantly lower pH. Clinical skin ratings showed significantly lower ratings for the SAP-containing pads compared to the lower weight fluff pulp pad, but not compared to the higher weight fluff pad (Level of Evidence 2).

### **2. LABORATORY STUDIES OF DIAPER PATCHES**

Wilson and Dallas (Wilson & Dallas 1990) used the adult normal volar forearm skin model to compare patches taken from 16 different infant diapers. They found that disposable diapers containing SAP left the skin significantly drier than washable diapers and disposable diapers without SAP ( $p < 0.01$ ). Disposable diapers without SAP did not differ significantly from reusable diapers and there were no significant differences between products within any of the three groupings (Level of Evidence 2).

However, in a subsequent study involving 20 disposable and washable adult incontinence pads incorporating a similar range of materials to the baby diaper study Dallas and Wilson (Dallas & Wilson 1992) found significant differences between products

within each of the three product groupings but not between groupings (Level of Evidence, 2). Grove et al. (Grove et al. 1998) used a similar approach to compare three infant diapers and found a significant difference in skin wetness between two that contained similar quantities of SAP ( $p < 0.001$ ). The one in which the SAP was in a layer near the water-proof backing kept the skin dryer than that in which it was near the coverstock. The third diaper – which had a microporous (breathable) backing kept the skin significantly dryer than each of the other two ( $p < 0.001$ ) (Level of Evidence 2).

### **c) Clinical studies of adult absorbent products**

There has been one clinical study of adult incontinent patients comparing underpads with and without SAP, diapers with and without SAP and washable cloth underpads and which used skin condition as the primary outcome variable (Brown 1994b). This study included 166 incontinent patients (urine, faeces or both) from three acute care facilities who were divided into the 5 groups. It is unclear whether randomisation to group occurred by patient or by facility. One facility used the washable cloth underpads only for their patients. Other patients tested either diapers or underpads and crossed-over from without SAP to with SAP products after 6 weeks. Skin measurements were made for colour, integrity and symptoms using rating scales. Both blind and non-blind measurements were made.

Findings were rather complex and difficult to interpret and no corrections for multiple comparisons appear to have been made. Overall there were no differences in skin measurements between the diaper and underpad groups, but for some measurement sub-groups, differences were found with mean colour scores being significantly higher (worse) in the without-SAP diaper group and the washable cloth underpad group. Blinded 'worst' skin colour scores were highest for without-SAP diapers and washable cloth underpads and lowest for with-SAP products. Overall the findings supported the favourable affects of SAP on skin health but, as with the infant diaper studies, total absorbency of the products was not reported (Level of Evidence 2).

Hu et al. (Hu, Kaltreider & Igou 1990) randomised an unnamed range of disposable insert pads with mesh pants to 34 nursing home residents who were matched (based on incontinence severity) with 34 residents who received the usual reusable cloth diaper product. Skin condition was rated at baseline and after the 5 week intervention period by a blinded

nurse researcher. Skin condition was reported to be significantly better in the disposable pad group (Level of Evidence 2).

### **3. CLINICAL STUDIES OF SKIN-CARE PRODUCTS AND NURSING PRACTICES TO MAINTAIN OR IMPROVE SKIN HEALTH**

The skin of incontinent people requires frequent cleansing to remove urine and/or faeces. Soap and water is in common use (Skewes 1997) but it is known that repeated exposure to anionic surfactants (common in soaps) results in skin irritation (van, V & Maibach 1990); (Klein, Grubauer & Fritsch 1992). In addition, the action of washing is also considered likely to contribute to mechanical damage of the stratum corneum. Alternative cleansers are available which have been formulated with the intention of overcoming some of the limitations of soap and water. Although overhydration of skin is detrimental, an excessively dry stratum corneum develops cracks and fissures and can be as ineffective a barrier as an over hydrated one (Tsai & Maibach 1999).

The use of topical products aiming to prevent or treat skin irritation is common but there is a lack of standardisation in definitions and descriptions of products, which makes comparisons difficult. Products such as 'moisturisers' or 'barriers' may be applied to the skin after cleansing, and some cleansers also incorporate moisturisers. The aim of moisturisers (also known as emollients) is to hydrate the skin by preventing trans-epidermal water loss through occlusion (e.g. petrolatum), by drawing water into the stratum corneum by the addition of a humectant (a hygroscopic substance, e.g. glycerol) or by adding water in the applied water-miscible product. These modes of action are often combined in the same product, but there are exceptions - such as petrolatum - which only work by occlusion (Ghadially, Halkier-Sorensen & Elias 1992). Some products are designed specifically to prevent penetration of water into the stratum corneum ('barrier' products) such as liquid skin sealants containing polymers, and may allow trans-epidermal water loss whilst preventing external water penetration. Simple occlusive products such as petrolatum may also act as barrier products to water but also occlude trans-epidermal water loss.

Topical creams are commonly used to prevent and treat dermatitis but controlled experiments to assess efficacy on human and animal skin have produced equivocal results. Ghadially et al. (Ghadially, Halkier-Sorensen & Elias 1992) showed that barrier

recovery (measured by TEWL) on experimentally irritated skin was accelerated by the application of petrolatum and De et al. (De et al. 2001) showed similar results using a different moisturising cream. Hannuksela and Kinnunen (Hannuksela & Kinnunen 1992) showed that treatment with moisturisers prevented the development of irritation in an experiment involving frequent skin washing with liquid detergent. However, Gabard (Gabard 1994) was unable to demonstrate significant acceleration of barrier recovery to chronically irritated skin following application of different moisturisers using a chronic irritation model and also found that some creams enhanced irritation.

The efficacy of barrier products in preventing water penetration of the skin has been tested in laboratory settings. Vinson and Proch (Vinson & Proch 1998) applied wet patches with a water-soluble marker to skin coated with three different barrier products and measured dye extracted from the skin by absorbance spectrophotometry. One multiple barrier product performed significantly better than a petrolatum-based and an allantoin-based protectant. Waring and Hoggarth (Waring & Hoggarth 2004) used a Chromameter to measure skin colour change after staining skin with a water-soluble dye, covering it with a barrier product and washing the skin. Petrolatum products were found to be more effective barriers than dimethicone-based products.

Other practices that may affect skin health include frequency of pad changing. Increasing pad changing may reduce skin wetness by application of a dry pad and may therefore benefit skin health. Increased pad changing is commonly recommended to prevent or treat dermatitis particularly in infants (Berg 1987).

#### ***a) Quality of data***

Studies of skin cleansing and/or moisturising/barrier products to prevent perineal dermatitis have been limited by being uncontrolled (Warshaw et al. 2002), (Dealey 1995); (Bale et al. 2004); (Hunter et al. 2003) and of small size and lacking adequate power calculations (Byers et al. 1995); (Whittingham & May 1998); (Lyder, Clemes-Lowrance, Davis, Sullivan & Zucker 1992), or not including any clinical outcome measures (Byers, Ryan, Regan, Shields & Carta 1995). Measurement of dermatitis may also have been compromised by reactive hyperaemia on skin areas subject to pressure. Only three randomised controlled trials of a topical preparation to prevent perineal dermatitis could be found and one randomised crossover trial of pad changing frequency.

## **b) Results**

### **1. SKIN CLEANSING / MOISTURISING PRODUCTS TO PREVENT DERMATITIS**

Byers et al. (Byers, Ryan, Regan, Shields & Carta 1995) compared four different cleansing/moisturising regimes including soap and water using a multiple cross-over design. Despite having a very small sample size ( $n = 12$  elderly women) they found statistically significant differences in TEWL, pH and erythema between some of the regimes, and soap and water was found to be the least effective product for skin health. No clinical outcomes were measured and differences in outcomes were small (Level of Evidence 2).

Cooper and Gray (Cooper & Gray 2001) randomised 93 long-term elderly subjects to skin cleansing with soap and water or with a foam cleanser over a 14 day period and blindly assessed perineal skin photographs at zero, seven and 14 days. The skin of 37% of subjects using soap and water remained 'healthy' compared to 66% of subjects using the foam cleanser. However, statistical analysis was not carried out (Level of Evidence 3).

Lewis-Byers and Thayer (Lewis-Byers & Thayer 2002) randomised 32 nursing home residents with incontinence to a soap and water or no-rinse cleanser regime over a period of three weeks. No significant differences in skin condition were found but no power calculations were included (Level of Evidence 3).

Although these studies did not demonstrate robust differences in skin outcomes when using different cleansing regimes, they do indicate other benefits - in particular, that savings in nursing time may be made (Whittingham & May 1998); (Byers, Ryan, Regan, Shields & Carta 1995); (Lewis-Byers & Thayer 2002) and that staff opinion was favourable towards cleansers rather than soap and water. However, no detailed comprehensive economic analyses have been made.

### **2. SKIN PRODUCTS TO TREAT DERMATITIS**

In a double blind controlled trial of 64 subjects, Anthony et al., (Anthony et al. 1987) compared the efficacy of cream formulated to treat dermatitis (Sudocrem) with zinc cream BP. Thirty subjects showed inflammatory lesions of the buttocks and a significantly greater proportion of subjects allocated to Sudocrem showed reduction in skin redness at both seven days and 14 days. No differences were found in the prevention of inflammatory lesions bet-

ween the two groups. Skin measurements were made over the ischial tuberosities but the effect of reactive hyperaemia was not accounted for. There was no control group receiving no skin treatment and therefore it was not possible to establish the efficacy of using cream as treatment per se (Level of Evidence 2).

### **3. PAD CHANGING FREQUENCY**

Fader et al. (Fader, Clarke-O'Neill, Cook, Dean, Brooks, Cottenden & Malone-Lee 2003) investigated the effect of different frequency of night-time pad changing on 81 incontinent nursing / residential home subjects from 20 homes. Following a two week baseline period, subjects were randomised by home to pad changing at 22.00 and 06.00 for four weeks followed by 22.00, 02.00 and 06.00 for four weeks, or vice versa. Skin measurements of instrumental erythema (using an erythema meter), visual rating, trans-epidermal water loss and pH were made at baseline and during the last two weeks of each regime with instrumental erythema measurements used as the primary outcome variable. Trans-epidermal water loss measurements were significantly higher when pads were changed less frequently (22.00 and 06.00) indicating that skin was wetter. No other significant differences were found. However 5 subjects developed stage II pressure ulcers in the less frequent pad changing regime compared to none in the frequent pad changing regime. Although more frequent pad changing did not demonstrate less dermatitis / erythema, the pressure ulcer findings - though non-significant - make it unwise to conclude that less frequent pad changing does not damage skin health (Level of Evidence 2)

## **4. SUMMARY**

- Perineal dermatitis is a common problem amongst absorbent product users. (Level of Evidence 2).
- Skin wetness is probably the main cause of perineal dermatitis (Level of Evidence 2).
- Faecal incontinence is more irritating than urinary incontinence, but the combined effects of urine and faeces is particularly damaging to skin (Level of Evidence 2).
- Absorbent pads containing super absorbent polymers are associated with reduced skin wetness (Level of Evidence 3).

- Wet skin is more vulnerable to friction and abrasion injury (Level of Evidence 2).
- Pressure ulcers are associated with urinary and faecal incontinence (Level of Evidence 2).
- Absorbent products may raise interface pressures measured under the buttocks (Level of Evidence 3).
- There are indications that skin cleansers may be more cost-effective than soap and water and may be better for skin health (Level of Evidence 2).
- Barrier skin products may prevent water penetration into the stratum corneum (Level of Evidence 3).
- Regular use of topical preparations such as moisturisers or barrier creams may protect skin from dermatitis, but this has not been demonstrated in a clinical trial (Level of Evidence 3).
- More frequent pad changing has not been shown to prevent dermatitis, but less frequent pad changes may be associated with pressure ulcers (Level of Evidence 3).

## 5. RECOMMENDATIONS

- Absorbent pads with SAP should be selected in preference to those without (Grade of Recommendation B).
- Absorbent pads should be changed regularly to minimise wet skin (Grade of Recommendation C).
- Patients with faecal or double incontinence should be changed as soon as possible after incontinence has occurred to prevent the development of dermatitis from protease and lipase activity (Grade of Recommendation B).
- Patients should be washed gently at times of pad change with either soap and water or cleansers. Cleanser may be less time-consuming than soap and water. (Grade of Recommendation C).
- Barrier creams may be applied to skin within the pad area to reduce water penetration of the skin (Grade of Recommendation C).
- Buttock and sacral areas should be protected using topical skin barrier products, containment products or diversion devices in patients vulnerable to perineal dermatitis or pressure ulcers (Grade of Recommendation C).

## 6. RESEARCH PRIORITIES

Controlled randomized trials that investigate the effectiveness of skin care products to prevent or treat perineal skin damage due to urinary and faecal incontinence are recommended. The studies should determine appropriate sample sizes using power analyses. Analyses need to be powered to distinguish effects on participants with faecal or double incontinence. Objective measures from instruments, standardized clinical assessments, and patient symptom ratings can be included. Comparisons among products of various compositions are encouraged.

## II. ODOUR CONTROL PRODUCTS

Fear of smelling is a major concern that preoccupies many people suffering from incontinence and it is an issue that has been raised in several qualitative studies that have explored the subjective opinion of the patient (eg (Ashworth & Hagan 1993); (Roe & May 1999); and (Paterson, Dunn, Kowanko, van, Stein & Pretty 2003)). Accordingly, there is a demand for products which will mask odour or, preferably, prevent it.

### 1. PRODUCTS FOR URINARY INCONTINENCE

Fresh, infection-free urine smells only slightly but bacterial action on urea over time yields pungent smelling ammonia.

A variety of anti-microbial solutions are available for washing such products as hand-held urinals or for treating urine spillage onto soft furnishings such as carpets. They aim to prevent smell by destroying the bacteria responsible for break down of urea. There are no robust published studies that have sought to evaluate such products. Another approach is to mask the smell of stale urine using a strong but (hopefully) pleasant smelling liquid. There are no robust published studies on such products either but anecdotal evidence suggests that, in time, the masking smell comes to be associated with the incontinence that it is intended to disguise. Several companies supply products (washable bedpads, carpets, chairs, clothing and bed linen) made with fabrics that have been treated with anti-microbial agents intended to reduce the smell of any urine on or in them. However, again, there have been no robust published studies to investigate efficacy.

One of the 12 disposable bodyworn pads for lightly incontinent women evaluated by Clarke-O'Neill et al. (Clarke-O'Neill, Pettersson, Fader, Cottenden & Brooks 2004) was treated with a lavender scent but it was not found to perform significantly better than the other products in terms of preventing smell. However, the scent was appreciated by 18% of the 50 test subjects, who commented favourably on it.

## 2. PRODUCTS FOR FAECAL INCONTINENCE

Odour associated with faecal incontinence may occur from involuntarily leaked stool or flatus. In a study with subjects eating a self selected diet, Moore et al. (Moore, Jessop & Osborne 1987) identified the volatile chemicals primarily responsible for faecal odours as the methyl sulphides: methanethiol, dimethyl disulphide, and dimethyl trisulphide. Hydrogen sulphide was thought to make a smaller contribution. In a subsequent study with persons consuming a bolus of pinto beans and lactulose (a non-absorbable carbohydrate) Suarez et al. (Suarez, Springfield & Levitt 1998) attributed the odour of flatus to the sulphur compounds, hydrogen sulphide, methanethiol, and dimethyl sulphide. The intensity of the odour in flatus was related to the concentration of the sulphur-containing compounds: the ability of the human nose to recognise malodorous odour appears to be related to the amount of gas expelled (Suarez, Springfield & Levitt 1998).

