Committee 20

Management Using Continence Products

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I. INTRODUCTION

Not all incontinence can be cured completely and even those who are ultimately successfully treated may have to live with incontinence for a time, for example, whilst 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. In short, the possible role of continence products should be considered at each stage of patient assessment and treatment and, if treatment is not available, appropriate, acceptable or (fully) successful – subsequent management. 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 [1].

This chapter is aimed primarily at healthcare professionals seeking to make informed decisions as they choose – or help their patients to choose - between continence product categories and then select a specific product within their chosen category. We have also aimed to make this information accessible to the user, particularly in the summary and recommendation sections. The chapter includes a section for each of the major product categories, each section reviewing published data and – where possible - identifying evidence-based recom-mendations for product selection and use. Products designed to deal with skin and odour problems caused by incontinence are also addressed.

The sections on the major product categories are preceded by two others. The first provides overall guidelines for product selection, describing the key elements of patient assessment and suggesting a classification of people with incontinence into a number of broad groups based on gender, age (adult or child) and the nature and severity of their incontinence. A table is provided for each group summarising the user characteristics, priorities and contexts which commonly favour or discourage the use of each of the major product categories available to them. Following these overall guidelines and preceding the sections on the major product categories, a review is provided of the methodological challenges of conducting continence product evaluations and interpreting the results.

Unfortunately, much of the evidence base for product selection and effective use is patchy and, where there is little published data to provide confident evidence-based advice on an issue commonly raised by patients and caregivers, an expert opinion is offered as the best advice available. The hope is that highlighting knowledge gaps in this way will help stimulate the research necessary to provide more robust evidence-based advice in the future.

The literature search strategy to identify material for this chapter additional to that reviewed for the third consultation [2] was conducted as follows. MEDLINE and CINAHL databases were searched from 2003 – 2008 for English language publications. Detailed search strategies were developed for each electronic database searched. Consideration was given to variations in terms used and spellings of terms in different countries so that studies were not missed. Relevant abstracts were examined and then pertinent articles were retrieved and reviewed, and the reference lists searched for further studies. For product categories associated with little or no research literature, analysis relied on expert opinion from clinical practice papers.

The following main search terms were used: incontinence AND device*, toilet* AND facilities, commode*, urinal*, bedpan*, urinary AND sheath*, condom AND catheter*, incontinence OR absorbent pad*, urinary AND catheter* (in title), urinary AND leg bag* OR legbag* OR drainage bag, faecal OR fecal AND incontinence AND plug OR pouch OR bag OR manage* system, flatus AND odour OR odor AND device, incontinence OR perineal AND dermatitis OR inflammation OR skin damage.

II. OVERALL GUIDELINES FOR SELECTING CONTINENCE PRODUCTS

Selecting suitable continence products is critical for the well-being and quality of life of patients and carers. The ability to contain and conceal incontinence enables individuals to protect their public identity as a "continent person" and avoid the stigma associated with incontinence [3]. Failure to do so can result in limited social and professional opportunities, place relationships in jeopardy and detrimentally affect emotional and mental wellbeing [4]. The ability to contain and conceal incontinence enables carers to feel confident that the person(s) they care for will not be embarrassed publicly. It reduces the level of care required in relation to maintaining hygiene, skin care and laundry for the person who is dependant upon continence products [5].

Fortunately there is a diverse range of different products to choose from. However, without comprehensive and current information on the products available, this plethora of choice can be overwhelming and confusing [5]. Furthermore, the range of products actually accessible to users can vary enormously between and within countries, depending on the funding available, healthcare policy and the logistics of supply [5].

The choice of appropriate products for an individual with incontinence is influenced by the resources and care available and patient / carer preference, as well as assessment of specific client characteristics and needs [6,7].

The stigma associated with incontinence means that another measure by which the success of products is judged is their ability to conceal the problem [8]. Such concealment may involve compromises: for example, in order to prevent leakage from a product, those with a larger capacity than strictly necessary may be preferred but this can in itself introduce issues to do with discretion when the product is worn. The intimate and stigmatised nature of incontinence means that issues relating to self-image can affect some patients' preferences. This may be especially marked in younger people for whom body-image may be particularly important and for whom disruption to normal social and interpersonal development may result in isolation or lack of access to normal experiences [9,10].

1. PRODUCT CATEGORIES

The continence products considered in this chapter may be divided into those that are intended to assist with toileting and those to manage urinary retention and / or contain incontinence (urinary and / or faecal) **(Fig II-1)**.
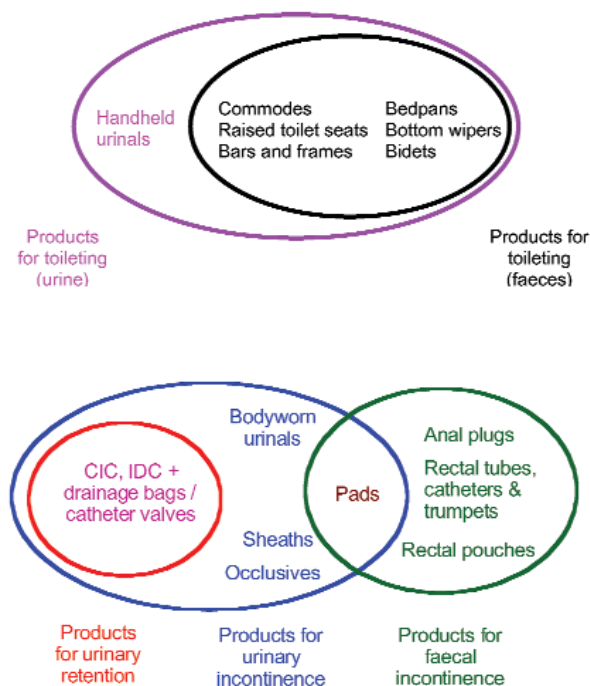

Figure II-1: Products for toileting (top) and for managing incontinence and / or urinary retention (bottom). CIC = Clean intermittent catheterisation; IDC = Indwelling catheter.
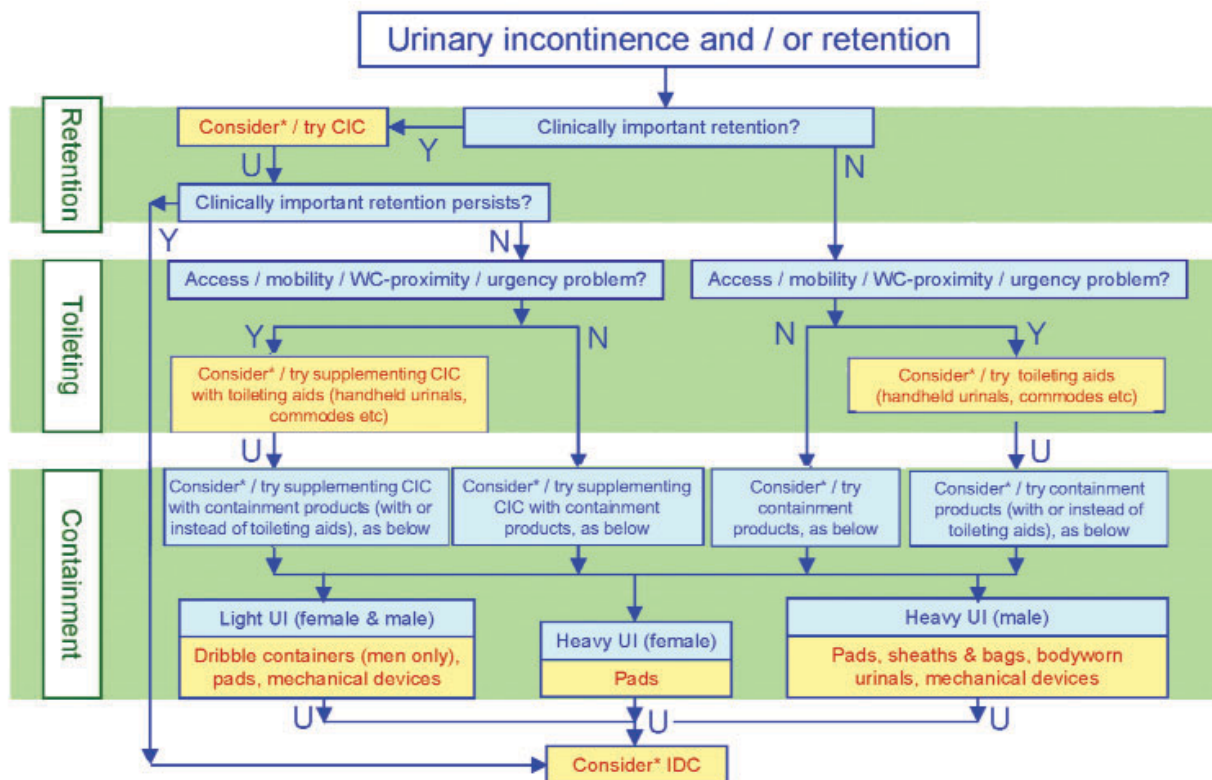
All toileting products can be useful for dealing with urine and / or faeces except for handheld urinals which are just for urine. Containment / control products are subdivided into three overlapping classes: those for urinary retention, urinary incontinence, and faecal incontinence. So, for example, 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 experiencing both problems will need two products (one from each ellipse) or one product from the intersection of the two ellipses.

2. IDENTIFYING THE NEEDS

The algorithms below (**Figs II-2 and II-3**) are designed to provide guidance for determining broadly which product(s) is likely to be of benefit to a particular patient. There are three main questions:

• Is there urinary retention (with or without incontinence)?

• Are there problems with toilet access (e.g. the proximity or design of the toilet; mobility or urgency problems for the patient)?