Different states of health and gastrointestinal function, diet composition, relative concentrations of sulphide gases and, possibly, short chain fatty acids or ammonia are expected to contribute to the odour of faeces and flatus (Moore, Jessop & Osborne 1987) and (Suarez, Springfield & Levitt 1998).

There are several commercially available devices that are designed to absorb the odour of flatus. One product has been tested on the flatus of normal subjects. Originally called the "Toot Trapper," the renamed "Flatulence Filter," (UltraTech products, Inc., Houston, TX, USA) is a cushion or pad (which can be placed directly against the anus) that is lined with activated charcoal. Both the cushion and pad are encased in either a washable or a disposable cover. There are no reports of it being evaluated by persons with faecal incontinence.

There are similar products by other manufacturers (e.g., Flat-D by Flat-D Innovations, Inc., Iowa, USA and GasMedic and GasBGon by Dairiair and manufactured by ECVC, Greenville, NC, USA) but scientific investigation of their effectiveness is lacking.

Some products aim to reduce the amount of malodo-

rous flatus that is produced. Administration of the probiotic, *Lactobacillus plantarum*, ( $5 \times 10^7$  cfu/ml) in a randomized trial of 60 patients with IBS significantly reduced flatulence by half in 44% of patients. Only 18% of the placebo group reported reductions of flatulence (Nobaek et al. 2000). Although administration of charcoal, yucca and zinc acetate reduced the percentage of episodes of malodorous gas (Giffard et al., 2001), there are inconsistent findings about reductions in flatulence from ingesting activated charcoal in humans (Suarez et al. 1999); (Hall, Jr., Thompson & Strother 1981). The over-the-counter product, Beano, which contains alpha-galactosidase, was shown to reduce flatulence in normal persons for the few hours following the consumption of a meal of beans (Ganiats et al.).

Although a reduction in the amount of intestinal gas produced may decrease the volume of odour, it may not decrease its potency or perceived odour.

A few products are available that aim to prevent, absorb, or control odour associated with involuntarily leaked stool or flatus associated with faecal incontinence. These include cushions and pads that absorb odour as well as probiotics and enzymes, which aim to reduce production of malodorous gas. In spite of the fact that odour prevention is such a key issue for those with faecal incontinence, there are no robust published studies that have evaluated the efficacy of any odour control products."

## 3. RECOMMENDATIONS

- Although there is insufficient evidence to recommend the use of any odour control products, there is anecdotal evidence of efficacy for some users. Accordingly, there may be value in offering patients the opportunity to try products for themselves (Grade of Recommendation D).

## 4. RESEARCH PRIORITIES

- Investigation of whether probiotics or changes in dietary intake can modulate or reduce the odour of flatulence or leaked faeces.
- Development of an absorbent product that can reduce the odour of leaked faeces while protecting the skin.
- Investigation of the efficacy of anti-microbial agents in textile products (soft furnishings and bedding) for reducing odour associated with urinary and faecal incontinence.

## REFERENCES

- Addison, R. 1999, "Catheter valves: a special focus on the Bard Flip-Flo catheter", *British Journal of Nursing*, vol. 8, no. 9, pp. 576-80.
- Aguilera, P. A. & Choi, T. 2004, Ultrasound-guided suprapubic cystostomy catheter placement in the emergency department.
- Altman, D. G., Schulz, K. F., Moher, D., Egger, M., Davidoff, F., Elbourne, D., Gotzsche, P. C. & Lang, T. 2001, "The revised CONSORT statement for reporting randomized trials: explanation and elaboration", *Ann.Intern.Med.*, vol. 134, no. 8, pp. 663-694.
- Aly, R., Shirley, C., Cunico, B. & Maibach, H. I. 1978, "Effect of prolonged occlusion on the microbial flora, pH, carbon dioxide and transepidermal water loss on human skin", *J.Invest Dermatol.*, vol. 71, no. 6, pp. 378-381.
- Anderson, P. J., Walsh, J. M., Louey, M. A., Meade, C. & Fairbrother, G. 2002, "Comparing first and subsequent suprapubic catheter change: complications and costs", *Urologic Nursing*, vol. 22, no. 5, pp. 324-5.
- Anthony, D., Barnes, E., Malone-Lee, J. & Pluck, R. 1987, "A clinical study of Sudocrem in the management of dermatitis due to the physical stress of incontinence in a geriatric population", *J.Adv.Nurs.*, vol. 12, no. 5, pp. 599-603.
- Armitage, P. & Berry, G. 1994, *Statistical methods in medical research*, 3rd edn, Blackwell Oxford.
- Ashworth, P. D. & Hagan, M. T. 1993, "The meaning of incontinence: a qualitative study of non-geriatric urinary incontinence sufferers", *J.Adv.Nurs.*, vol. 18, no. 9, pp. 1415-1423.
- Baan, A. H., Vermeulen, H., van der, M. J., Bossuyt, P., Olszyna, D. & Gouma, D. J. 2003, "The effect of suprapubic catheterization versus transurethral catheterization after abdominal surgery on urinary tract infection: a randomized controlled trial", *Dig.Surg.*, vol. 20, no. 4, pp. 290-295.
- Baker, J. & Norton, P. 1996, "Evaluation of absorbent products for women with mild to moderate urinary incontinence", *Appl.Nurs.Res.*, vol. 9, no. 1, pp. 29-33.
- Bakke, A., Digranes, A. & Hoisaeter, P. A. 1997, "Physical predictors of infection in patients treated with clean intermittent catheterization: a prospective 7-year study", *British Journal of Urology*, vol. 79, no. 1, pp. 85-90.
- Bakke, A. & Vollset, S. E. 1993, "Risk factors for bacteriuria and clinical urinary tract infection in patients treated with clean intermittent catheterization", *Journal of Urology*, vol. 149, no. 3, pp. 527-31.
- Bale, S., Tebble, N., Jones, V. & Price, P. 2004, "The benefits of implementing a new skin care protocol in nursing homes", *J.Tissue Viability.*, vol. 14, no. 2, pp. 44-50.
- Ballinger, C., Pain, H., Pascoe, J. & Gore, S. 1996, "Choosing a commode for the ward environment", *Br.J.Nurs.*, vol. 5, no. 8, pp. 485-500.
- Balmforth, J. & Cardozo, L. D. 2003, "Trends toward less invasive treatment of female stress urinary incontinence", *Urology*, vol. 62, no. 4 Suppl 1, pp. 52-60.
- Barroso, U., Jednak, R., Fleming, P., Barthold, J. S. & Gonzalez, R. 2000, "Bladder calculi in children who perform clean intermittent catheterization", *BJU International*, vol. 85, no. 7, pp. 879-84.
- Beber, C. R. 1980, "Freedom for the incontinent", *Am.J.Nurs.*, vol. 80, no. 3, pp. 482-484.
- Beitz, J. M. 1997, "Ask the experts—caring for the fecally incontinent", *Crit Care Nurse*, vol. 17, no. 4, pp. 86-89.
- Bejany, D. E., Lockhart, J. L. & Rhamy, R. K. 1987, "Malignant vesical tumors following spinal cord injury", *Journal of Urology*, vol. 138, no. 6, pp. 1390-2.
- Bellin, P., Smith, J., Poll, W., Bogojavlensky, S., Knoll, D., Childs, S., Tuttle, J., Barada, J. & Dann, J. 1998, "Results of a multicenter trial of the CapSure (Re/Stor) Continence shield on women with stress urinary incontinence", *Urology*, vol. 51, no. 5, pp. 697-706.
- Bennett, C. J., Young, M. N., Razi, S. S., Adkins, R., Diaz, F. & McCrary, A. 1997, "The effect of urethral introducer tip catheters on the incidence of urinary tract infection outcomes in spinal cord injured patients", *Journal of Urology*, vol. 158, no. 2, pp. 519-21.
- Berg, R. W. 1987, "Etiologic factors in diaper dermatitis: a model for development of improved diapers", *Pediatrician.*, vol. 14 Suppl 1, pp. 27-33.
- Berg, R. W., Buckingham, K. W. & Stewart, R. L. 1986, "Etiologic factors in diaper dermatitis: the role of urine", *Pediatr.Dermatol.*, vol. 3, no. 2, pp. 102-106.
- Berge, B., Heicappell, R., Steiner, U. & Miller, K. 1999, "Urothelial carcinoma in a suprapubic cystostomy tract 27 years after tube removal", *J.Urol.*, vol. 162, no. 3 Pt 1, pp. 797-798.
- Bergquist, S. & Frantz, R. 1999, "Pressure ulcers in community-based older adults receiving home health care. Prevalence, incidence, and associated risk factors", *Adv.Wound.Care*, vol. 12, no. 7, pp. 339-351.
- Bhatia, N. N. & Bergman, A. 1985, "Pessary test in women with urinary incontinence", *Obstet.Gynecol.*, vol. 65, no. 2, pp. 220-226.
- Bibby, J. M., Cox, A. J. & Hukins, D. W. 1995, "Feasibility of preventing encrustation of urinary catheters.", *Cells and Materials*, vol. 2, pp. 183-195.
- Biering-Sorensen, F., Nielans, H. M., Dorflinger, T. & Sorensen, B. 1999, "Urological situation five years after spinal cord injury", *Scandinavian Journal of Urology & Nephrology*, vol. 33, no. 3, pp. 157-61.
- Biswas, N. C. 1988, "A silastic vaginal device for the treatment of genuine stress incontinence.", *Neurourology & Urodynamics* no. 7, pp. 271-272.
- Blake, P. A., Kim, C. O., Lopez, A. E. & Krongrad, A. 1996, "Verrucous carcinoma of a suprapubic cystostomy track", *J.Urol.*, vol. 156, no. 1, p. 174.
- Bliss, D. Z., Savik, K., Fan, Q. & Harms, S. 2003, "Risks for perineal dermatitis in nursing home elders: A prospective analysis [Abstract]", *The Gerontologist*, vol. 43, p. 117.
- Bliss, D. Z., Savik, K., Fan, Q., Wyman, J. & Harms, S. 2002, "Perineal derineal dermatitis in nursing home elders: prevalence and correlates. [Abstract]", *The Gerontologist*, vol. 42, p. 11.
- Bologna, R. A., Tu, L. M., Polansky, M., Fraimow, H. D., Gordon, D. A. & Whitmore, K. E. 1999, "Hydrogel/silver ion-coated urinary catheter reduces nosocomial urinary tract infection rates in intensive care unit patients: a multicenter study", *Urology*, vol. 54, no. 6, pp. 982-7.
- Boos, K., Anders, K., Hextall, A., Tooz-Hobson, P. & Cardozo, L. 1998, "Randomised trial of Reliance versus FemAssist devices in the management of genuine stress incontinence.", *Neurourology & Urodynamics*, vol. 17, no. 4, pp. 455-456.
- Bosley, C. 1994, "Three methods of stool management for patients with diarrhea", *Ostomy.Wound.Manage.*, vol. 40, no. 1, pp. 52-57.
- Bradbury, S. M. 1985, "Incontinence pads and clostridium infection", *J.Hosp.Infect.*, vol. 6, no. 1, p. 115.
- Branagan, G. & Moran, B. 2002, "Published Evidence Favors the Use of Suprapubic Catheters in Pelvic Colorectal Surgery.", *Diseases of the Colon & Rectum*, vol. 45, no. 8, pp. 1104-1108.
- Brandeis, G. H., Ooi, W. L., Hossain, M., Morris, J. N. & Lipsitz, L. A. 1994, "A longitudinal study of risk factors associated with the formation of pressure ulcers in nursing homes", *J.Am.Geriatr.Soc.*, vol. 42, no. 4, pp. 388-393.

- Brazzelli M, Shirran E, Vale L.. Absorbent products for containing urinary and/or faecal incontinence in adults (Cochrane Review). In: The Cochrane Library, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Brink, C. A. 1990, "Absorbent pads, garments, and management strategies", *J.Am.Geriatr.Soc.*, vol. 38, no. 3, pp. 368-373.
- British standard institute 1990, BS1695 Part 1. Specification for sterile single use urethral catheters of the Nelaton and Foley types., British Standards Institution, BS 1695.
- Brosnahan J, Jull A, Tracy C. Types of urethral catheters for management of short-term voiding problems in hospitalised adults (Cochrane Review). In: The Cochrane Library, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Brown, D. S. 1994a, "Diapers and underpads, Part 1: Skin integrity outcomes", *Ostomy.Wound.Manage.*, vol. 40, no. 9, pp. 20-6, 28.
- Brown, D. S. 1994b, "Diapers and underpads, Part 2: Cost outcomes", *Ostomy.Wound.Manage.*, vol. 40, no. 9, pp. 34-6, 38, 40.
- Brown, D. S. & Sears, M. 1993, "Perineal dermatitis: a conceptual framework", *Ostomy.Wound.Manage.*, vol. 39, no. 7, pp. 20-25.
- Brubaker, L., Harris, T., Gleason, D., Newman, D. & North, B. 1999, "The external urethral barrier for stress incontinence: a multicenter trial of safety and efficacy. Miniguard Investigators Group", *Obstet.Gynecol.*, vol. 93, no. 6, pp. 932-937.
- Buckingham, K. W. & Berg, R. W. 1986, "Etiologic factors in diaper dermatitis: the role of feces", *Pediatr.Dermatol.*, vol. 3, no. 2, pp. 107-112.
- Burgdorfer, H., Heidler, H. & Madersbacher, H. 1997, "Manual neuro-urology and spinal cord lesion: guidelines for urological care of spinal cord injury patient.", Parco-Pharma GmbH.
- Burke, J. P., Garibaldi, R. A., Britt, M. R., Jacobson, J. A., Conti, M. & Alling, D. W. 1981, "Prevention of catheter-associated urinary tract infections. Efficacy of daily meatal care regimens", *Am.J.Med.*, vol. 70, no. 3, pp. 655-658.
- Burke, J. P., Jacobson, J. A., Garibaldi, R. A., Conti, M. T. & Alling, D. W. 1983, "Evaluation of daily meatal care with poly-antibiotic ointment in prevention of urinary catheter-associated bacteriuria", *J.Urol.*, vol. 129, no. 2, pp. 331-334.
- Burns, J. R. & Gauthier, J. F. 1984, "Prevention of urinary catheter encrustations by acetohydroxamic acid", *Journal of Urology*, vol. 132, no. 3, pp. 455-6.
- Butler, H. K. & Kunin, C. M. 1968, "Evaluation of polymyxin catheter lubricant and impregnated catheters", *J.Urol.*, vol. 100, no. 4, pp. 560-566.
- Byers, P. H., Ryan, P. A., Regan, M. B., Shields, A. & Carta, S. G. 1995, "Effects of incontinence care cleansing regimens on skin integrity", *J.Wound.Ostomy.Continence.Nurs.*, vol. 22, no. 4, pp. 187-192.
- Campbell, R. L., Seymour, J. L., Stone, L. C. & Milligan, M. C. 1987, "Clinical studies with disposable diapers containing absorbent gelling materials: evaluation of effects on infant skin condition", *J.Am.Acad.Dermatol.*, vol. 17, no. 6, pp. 978-987.
- Caplan, R. M. 1966, "The irritant role of feces in the genesis of perianal itch", *Gastroenterology*, vol. 50, no. 1, pp. 19-23.
- Chen, Y., Devivo, M. J. & Lloyd, L. K. 2001, "Bladder stone incidence in persons with spinal cord injury: determinants and trends, 1973-1996", *Urology*, vol. 58, no. 5, pp. 665-70.
- Cheng, H. J. 1988, Manufacture and clinical employment of an antibiotic silicon-rubber catheter. *Eur Urol* vol.14, no1, pp. 72-4
- Cho, Y. H., Lee, S. J., Lee, J. Y., Kim, S. W., Kwon, I. C., Chung, S. Y. & Yoon, M. S. 2001, "Prophylactic efficacy of a new gentamicin-releasing urethral catheter in short-term catheterized rabbits. *BJU International*, vol. 87, no. 1, pp. 104-9.
- Choong, S. K. & Whitfield, H. N. 2000, "Urinary encrustation of alloplastic materials", *J.Endourol.*, vol. 14, no. 1, pp. 19-23.
- Choong, S. K. S., Hallson, P., Whitfield, H. N. & Fry, C. H. 1999, "The physicochemical basis of urinary catheter encrustation, *BJU International* May 1999;83(7):770-775.
- Christiansen, J. & Roed-Petersen, K. 1993, "Clinical assessment of the anal continence plug", *Dis.Colon Rectum*, vol. 36, no. 8, pp. 740-742.
- Chye, P. L. H. 1990 The management of post prostatectomy incontinence. <http://www.dpa.org.sg/sfcs/post-tur.html>.
- Clancy, B. & Malone-Lee, J. 1991, "Reducing the leakage of bodyworn incontinence pads", *J.Adv.Nurs.*, vol. 16, no. 2, pp. 187-193.
- Clarke-O'Neill, S., Pettersson, L., Fader, M., Cottenden, A. & Brooks, R. 2004, "A multicenter comparative evaluation: disposable pads for women with light incontinence", *J.Wound.Ostomy.Continence.Nurs.*, vol. 31, no. 1, pp. 32-42.
- Clarke-O'Neill, S., Pettersson, L., Fader, M., Dean, G., Brooks, R. & Cottenden, A. 2002b, "A multicentre comparative evaluation: washable pants with an integral pad for light incontinence", *J.Clin.Nurs.*, vol. 11, no. 1, pp. 79-89.
- Classen, D. C., Larsen, R. A., Burke, J. P., Alling, D. W. & Stevens, L. E. 1991a, "Daily meatal care for prevention of catheter-associated bacteriuria: results using frequent applications of polyantibiotic cream", *Infection Control & Hospital Epidemiology*, vol. 12, no. 3, pp. 157-62.
- Classen, D. C., Larsen, R. A., Burke, J. P. & Stevens, L. E. 1991b, "Prevention of catheter-associated bacteriuria: clinical trial of methods to block three known pathways of infection", *American Journal of Infection Control*, vol. 19, no. 3, pp. 136-42.
- Cooper, P. & Gray, D. 2001, "Comparison of two skin care regimes for incontinence", *Br.J.Nurs.*, vol. 10, no. 6 Suppl, pp. S6, S8, S10.
- Cottenden, A. M. 1992, "Aids and appliances for incontinence.," in *The promotion and management of continence*, Prentice Hall.
- Cottenden, A. M., Fader, M. J., Pettersson, L. & Brooks, R. J. 2003, "How well does ISO 11948-1 (the Rothwell method) for measuring the absorption capacity of incontinence pads in the laboratory correlate with clinical pad performance", *Med.Eng Phys.*, vol. 25, no. 7, pp. 603-613.
- Cottenden, A. M. & Ledger, D. J. 1993, "Predicting the leakage performance of bodyworn disposable incontinence pads using laboratory tests", *J.Biomed.Eng.*, vol. 15, no. 3, pp. 212-220.
- Cottenden, A. M., Moore, K. N., Fader, M. J. & Cremer, A. W. 1999, "Is there a risk of cross-infection from laundered reusable bedpads?", *Br.J.Nurs.*, vol. 8, no. 17, pp. 1161-1163.
- Cottenden, A. M., Rothwell, J. G., Leander, H., Grau, C. & Brooks, R. J. 2002, "An investigation of the repeatability and reproducibility of ISO 11948-1 (the Rothwell method) for measuring the absorption capacity of incontinence pads", *Med.Eng Phys.*, vol. 24, no. 2, pp. 159-163.
- Cox, A. J., Harries, J. E., Hukins, D. W., Kennedy, A. P. & Sutton, T. M. 1987, "Calcium phosphate in catheter encrustation", *Br.J.Urol.*, vol. 59, no. 2, pp. 159-163.
- Cox, A. J., Millington, R. S., Hukins, D. W. & Sutton, T. M. 1989, "Resistance of catheters coated with a modified hydrogel to encrustation during an in vitro test", *Urol.Res.*, vol. 17, no. 6, pp. 353-356.
- Crowe, H., Clift, R., Duggan, G., Bolton, D. & Costello, A. 1994, "Randomized study of the effect of midnight removal of urinary catheters", *Urologic Nursing*, vol. 14, no. 1, pp. 18-20.
- Daifuku, R. & Stamm, W. E. 1984, "Association of rectal and urethral colonization with urinary tract infection in patients with indwelling catheters.", *JAMA*, vol. 252, no. 15, pp. 2028-2030.

- Dallas, M. J. & Wilson, P. A. 1992, "Adult in continence products: performance evaluation on healthy skin.", *INDA Journal of Nonwovens Research*, vol. 4, no. 2, pp. 26-32.
- Darouiche, R. O., Smith, J. A. Jr., Hanna, H., Dhabuwala, C. B., Steiner, M. S., Babaian, R. J., Boone, T. B., Scardino, P. T., Thornby, J. I. & Raad, I. 1999, "Efficacy of antimicrobial-impregnated bladder catheters in reducing catheter-associated bacteriuria: a prospective, randomized, multicenter clinical trial", *Urology*, vol. 54, no. 6, pp. 976-81.
- Davies, A. J., Desai, H. N., Turton, S. & Dyas, A. 1987, "Does instillation of chlorhexidine into the bladder of catheterized geriatric patients help reduce bacteriuria?", *Journal of Hospital Infection*, vol. 9, no. 1, pp. 72-5.
- Davies, A. J. & Shroff, K. J. 1983, "When should a urine specimen be examined after removal of a urinary catheter?", *Journal of Hospital Infection*, vol. 4, no. 2, pp. 177-80.
- Davila, G. W. 1996, "Introl bladder neck support prosthesis: a non-surgical urethropexy", *J.Endourol.*, vol. 10, no. 3, pp. 293-296.
- Davila, G. W., Neal, D., Horbach, N., Peacher, J., Doughtie, J. D. & Karram, M. 1999, "A bladder-neck support prosthesis for women with stress and mixed incontinence", *Obstet.Gynecol.*, vol. 93, no. 6, pp. 938-942.
- Davis, J. A., Leyden, J. J., Grove, G. L. & Raynor, W. J. 1989, "Comparison of disposable diapers with fluff absorbent and fluff plus absorbent polymers: effects on skin hydration, skin pH, and diaper dermatitis", *Pediatr.Dermatol.*, vol. 6, no. 2, pp. 102-108.
- De, P. K., Hachem, J. P., Vanpee, E., Goossens, A., Germaux, M. A., Lachapelle, J. M., Lambert, J., Matthieu, L., Roseeuw, D., Suys, E., Van, H. E. & Rogiers, V. 2001, "Beneficial effects of a skin tolerance-tested moisturizing cream on the barrier function in experimentally-elicited irritant and allergic contact dermatitis", *Contact Dermatitis*, vol. 44, no. 6, pp. 337-343.
- Dealey, C. 1995, "Pressure sores and incontinence: a study evaluating the use of topical agents in skin care", *J.Wound.Care*, vol. 4, no. 3, pp. 103-105.
- Delnay, K. M., Stonehill, W. H., Goldman, H., Jukkola, A. F. & Dmochowski, R. R. 1999, "Bladder histological changes associated with chronic indwelling urinary catheter. *Journal of Urology*.1999 Apr;161(4):1106-8; discussion 1108-9.
- Disposable bedpads for incontinence: predicting their clinical leakage properties using laboratory tests; *Medical Engineering and Physics*; 1998, 20, 347-359; AM Cottenden, GE Dean, RJ Brooks, RF Haines-Nutt, JG Rothwell and PH Penfold
- Doherty, W. 1999, "The Sims Portex Catheter Valve: an alternative to the leg bag", *British Journal of Nursing*, vol. 8, no. 7, pp. 459-62.
- Dolman, M. 1988, "Continence. The cost of incontinence", *Nurs.Times*, vol. 84, no. 31, pp. 67-69.
- Donnellan, S. M. & Bolton, D. M. 1999, "The impact of contemporary bladder management techniques on struvite calculi associated with spinal cord injury", *BJU International*, vol. 84, no. 3, pp. 280-5.
- Downer, A., Morris, N., Feast, W. J. & Stickler, D. 2003, "Polymer surface properties and their effect on the adhesion of *Proteus mirabilis*", *Proceedings of the Institution of Mechanical Engineers. Part H*, vol. 217, no. 4, pp. 279-89.
- Dromerick, A. W. & Edwards, D. F. 2003, "Relation of postvoid residual to urinary tract infection during stroke rehabilitation", *Arch.Phys.Med.Rehabil.*, vol. 84, no. 9, pp. 1369-1372.
- Dudley, M. N. & Barriere, S. L. 1981, "Antimicrobial irrigations in the prevention and treatment of catheter-related urinary tract infections", *American Journal of Hospital Pharmacy*, vol. 38, no. 1, pp. 59-65.
- Dunn, M., Brandt, D. & Nygaard, I. 2002, "Treatment of exercise incontinence with a urethral insert: a pilot study.", *The Physician and Sports Medicine*, vol. 30, no. 1.
- Dunn, S., Kowanko, I., Paterson, J. & Pretty, L. 2002, "Systematic review of the effectiveness of urinary continence products", *J.Wound.Ostomy.Continence.Nurs.*, vol. 29, no. 3, pp. 129-142.
- Duso, S. 1992, "Product notebook: a new fecal containment device. A case study describing one use of the Bard FCD fecal containment device", *Ostomy.Wound.Manage.*, vol. 38, no. 5, pp. 38-41.
- Ebner, A., Madersbacher, H., Schober, F., & Marbeger, H. 1985. Hydrodynamic properties of Foley catheters and its clinical relevance. In *Proceedings of the International Continence Society. 15th Meeting*. London, England. 217-218.
- Echols, J., B. Freidman, et al. (2004). Initial experience with a new system for the control and containment of fecal output for the protection of patients in a large burn center. *John A. Boswick, MD, Burn and Wound Care Symposium Maui, HI*.
- Eckford, S. D., Jackson, S. R., Lewis, P. A. & Abrams, P. 1996, "The continence control pad—a new external urethral occlusion device in the management of stress incontinence", *Br.J.Urol.*, vol. 77, no. 4, pp. 538-540.
- Eckstein, H. B. 1979, "Intermittent Catheterisation of the bladder in patients with neuropathic incontinence of urine", *Z.Kinderchir. Grenzgeb.*, vol. 28, no. 4, pp. 408-412.
- Elliot, S., Striker, L. J., Doi, T., Linehan, W. M. & Striker, G. E. 1989, "Hepatoma G2 conditioned medium facilitates early outgrowth of endothelial cells from isolated glomeruli", *Kidney Int.*, vol. 35, no. 5, pp. 1245-1248.
- Emmerson, A. M. 1996, "Hospital hygiene in Great Britain", *Zentralbl.Hyg.Umweltmed.*, vol. 199, no. 2-4, pp. 168-171.
- EPINE Working Group 1992, "Prevalence of hospital-acquired infection in Spain.", *J Hosp Inf*, vol. 20, no. 1, pp. 1-13.
- Evans, A. & Feneley, R. 2000, "A study of current nursing management of long-term suprapubic catheters", *British Journal of Community Nursing*, vol. 5, no. 5, pp. 240-5.
- Fader, M. 2002, "Access to toilets and toileting." in *Bowel care in older people: research and practice*, J. Potter, C. Norton & C. Cottenden, eds., Royal College of Physicians, London.
- Fader, M., Barnes, E., Malone-Lee, J. & Cottenden, A. 1987, "Continence. Choosing the right garment", *Nurs.Times*, vol. 83, no. 15, pp. 78-85.
- Fader, M., Clarke-O'Neill, S., Cook, D., Dean, G., Brooks, R., Cottenden, A. & Malone-Lee, J. 2003, "Management of night-time urinary incontinence in residential settings for older people: an investigation into the effects of different pad changing regimes on skin health", *J.Clin.Nurs.*, vol. 12, no. 3, pp. 374-386.
- Fader, M., Cottenden, A. & Brooks, R. 2001, "The CPE network: creating an evidence base for continence product selection", *J.Wound.Ostomy.Continence.Nurs.*, vol. 28, no. 2, pp. 106-112.
- Fader, M., Moore, K. N., Cottenden, A. M., Pettersson, L., Brooks, R. & Malone-Lee, J. 2001a, "Coated catheters for intermittent catheterization: smooth or sticky?", *BJU International*, vol. 88, no. 4, pp. 373-7.
- Fader, M., Pettersson, L., Brooks, R., Dean, G., Wells, M., Cottenden, A. & Malone-Lee, J. 1997, "A multicentre comparative evaluation of catheter valves", *British Journal of Nursing*, vol. 6, no. 7, pp. 359, 362-4, 366-7.
- Fader, M., Pettersson, L., Dean, G., Brooks, R. & Cottenden, A. 1999b, "The selection of female urinals: results of a multicentre evaluation", *Br.J.Nurs.*, vol. 8, no. 14, pp. 918-5.
- Fader, M., Pettersson, L., Dean, G., Brooks, R., Cottenden, A. M. & Malone-Lee, J. 2001b, "Sheaths for urinary incontinence: a randomized crossover trial", *BJU.Int.*, vol. 88, no. 4, pp. 367-372.