• Is there urinary incontinence or faecal incontinence or both?
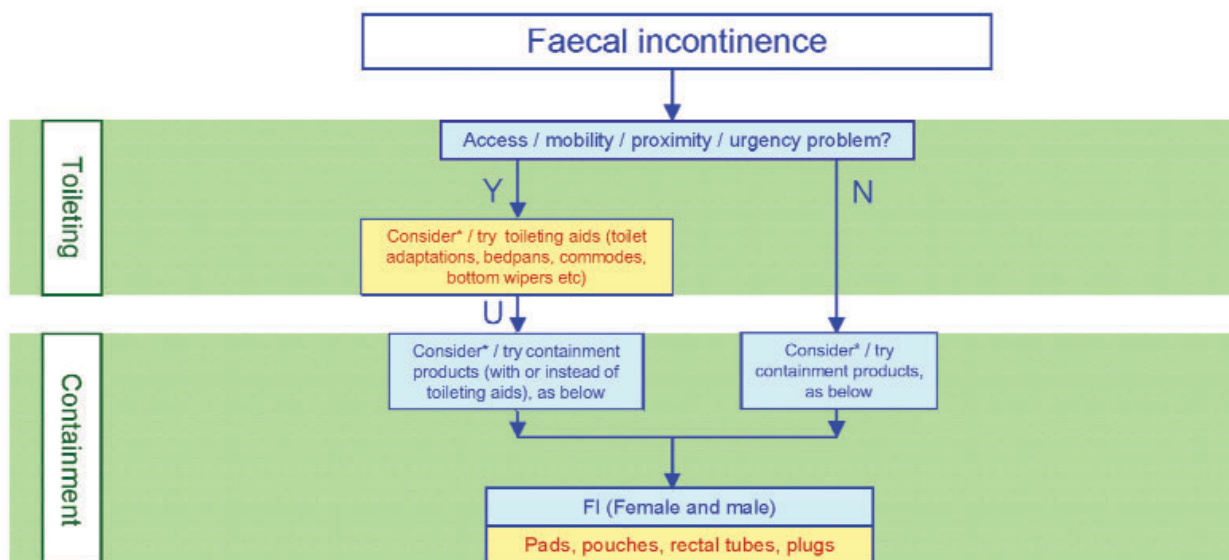
Answers to these questions will determine which one (or both) of the algorithms is most appropriate for an individual and help identify the category(s) of products most likely to help.

Urinary incontinence and / or retention

Retention
- Clinically important retention? — Y → Consider* / try CIC
  - U ↓
- Clinically important retention persists?
  - N

Toileting
- Access / mobility / WC-proximity / urgency problem? (left) — Y → Consider* / try supplementing CIC with toileting aids (handheld urinals, commodes etc) — U
  - N
- Access / mobility / WC-proximity / urgency problem? (right) — N / Y → Consider* / try toileting aids (handheld urinals, commodes etc) — U

Containment
- Consider* / try supplementing CIC with containment products (with or instead of toileting aids), as below
- Consider* / try supplementing CIC with containment products, as below
- Consider* / try containment products, as below
- Consider* / try containment products (with or instead of toileting aids), as below

- Light UI (female & male): Dribble containers (men only), pads, mechanical devices
- Heavy UI (female): Pads
- Heavy UI (male): Pads, sheaths & bags, bodyworn urinals, mechanical devices

→ Consider* IDC

Y = Yes   N = No   U = Unsatisfactory outcome
* NB physical characteristics; cognitive ability; personal preferences etc

*Figure II-2: Algorithm to help identify the category(s) of products most likely to help a patient with urinary incontinence and / or urinary 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. (CIC = Clean intermittent catheterisation; IDC = Indwelling catheter).*

Faecal incontinence

Toileting
- Access / mobility / proximity / urgency problem?
  - Y → Consider* / try toileting aids (toilet adaptations, bedpans, commodes, bottom wipers etc) — U
  - N

Containment
- Consider* / try containment products (with or instead of toileting aids), as below
- Consider* / try containment products, as below

- FI (Female and male): Pads, pouches, rectal tubes, plugs

Y = Yes   N = No   U = Unsatisfactory outcome
* NB physical characteristics; cognitive ability; personal preferences etc

*Figure II-3: Algorithm to help identify the category(s) of products most likely to help a patient with 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.*

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3. PATIENT ASSESSMENT FACTORS

A careful patient assessment is an important part of the process of product selection and **Table II-1** summarises the key elements to be considered.

The choice of appropriate products for an individual with incontinence is dependent upon the resources and care available. It must also be influenced by patient and carer preference as well as assessment of specific client characteristics and needs [6,7].

Assessment of physical characteristics such as anthropometrics, level of independence, mobility and dexterity, mental acuity and the nature of the incontinence will determine which products may be appropriate. In addition to these factors, successful product choice and effective use involves other practical and psychosocial considerations. Product effectiveness depends upon the same factors as any assistive device intended to address a disability or impairment: patient participation in device selection [11] provision of adequate instructions for use [12] and the need for products to fulfil their function reliably and not be difficult to use [9-12,13].

While **Table II-1** provides general guidance on patient assessment relating to product selection, later sections in the chapter provide further discussion on assessment issues specifically related to the various product categories.

In addition to selection of appropriate and effective products following patient assessment, education and training of users or carers in the correct use of the devices is of importance if product use is to be optimal. This may be a simple matter of instruction in the effective fitting and changing of absorbent products, or may involve more in-depth training in the ongoing care of, for example, a suprapubic catheter.

Incontinence is often a long term condition and so monitoring and periodic reassessment is essential to maintain effective management with products.

4. MAIN USER GROUPS

Although needs, priorities and preferences vary between people with incontinence it is useful to divide patients into major user groups to help identify the category(s) of products most likely to benefit an individual. Seven primary groups are identified in this chapter:

- People with urinary retention.
- People who need help with toileting / toilet access.
- Females with light urinary incontinence.
- Males with light urinary incontinence.
- Females with moderate / heavy urinary incontinence.
- Males with moderate / heavy urinary incontinence.
- People with faecal incontinence.

An individual may belong to more than one group. Each group includes children and young people: the products available for them are broadly similar to those for adults.

5. CHOOSING BETWEEN PRODUCT CATEGORIES

Figs II-4 to II-9 summarise the user characteristics, priorities and contexts which favour or discourage the use of each of the categories of products available for six of the seven user groups identified in section II.4. Assistance with choosing appropriate products for the first group (people with urinary retention) is given in the section on catheters (**Table XII-1**) as all the product options for these people are in the same category (catheters).

The recommendations given in these charts are based on the evidence presented in the sections of the chapter dedicated to different product categories and they are intended to help identify which product category (categories) are most likely to help an individual. However, it should be remembered that the same product will not suit all people, even if they have very similar assessment outcomes on the factors summarised in **Table II-1**. Different people prefer different products and where possible patients should be given access to a range with which to experiment to determine the most satisfactory product(s). Similarly, the balance of priorities varies between users; for example, some pad users will opt for a bulky and, therefore, less discreet product to achieve an acceptably low risk of leakage while others will see the balance differently. It should also be noted that a mix of products from different categories may provide the best solution; for example, needs may vary between day / night and home / away. Once a product category of interest has been identified the corresponding chapter section should be consulted for further help.
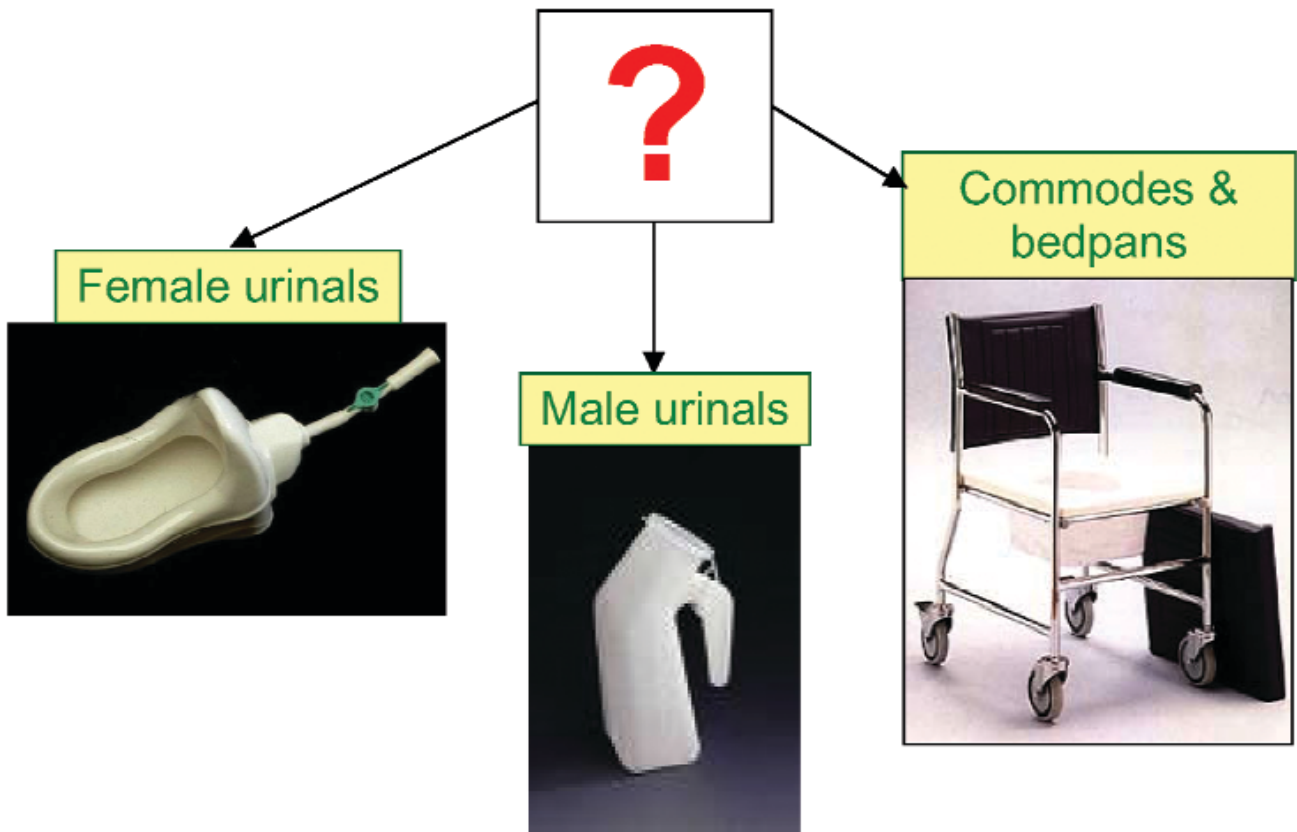
6. SUMMARY

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.