- Faergemann, J., Aly, R., Wilson, D. R. & Maibach, H. I. 1983, "Skin occlusion: effect on Pityrosporum orbiculare, skin PCO<sub>2</sub>, pH, transepidermal water loss, and water content", *Arch.Dermatol.Res.*, vol. 275, no. 6, pp. 383-387.
- Fantl JA, Newman DK, Colling J et al. 1996 Managing Acute and Chronic Urinary Incontinence. Clinical Practice Guideline. Quick Reference Guide for Clinicians, No.2, 1996 Update. Rockville, MD: U.S. Department of Health and Human Services, Public Health Services, Agency for Health Care Policy and Research. AHCPR Pub. No. 96-0686.
- Faria, D. T., Shwayder, T. & Krull, E. A. 1996, "Perineal skin injury: extrinsic environmental risk factors", *Ostomy.Wound.Manage.*, vol. 42, no. 7, pp. 28-4, 36.
- Fernandez, R. & Griffiths, R. 2004, Policies for removal of indwelling urethral catheters for short-term management of voiding in adults and children 1.
- Fernandez, R. S., Griffiths, R. D. & Murie, P. 2003, "Peripheral venous catheters: a review of current practices", *J.Infus.Nurs.*, vol. 26, no. 6, pp. 388-392.
- Fernandez R & Griffiths R. Policies for removal of indwelling urethral catheters for short-term management of voiding in adults and children (Cochran Review). In: *The Cochrane Library*, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Firestein, M., Mendelson, G., Gronich, D., Granot, E., Ben-Israel, J. & Raz, R. 2001, "Can Antibiotic Use During Routine Replacement of Long-Term Urinary Catheter Prevent Bacteriuria? [Article]", *Infectious Diseases in Clinical Practice* March/April 2001;10 vol. 3, no 3 :133-135.
- Fluhr, J. W., Lazzarini, S., Distante, F., Gloor, M. & Berardesca, E. 1999, "Effects of prolonged occlusion on stratum corneum barrier function and water holding capacity", *Skin Pharmacol.Appl.Skin Physiol*, vol. 12, no. 4, pp. 193-198.
- Fowler, C. 1998, "Bladder problems," MS Research Trust, Letchworth, UK.
- Fox, C. L. & Modak, S. M. 1974, "Mechanism of silver sulphadiazine action on burn wound infections.", *Antimicrob.Agents Chemother.*, vol. 5, p. 582.
- Fraczyk, L., Godfrey, H. & Feneley, R. 2003, "A pilot study of users' experiences of urinary catheter drainage bags", *British Journal of Community Nursing*, vol. 8, no. 3, pp. 104-11.
- Freedman, P. 1991, "The rectal pouch: a safer alternative to rectal tubes", *Am.J.Nurs.*, vol. 91, no. 5, pp. 105-106.
- Gabard, B. 1994, "Testing the efficacy of moisturisers.", in *Bioengineering of the skin: water and the stratum corneum.*, P. Elsner, E. Berardesca & H. Maibach, eds., CRC Press.
- Gaonkar, T. A., Sampath, L. A. & Modak, S. M. 2003, "Evaluation of the antimicrobial efficacy of urinary catheters impregnated with antiseptics in an in vitro urinary tract model", *Infection Control & Hospital Epidemiology*, vol. 24, no. 7, pp. 506-13.
- Garibaldi, R. A., Burke, J. P., Britt, M. R., Miller, W. A. & Smith, C. B. 1980, "Meatal colonization and catheter-associated bacteriuria", *New England Journal of Medicine*, vol. 303, no. 6, pp. 316-318.
- Garibaldi, R. A., Burke, J. P., Dickman, M. L. & Smith, C. B. 1974, "Factors predisposing to bacteriuria during indwelling urethral catheterization", *New England Journal of Medicine*, vol. 291, pp. 215-219.
- German, K., Rowley, P., Stone, D., Kumar, U. & Blackford, H. N. 1997, "A randomized cross-over study comparing the use of a catheter valve and a leg-bag in urethral catheterized male patients", *Br.J.Urol.*, vol. 79, no. 1, pp. 96-98.
- Getliffe, K. 2003, "Managing recurrent urinary catheter blockage: problems, promises, and practicalities. *Journal of Wound, Ostomy & Continence Nursing*.2003 May;30(3):146-51.
- Getliffe, K. 1996, "Care of urinary catheters", *Elderly Care*, vol. 8, no. 2, pp. 23-6.
- Getliffe, K. A. 1994a, "The characteristics and management of patients with recurrent blockage of long-term urinary catheters", *Journal of Advanced Nursing*, vol. 20, no. 1, pp. 140-9.
- Getliffe, K. A. 1994b, "The use of bladder wash-outs to reduce urinary catheter encrustation", *British Journal of Urology*, vol. 73, no. 6, pp. 696-700.
- Getliffe, K. A., Hughes, S. C. & Le, C. M. 2000, "The dissolution of urinary catheter encrustation", *BJU.Int.*, vol. 85, no. 1, pp. 60-64.
- Ghadially, R., Halkier-Sorensen, L. & Elias, P. M. 1992, "Effects of petrolatum on stratum corneum structure and function", *J.Am.Acad.Dermatol.*, vol. 26, no. 3 Pt 2, pp. 387-396.
- Giannantoni, A., Di Stasi, S. M., Scivoletto, G., Virgili, G., Dolci, S. & Porena, M. 2001, "Intermittent catheterization with a prelubricated catheter in spinal cord injured patients: a prospective randomized crossover study", *Journal of Urology*, vol. 166, no. 1, pp. 130-3.
- Gibb, H. & Wong, G. 1994, "How to choose: nurses' judgements of the effectiveness of a range of currently marketed continence aids", *J.Clin.Nurs.*, vol. 3, no. 2, pp. 77-86.
- Gillan, J. 1999, "Seat of the motions", *Nursing Times*, vol. 95, p. 26.
- Gillespie, W. A., Simpson, R. A., Jones, J. E., Nashef, L., Teasdale, C. & Speller, D. C. 1983, "Does the addition of disinfectant to urine drainage bags prevent infection in catheterised patients?", *Lancet*, vol. 1, no. 8332, pp. 1037-9.
- Glavind, K. 1997, "Use of a vaginal sponge during aerobic exercises in patients with stress urinary incontinence", *Int.Urogynecol.J.Pelvic.Floor.Dysfunct.*, vol. 8, no. 6, pp. 351-353.
- Gleeson, M. J., Cunnane, G. & Grainger, R. 1991, "Spontaneous perforation of an augmented bladder", *Br.J.Urol.*, vol. 68, no. 6, p. 655.
- Glenister, H. 1987, "The journal of infection control nursing. The passage of infection", *Nurs.Times*, vol. 83, no. 22, pp. 68-73.
- Goldblum, D. & Brugger, J. J. 1999, "Bowel obstruction caused by dislocation of a suprapubic catheter", *Surg.Endosc.*, vol. 13, no. 3, pp. 283-284.
- Goldyn, V., Buck, R. & Chenelly, S. 1992, "Two incontinence management devices: the benefits of the "incontinence bag" and the freedom catheter", *Ostomy.Wound.Manage.*, vol. 38, no. 2, pp. 28-35.
- Golji, H. 1981, "Complications of external condom drainage", *Paraplegia*, vol. 19, no. 3, pp. 189-197.
- Gonzalzo, M. L. & Walsh, P. C. 2003, "Balloon cuffing and management of the entrapped Foley catheter", *Urology*, vol. 61, no. 4, pp. 825-7.
- Graham, D. T., Mark, G. E. & Pomeroy, A. R. 1983, "Cellular toxicity of urinary catheters", *Med.J.Aust.*, vol. 1, no. 10, pp. 456-459.
- Grant, R. 1982, "Washable pads or disposable diapers?", *Geriatr. Nurs.*, vol. 3, no. 4, pp. 248-251.
- Gray, M. 2004, "Preventing and managing perineal dermatitis: a shared goal for wound and continence care", *J.Wound.Ostomy.Continence.Nurs.*, vol. 31, no. 1 Suppl, p. S2-S9.
- Gray, M. 2001. "Skin, continence and outcome measures", in 16th Annual symposium on advances in skin and wound care., Orlando, Florida, USA.
- Griffith, D.P.& Gleeson, M.J. 1991, Randomized, double-blind trial of Lithostat (acetohydroxamic acid) in the palliative treatment of infection-induced urinary calculi. *Eur Urol.* 20(3):243-7, 243-7
- Groah, S. L., Weitzenkamp, D. A., Lammertse, D. P., Whiteneck, G. G., Lezotte, D. C. & Hamman, R. F. 2002, "Excess risk of bladder cancer in spinal cord injury: evidence for an association between indwelling catheter use and bladder cancer", *Archives of Physical Medi-*

- cine & Rehabilitation, vol. 83, no. 3, pp. 346-51.
- Grogan, T. A. & Kramer, D. J. 2002, "The rectal trumpet: use of a nasopharyngeal airway to contain fecal incontinence in critically ill patients", *J.Wound.Ostomy.Continence Nurs.*, vol. 29, no. 4, pp. 193-201.
- Grove, G. L., Lemmen, J. T., Garafalo, M. & Akin, F. J. 1998, "Assessment of skin hydration caused by diapers and incontinence articles", *Curr.Probl.Dermatol.*, vol. 26, pp. 183-195.
- Gujral, S., Kirkwood, L. & Hinchliffe, A. 1999, "Suprapubic catheterization: a suitable procedure for clinical nurse specialists in selected patients", *BJU.Int.*, vol. 83, no. 9, pp. 954-956.
- Gunther, R. A. & Clark, M. 2000, "The effect of a dynamic pressure-redistributing bed support surface upon systemic lymph flow and composition", *J.Tissue Viability.*, vol. 10, no. 3, pp. 10-15.
- Hackler, R. H. 1982, "Long-term suprapubic cystostomy drainage in spinal cord injury patients", *British Journal of Urology*, vol. 54, no. 2, pp. 120-1.
- Haeker, S. 1986, "What's best—reusable or disposable incontinence products?", *Text Rent.*, vol. 69, no. 9, pp. 86-91.
- Hahn, I. & Milsom, I. 1996, "Treatment of female stress urinary incontinence with a new anatomically shaped vaginal device (Conveen Continence Guard)", *Br.J.Urol.*, vol. 77, no. 5, pp. 711-715.
- Hall, R. G., Jr., Thompson, H. & Strother, A. 1981, "Effects of orally administered activated charcoal on intestinal gas", *Am.J.Gastroenterol.*, vol. 75, no. 3, pp. 192-196.
- Hamid, R., Bycroft, J., Arya, M. & Shah, P. J. R. 2003, "Screening Cystoscopy And Biopsy In Patients With Neuropathic Bladder And Chronic Suprapubic Indwelling Catheters: Is It Valid? [Article]", *Journal of Urology* ;170 vol 70, no2 (Part 1) pp.425-427.
- Hamid, R., Peters, J. & Shah, P. J. 2002, "Pitfall in insertion of suprapubic catheter in patients with spinal cord injuries", *Spinal Cord.*, vol. 40, no. 10, pp. 542-543.
- Hanlon, M. & Cofone, E. 1996, "Patient with frequent liquid stools resulting in a chemical dermatitis and a perianal ulcer", *J.Wound.Ostomy.Continence Nurs.*, vol. 23, no. 3, pp. 174-177.
- Hannuksela, A. & Kinnunen, T. 1992, "Moisturizers prevent irritant dermatitis", *Acta Derm.Venereol.*, vol. 72, no. 1, pp. 42-44.
- Harding, G. K., Nicolle, L. E., Ronald, A. R., Preiksaitis, J. K., Forward, K. R., Low, D. E. & Cheang, M. 1991, "How long should catheter-acquired urinary tract infection in women be treated? A randomized controlled study", *Annals of Internal Medicine*, vol. 114, no. 9, pp. 713-9.
- Harper, D. W., O'Hara, P. A., Lareau, J., Cass, J., Black, E. K., Stewart, S. & Sigouin, J. 1995, "Reusable versus disposable incontinent briefs: a multiperspective crossover clinical trial", *Journal of Applied Gerontology*, vol. 14, no. 4, pp. 391-407.
- Hedlund, H., Hjelmas, K., Jonsson, O., Klarskov, P. & Talja, M. 2001, "Hydrophilic versus non-coated catheters for intermittent catheterization", *Scandinavian Journal of Urology & Nephrology*, vol. 35, no. 1, pp. 49-53.
- Heit, M. 1997, "Infectious peritonitis complicating suprapubic catheter removal", *Int.Urogynecol.J.Pelvic.Floor.Dysfunct.*, vol. 8, no. 1, pp. 47-49.
- Hellstrom, L., Ekelund, P., Larsson, M. & Milsom, I. 1993, "Adapting incontinent patients incontinence aids to their leakage volumes", *Scand.J.Caring.Sci.*, vol. 7, no. 2, pp. 67-71.
- Henderson, D. J. & Rogers, W. F. 1971, "Hospital trials of incontinence underpads", *Nurs.Times*, vol. 67, no. 5, pp. 141-143.
- Hesse, A., Nolde, A., Klump, B., Marklein, G. & Tuschewitzki, G. J. 1992, "In vitro investigations into the formation and dissolution of infection-induced catheter encrustations", *Br.J.Urol.*, vol. 70, no. 4, pp. 429-434.
- Hirsh, D. D., Fainstein, V. & Musher, D. M. 1979, "Do condom catheter collecting systems cause urinary tract infection?", *JAMA*, vol. 242, no. 4, pp. 340-341.
- Holden, D. & Rao, P. N. 1991, "Management of staghorn stones using a combination of lithotripsy, percutaneous nephrolithotomy and Solution R irrigation", *Br.J.Urol.*, vol. 67, no. 1, pp. 13-17.
- Holliman, R., Seal, D. V., Archer, H. & Doman, S. 1987, "Controlled trial of chemical disinfection of urinary drainage bags. Reduction in hospital-acquired catheter-associated infection", *British Journal of Urology*, vol. 60, no. 5, pp. 419-22.
- Horgan, A. F., Prasad, B., Waldron, D. J. & O'Sullivan, D. C. 1992, "Acute urinary retention. Comparison of suprapubic and urethral catheterisation", *British Journal of Urology*, vol. 70, no. 2, pp. 149-51.
- Hu, T. W., Kaltreider, D. L. & Igou, J. 1989, "Incontinence products: which is best?", *Geriatr.Nurs.*, vol. 10, no. 4, pp. 184-186.
- Hu, T. W., Kaltreider, D. L. & Igou, J. 1990, "The cost-effectiveness of disposable versus reusable diapers. A controlled experiment in a nursing home", *J.Gerontol.Nurs.*, vol. 16, no. 2, pp. 19-24.
- Hu, T. W., Kaltreider, D. L. & Igou, J. F. 1988, "Disposable versus reusable incontinent products: a controlled cost-effectiveness experiment", *Ostomy.Wound.Manage.*, vol. 21, pp. 46-53.
- Hunter, S., Anderson, J., Hanson, D., Thompson, P., Langemo, D. & Klug, M. G. 2003, "Clinical trial of a prevention and treatment protocol for skin breakdown in two nursing homes", *J.Wound.Ostomy.Continence.Nurs.*, vol. 30, no. 5, pp. 250-258.
- Huth, T. S., Burke, J. P., Larsen, R. A., Classen, D. C. & Stevens, L. E. 1992, "Clinical trial of junction seals for the prevention of urinary catheter-associated bacteriuria", *Archives of Internal Medicine*, vol. 152, no. 4, pp. 807-12.
- Iacovou, J. W. 1994, "Supra-pubic catheterisation of the urinary bladder.", *Hospital Update*, vol. March, pp. 159-162.
- Ibrahim, A. I. & Rashid, M. 2002, "Comparison of local povidone-iodine antiseptics with parenteral antibacterial prophylaxis for prevention of infective complications of TURP: a prospective randomized controlled study", *European Urology*, vol. 41, no. 3, pp. 250-6.
- International Standards Organisation 1996; ISO 11948-1: Urine absorbing aids. Part 1: Whole-product testing. International Standards Organisation, Geneva, Switzerland.
- International Standards Organisation 1996. ISO 8669-2: urine collection bags-- Part 2: Requirements and test methods. International Standards Organisation, Geneva, Switzerland.
- International Standards Organisation 1988. ISO 8669-1: Urine collection bags-- Part 1: Vocabulary. International Standards Organisation, Geneva, Switzerland.
- Jacobs, D., Heimbach, D. & Hesse, A. 2001, "Chemolysis of struvite stones by acidification of artificial urine—an in vitro study", *Scand.J.Urol.Nephrol.*, vol. 35, no. 5, pp. 345-349.
- Jakobsson, L., Hallberg, I. R. & Loven, L. 2000, "Experiences of micturition problems, indwelling catheter treatment and sexual life consequences in men with prostate cancer", *J.Adv.Nurs.*, vol. 31, no. 1, pp. 59-67.
- Jamison J, Maguire S, McCann J. Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders (Cochrane Review). In: *The Cochrane Library*, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Jannings, W. & Kelly, M. 2001, "Difficulty in removing suprapubic urinary catheters in home based patients: a comparative descriptive study", *Australian Journal of Advanced Nursing*, vol. 19, no. 2, pp. 20-5.

- Jayachandran, M. D., Moopan, U. M. M. & Kim, H. 1985, "Complications from external (condom) urinary drainage devices.", *Urology*, vol. 25, no. 1, pp. 31-34.
- Jepsen, O. B., Larsen, S. O., Dankert, J., Daschner, F., Gronroos, P., Meers, P. D., Nystrom, B., Rotter, M., & Sander, J. 1982, "Urinary-tract infection and bacteraemia in hospitalized medical patients—a European multicentre prevalence survey on nosocomial infection", *Journal of Hospital Infection*, vol. 3, no. 3, pp. 241-52.
- Jepson RG, Mihaljevic L, Craig J.. Cranberries for preventing urinary tract infections (Cochrane Review). In: *The Cochrane Library*, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Johnson, J. R., Delavari, P. & Azar, M. 1999, "Activities of a nitrofurazone-containing urinary catheter and a silver hydrogel catheter against multidrug-resistant bacteria characteristic of catheter-associated urinary tract infection", *Antimicrobial Agents & Chemotherapy*, vol. 43, no. 12, pp. 2990-5.
- Johnson, J. R., Roberts, P. L., Olsen, R. J., Moyer, K. A. & Stamm, W. E. 1990, "Prevention of catheter-associated urinary tract infection with a silver oxide-coated urinary catheter: clinical and microbiologic correlates", *Journal of Infectious Diseases*, vol. 162, no. 5, pp. 1145-50.
- Karchmer, T. B., Giannetta, E. T., Muto, C. A., Strain, B. A. & Farr, B. M. 2000, "A randomized crossover study of silver-coated urinary catheters in hospitalized patients", *Archives of Internal Medicine*, vol. 160, no. 21, pp. 3294-8.
- Kaufman, J. M., Fam, B., Jacobs, S. C., Gabilondo, F., Yalla, S., Kane, J. P. & Rossier, A. B. 1977, "Bladder cancer and squamous metaplasia in spinal cord injury patients", *Journal of Urology*, vol. 118, no. 6, pp. 967-71.
- Keerasuntonpong, A., Thearawiboon, W., Panthawan, A., Judaeng, T., Kachintorn, K., Jintanotaitavorn, D., Suddhisanon, L., Waitayapiches, S., Tiangrim, S. & Thamlikitkul, V. 2003, "Incidence of urinary tract infections in patients with short-term indwelling urethral catheters: a comparison between a 3-day urinary drainage bag change and no change regimens", *AJIC: American Journal of Infection Control*, vol. 31, no. 1, pp. 9-12.
- Kelleher, M. M. 2002, "Removal of urinary catheters: midnight vs 0600 hours", *British Journal of Nursing*, vol. 11, no. 2, pp. 84-90.
- Keller, P. A., Sinkovic, S. P. & Miles, S. J. 1990, "Skin dryness: a major factor in reducing incontinence dermatitis", *Ostomy Wound Manage.*, vol. 30, pp. 60-64.
- Kennedy, A. P., Brocklehurst, J. C. & Lye, M. D. 1983, "Factors related to the problems of long-term catheterization", *Journal of Advanced Nursing*, vol. 8, no. 3, pp. 207-12.
- Kennedy, A. P., Brocklehurst, J. C., Robinson, J. M. & Faragher, E. B. 1992, "Assessment of the use of bladder washouts/instillations in patients with long-term indwelling catheters", *British Journal of Urology*, vol. 70, no. 6, pp. 610-5.
- Kessler, T., Jansen, B. & Hesse, A. 2002, "Effect of blackcurrant-, cranberry- and plum juice consumption on risk factors associated with kidney stone formation", *Eur.J.Clin.Nutr.*, vol. 56, no. 10, pp. 1020-1023.
- Kim, J., Shim, M. C., Choi, B. Y., Ahn, S. H., Jang, S. H. & Shin, H. J. 2001, "Clinical application of continent anal plug in bedridden patients with intractable diarrhea", *Dis.Colon Rectum*, vol. 44, no. 8, pp. 1162-1167.
- King, R. B., Carlson, C. E., Mervine, J., Wu, Y. & Yarkony, G. M. 1992, "Clean and sterile intermittent catheterization methods in hospitalized patients with spinal cord injury", *Archives of Physical Medicine & Rehabilitation*, vol. 73, no. 9, pp. 798-802.
- Klein, G., Grubauer, G. & Fritsch, P. 1992, "The influence of daily dish-washing with synthetic detergent on human skin", *Br.J.Dermatol.*, vol. 127, no. 2, pp. 131-137.
- Kligman, A. M. 1994, "Hydration injury to human skin.", in Bioengineering of the skin: water and the stratum corneum, P. Elsner, E. Berardesca & H. Maibach, eds., CRC Press.
- Knoff, T. 1985, Methenamine hippurate. Short-term catheterization in gynecologic surgery. A double-blind comparison of Hiprex and placebo, *Tidsskrift for Den Norske Laegeforening*, vol. 105, no. 7, pp. 498-9.
- Kohler-Ockmore, J. & Feneley, R. C. 1996, "Long-term catheterization of the bladder: prevalence and morbidity", *British Journal of Urology*, vol. 77, no. 3, pp. 347-51.
- Kondo, A., Yokoyama, E., Koshiha, K., Fukui, J., Gotoh, M., Yoshikawa, Y., Yamada, T. & Takei, M. 1997, "Bladder neck support prosthesis: a nonoperative treatment for stress or mixed urinary incontinence", *J.Urol.*, vol. 157, no. 3, pp. 824-827.
- Kunin, C. M. 1989, "Blockage of urinary catheters: role of microorganisms and constituents of the urine on formation of encrustations", *Journal of Clinical Epidemiology*, vol. 42, no. 9, pp. 835-42.
- Kunin, C. M., Chin, Q. F. & Chambers, S. 1987a, "Formation of encrustations on indwelling urinary catheters in the elderly: a comparison of different types of catheter materials in "blockers" and "non-blockers"", *Journal of Urology*, vol. 138, no. 4, pp. 899-902.
- Kunin, C. M., Chin, Q. F. & Chambers, S. 1987b, "Indwelling urinary catheters in the elderly. Relation of "catheter life" to formation of encrustations in patients with and without blocked catheters", *American Journal of Medicine*, vol. 82, no. 3, pp. 405-11.
- Kunin, C. M., Douthitt, S., Dancing, J., Anderson, J. & Moeschberger, M. 1992, "The association between the use of urinary catheters and morbidity and mortality among elderly patients in nursing homes", *Am.J.Epidemiol.*, vol. 135, no. 3, pp. 291-301.
- Kurtz, M. J., Van Zandt, K. & Burns, J. L. 1995, "Comparison study of home catheter cleaning methods", *Rehabilitation Nursing*, vol. 20, no. 4, pp. 212-4.
- Ladehoff, P., Jacobsen, J. C., Olsen, H., Pedersen, G. T. & Sorensen, T. 1984, "[The preventive effect of methenamine hippurate (Hauptrex) on urinary infections after short-term catheterization. A clinical study]", *Ugeskrift for Laeger*, vol. 146, no. 19, pp. 1433-4.
- Lai, K. K. & Fontecchio, S. A. 2002, "Use of silver-hydrogel urinary catheters on the incidence of catheter-associated urinary tract infections in hospitalized patients", *AJIC: American Journal of Infection Control*, vol. 30, no. 4, pp. 221-5.
- Lane, A. T., Rehder, P. A. & Helm, K. 1990, "Evaluations of diapers containing absorbent gelling material with conventional disposable diapers in newborn infants", *Am.J.Dis.Child*, vol. 144, no. 3, pp. 315-318.
- Lapides, J., Diokno, A. C., Lowe, B. S. & Kalish, M. D. 1974, "Followup on unsterile intermittent self-catheterization", *Journal of Urology*, vol. 111, no. 2, pp. 184-7.
- Lapides, J., Diokno, A. C., Silber, S. J. & Lowe, B. S. 1972, "Clean, intermittent self-catheterization in the treatment of urinary tract disease", *J.Urol.*, vol. 107, no. 3, pp. 458-461.
- Lavallee, D. J., Lapierre, N. M., Henwood, P. K., Pivik, J. R., Best, M., Springthorpe, V. S. & Sattar, S. A. 1995, "Catheter cleaning for re-use in intermittent catheterization: new light on an old problem", *Sci Nursing*, vol. 12, no. 1, pp. 10-2.
- Lawrentschuk, N., Lee, D., Marriott, P. & Russell, J. M. 2003, "Suprapubic stab cystostomy: a safer technique", *Urology*, vol. 62, no. 5, pp. 932-934.
- Lazarus, S. M., LaGuerre, J. N., Kay, H., Weinberg, S. & Levowitz, B. S. 1971, "A hydrophilic polymer-coated antimicrobial urethral catheter", *J.Biomed.Mater.Res.*, vol. 5, no. 3, pp. 129-138.
- Leclair, J. M., Cycan, K. A., Munster, A. M., Neste, C. M., Murphy, P. A., 2000, "Effect of a nitrofurazone-impregnated urinary catheter on the incidence of catheter-associated uti in burn patients. *Infection*

- Control & Hospital Epidemiology February; vol. 21, no 2, p 165.
- Lee B, Bhuta T, Craig J, Simpson J. Methenamine hippurate for preventing urinary tract infections (Cochrane Review). In: The Cochrane Library, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Leiby, D. M. & Shanahan, N. 1994, "Clinical study: assessing the performance and skin environments of two reusable underpads", *Ostomy.Wound.Manage.*, vol. 40, no. 8, pp. 30-37.
- Leigh, D. A. & Petch, V. J. 1987, "Sterility of incontinence pads and sheets", *J.Hosp.Infect.*, vol. 9, no. 1, pp. 91-93.
- Lewington, C., Morgan, M., Noone, P., & Kaisary, A. V. 1989 "The value of catheter valve use in long-term bladder drainage." In British Association of Urological Surgeons (BAUS) Conference proceedings.
- Lewis-Byers, K. & Thayer, D. 2002, "An evaluation of two incontinence skin care protocols in a long-term care setting", *Ostomy.Wound.Manage.*, vol. 48, no. 12, pp. 44-51.
- Leyden, J. J. 1986, "Diaper dermatitis", *Dermatol.Clin.*, vol. 4, no. 1, pp. 23-28.
- Lilas, L. A., Andrews, S. J. & Hanbury, D. C. 1999, "Point of technique. The tunnelled suprapubic catheter", *BJU.Int.*, vol. 83, no. 9, pp. 1060-1062.
- Lobel, R. W. & Sand, P. K. 1997, "Incisional hernia after suprapubic catheterization", *Obstet.Gynecol.*, vol. 89, no. 5 Pt 2, pp. 844-846.
- Lukeman, D. 1997, "Mainly children: childhood enuresis and encopresis.", in *Promoting continence: A clinical and research resource*, K. Getliffe, M. Dolman & B. Tindall, eds., Bailliere Tindall, London, p. 138.
- Lundgren, J., Bengtsson, O., Israelsson, A., Jonsson, A. C., Lindh, A. S. & Utas, J. 2000, "The importance of osmolality for intermittent catheterization of the urethra", *Spinal Cord*, vol. 38, no. 1, pp. 45-50.
- Lyder, C. H., Clemes-Lowrance, C., Davis, A., Sullivan, L. & Zucker, A. 1992, "Structured skin care regimen to prevent perineal dermatitis in the elderly", *J.ET Nurs.*, vol. 19, no. 1, pp. 12-16.
- Lyth, D. R., Braslis, K. & Iacovou, J. W. 1997, "The infusion trial of micturition", *British Journal of Urology*, vol. 79, no. 1, pp. 94-5.
- Macaulay, M., Clarke-O'Neill, S., Fader, M., Pettersson, L. & Cottenden, A. 2004a, "Are washable absorbents effective at containing urinary incontinence?", *Nurs.Times*, vol. 100, no. 12, pp. 58-62.
- Macaulay, M., Pettersson, L., Fader, M., Cottenden, A. & Brooks, R. 2004b, "Disposable pull-ups versus disposable nappies for children with a disability", *Nurs.Times*, vol. 100, no. 20, pp. 64-65.
- MacIntosh, J. 1998, "Realising the potential of urinals for women.", *Journal of community nursing*, vol. 12, no. 8, pp. 14-18.
- Maibach, H. I. & Kligman, A. M. 1962, "The biology of experimental human cutaneous moniliasis (*Candida albicans*)", *Arch.Dermatol.*, vol. 85, pp. 233-257.
- Maizels, M. & Schaeffer, A. J. 1980, "Decreased incidence of bacteriuria associated with periodic instillations of hydrogen peroxide into the urethral catheter drainage bag", *Journal of Urology*, vol. 123, no. 6, pp. 841-5.
- Maki, D. G., Knasinski, V., Halvorson, K. T. & Tambyah, P.A. 1998. A novel silver hydrogel-impregnated indwelling catheter reduces catheter-related urinary tract infections. A prospective double-blind trial. *Infect.Control Hosp.Epidemiol.* vol. 19, p. 682.
- Maki, D. G. & Tambyah, P. A. 2001, "Engineering out the risk for infection with urinary catheters", *Emerging Infectious Diseases*, vol. 7, no. 2, pp. 342-7.
- Maklebust, J. & Magnan, M. A. 1994, "Risk factors associated with having a pressure ulcer: a secondary data analysis", *Adv.Wound.Care*, vol. 7, no. 6, pp. 25, 27-4.
- Malassigne, P., Nelson, A., Amerson, T., Salzstein, R. & Binard, J. 1993, "Toward the design of a new bowel care chair for the spinal cord injured: a pilot study", *SCI.Nurs.*, vol. 10, no. 3, pp. 84-90.
- Malassigne, P., Nelson, A. L., Cors, M. W. & Amerson, T. 1995, "Design of the advanced commode-shower chair for spinal cord injured individuals.", *Journal of rehabilitation research and development*, vol. 37, pp. 373-382.
- Mantani, N., Ochiai, H., Imanishi, N., Kogure, T., Terasawa, K. & Tamura, J. 2003, "A case-control study of purple urine bag syndrome in geriatric wards", *Journal of Infection & Chemotherapy*, vol. 9, no. 1, pp. 53-7.
- Maynard, F. M. & Diokno, A. C. 1984, "Urinary infection and complications during clean intermittent catheterization following spinal cord injury", *J.Urol.*, vol. 132, no. 5, pp. 943-946.
- Medical Devices Agency. Basic Commodes: A Comparative Evaluation. Disability Equipment Assessment Report A5. London: MDA, October 1993.
- Medical Devices Agency. Penile sheaths: a comparative evaluation. Disability Equipment Assessment Report A15. London: MDA, 1995.
- Medical Devices Agency. Sterile 500ml legbags for urine drainage: a multi-centre comparative evaluation. Disability Equipment Assessment Report A20. London: MDA, 1996.
- Medical Devices Agency. Disposable, shaped bodyworn pads with pants for heavy incontinence: an evaluation. Disability Equipment Assessment Report No.IN.1. London: MDA, March 1998.
- Medical Devices Agency. Non-sterile 500ml-700ml legbags for urine drainage: an evaluation. Disability Equipment Assessment Report IN2. London: MDA, 1999.
- Medical Devices Agency. All-in-one disposable bodyworn pads for heavy incontinence: an evaluation. Disability Equipment Assessment Report No. IN.4. London: MDA, October 1999.
- Medical Devices Agency. Disposable pads for light incontinence. Disability Equipment Assessment Report IN9. London: MDA, 2002.
- Medical Devices Agency. Absorbent products for men with light incontinence: an evaluation. Disability Equipment Assessment Report. London: MDA, 2005.
- Mehta, A., Makris, A., Saad, A. & Callaghan, P. S. 1999, "Incisional hernia after suprapubic catheter insertion", *BJU.Int.*, vol. 84, no. 4, pp. 526-527.
- Merret, S., Adams, A. & Jordan, J. 1988, "Incontinence research provides some answers", *The Australian Nurses Journal*, vol. 18, no. 2, pp. 17-18.
- Michielsen, D. P. & Wyndaele, J. J. 1999, "Management of false passages in patients practising clean intermittent self catheterisation", *Spinal Cord.*, vol. 37, no. 3, pp. 201-203.
- Miller, J. L. & Bavendam, T. 1996, "Treatment with the Reliance urinary control insert: one-year experience", *J.Endourol.*, vol. 10, no. 3, pp. 287-292.
- Mitsui, T., Minami, K., Furuno, T., Morita, H. & Koyanagi, T. 2000, "Is suprapubic cystostomy an optimal urinary management in high quadriplegics?. A comparative study of suprapubic cystostomy and clean intermittent catheterization", *European Urology*, vol. 38, no. 4, pp. 434-8.
- Mittiness, L. S. & Barker, J. C. 1995, "Stigmatizing a "normal" condition: urinary incontinence in late life", *Med.Anthropol.Q.*, vol. 9, no. 2, pp. 188-210.
- Moore, J. G., Jessop, L. D. & Osborne, D. N. 1987, "Gas-chromatographic and mass-spectrometric analysis of the odor of human feces", *Gastroenterology*, vol. 93, no. 6, pp. 1321-1329.
- Moore, K. H., Foote, A., Burton, G. & King, J. 1999a, "An open study of the bladder neck support prosthesis in genuine stress incontinence", *Br.J.Obstet.Gynaecol.*, vol. 106, no. 1, pp. 42-49.