7. 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).
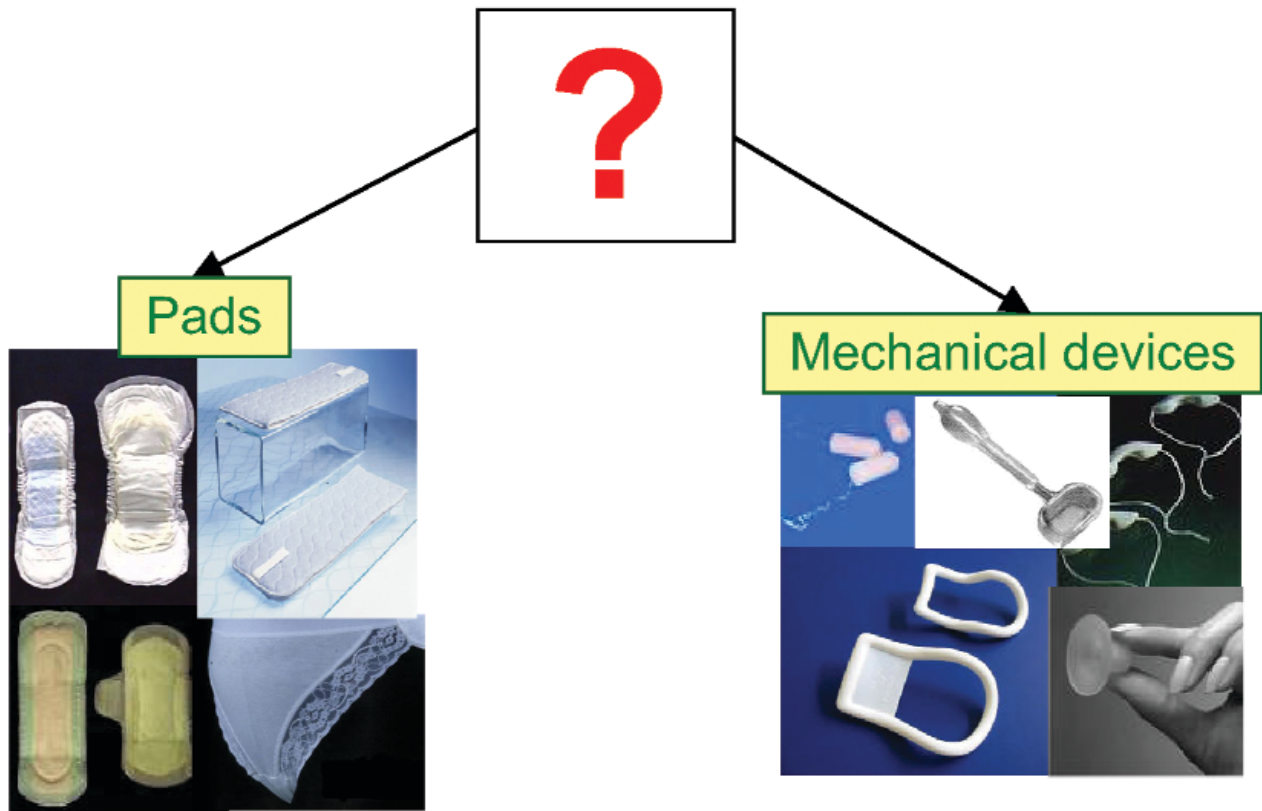
Table II-1. Key elements of assessing a patient and his / her environment

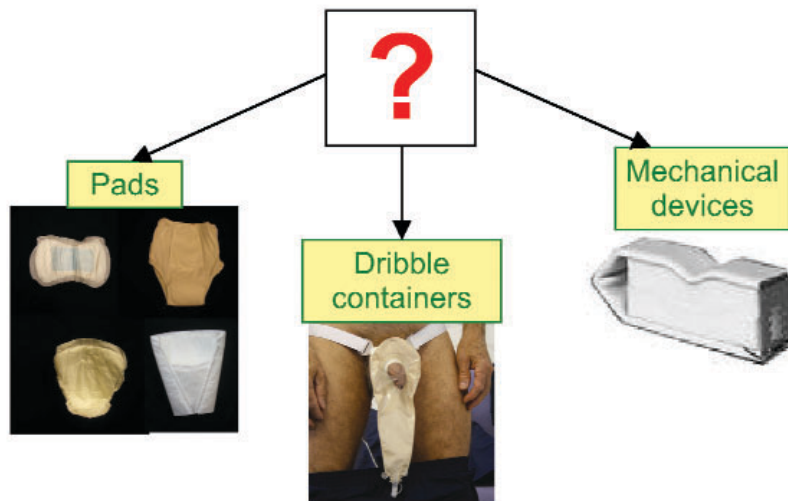| Element	Rationale
Nature of the continence problem	The frequency, volume and flow rate of the incontinence influences product suitability. Generally smaller, more discreet products should be tried before larger bulkier products. If catheterisation is necessary, intermittent catheterisation is a less invasive option than indwelling catheterisation.
Gender	Males may consider and prefer sheaths as a more masculine option to pads. Females may be attracted to products that are more feminine in design and presentation. Some 'unisex' products such absorbent pads have different designs that work better for men (or women).
Physical characteristics	Anthropometrics (e.g. height and waist, thigh, penile circumference) will influence the comfort and effectiveness of a product.
Mental acuity	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. mechanical devices or catheter valves) should be avoided if mental impairment is present.
Mobility	Impaired mobility may make some product choices impractical or require toilet or clothing modification to allow effective use of the product.
Dexterity	Problems with hand or finger movement can make it difficult to use some products (eg taps on leg bags, straps with buttons).
Eyesight	Impaired eyesight limits effective application and management of some products.
Leg abduction problems	Difficulty with abduction can make the use of some products impractical or ineffective.
Lifestyle and environments	Daily activities and environments can influence the choice of product and a mixture of products may provide optimum management. Different products may be most satisfactory for daytime and going out (when discreetness may be a priority) and night-time or staying in (when comfort may be a priority), for holidays (when large quantities of disposables may be a problem) or for use at work. The proximity and accessibility of a toilet in the various environments may be a key factor.
Independence / assistance	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.
Laundry facilities	Washable pads 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.
Disposal facilities	Ability to appropriately, safely and discreetly dispose of the selected products needs to be considered.
Storage facilities	Some products – notably, pads for heavy incontinence – can be bulky. Adequate space to store supplies between deliveries / purchases needs to be available.
Personal preferences	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.
Personal priorities	Everyone wants to avoid leakage but other factors such as discreetness may be more or less important to individuals.

Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Female handheld urinals (Section IV.1)	• Any woman with mobility/urgency/access problems (C) • Able to stand or crouch (B/C) • Able to move to edge of chair (B/C)		• Many urinals: experiment using a library of urinals. • Urinals are less likely to succeed if woman needs to lie down or sit back in a chair.
Male handheld urinals (Section IV. 2)	• Any man with mobility/urgency/access problems (C) • Some manual dexterity (C) • Design concept acceptable (C)	• Inability to empty urinal independently (C) • Poor balance (C) • Impaired forward arm reach and wrist function (C) • Impaired cognition (C)	• Clothing adaptation may be needed. • NB Non-spill adaptors. • NB Flat-pack urinals for travel.
Commodes (Section V)	• Anyone with mobility/urgency/access problems (C)	• In rooms used by others (C) • Institutional settings (shower chairs preferred) (C) • Where there is a safety risk.	• Ensure privacy and dignity.
Bedpans (Section V)	• Unable to use toilet or commode / shower-chair (C)	• In general (C)	• Ensure privacy and dignity.

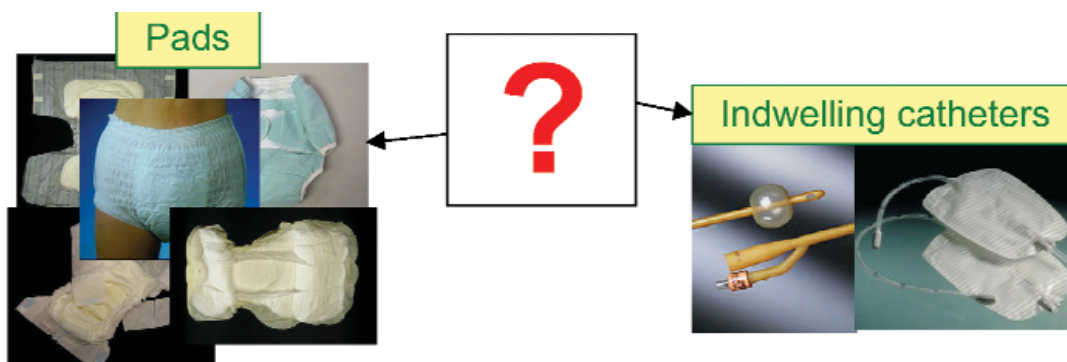*Figure II-4: Products for people who need assistance with toileting.*

Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Pads (Section VI.5)	• In general (C)		• See Fig VI-16 for details.
Mechanical devices (Section X)	• Incontinence is predominantly stress (C) • Manual dexterity is good (C) • Sound cognition (C) • Device concept is acceptable / preferred (C) • Preventing leakage rather than containing it is attractive (C)	• Incontinence has a significant urgency component (C) • Concerns over risks of UTI are high (intra-urethral device) (C)	

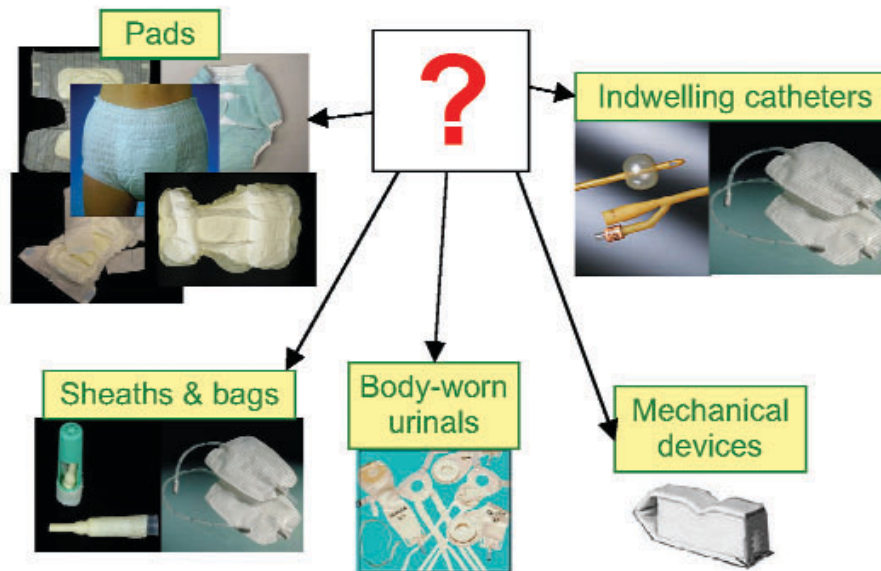Figure II-5: Products for females with light urinary incontinence

Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Pads (Section VI.6)	• In general		• See Fig VI-17 for details.
Dribble containers (Section IX.2)	• Device concept is acceptable / preferred (C)	• Unknown	
Mechanical devices (Section XI)	• Highly motivated (C) • Periodic / intermittent use (C) • Incontinence is predominantly stress (C) • Device concept is acceptable / preferred (C) • Preventing leakage rather than containing it is attractive (C)	• Incontinence has a significant urgency element (C) • Doubtful level of cognition (C) • Risk of skin / tissue damage (C) • Bladder sensation poor (C) • Poor dexterity (C)	• Skilled fitting by a professional is needed.

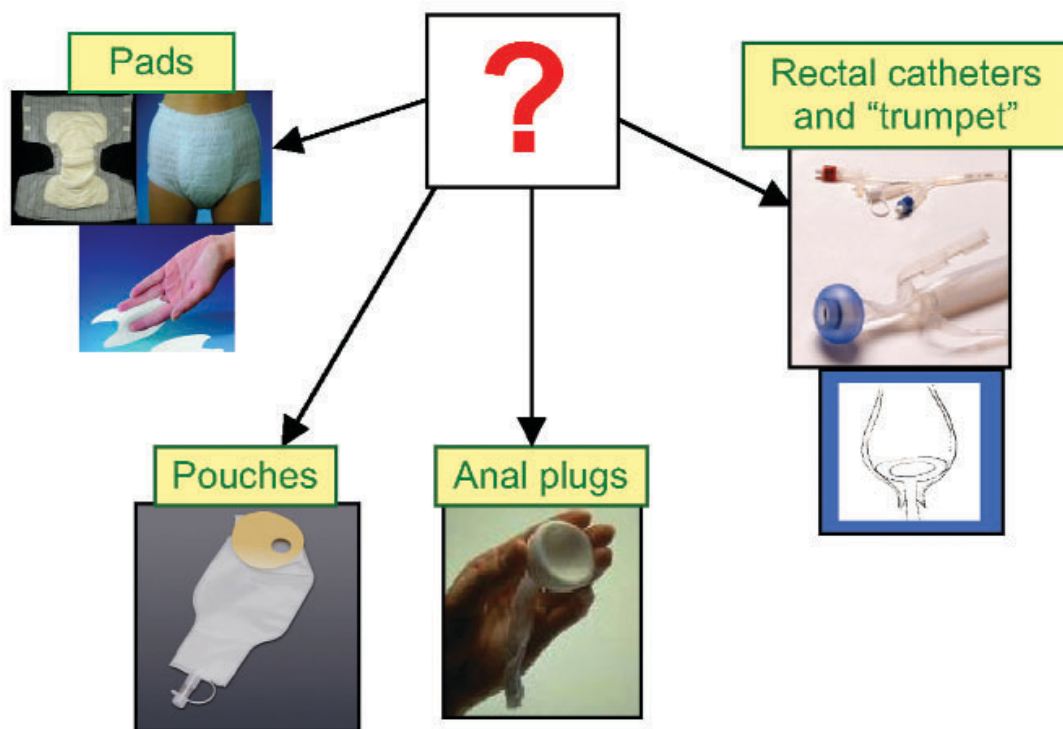*Figure II-6: Products for males with light urinary incontinence*

Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Pads (Section VI.7)	• In general (C)	• Skin is severely damaged (C)	• See Fig VI-18 for details.
Indwelling Catheters (Section XII.2)	• Retention / voiding problem (if no alternative) (C) • Skin is severely damaged (C) • Pads (or other products) unsuccessful / inappropriate (C) • Unable to perform CIC (C)	In general (A), but particularly if: • History of urethral trauma • Cognitive impairment (danger of interfering with catheter) • Avoidance of UTI is a priority	• See Table XII-1 for details.

Figure II-7: Products for females with moderate / heavy urinary incontinence.

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Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Pads (Section VI.7)	• In general – particularly if active (C)	• Skin is severely damaged (C)	• See Fig VI-18 for details.
Sheaths & bags (Sections VII & VIII)	• Less risk of bacteriuria, recurrent UTI's or death than indwelling catheters (C) • More comfortable than indwelling catheters (C) • Acceptable / preferred to pads (C) • Minimal physical intervention is a priority (C) • Good dexterity (C) • Sound cognition (C)	• Local skin breakdown (C) • Bacteriuria, UTI (C) • Carer / user unable / reluctant to apply (C)	• Sheaths with integral adhesive are more popular than sheath with separate adhesive strip. • Sheath applicators are often ineffective and unpopular.
Body-worn urinals (Section IX.2)	• Desire to avoid pads (C) • Concept acceptable/preferred (C) • Mobile (not wheelchair user) (C)	• Latex / materials allergy (C)	
Mechanical devices (Section XI)	• Highly motivated (C) • Periodic / intermittent use (C) • Incontinence is predominantly stress (C) • Device concept is acceptable / preferred (C) • Preventing leakage rather than containing it is attractive (C)	• Incontinence has a significant urgency element (C) • Doubtful level of cognition (C) • Risk of skin / tissue damage (C) • Bladder sensation poor (C) • Poor dexterity (C)	• Skilled fitting by a professional is needed.
Indwelling catheters (Section XII.2)	• Retention / voiding problem (C) • Skin is severely damaged (C) • Pads (or other products) unsuccessful / inappropriate (C) • Unable to perform CIC (C)	In general (A), but particularly if: • History of urethral trauma • Cognitive impairment (danger of interfering with catheter) • Avoidance of UTI is a priority	• See Table XII-1 for details.

Figure II-8: Products for males with moderate / heavy urinary incontinence.

Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Pads (Section VI.11)	• In general (C)	• Skin problems (C)	• Few pads are specifically for faecal incontinence. • Dressing between buttocks favoured by some men for minor faecal incontinence
Pouches (Section XIII.6)	• Acute situations (C) • Liquid stool (C) • Post-surgical / enema drainage (C) • Immobile / in bed (C) • Risk of skin problems (C)	• Skin problems (C)	• Skin problems may depend on adhesive material.
Anal plugs (Section XIII.3)	• • Children tolerate better than adults (C) • After using enemas or rectal irrigation (C) • Spina bifida, anorectal malformation, rectal sphincter damage / tear (C) • Periodic use (eg sports or special occasions) (B/C)	• Possibly if there is bowel/rectal disease • Spinal cord patients with autonomic dysreflexia (C) • Device concept unacceptable (C) • Disruptive of successful established routines (B/C)	• Discomfort / pain influenced by plug design. • Discomfort and frequent expulsion are common cause of rejection. • Leakage around plug may occur.
Rectal trumpets (Section XIII.4)	• Acutely ill (C) • Liquid stool (B/C) • Post-surgical enema drainage (C) • Immobile / in bed (C) • Risk of skin problems (C)	• Skin problems (C)	
Rectal catheters (Section XIII.5)	• Acutely ill (C) • Liquid stool (B/C) • Immobile / in bed (C) • Skin problems or skin at high risk (B/C) • Wound contamination due to faecal incontinence (B/C)	• Possibly if there is bowel disease, large haemorrhoids, stricture / stenosis • Recent rectal surgery / injury (C) • Long term use	

Figure II-9: Products for people with faecal incontinence.

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III. PRODUCT EVALUATION METHODOLOGY

This section aims to assist those planning clinical trials of products. There have been relatively few large clinical trials of continence products (with the exception of urinary catheters) and for most product categories research evidence to guide the selection of individual products / designs / features is limited and in some cases absent.

Measuring the performance of continence products is methodologically challenging. Manufacturers modify and change their products regularly - in terms of both 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 [14] which are discussed below.

It is common for practitioners to be asked (by their employers or by companies) to do a small evaluation or trial – sometimes to 'test out' a new product and sometimes to help choose between competing brands for bulk-buying. Such trials should be approached with caution; they can be very demanding but their results may be of very limited value even for local use. The methodological challenges identified below still apply but are compounded by small sample size and restricted product selection. These studies are likely to be helpful only for identifying gross product short-comings or benefits.

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 could be made. **Table III-1** shows an example range of questions that may be asked about one particular product category (absorbent pads – following question 1) and many combinations and permutations of products / designs / feature are possible.

In the field of absorbent products the practitioner and / or patient wishes to know whether to use an underpad or a bodyworn product, a reusable or a disposable,

Table III-1. Levels of questions

- Which product category (eg catheter, sheath, absorbent pad)?

- Which design of product design (eg pull-up or diaper design of pad)?

- Which material type (eg reusable or disposable)?

- Which features (eg with / without elastic gathers)?

- Which product brand?

a diaper or an insert (if they select a bodyworn), a diaper with internal elastication (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 design' 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 design 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 (**Table III-1**) 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 [15] 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 (most often just one) of 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. 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 [16,17]. 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 in most categories simply because a 'control' product does not usually 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) are 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 [18] to ensure balance.

It is important that clinical trials of single designs 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 distinctions 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 products 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 participant ratings of product performance. Diaries of product-related events such as leakage, laundry generation and product consumption are also commonly included. Subjects in some absorbent pad studies have been asked to identify and prioritise items of product performance [19, 21] to inform questionnaires and **Table III-2** shows the most common items of high priority to women with light urinary incontinence identified by Getliffe and colleagues [20].