- Moore, K. H., Simons, A., Dowell, C., Bryant, C. & Prashar, S. 1999b, "Efficacy and user acceptability of the urethral occlusive device in women with urinary incontinence", *J.Urol.*, vol. 162, no. 2, pp. 464-468.
- Moore, K. N., Schieman, S., Ackerman, T., Dzus, H. Y., Metcalfe, J. B. & Voaklander, D. C. 2004, "Assessing comfort, safety, and patient satisfaction with three commonly used penile compression devices", *Urology*, vol. 63, no. 1, pp. 150-154.
- Morris, N. S. & Stickler, D. J. 1998a, "Encrustation of indwelling urethral catheters by *Proteus mirabilis* biofilms growing in human urine.[see comment]", *Journal of Hospital Infection*, vol. 39, no. 3, pp. 227-34.
- Morris, N. S. & Stickler, D. J. 2001, "Does drinking cranberry juice produce urine inhibitory to the development of crystalline, catheter-blocking *Proteus mirabilis* biofilms?", *BJU International*, vol. 88, no. 3, pp. 192-7.
- Morris, N. S. & Stickler, D. J. 1998b, "The effect of urease inhibitors on the encrustation of urethral catheters", *Urological Research*, vol. 26, no. 4, pp. 275-9.
- Morris, N. S., Stickler, D. J. & Winters, C. 1997, "Which indwelling urethral catheters resist encrustation by *Proteus mirabilis* biofilms?", *British Journal of Urology*, vol. 80, no. 1, pp. 58-63.
- Mortensen, N. & Humphreys, M. S. 1991, "The anal continence plug: a disposable device for patients with anorectal incontinence", *Lancet*, vol. 338, no. 8762, pp. 295-297.
- Mulhall, A. B., Chapman, R. G. & Crow, R. A. 1988, "Bacteriuria during indwelling urethral catheterization", *J.Hosp.Infect.*, vol. 11, no. 3, pp. 253-262.
- Nacey, J. N. & Delahunt, B. 1991, "Urinary catheter toxicity", *N.Z.Med.J.*, vol. 104, no. 918, pp. 355-356.
- Nacey, J. N., Tulloch, A. G. & Ferguson, A. F. 1985, "Catheter-induced urethritis: a comparison between latex and silicone catheters in a prospective clinical trial", *British Journal of Urology*, vol. 57, no. 3, pp. 325-8.
- Naylor, J. R. & Mulley, G. P. 1993, "Commodities: inconvenient conveniences", *BMJ*, vol. 307, no. 6914, pp. 1258-1260.
- Nazarko, L. 1995, "Commode design for frail and disabled people", *Prof.Nurse*, vol. 11, no. 2, pp. 95-97.
- Nelson, A., Malassigne, P., Amerson, T., Saltzstein, R. & Binard, J. 1993, "Descriptive study of bowel care practices and equipment in spinal cord injury", *SCI.Nurs.*, vol. 10, no. 2, pp. 65-67.
- Nelson, A. L., Malassigne, P. & Murray, J. 1994, "Comparison of seat pressures on three bowel care/shower chairs in spinal cord injury", *SCI.Nurs.*, vol. 11, no. 4, pp. 105-107.
- NICE (2003). Final guideline - Prevention of health care Associated Infections in Primary and Community Care. ([www.NICE.org.uk](http://www.NICE.org.uk))
- Nichols, T. & Balis, N. 2000, "Male External Urinary Catheter Design Survey", in 32nd Annual Wound Ostomy, Continence Conference.
- Nickel, J. C., Costerton, J. W., McLean, R. J. & Olson, M. 1994, "Bacterial biofilms: influence on the pathogenesis, diagnosis and treatment of urinary tract infections", *J.Antimicrob.Chemother.*, vol. 33 Suppl A, pp. 31-41.
- Nickel, J. C., Grant, S. K. & Costerton, J. W. 1985, "Catheter-associated bacteriuria. An experimental study", *Urology*, vol. 26, no. 4, pp. 369-75.
- Nicolle, L. E. 2001, "Urinary tract infections in long-term-care facilities", *Infect.Control Hosp.Epidemiol.*, vol. 22, no. 3, pp. 167-175.
- Nicolle, L. E., Mayhew, W. J. & Bryan, L. 1987, "Prospective randomized comparison of therapy and no therapy for asymptomatic bacteriuria in institutionalized elderly women", *American Journal of Medicine*, vol. 83, no. 1, pp. 27-33.
- Niel-Weise, B. S., Arend, S. M. & van den Broek, P. J. 2002, "Is there evidence for recommending silver-coated urinary catheters in guidelines?", *J.Hosp.Infect.*, vol. 52, no. 2, pp. 81-87.
- Niel-Weise, B.S. & van den Broek, P.J. "Urinary catheter policies for long-term management of voiding in adults and children". (Cochrane review). In: *The Cochrane Library*, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Nielsen, K. K., Walter, S., Maegaard, E. & Kromann-Andersen, B. 1993, "The urethral plug II: an alternative treatment in women with genuine urinary stress incontinence", *Br.J.Urol.*, vol. 72, no. 4, pp. 428-432.
- Nobaek, S., Johansson, M. L., Molin, G., Ahrne, S. & Jeppsson, B. 2000, "Alteration of intestinal microflora is associated with reduction in abdominal bloating and pain in patients with irritable bowel syndrome", *Am.J.Gastroenterol.*, vol. 95, no. 5, pp. 1231-1238.
- Nomura, S., Ishido, T., Teranishi, J. & Makiyama, K. 2000b, "Long-term analysis of suprapubic cystostomy drainage in patients with neurogenic bladder", *Urologia Internationalis*, vol. 65, no. 4, pp. 185-9.
- Nomura, S., Ishido, T., Teranishi, J. & Makiyama, K. 2000a, "Long-term analysis of suprapubic cystostomy drainage in patients with neurogenic bladder", *Urol.Int.*, vol. 65, no. 4, pp. 185-189.
- Norberg, B., Norberg, A. & Parkhede, U. 1983, "The spontaneous variation of catheter life in long-stay geriatric inpatients with indwelling catheters", *Gerontology*, vol. 29, no. 5, pp. 332-335.
- Norton, C. & Kamm, M. A. 2001, "Anal plug for faecal incontinence", *Colorectal Dis.*, vol. 3, no. 5, pp. 323-327.
- Nygaard, I. 1995, "Prevention of exercise incontinence with mechanical devices", *J.Reprod.Med.*, vol. 40, no. 2, pp. 89-94.
- O'Kelly, T. J., Mathew, A., Ross, S. & Munro, A. 1995, "Optimum method for urinary drainage in major abdominal surgery: a prospective randomized trial of suprapubic versus urethral catheterization", *British Journal of Surgery*, vol. 82, no. 10, pp. 1367-8.
- Ord, J., Lunn, D. & Reynard, J. 2003, "Bladder management and risk of bladder stone formation in spinal cord injured patients", *J.Urol.*, vol. 170, no. 5, pp. 1734-1737.
- Orikasa, S., Koyanagi, T., Motomura, M., Kudo, T. & Togashi, M. 1976, "Experience with non-sterile intermittent self-catheterization", *J.Urol.*, vol. 115, no. 2, pp. 141-142.
- Ouslander, J. G., Greengold, B. & Chen, S. 1987, "External catheter use and urinary tract infections among incontinent male nursing home patients", *J.Am.Geriatr.Soc.*, vol. 35, no. 12, pp. 1063-1070.
- Pachler, J. & Frimodt-Moller, C. 1999, "A comparison of prelubricated hydrophilic and non-hydrophilic polyvinyl chloride catheters for urethral catheterization", *BJU International*, vol. 83, no. 7, pp. 767-9.
- Page, G, Buntinx, F., & Hanssens, M. Indwelling bladder catheterization as part of postoperative care for caesarean section. (Cochrane Review). In: *The Cochrane Library*, issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.
- Pariente, J. L., Bordenave, L., Jacob, F., Bareille, R., Baquey, C. & Le Guillou, M. 2000, "Cytotoxicity assessment of latex urinary catheters on cultured human urothelial cells", *European Urology*, vol. 38, no. 5, pp. 640-3.
- Park, J. H., Cho, Y. W., Kwon, I. C., Jeong, S. Y. & Bae, Y. H. 2002, "Assessment of PEO/PTMO multiblock copolymer/segmented polyurethane blends as coating materials for urinary catheters: in vitro bacterial adhesion and encrustation behavior", *Biomaterials*, vol. 23, no. 19, pp. 3991-4000.
- Parkin, J., Scanlan, J., Woolley, M., Grover, D., Evans, A. & Feneley, R. C. 2002, "Urinary catheter 'deflation cuff' formation: clinical audit and quantitative in vitro analysis", *BJU International*, vol. 90, no. 7, pp. 666-71.
- Pascoe, G. & Clovis, S. 2001, "Evaluation of two coated catheters in intermittent self-catheterization", *British Journal of Nursing*, vol. 10,

no. 5, pp. 325-9.

Patel, M. I., Watts, W. & Grant, A. 2001, "The optimal form of urinary drainage after acute retention of urine", *BJU International*, vol. 88, no. 1, pp. 26-9.

Pateman, B. & Johnson, M. 2000, "Men's lived experiences following transurethral prostatectomy for benign prostatic hypertrophy", *J.Adv.Nurs.*, vol. 31, no. 1, pp. 51-58.

Paterson, J. 2000, "Stigma associated with post-prostatectomy urinary incontinence.", *Journal of Wound, Ostomy and Continence Nursing*, vol. 27, no. 3, pp. 168-173.

Paterson, J., Dunn, S., Kowanko, I., van, L. A., Stein, I. & Pretty, L. 2003, "Selection of continence products: perspectives of people who have incontinence and their carers", *Disabil.Rehabil.*, vol. 25, no. 17, pp. 955-963.

Peifer, D. J. & Hanover, R. Y. 1997, "Clinical evaluation of the easy-flow catheter", *J.Rehabil.Res.Dev.*, vol. 34, no. 2, pp. 215-219.

Penders, J., Huylenbroeck, A. A., Everaert, K., Van Laere, M. & Verschraegen, G. L. 2003, "Urinary infections in patients with spinal cord injury", *Spinal Cord*, vol. 41, no. 10, pp. 549-52.

Perrin, L. C., Penfold, C. & McLeish, A. 1997, "A prospective randomized controlled trial comparing suprapubic with urethral catheterization in rectal surgery", *Australian & New Zealand Journal of Surgery*, vol. 67, no. 8, pp. 554-6.

Perrouin-Verbe, B., Labat, J. J., Richard, I., Mauduyt de la Greve, I., Buzelin, J. M. & Mathe, J. F. 1995, "Clean intermittent catheterisation from the acute period in spinal cord injury patients. Long term evaluation of urethral and genital tolerance", *Paraplegia*, vol. 33, no. 11, pp. 619-24.

Peschers, U., Zen, R. F., Schaer, G. N. & Schussler, B. 1996, The VIVA urethral plug: a sensible expansion of the spectrum for conservative therapy of urinary stress incontinence?, *Geburtshilfe Frauenheilkd.*, vol. 56, no. 3, pp. 118-123.