Outcome variables in studies designed to compare catheterisation strategies and / or catheter materials

Table III-2. Most common items of high priority to women with light incontinence using absorbent products. Getliffe et al. [27]

Daytime	% women (N =99)	Nightime:	% of women (N=81)
Hold urine without leaking	83.8	Hold urine without leaking	93.8
Contain smell	75.8	Stay in place	77.8
Stay in place	54.5	Contain smell	54.3
Discreetness	41.1	Comfortable when wet	54.3
Comfort when wet	40.4	To keep skin dry	48.1

or other design features commonly encompass measures of urinary tract infection, tissue trauma and recurrent catheter encrustation leading to blockage (see Section XII-2).

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 [22] has measured the test re-test reliability of a questionnaire to assess sheath performance and found moderately good Kappa scores (around 0.7) when assessing the same sheath twice with four weeks between measurement periods.

Skin health, urinary tract infection, 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.[23]). 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 feedom from leakage) - are ill-advised. Patient overall opinion or satisfaction with the product should therefore be used as the primary outcome variable[14].

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 which are designed to contain incontinence rather than reduce or prevent it. The first stage in the development of a quality of life tool for absorbent product users has been reported by Getliffe et al. [20] and a similar tool for catheter users is known to be under development.

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 for many products (eg pads) 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.

- Incidence of urinary tract infection should be included when testing invasive devices such as catheters, but "significant" UTI/ bacteriuria needs to be carefully defined (see Section XII.2.8).

- The primary outcome variables should be patient overall opinion / satisfaction and patient preference.

- Health economics should be measured alongside product performance.

4. RESEARCH PRIORITIES

- The development of Quality of Life tools for users of continence products.

IV. 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 be confident of no spillage. It should not require excessive physical effort on their part and should be easy to empty without spillage.

General guidelines on patient assessment for product selection are discussed in Section II. Aspects of patient assessment particularly important for handheld urinals are user postures (in bed, on side of bed, back in

chair, on edge of chair, standing/crouching/kneeling), leg abduction, approach of urinal (from front, side, behind, above), ability to initiate void, dexterity and strength to position and remove urinal, level and availability of assistance, user preference.

There has only been one clinical trial [24] of female urinals and there are no published trials of male urinals. However, much helpful guidance and expert opinion has been published [25-28].

1. FEMALE HANDHELD URINALS

Female handheld urinals come in a variety of shapes and sizes (**Fig IV-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 – (see below). Some have handles to facilitate grip and positioning. Some are intended to empty into a drainage bag during or after use.
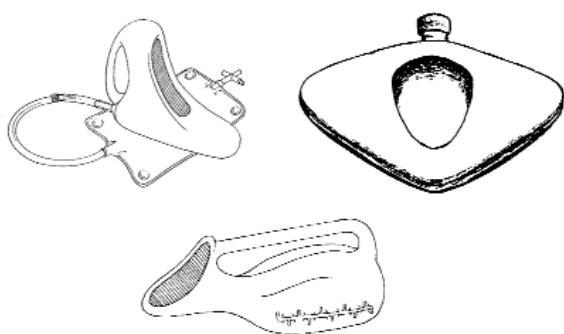

Figure IV-1: A variety of female handheld urinals.

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. [24] 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 (Subaseal), In general, subjects with higher levels of dependency found fewer urinals to be suitable for their needs.

Recently the development of a powered urinal designed to pump urine into a reservoir has been described [29]. The aim of the device was to provide active removal of urine without leakage and without the need for gravity-assisted drainage. The urinal was tested by 80 women from six countries. Although evaluated as 'good' or 'okay' by more than three-quarters of the women, nearly half the women found the device 'poor' for weight and size. Problems with reliability of the device were also common and the authors concluded that the current device needed further refinement but may have potential as an alternative to conventional urinals. Although this device is not currently on the market, at least one other powered device is available. However, there are no published reports on efficacy.

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 or integral non-spill adaptor containing a flutter valve to impede back-flow of urine from the urinal. There are no published trials of such products.

A review paper by Vickerman [28] makes recommendations for selecting suitable urinals for men. A flat bottom urinal may be more stable (and less likely to spill) for those using a urinal in bed. Urinals made from soft plastic (jug-style or with a funnel) may be easier to grip for those with poor manual dexterity. Urinals designed to be attached to a drainage bag (for emptying the urinal) may also be helpful to men living at home with limited support.

Vickerman also suggests that home-made devices (such as empty wide-mouthed containers with a handle and lid (for example, those used for clothes-washing liquid or conditioner) may be a practical (and cheap) option for some men. For those with a retracted penis female urinals may be easier to use than male products.

3. GENERAL POINTS FROM THE LITERATURE, INCLUDING EXPERT OPINION

The literature [25-28] suggests that succes-sful use of urinals depends on many factors which are summarised below.

- Experimentation is often needed to find the optimum urinal for an individual. A 'library' of urinals (i.e. a collection of different types of urinals to be lent out to users for experimentation) has therefore been recommended [27] but rigorous cleaning methods are needed (see below).

- Clothing alterations can aid quick and easy use of a urinal. For men, extending the fly opening of trousers or replacing zips with *Velcro* can be helpful, as can boxer shorts. For women drop-front pants may be needed, particularly if mobility is limited.

- Disposable and reusable 'travel' hand-held urinals are available for both men and women. These

urinals fold away to fit into a pocket and may therefore be more discreetly portable than conventional urinals.

- Some disposable urinals include superabsorbent polymer in their reservoirs which turn urine into a gel and help to prevent spillage. Sachets of superabsorbent polymer may also be added to reusable urinals.

- Use of a urinal is not always free from leakage and provision of absorbent chair or bedpads to protect bedding, clothes and furniture (particularly when testing out urinals) may be necessary.

- The limited range of urinal options in acute settings, where often only bedpans are available, has been criticised and the process of introducing hand-held urinals to hospital services has been described and recommended [30].

- When used by one individual in the home, urinals can be cleaned with soap and water between uses. But where urinals are shared (i.e. cleaned and used by others), or if a library of urinals is used then robust methods are necessary. Some urinals can be cleaned in a bedpan washer but cleaning methods vary with different designs and materials and compliance with local infection control procedures will be needed.

4. RECOMMENDATIONS

- There is a wide range of female urinals and experimentation is likely to be necessary to identify the best one for an individual (dependent on their individual needs and abilities).

- A library of female urinals (used with robust cleaning methods) will help to facilitate experimentation (Grade of Recommendation B).

- Male urinals are less varied than female urinals, but may be supplemented by use of less conventional receptacles (e.g. jugs, home-made devices); experimentation will help to identify best options.

- Section IV.3 addresses other more general recommendations regarding urinal use.

5. PRIORITIES FOR RESEARCH

- Further development of female urinals is encouraged, particularly for supine users and those unable to move to the edge of a chair.

- The range of male and travel urinals need to be evaluated to provide guidance for users and carers.

V. 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. Bottom wipers and bidets can also be useful. 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 IV) may also be used to collect faeces.

General guidelines on patient assessment for product selection are discussed in Section II. Aspects of assessment that are particularly important regarding commodes and bedpans begin with appropriate indications for their use since Matsumoto and Inoue [31] reported that incontinent elderly persons or their caregivers misunderstand indications of commode use for incontinence. Other patient assessment elements include: a) physical characteristics of the person with incontinence (e.g. can an obese person fit on a commode and use its handrails?); b) mental acuity (e.g. will a person with dementia recognize a commode or bedpan as a device to be used for defecation?); c) need for supervision or foot supports whilst on the commode (what is the risk of falling?); d) mobility (e.g. does the person need a commode or bedpan?), ability to transfer and method of transfer to the commode (e.g. hoist, carer help, independent with transfer board), need for static or mobile commode (particularly when considering using commode over a toilet), postural stability and need for supportive commode, e) level of assistance needed and physical burden to caregiver involved; and f) personal preferences (e.g. comfort of bedpan type) including need for 'non-commode-like' appearance (e.g., particularly when used in own room, particularly the living room). Patient assessment findings need to be evaluated in terms of the safety and stability properties of a commode. The proximity of the area for waste disposal, storage facilities (i.e., the location / visibility of the commode in the household), the availability of privacy during defaecation, and length of time likely to remain on the commode (is there a need for a pressure-relieving commode cushion?), are additional factors to be considered.

Commodes (or better still toilets) are preferable to bedpans (which are relatively difficult to use and do not permit appropriate posture for passing urine/faeces). Bedpans are generally reserved for people who are confined to bed (e.g. post-operatively) and for whom safety (risk of falling) is an important assessment issue.

1. RESULTS

Fader (32) 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 [33] 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 [34]. 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. [35].

The maintenance of hospital commodes can be a problem and Gillan [36] complained about the poor condition of commodes in wards for elderly people. Dassut [37] has recommended a commode cleaning and identification system, to help overcome this problem.

Naylor & Mulley [38] 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 that lingered even after a commode had been emptied, and recommended the use of a chemical toilet.

Thorough cleaning of commodes or bedpans after every use is necessary for hygienic purposes and to eliminate odours. Naylor & Mulley [38] report that typically a caregiver rather than the commode user empties and cleans a commode. No recommendations for cleaning a home commode or bedpan were found in the published literature. In institutional settings, large sinks with spray hoses or special sanitizing equipment are available. The size and shape of a bedpan or commode receptacle may be difficult to fit under a standard sink basin in the home. Whether certain commode cleaning products reduce any residual odour more than others is not known. Toilet bowl cleaning products are suitable for cleaning a commode or bedpan; many contain bleach or antibacterial ingredients but their effect on reducing odour of commodes or bedpans has not been studied. Gel formulations are advertised by manufacturers as being better able to cling to hard-to-reach surfaces than liquid agents. Use of a deodorizer can be considered (Level of evidence 4).

Nelson and colleagues [39] 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 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 [40]. Pressure mapping devices were used to measure seat pressures on three subjects who tested all three bowel / shower chairs to inform seat design [41].

These researchers [42] then set about designing a more advanced commode-shower chair. It had lockable, swing-away armrests and lever activated brakes to facilitate tranfers. 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.

Matsumoto and Inoue [31] examined whether use of a commode in the home might prevent or delay nursing home admission of elderly people who were incontinent. A five-year follow-up of multiple predictors of institutionalization in elderly people in a rural town in Japan showed that 40% of incontinent men and only 17% of incontinent women used a commode. Use of a commode was not associated with institutionalization. The authors suggested several possible reasons: misunderstanding of appropriate indications for a commode based on the type of incontinence; physical

burden in assisting a care recipient to use a commode that seemed no different than for cleansing after an incontinence episode; and inadequate muscle strength of the elderly for using either a Japanese-style or Western commode.

Bedpans and other portable receptacles are not well described in the literature. Wells and Brink [43] describe three general shapes of bedpans: concave, cutaway, and shovel. The concave pan has a rounded triangle shape that slopes back to front and a curved seat. The cutaway has a rounded triangle shape with a flatter seat and rolled edges that allow for handgripping. The shovel shape, commonly called a "fracture pan" is a wedge or rectangle shape that has a flattened end that goes under the individual and a handle at the distal end. Generally bedpans are considered to be unsuitable for defecation for safety and acceptability reasons. However, for individuals with specific needs (e.g. frequency and urgency of defecation) a portable receptacle may be beneficial. Although many portable urinals are now available for both men and women , very few are recommended for defecation [44] 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, or caregivers. 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. Bedpans have other disadvantages including difficulty removing the bedpan from under an individual without spilling (particularly if the individual is obese), risk of spilling and odour when transporting the contents for disposal since none have lids, and lack of privacy during use.

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 and bedpans are: lack of privacy; embarrassment over use; odour; poor aesthetics; poor perineal cleansing accessibility; and inadequate facilities for cleaning the devices in the home (Level of Evidence 2).

- Defaecation 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 defaecation (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 user's 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 defaecation 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 Recom-mendation 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).
- Cleaning of bedpans and commodes should be carried out after each use following local infection control policies (in institutional settings) (Grade of Recommendation C)
- For individual's at home there are no published guidelines regarding frequency of cleaning or type of cleaning product. However, thorough cleaning after bowel evacuation (to avoid odour and maintain aesthetics) is important, together with rinsing after urine has been passed. Cleaning needs may vary according to personal hygiene standards and offensiveness of urine/faecal smells (Grade of Recommendation C).

4. PRIORITIES FOR RESEARCH

- 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

VI. ABSORBENT PRODUCTS

1. INTRODUCTION

Absorbent products (commonly known as pads) are available in a wide range of sizes and absorbencies encompassing light through to very heavy incontinence. Most pads are bodyworn but some are used on the bed or chair (underpads, see Section VI.2); in this section the term 'pad' refers to bodyworn absorbent products. 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, but see the discussion in Section VI.4. Although absorbent pads are most commonly used for urinary incontinence they are also used by individuals for both faecal and urinary / 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 volumes of urine ("dribble"), whilst others may be dry for days but then have a higher volume, higher flow-rate incontinence incident ("gush" or "flooding"). 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 [45]. 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 quantities contained by pads from different sub-groups; thus in a study of insert pads for moderate-heavy incontinence used by older people in residential care around 15% of insert pads for moderate-heavy incontinence contained less than 100g of urine [46] and in a study of older women with light incontinence living in the community about 10% of insert pads for light incontinence were found to contain more than 100g of urine [47].

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 [48] 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 pads comprising 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.

General guidelines on patient assessment for product selection are discussed in Section II.

Aspects of assessment that are particularly important regarding absorbent pads are frequency / severity of leakage, day / night incontinence, gender (some products are designed for or are better for men / women than others), ability to change pad independently / need for carer, pad changing position (standing / lying), laundry / drying facilities, individual priorities (e.g. need for discreetness), personal preference for design / materials (washable / disposable), lifestyle (at home / travel / work etc).

Aspects of absorbent pad performance have been identified and prioritised (during interviews) by men and women taking part in a series of clinical trials of such products [20]. There was considerable consistency across patient groups (light / heavy, men / women) with the ability of a product to hold urine without leakage being the top priority, and the following aspects also being considered to be of high priority: discreetness, containment of smell, ability to stay in place, comfort when wet and ability to keep skin dry.

2. ABSORBENT PRODUCT CATEGORIES

Absorbent products may be classified into two broad categories - disposable (single-use) and washable (reusable) - 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 by size (to fit users of different sizes) and / or absorbency (to cater for different severities of incontinence). Some designs are further subdivided into those intended for men, women or children. This classification is shown in **Table VI-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 VI-1**). Some patients experience problems with keeping pads in place using the commonly supplied net pants. As a result, many use more robust stretch pants purchased privately (i.e. cotton / Lycra, etc). Many disposable inserts (**Fig VI-2 and Fig VI-3**) have an adhesive strip on the back to help secure them and may have an indicator that changes colour when the pad is wet to
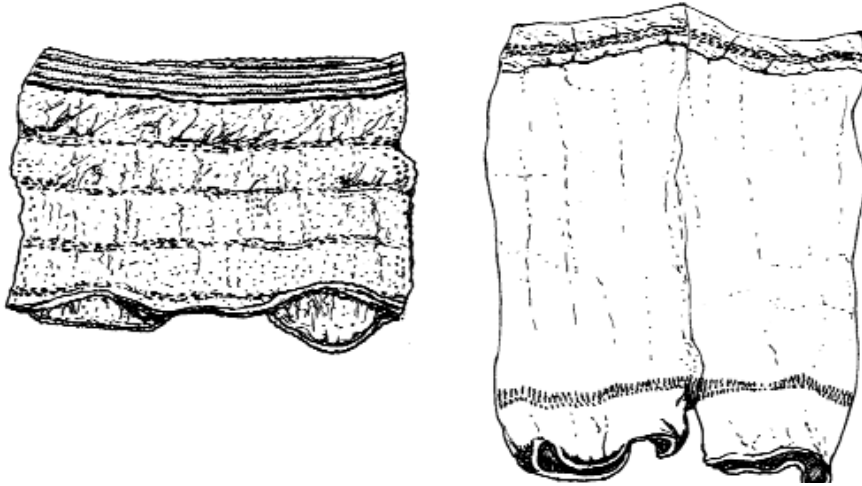
Figure VI-1: Mesh pants with (right) and without (left) legs, for securing incontinence pads in position.
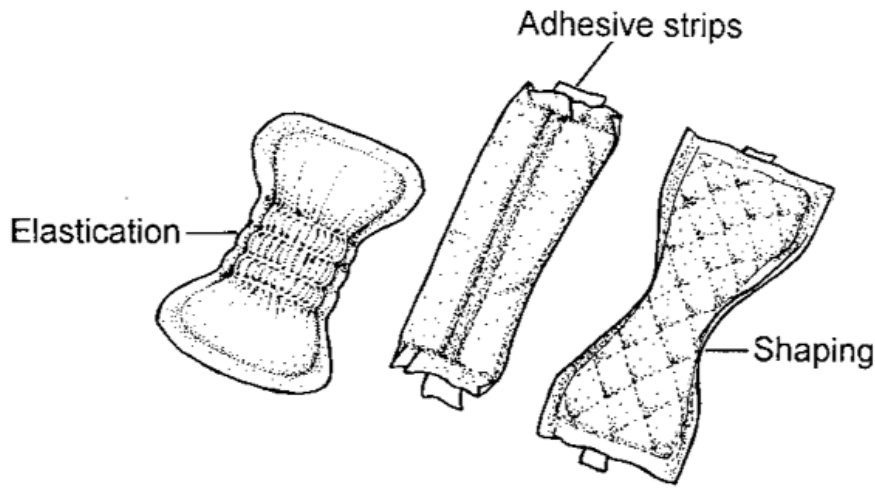

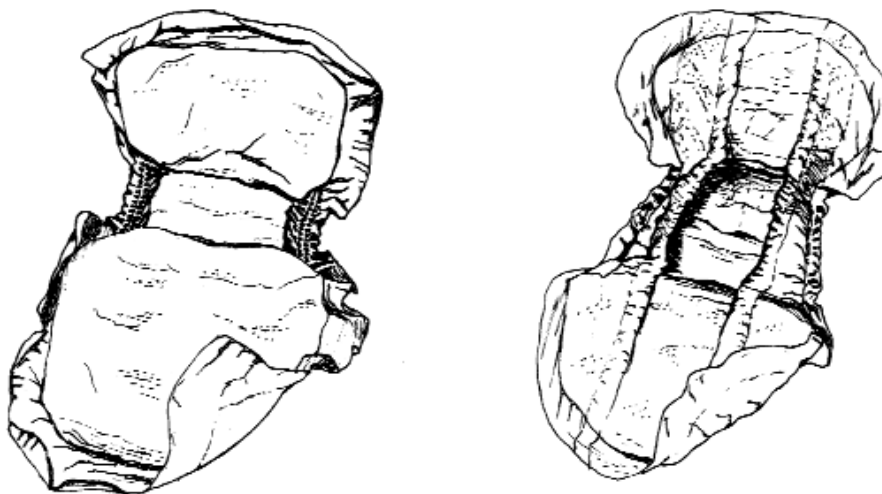*Figure VI-2: Disposable inserts for light incontinence.*

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

Table VI-1. Classification of absorbent continence products

Categories:	Disposable (single use)		Washable (reusable)	
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 gender of the intended users (M, F or unisex).			

* The products within a given design group may vary considerably in their features and their constituent materials.

signal the need for a 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 more usually shaped to fit the body more snugly. Elastication at the legs may also be used to enhance fit. Washable inserts (**Fig VI-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 urinary incontinence. For light faecal incontinence, the liner may be a small cotton gauze dressing placed against the anus and held in place by the cheeks of the buttocks (**Fig VI-5**).

• *Diapers* (sometimes called *all-in-ones* or *briefs*) are adult-size versions of babies' diapers. Disposable diapers (**Figs VI-6**) 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 VI-7**). Washable diapers are usually elasticated at the waist and legs and are fixed with Velcro or press-studs (**Fig VI-8**). Diapers are intended for moderate to very-heavy incontinence.

• *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 VI-9 to VI-11**). Disposable pull-ups (**Fig VI-9**) are usually elasticated throughout the pants to give a close fit. Both disposable and washable pull-ups have versions for different levels of incontinence. Washable pull-ups for light incontinence are often known as pants with integral pad (**Fig VI-11**).