Pfrommer, W., Holschneider, A. M., Loffler, N., Schauff, B. & Ure, B. M. 2000, "A new polyurethane anal plug in the treatment of incontinence after anal atresia repair", *Eur.J.Pediatr.Surg.*, vol. 10, no. 3, pp. 186-190.

Phipps S, Lim YN, N'Dow J, Rane A. Short term urinary catheter policies following urogenital surgery in adults. (Cochrane Review). In: *The Cochrane Library*, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.

Pickard, W. G. & Grundy, D. J. 1996, "A comparison of two methods of sterile urethral catheterisation in spinal cord injured adults", *Paraplegia*, vol. 34, no. 1, pp. 30-3.

Pieper, B., Cleland, V., Johnson, D. E. & O'Reilly, J. L. 1989, "Inventing urine incontinence devices for women", *Image J.Nurs.Sch*, vol. 21, no. 4, pp. 205-209.

Platt, R., Polk, B. F., Murdock, B. & Rosner, B. 1982, "Mortality associated with nosocomial urinary-tract infection", *New England Journal of Medicine*, vol. 307, no. 11, pp. 637-42.

Platt, R., Polk, B. F., Murdock, B. & Rosner, B. 1983, "Reduction of mortality associated with nosocomial urinary tract infection", *Lancet*, vol. 1, no. 8330, pp. 893-897.

Plowman, R., Graves, N., Esquivel, J., & Roberts, J. A. 2001, "An economic model to assess the cost and benefits of the routine use of silver alloy coated urinary catheters to reduce the risk of urinary tract infections in catheterized patients ". *Journal of Hospital Infection*.2001 vol. 48 no1, pp33-42

Plowman, R., Graves, N., Esquivel, J., & Roberts, J. A. 2001, "An economic model to assess the cost and benefits of the routine use of silver alloy coated urinary catheters to reduce the risk of urinary tract infections in catheterized patients ". *Journal of Hospital Infection*.2001 May ;48(1) :33-42

Pohl, H. G., Bauer, S. B., Borer, J. G., Diamond, D. A., Kelly, M. D., Grant, R., Briscoe, C. J., Doonan, G. & Retik, A. B. 2002, "The outcome of voiding dysfunction managed with clean intermittent catheterization in neurologically and anatomically normal children", *BJU International*, vol. 89, no. 9, pp. 923-7.

Pomfret, I. 1995, "Bladder irrigation", *Community Nursing*, vol. December, pp. 24-29.

Pratt, R. J., Pellowe, C., Loveday, H. P., Robinson, N., Smith, G. W., Barrett, S., Davey, P., Harper, P., Loveday, C., McDougall, C., Mulhall, A., Privett, S., Smales, C., Taylor, L., Weller, B. Wilcox 2001, "The epic project: developing national evidence-based guidelines for preventing healthcare associated infections. Phase I: Guidelines for preventing hospital-acquired infections. Department of Health (England). *Journal of Hospital Infection*, vol. 47, no. Suppl, pp. 3-82.

Prieto-Fingerhut, T., Banovac, K. & Lynne, C. M. 1997, "A study comparing sterile and nonsterile urethral catheterization in patients with spinal cord injury", *Rehabilitation Nursing*, vol. 22, no. 6, pp. 299-302.

Proudfoot, L. M., Farmer, E. S. & McIntosh, J. B. 1994, "Testing incontinence pads using single-case research designs", *Br.J.Nurs.*, vol. 3, no. 7, pp. 316, 318-320, 322.

Pugach, J. L., DiTizio, V., Mittelman, M. W., Bruce, A. W., DiCosmo, F. & Khoury, A. E. 1999, "Antibiotic hydrogel coated Foley catheters for prevention of urinary tract infection in a rabbit model", *Journal of Urology*, vol. 162, no. 3 Pt 1, pp. 883-7.

Rainville, N. 1987, "Does a foley belong in the rectum?", *Am.J.Nurs.*, vol. 87, no. 2, p. 175.

Rasmussen, O., Korner, B., Moller-Sorensen, P. & Kronburg, O. 1977, "Suprapubic versus urethral bladder drainage following surgery for rectal cancer.", *Acta Chirurgica Scandinavica*, vol. 143, pp. 371-374.

Ratnaval, C. D., Renwick, P., Farouk, R., Monson, J. R. & Lee, P. W. 1996, "Suprapubic versus transurethral catheterisation of males undergoing pelvic colorectal surgery", *International Journal of Colorectal Disease*, vol. 11, no. 4, pp. 177-9.

Raz, R., Schiller, D. & Nicolle, L. E. 2000, "Chronic indwelling catheter replacement before antimicrobial therapy for symptomatic urinary tract infection", *J.Urol.*, vol. 164, no. 4, pp. 1254-1258.

Razdan, S., Leboeuf, L., Meinbach, D. S., Weinstein, D. & Gousse, A. E. 2003, "Current practice patterns in the urologic surveillance and management of patients with spinal cord injury", *Urology*, vol. 61, no. 5, pp. 893-6.

Realini, J. P. & Walters, M. D. 1990, "Vaginal diaphragm rings in the treatment of stress urinary incontinence", *J.Am.Board Fam.Pract.*, vol. 3, no. 2, pp. 99-103.

Reiche, T., Lisby, G., Jorgensen, S., Christensen, A. B. & Nordling, J. 2000, "A prospective, controlled, randomized study of the effect of a slow-release silver device on the frequency of urinary tract infection in newly catheterized patients", *BJU International*, vol. 85, no. 1, pp. 54-9.

Roe, B. & May, C. 1999, "Incontinence and sexuality: findings from a qualitative perspective", *J.Adv.Nurs.*, vol. 30, no. 3, pp. 573-579.

Roe, B. H. 1990b, "Study of the effects of education on the management of urine drainage systems by patients and carers", *Journal of Advanced Nursing*, vol. 15, no. 5, pp. 517-24.

Roe, B. H. 1990a, "Study of the effects of education on patients' knowledge and acceptance of their indwelling urethral catheters", *Journal of Advanced Nursing*, vol. 15, no. 2, pp. 223-31.

Rooney, M. 1994, "Impacting health care: study of a reusable urinary drainage system", *SCI.Nurs.*, vol. 11, no. 1, pp. 16-18.

Ross, V. 1993, "The fecal containment device: one answer to a dreaded procedure", *Ostomy.Wound.Manage.*, vol. 39, no. 7, pp. 42-4, 46.

Rowley, P., German, K., Kumar, U., Stone, D., Stone, V. & Blackford, H. N. 1995. A randomized cross-over study comparing the catheter

- valve with the leg bag in male patients with urethral catheters, in International Continence Society Proceedings, Sydney, Australia.
- Rutschmann, O. T. & Zwahlen, A. 1995, "Use of norfloxacin for prevention of symptomatic urinary tract infection in chronically catheterized patients", *European Journal of Clinical Microbiology & Infectious Diseases*, vol. 14, no. 5, pp. 441-4.
- Ruutu, M., Alfthan, O., Heikkinen, L., Jarvinen, A., Konttinen, M., Lehtonen, T., Merikallio, E. & Standertskjold-Nordenstam, C. G. 1984, "Unexpected urethral strictures after short-term catheterization in open-heart surgery", *Scand.J.Urol.Nephrol.*, vol. 18, no. 1, pp. 9-12.
- Ruutu, M., Alfthan, O., Heikkinen, L., Jarvinen, A., Lehtonen, T., Merikallio, E. & Standertskjold-Nordenstam, C. G. 1982, "'Epidemic' of acute urethral stricture after open-heart surgery", *Lancet*, vol. 1, no. 8265, p. 218.
- Ruutu, M., Alfthan, O., Talja, M. & Andersson, L. C. 1985, "Cytotoxicity of latex urinary catheters", *British Journal of Urology*, vol. 57, no. 1, pp. 82-7.
- Sabbuba, N. A., Mahenthalingam, E. & Stickler, D. J. 2003, "Molecular epidemiology of *Proteus mirabilis* infections of the catheterized urinary tract", *Journal of Clinical Microbiology*, vol. 41, no. 11, pp. 4961-5.
- Saint, S., Elmore, J. G., Sullivan, S. D., Emerson, S. S. & Koepsell, T. D. 1998, "The efficacy of silver alloy-coated urinary catheters in preventing urinary tract infection: a meta-analysis", *American Journal of Medicine*, vol. 105, no. 3, pp. 236-41.
- Saint, S. & Lipsky, B. A. 1999, "Preventing catheter-related bacteriuria: should we? Can we? How?", *Arch.Intern.Med.*, vol. 159, no. 8, pp. 800-808.
- Saint, S., Lipsky, B. A., Baker, P. D., McDonald, L. L. & Ossenkop, K. 1999, "Urinary catheters: what type do men and their nurses prefer?", *Journal of the American Geriatrics Society*, vol. 47, no. 12, pp. 1453-7.
- Saint, S., Veenstra, D. L. & Lipsky, B. A. 2000, "The clinical and economic consequences of nosocomial central venous catheter-related infection: are antimicrobial catheters useful?", *Infect.Control Hosp.Epidemiol.*, vol. 21, no. 6, pp. 375-380.
- Saint, S., Veenstra, D. L., Sullivan, S. D., Chenoweth, C. & Fendrick, A. M. 2000, "The potential clinical and economic benefits of silver alloy urinary catheters in preventing urinary tract infection", *Arch.Intern.Med.*, vol. 160, no. 17, pp. 2670-2675.
- Sand, P. K., Staskin, D., Miller, J., Diokno, A., Sant, G. R., Davila, G. W., Knapp, P., Rappaport, S. & Tutrone, R. 1999, "Effect of a urinary control insert on quality of life in incontinent women", *Int.Urogynecol.J.Pelvic.Floor.Dysfunct.*, vol. 10, no. 2, pp. 100-105.
- Sander, P., Thyssen, H., Lose, G. & Andersen, J. T. 1999, "Effect of a vaginal device on quality of life with urinary stress incontinence", *Obstet.Gynecol.*, vol. 93, no. 3, pp. 407-411.
- Sartor, C., Sambuc, R., Bimar, M. C., Gulian, C. & De, M. P. 1995, "Prevalence surveys of nosocomial infections using a random sampling method in Marseille hospitals", *J.Hosp.Infect.*, vol. 29, no. 3, pp. 209-216.
- Schaafsma, R. J., Delaere, K. P. & Theunissen, P. H. 1999, "Squamous cell carcinoma of suprapubic cystostomy tract without bladder involvement", *Spinal Cord.*, vol. 37, no. 5, pp. 373-374.
- Schiotz, H. A. 1996, "Antiseptic catheter gel and urinary tract infection after short-term postoperative catheterization in women", *Archives of Gynecology & Obstetrics*, vol. 258, no. 2, pp. 97-100.
- Schiotz, H. A. & Guttu, K. 2002, "Value of urinary prophylaxis with methenamine in gynecologic surgery", *Acta Obstetrica et Gynecologica Scandinavica*, vol. 81, no. 8, pp. 743-6.
- Schlager, T. A., Anderson, S., Trudell, J. & Hendley, J. O. 1998, "Nitrofurantoin prophylaxis for bacteriuria and urinary tract infection in children with neurogenic bladder on intermittent catheterization", *Journal of Pediatrics*, vol. 132, no. 4, pp. 704-8.
- Schlager, T. A., Clark, M. & Anderson, S. 2001, "Effect of a single-use sterile catheter for each void on the frequency of bacteriuria in children with neurogenic bladder on intermittent catheterization for bladder emptying", *Pediatrics*, vol. 108, no. 4, p. E71.
- Schneeberger, P. M., Vreede, R. W., Bogdanowicz, J. F. & van Dijk, W. C. 1992, "A randomized study on the effect of bladder irrigation with povidone-iodine before removal of an indwelling catheter", *Journal of Hospital Infection*, vol. 21, no. 3, pp. 223-9.
- Schnetz, E., Kuss, O., Schmitt, J., Diepgen, T. L., Kuhn, M. & Fartasch, M. 1999, "Intra-and inter-individual variations in transepidermal water loss on the face: facial locations for bioengineering studies", *Contact Dermatitis*, vol. 40, no. 5, pp. 243-247.
- Sethia, K. K., Selkon, J. B., Berry, A. R., Turner, C. M., Kettlewell, M. G. & Gough, M. H. 1987, "Prospective randomized controlled trial of urethral versus suprapubic catheterization", *British Journal of Surgery*, vol. 74, no. 7, pp. 624-5.
- Seymour, W. 1998, "Coping with embarrassment: bodily continence..", in *Remaking the Body: Rehabilitation and Change.*, Routledge, London, pp. 154-176.
- Shekelle, P. G., Morton, S. C., Clark, K. A., Pathak, M. & Vickrey, B. G. 1999, "Systematic review of risk factors for urinary tract infection in adults with spinal cord dysfunction", *Journal of Spinal Cord Medicine*, vol. 22, no. 4, pp. 258-72.
- Sherbondy, A. L., Cooper, C. S., Kalinowski, S. E., Boyt, M. A. & Hawtrey, C. E. 2002, "Variability in catheter microwave sterilization techniques in a single clinic population", *Journal of Urology*, vol. 168, no. 2, pp. 562-4.
- Sheriff, M. K., Foley, S., McFarlane, J., Nauth-Misir, R., Craggs, M. & Shah, P. J. 1998, "Long-term suprapubic catheterisation: clinical outcome and satisfaction survey", *Spinal Cord.*, vol. 36, no. 3, pp. 171-176.
- Shinopulos, N. M., Dann, J. A. & Smith, J. J., III 1999, "Patient selection and education for use of the CapSure (Re/Stor) continence shield", *Urol.Nurs.*, vol. 19, no. 2, pp. 135-140.
- Simpson, L. 2001, "Indwelling urethral catheters", *Nursing Standard*, vol. 15, no. 46, pp. 47-53.
- Skewes, S. M. 1997, "Bathing: it's a tough job!", *J.Gerontol.Nurs.*, vol. 23, no. 5, pp. 45-49.
- Spector, W. D. & Fortinsky, R. H. 1998, "Pressure ulcer prevalence in Ohio nursing homes: clinical and facility correlates", *J.Aging Health*, vol. 10, no. 1, pp. 62-80.
- Sprott, M. S., Kearns, A. M. & Keenlyside, D. 1988, "A microbiological study of absorbent pads", *J.Hosp.Infect.*, vol. 12, no. 2, pp. 125-129.
- Stamm, W. E. 1998, *Urinary tract infections* Lippincott-Raven, Philadelphia.
- Stamm, W. E. 1991, "Catheter-associated urinary tract infections: epidemiology, pathogenesis, and prevention", *Am.J.Med.*, vol. 91, no. 3B, pp. 65S-71S.
- Stansfield, R. & Caudle, S. 1997, "Bacillus cereus and orthopaedic surgical wound infection associated with incontinence pads manufactured from virgin wood pulp", *J.Hosp.Infect.*, vol. 37, no. 4, pp. 336-338.
- Staskin, D., Bavendam, T., Miller, J., Davila, G. W., Diokno, A., Knapp, P., Rappaport, S., Sand, P., Sant, G. & Tutrone, R. 1996, "Effectiveness of a urinary control insert in the management of stress urinary incontinence: early results of a multicenter study", *Urology*, vol. 47, no. 5, pp. 629-636.
- Stickler, D., Dolman, J., Rolfe, S. & Chawla, J. 1989, "Activity of antiseptics against *Escherichia coli* growing as biofilms on silicone

- surfaces", *Eur.J.Clin.Microbiol.Infect.Dis.*, vol. 8, no. 11, pp. 974-978.
- Stickler, D., Young, R., Jones, G., Sabbuba, N., & Morris, N. 2003, "Why are Foley catheters so vulnerable to encrustation and blockage by crystalline bacterial biofilm?" *Urol Res.* 2003 Oct;31(5):306-11. Epub 2003 Jul 11.
- Stickler, D. J. & Chawla, J. C. 1987, "The role of antiseptics in the management of patients with long-term indwelling bladder catheters", *Journal of Hospital Infection*, vol. 10, no. 3, pp. 219-28.
- Stickler, D. J., Clayton, C. L. & Chawla, J. C. 1987, "Assessment of antiseptic bladder washout procedures using a physical model of the catheterised bladder", *British Journal of Urology*, vol. 60, no. 5, pp. 413-8.
- Stickler, D. J., Jones, G. L. & Russell, A. D. 2003, "Control of encrustation and blockage of Foley catheters", *Lancet*, vol. 361, no. 9367, pp. 1435-1437.
- Stickler, D. J. & Zimakoff, J. 1994, "Complications of urinary tract infections associated with devices used for long-term bladder management", *Journal of Hospital Infection*, vol. 28, no. 3, pp. 177-94.
- Stokes, S., Wheeler, J. S., & Reyes, C. V. 1995, "Squamous cell carcinoma arising from a suprapubic cystostomy tract with extension into the bladder", *J.Urol.*, vol. 154, no. 3, pp. 1132-1133.
- Stonehill, W. H., Dmochowski, R. R., Patterson, A. L. & Cox, C. E. 1996, "Risk factors for bladder tumors in spinal cord injury patients", *Journal of Urology*, vol. 155, no. 4, pp. 1248-50.
- Suarez, F. L., Furne, J., Springfield, J. & Levitt, M. D. 1999, "Failure of activated charcoal to reduce the release of gases produced by the colonic flora", *Am.J.Gastroenterol.*, vol. 94, no. 1, pp. 208-212.
- Suarez, F. L., Springfield, J. & Levitt, M. D. 1998, "Identification of gases responsible for the odour of human flatus and evaluation of a device purported to reduce this odour", *Gut*, vol. 43, no. 1, pp. 100-104.
- Suarez, G. M., Baum, N. H. & Jacobs, J. 1991, "Use of standard contraceptive diaphragm in management of stress urinary incontinence", *Urology*, vol. 37, no. 2, pp. 119-122.
- Subramonian, K. & Harrison, S. C. 1999, "Re: Bladder histological changes associated with chronic indwelling urinary catheter. *Journal of Urology*, vol. 162, no. 6, pp. 2105-6.
- Suskind, R. R. & Ishihara, M. 1965, "The effects of wetting on cutaneous vulnerability", *Arch.Environ.Health*, vol. 11, no. 4, pp. 529-537.
- Sutherland, R. S., Kogan, B. A., Baskin, L. S. & Mevorach, R. A. 1996, "Clean intermittent catheterization in boys using the LoFric catheter", *Journal of Urology*, vol. 156, no. 6, pp. 2041-3.
- Talja, M., Korpela, A. & Jarvi, K. 1990, "Comparison of urethral reaction to full silicone, hydrogen-coated and siliconised latex catheters", *British Journal of Urology*, vol. 66, no. 6, pp. 652-7.
- Tambyah, P. A. & Maki, D. G. 2000a, "Catheter-associated urinary tract infection is rarely symptomatic: a prospective study of 1,497 catheterized patients", *Arch.Intern.Med.*, vol. 160, no. 5, pp. 678-682.
- Tambyah, P. A. & Maki, D. G. 2000b, "The relationship between pyuria and infection in patients with indwelling urinary catheters: a prospective study of 761 patients", *Arch.Intern.Med.*, vol. 160, no. 5, pp. 673-677.
- Tenke, P., Reidl, C. R., Jones, G., Williams, G. J., Stickler, D. & Nagy, E. 2004, "Bacterial biofilm formation on urological devices and heparin coating as preventative strategy.", *Int J Antimicrobial Agents*, vol. 23 (SUPPL 1), pp. 67-74.
- Theaker, C., Mannan, M., Ives, N. & Soni, N. 2000, "Risk factors for pressure sores in the critically ill", *Anaesthesia*, vol. 55, no. 3, pp. 221-224.
- Thelwell, S., Symon, C., Gay, S., Cottenden, A. & Feneley, R. 1995a, "Continence. Systems for leg bags", *Nurs.Times*, vol. 91, no. 16, pp. 62-64.
- Theofrastous, J. P. & Cobb, D. L. 2002, "A Randomized Trial of Suprapubic Versus Transurethral Bladder Drainage After Open Burch Urethropexy.", *Journal of Pelvic Surgery*, vol. 8, no. 2, pp. 72-77.
- Thibon, P., Le Coutour, X., Leroyer, R. & Fabry, J. 2000, "Randomized multi-centre trial of the effects of a catheter coated with hydrogel and silver salts on the incidence of hospital-acquired urinary tract infections", *Journal of Hospital Infection*, vol. 45, no. 2, pp. 117-24.
- Thompson, R. L., Haley, C. E., Searcy, M. A., Guenther, S. M., Kaiser, D. L., Groschel, D. H., Gillenwater, J. Y. & Wenzel, R. P. 1984, "Catheter-associated bacteriuria. Failure to reduce attack rates using periodic instillations of a disinfectant into urinary drainage systems", *JAMA*, vol. 251, no. 6, pp. 747-51.
- Thornburn, P., Cottenden, A. & Ledger, D. 1992, "Continence. Undercover trials", *Nurs.Times*, vol. 88, no. 13, pp. 72-78.
- Thornburn, P., Fader, M., Dean, G., Brooks, R. & Cottenden, A. 1997, "Improving the performance of small incontinence pads: a study of "wet comfort"", *J.Wound.Ostomy.Continence.Nurs.*, vol. 24, no. 4, pp. 219-225.
- Thyssen, H., Bidmead, J., Lose, G., Moller, B. K., Dwyer, P. & Cardozo, L. 2001, "A new intravaginal device for stress incontinence in women", *BJU.Int.*, vol. 88, no. 9, pp. 889-892.
- Thyssen, H. & Lose, G. 1996, "New disposable vaginal device (continence guard) in the treatment of female stress incontinence. Design, efficacy and short term safety", *Acta Obstet.Gynecol.Scand.*, vol. 75, no. 2, pp. 170-173.
- Thyssen, H., Sander, P. & Lose, G. 1999, "A vaginal device (continence guard) in the management of urge incontinence in women", *Int.Urogynecol.J.Pelvic.Floor.Dysfunct.*, vol. 10, no. 4, pp. 219-222.
- Tincello, D. G., Bolderson, J. & Richmond, D. H. 1997, "Preliminary experience with a urinary control device in the management of women with genuine stress incontinence", *Br.J.Urol.*, vol. 80, no. 5, pp. 752-756.
- Tsai, T. F. & Maibach, H. I. 1999, "How irritant is water? An overview", *Contact Dermatitis*, vol. 41, no. 6, pp. 311-314.
- Tyremann, N. O., Andersson, P. O., Kroon, L. & Orstam, S. 1986, "Urinary tract infection after vaginal surgery. Effect of prophylactic treatment with methenamine hippurate", *Acta Obstetrica et Gynecologica Scandinavica*, vol. 65, no. 7, pp. 731-3.
- Vaidyanathan, S., Soni, B. M., Dundas, S. & Krishnan, K. R. 1994, "Urethral cytology in spinal cord injury patients performing intermittent catheterisation", *Paraplegia*, vol. 32, no. 7, pp. 493-500.
- van den Broek, P. J., Daha, T. J. & Mouton, R. P. 1985, "Bladder irrigation with povidone-iodine in prevention of urinary-tract infections associated with intermittent urethral catheterisation", *Lancet*, vol. 1, no. 8428, pp. 563-5.
- van, d., V & Maibach, H. I. 1990, "A functional study of the skin barrier to evaporative water loss by means of repeated cellophane-tape stripping", *Clin.Exp.Dermatol.*, vol. 15, no. 3, pp. 180-182.
- Vapnek, J. M., Maynard, F. M. & Kim, J. 2003, "A prospective randomized trial of the LoFric hydrophilic coated catheter versus conventional plastic catheter for clean intermittent catheterization", *Journal of Urology*, vol. 169, no. 3, pp. 994-8.
- Verleyen, P., De Ridder, D., Van Poppel, H. & Baert, L. 1999, "Clinical application of the Bardex IC Foley catheter", *European Urology*, vol. 36, no. 3, pp. 240-6.
- Versi, E. & Harvey, M. A. 1998, "Efficacy of an external urethral device in women with genuine stress urinary incontinence", *Int.Urogynecol.J.Pelvic.Floor.Dysfunct.*, vol. 9, no. 5, pp. 271-274.
- Vinson, J. & Proch, J. 1998, "Inhibition of moisture penetration to the

- skin by a novel incontinence barrier product", *J.Wound. Ostomy. Continence.Nurs.*, vol. 25, no. 5, pp. 256-260.
- Waller, L., Jonsson, O., Norlen, L. & Sullivan, L. 1995, "Clean intermittent catheterization in spinal cord injury patients: long-term follow-up of a hydrophilic low friction technique.[see comment]", *Journal of Urology*, vol. 153, no. 2, pp. 345-8.
- Waller, L., Telander, M. & Sullivan, L. 1997, "The importance of osmolality in hydrophilic urethral catheters: a crossover study.[see comment]", *Spinal Cord*, vol. 35, no. 4, pp. 229-33.
- Waring, M. & Hoggarth, A. The measurement of skin barrier product efficacy. *JWOCN* 31[35], 31. 2004.
- Warren, J. W., Tenney, J. H., Hoopes, J. M., Muncie, H. L. & Anthony, W. C. 1982, "A prospective microbiologic study of bacteriuria in patients with chronic indwelling urethral catheters", *Journal of Infectious Diseases*, vol. 146, no. 6, pp. 719-23.
- Warshaw, E., Nix, D., Kula, J. & Markon, C. E. 2002, "Clinical and cost effectiveness of a cleanser protectant lotion for treatment of perineal skin breakdown in low-risk patients with incontinence", *Ostomy.Wound.Manage.*, vol. 48, no. 6, pp. 44-51.
- Watret, L. 1999, "Using a case-mix-adjusted pressure sore incidence study in a surgical directorate to improve patient outcomes in pressure ulcer prevention", *J.Tissue Viability.*, vol. 9, no. 4, pp. 121-125.
- Watson, R. & Kuhn, M. 1990, "The influence of component parts on the performance of urinary sheath systems", *J.Adv.Nurs.*, vol. 15, no. 4, pp. 417-422.
- Webb, R., Lawson, K. D. & Neal, D. 1990, "Clean intermittent self-catheterisation in 172 adults.", *BJU International* pp. 20-23.
- Webster, J., Hood, R. H., Burrige, C. A., Doidge, M. L., Phillips, K. M. & George, N. 2001, "Water or antiseptic for periurethral cleaning before urinary catheterization: a randomized controlled trial", *AJIC: American Journal of Infection Control*, vol. 29, no. 6, pp. 389-94.
- West, D. A., Cummings, J. M., Longo, W. E., Virgo, K. S., Johnson, F. E. & Parra, R. O. 1999, "Role of chronic catheterization in the development of bladder cancer in patients with spinal cord injury", *Urology*, vol. 53, no. 2, pp. 292-7.
- Whittingham, K. & May, S. 1998, "Cleansing regimens for continence care", *Prof.Nurse*, vol. 14, no. 3, pp. 167-172.
- Wilde, M. H. 2003a, "Life with an indwelling urinary catheter: the dialectic of stigma and acceptance", *Qualitative Health Research*, vol. 13, no. 9, pp. 1189-204.
- Wilde, M. H. 2003b, "Urinary tract infection in people with long-term urinary catheters", *Journal of Wound, Ostomy & Continence Nursing*, vol. 30, no. 6, pp. 314-23.
- Wilde, M. H. 2002a, "Understanding urinary catheter problems from the patient's point of view", *Home Healthcare Nurse*, vol. 20, no. 7, pp. 449-55.
- Wilde, M. H. 2002b, "Urine flowing: a phenomenological study of living with a urinary catheter.[see comment]", *Research in Nursing & Health*, vol. 25, no. 1, pp. 14-24.
- Wilson, C., Sandhu, S. S. & Kaisary, A. V. 1997, "A prospective randomized study comparing a catheter-valve with a standard drainage system", *British Journal of Urology*, vol. 80, no. 6, pp. 915-7.
- Wilson, M. & Coates, D. 1996, "Infection control and urine drainage bag design", *Prof.Nurse*, vol. 11, no. 4, pp. 245-9, 251.
- Wilson, P. A. & Dallas, M. J. 1990, "Diaper performance: maintenance of healthy skin", *Pediatr.Dermatol.*, vol. 7, no. 3, pp. 179-184.
- Wong, E. S. 1983, "Guideline for prevention of catheter-associated urinary tract infections", *American Journal of Infection Control*, vol. 11, no. 1, pp. 28-36.
- Woods, M., McCreanor, J. & Aitchison, M. 1999, "An assessment of urethral catheter valves", *Prof.Nurse*, vol. 14, no. 7, pp. 472-474.
- Wyndaele, J. J. 2002, "Intermittent catheterization: which is the optimal technique?", *Spinal Cord*, vol. 40, no. 9, pp. 432-7.
- Wyndaele, J. J., De Ridder, D., Everaert, K., Heilporn, A. & Congard-Chassol, B. 2000, "Evaluation of the use of Uroath-Gel(TM) catheters for intermittent self-catheterization by male patients using conventional catheters for a long time.", *Spinal Cord*, vol. 38, no. 2, pp. 97-99.
- Wyndaele, J. J. & Maes, D. 1990, "Clean intermittent self-catheterization: a 12-year followup", *Journal of Urology*, vol. 143, no. 5, pp. 906-8.
- Yang, C. C. & Clowers, D. E. 1999, "Screening cystoscopy in chronically catheterized spinal cord injury patients", *Spinal Cord*, vol. 37, no. 3, pp. 204-7.
- Zimmerer, R. E., Lawson, K. D. & Calvert, C. J. 1986, "The effects of wearing diapers on skin", *Pediatr.Dermatol.*, vol. 3, no. 2, pp. 95-101.
- Zommick, J. N., Simoneau, A. R., Skinner, D. G. & Ginsberg, D. A. 2003, "Continent lower urinary tract reconstruction in the cervical spinal cord injured population", *J.Urol.*, vol. 169, no. 6, pp. 2184-2187.