Some people use less conventional or home-made systems either instead of or as well as the designs described above. In particular terry-towelling squares may be used by those with heavy incontinence. These may be formed into briefs by folding into different configurations and fastening with pins and covered with plastic pants as a waterproof barrier. It is known that such pants may also be worn over more conventional designs in an attempt to reduce leakage and / or odour.

"Body" garments (like vests which have a crotch section which opens and closes with snap fasteners, much like those manufactured for babies) may be helpful to hold pads in place well and may reduce the rustling noise from plastic backing materials.

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 VI-12 and VI-13**). 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 VI-14**). Washable underpads (**Fig VI-15**) 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.

3. ABSORBENT PRODUCT MATERIALS

Absorbent products – disposable or washable – 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-linked 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
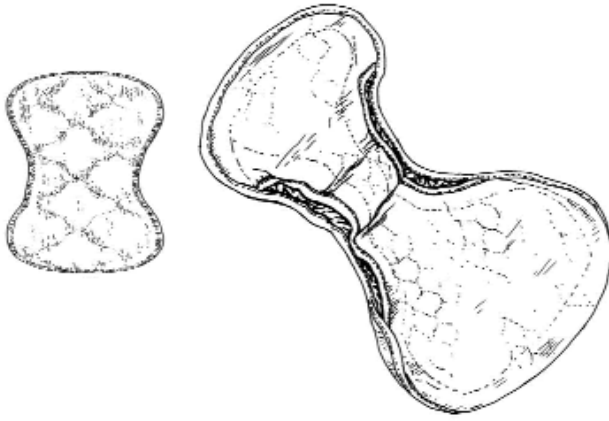
Figure VI-4: Reusable inserts for light (left) and moderate / heavy (right) incontinence.

Figure VI-5: Liner for light faecal incontinence. It is positioned against the anus and held in place by the cheeks of the buttocks
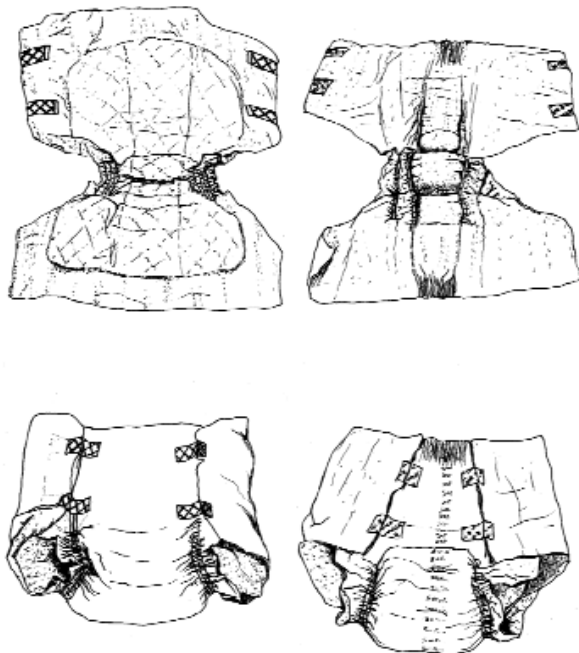
Figure VI-6: Disposable diapers with (right) and without (left) standing gathers, for moderate / heavy incontinence. Diapers are shown open (top) and with the tabs secured (bottom).

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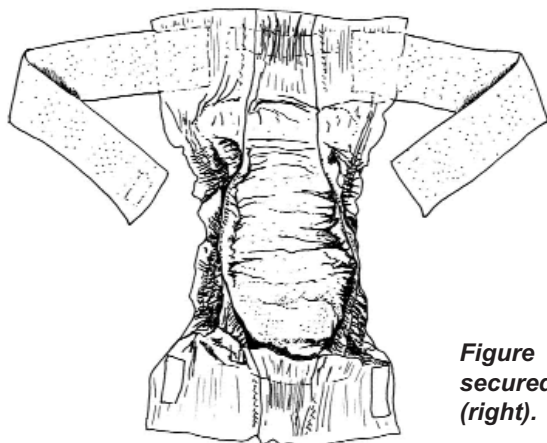
Figure VI-7: A modified (T-shaped) diaper. The waist band (left) is secured first and then the front pulled up and secured in position (right).
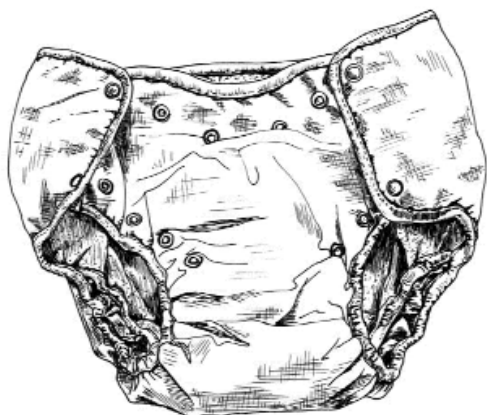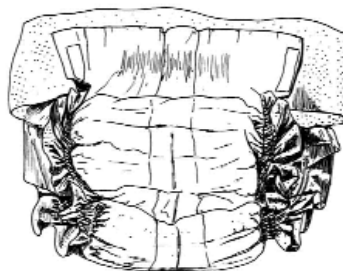
Figure VI-8: A reusable diaper.
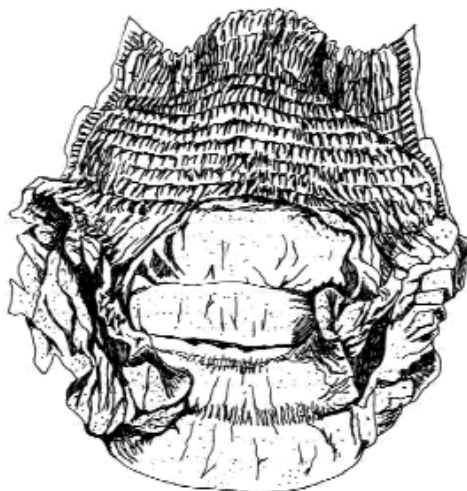
Figure VI-9:A disposable pull-up.

Figure VI-10: A reusable pull-up for heavy incontinence.
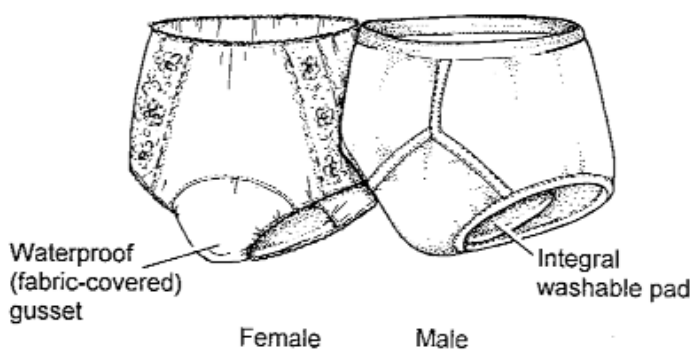
Figure VI-11: Reusable pull-up pant (also known as pants with integral pad) for lightly incontinent men (right) and women (left).

Pouch for penis

Adhesive strip helps positioning
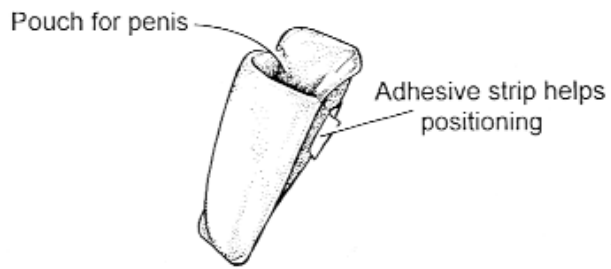
Figure VI-12: A disposable pouch for men.
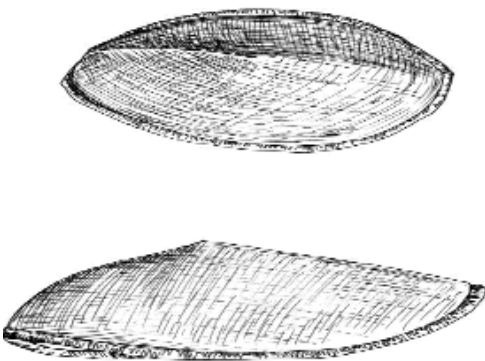
Figure VI-13: Reusable pouches for men: side view (left) and front view (right).
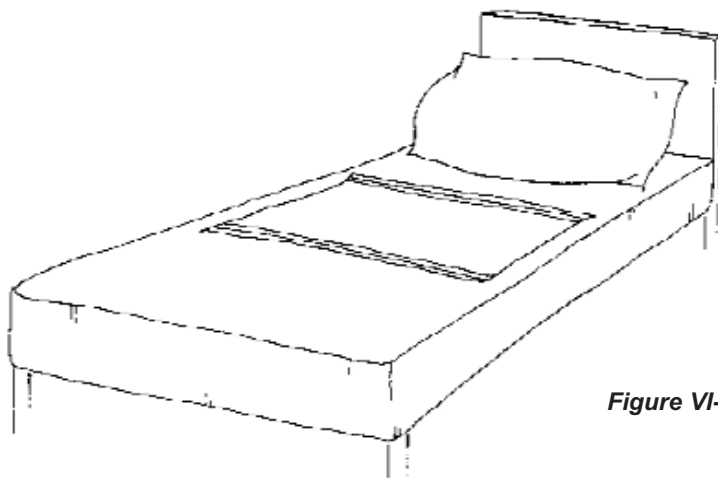
Figure VI-14: A disposable underpad.
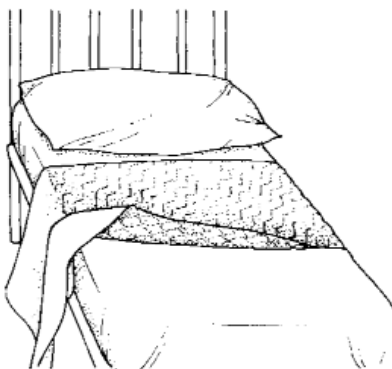
Figure VI-15: A reusable underpad.

two or more layers, each designed to perform a different function. For example, an upper layer might comprise low absorbency fibres engineered 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.

Washable 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 intended to have good dry comfort – or polyester – which is hydrophobic and intended to have good wet comfort.

Concern for the environment and also for controlling costs has led to an increase in the number of washable products available on the market. An important consideration in the comparison of washable and disposable designs is the relative environmental cost, particularly disposal (landfill) costs of disposable designs and energy costs associated with laundering the washables. A recent report on baby diapers concluded that there was no significant difference in environmental impact between three diaper systems (disposables, home and commercial laundered) although the types of impacts did vary [49].

4. ABSORBENT PRODUCT CAPACITY AND USER REQUIREMENTS

Pads come in a range of absorbencies to cater for users with different levels of urinary incontinence and, understandably, purchasers wish to know how much urine available pads will hold. But there is no simple answer: a pad does not have a volume of urine below which it is guaranteed not to leak; rather, the probability of success decreases as the volume of the urine increases. However, for higher absorbency pads the performance falls away more slowly with increasing urine volume than it does for lower absorbency products.

This is a complex concept to communicate in sales literature and product packaging and so companies commonly quote a simple absorption capacity figure. Some use the volume of fluid a pad will hold in a laboratory test - usually international standard ISO 11948-1 [50] - but this figure can be very misleading. Although it has been show to correlate well with the leakage performance of pads for some groups of users (see Section VI.7.2), the volume of urine which a pad will hold when tested with ISO 11948-1 is enormous compared with how much it will hold in real use. For this reason, some companies prefer to quote a "working capacity", which might be calculated as some proportion (companies vary in the proportion they

use) of the capacity in the laboratory. However, this is still misleading as it implies that the pad will not leak until the working capacity is exceeded. A simple, valid and widely accepted solution to this problem has yet to be devised.

It is equally difficult to determine the needs of users in terms of the volume of urine they need their pads to hold. Not only can different users leak widely differing volumes from each other but also a given user may leak widely differing volumes on different occasions. This means that, like pad performance, users' needs cannot be easily quantified. However, a number of studies have been published on work with pad users described as being lightly incontinent of urine in which the median and 90th percentile urine volumes in used pads have been of the order of 15ml and 100ml, respectively [51]. Similarly, a number of studies of pad users described as having moderate-heavy urinary incontinence have yielded corresponding figures of about 250ml and 600ml [51]. Accordingly, in this chapter the material is divided – somewhat simplistically – into that which relates to light incontinence and that which relates to moderate-heavy.

But the published work also makes it clear that some products work better for users whose incontinence is towards the lighter or the heavier end of the spectrum within each of these two groups and so, where necessary in the text and tables that follow, these distinctions are made by dividing light incontinence into "light LIGHT" and "heavy LIGHT"; and moderate-heavy incontinence into "light HEAVY" and heavy HEAVY".

5. ABSORBENT PRODUCTS FOR WOMEN WITH LIGHT URINARY INCONTINENCE

There are four main product designs for women with light incontinence (**Table VI-2**). In addition menstrual pads are known to be frequently used for light urinary incontinence. 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.

Aspects of assessment that are particularly important regarding pads for women with light incontinence include frequency / severity of leakage, day / night incontinence individual priorities (e.g. need for discreetness), personal preference for washables / disposables, lifestyle (home / travel / work).

a) Quality of data

A small number of robust comparative evaluations of absorbent pads for lightly incontinent women have been published and there has been a Cochrane review [52]. A recent study has compared the most common designs: disposable inserts, menstrual pads, washable

Table VI-2. Bodyworn absorbent products for women with light urinary incontinence

	Disposable	Washable
Design groups	Inserts (Fig VI-2)	Inserts (Fig VI-4)
	Pull-ups ie pants with integral pad	Pull-ups ie pants with integral pad (Fig VI-11)
	Menstrual pads	

inserts and washable pants with integral pad. 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. 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 crossover design, Fader et al [51] compared disposable inserts, menstrual pads, washable pants with integral pad, and washable inserts. Three products were selected (based on previous study results) to represent each design and each product was tested for one week (three weeks for each design block, total 12 weeks). Order was randomised. Product performance was characterised using a validated questionnaire to evaluate pad performance (leakage, discreetness etc) with a five point scale (very good – very poor) at the end of each week of product testing.

A pad change and leakage diary was used to record severity of leakage from pads (three-point scale: a lot, a little, or no leakage), and numbers of laundry items and pads used were recorded to estimate costs. Skin health changes were recorded weekly. At a final interview preferences were ranked (with and without costs), acceptability of the design recorded (highly acceptable – totally unacceptable) and overall opinion marked on a visual analogue scale (VAS) of 0-100 points (worst design – best design). This VAS score was used to estimate cost-effectiveness.

Eighty-five women (mean age 60) completed the study and 8691 used pads were weighed. The disposable insert was significantly better than the other designs on most variables except for discreetness. For leakage prevention, overall acceptability and preference, disposable inserts were found to be significantly better than menstrual pads, which were better than washable pants with integral pad, which were better than washable inserts. There was no clear benefit for skin health using either washable or disposable designs. Most women preferred the disposable insert pad but some preferred the other cheaper designs (6/85 preferred menstrual pads; 13/85 preferred washable pants), both of which were >50% cheaper to use than

disposable inserts). Washable inserts were significantly worse than the other designs (72/85 found them unacceptable). Overall there were generally more practical problems with washables, particularly when away from the home (Level of Evidence 1).

The authors concluded that allowing women to choose their preferred design of absorbent product (or combination of different designs for different circumstances) would be more cost-effective and provide better patient satisfaction than provision of disposable insert pads (the most expensive product) alone.

Clarke-O'Neill et al. [19] 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. However, the 'overall opinion' scores of the testers showed large 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 [53] compared all 10 washable 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 between products with the best performing product scoring 85% Good or OK compared with 34% for the least successful product (Level of Evidence 2).

Baker and Norton [54] 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 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 was inadequate. However, this study was carried out more than 10 years ago and products have changed considerably since then (Level of Evidence 2).

Thornburn et al. [17] studied 'wet comfort' using small disposable pads that had been experimentally made using different combinations of materials in an attempt to reduce 'wetback' (the tendency of pads to allow urine to escape back on to the wearer's skin Twenty women tested the pads. 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

There is robust evidence that disposable inserts are more effective in terms of leakage and more acceptable than menstrual pads, washable pants and washable inserts (Level of Evidence 1). Menstrual pads are cheaper and washable pants cheaper still (on a per-use basis) and are acceptable to many, particularly those with lighter incontinence and particularly when used at home. Washable inserts are not acceptable to most women. The user characteristics, priorities and contexts which favour or discourage the use of the different product designs are summarised in Fig VI-16.

d) Recommendations

- Disposable inserts are recommended as the most effective and preferred absorbent product for women with light incontinence (Grade of Recommendation B).
- Menstrual pads or washable pants may be sufficient for some patients with very light incontinence and are cheaper (Grade of Recommendation B).

- Washable inserts are not recommended (Grade of Recommendation B).
- Combinations of designs for different situations (e.g. disposable inserts for going out, washable pants with integral pad for staying at home) are likely to provide optimum management in terms of patient needs and cost-effectiveness, and product advice and provision (where purchased by institutions / services) should reflect this (Grade of Recommendation B).
- See also the general recommendations relating to pad selection in Section VI.11 and to washable pads in Section VI.12.

e) Research priorities

- Because the performance of washables was generally poor (particularly for leakage) compared to disposables, the development of better washable products is a priority.
- The use of combinations of designs for different situations needs to be evaluated.

6. ABSORBENT PRODUCTS FOR MEN WITH LIGHT URINARY INCONTINENCE

There are five main product designs for men with light urinary incontinence (**Table VI-4**). However, disposable and washable insert pads are often unappealing to men as they are frequently 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 VI-12 and VI-13**) are designed to be more suitable for men by containing the penis or penis and scrotum.

Aspects of assessment that are particularly important regarding pads for men with light incontinence include frequency / severity of leakage, day / night incontinence, retraction of penis, individual priorities (e.g. need for discreetness), personal preference for washables / disposables, and lifestyle (home / travel / work).

Only one study has been published which has evaluated absorbent products for men with light urinary incontinence (55). It compared the four main absorbent designs of products available in the UK in 2003:

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

	Disposable	Washable
Design groups	Inserts (Fig VI-2)	Inserts (Fig VI-4)
	Pouch (Fig VI-12)	Pouch (Fig VI-13)
		Pull-ups ie pants with integral pad (Fig VI-11)

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Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Disposable inserts	• Reliable leakage prevention is a priority (B)	• Low cost is a priority (B) • Discretion is a priority (B)	• Some users prefer a mix of products eg using different products at home / when out; or during the day / night.
Disposable menstrual / sanitary pads	• Low cost is a priority (B)	• Incontinence is heavy LIGHT (B)	
Washable pants	• Low cost is a priority (B) • The design concept is acceptable / preferred (B) • Incontinence is light LIGHT (B/C)	• Adequate laundry facilities are not available (C) • The design concept is unacceptable (C) • Carrying used pads when out is an issue (C) • Incontinence is heavy LIGHT (B/C)	
Washable inserts	• As for washable pants, but prefer separate pad (B/C)	• As for washable pants (B/C)	

Figure VI-16: Designs of pads for women with light urinary incontinence. For definitions of light LIGHT and heavy LIGHT, see Section VI.4.

disposable insert pads, pouches and leafs and washable pants with integral pad. All six leaf products (five disposable and one washable) and all six pouches (all disposable) on the UK market in 2003 were evaluated, together with a selected disposable insert pad and a selected washable pant with integral pouch (chosen to represent their respective designs).

Seventy men with light urinary incontinence completed the 14 week study and filled out 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 product performance and used pad weight. 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, but one product was significantly better than the other leafs (Tena). The disposable insert was also 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 place but poorly for leakage (Level of evidence 2). The user characteristics, priorities and contexts which favour or discourage the use of the different product designs are summarised in **Fig VI-17**.

a) Recommendations

- Disposable leafs are recommended as the most acceptable and effective design for men with light incontinence, but some men prefer other designs which should be considered as alternatives (Grade of Recommendation B).
- Simple insert pads are cheaper and may be acceptable to some men (Grade of Recommendation B).
- Washable pants with integral pad are likely to be most suitable for men with very light incontinence who have difficulties keeping an insert or pouch in place (Grade of Recommendation B).
- See also the general recommendations relating to pad selection in Section 6.11 and to washable pads in Section VI.12.

b) Research priorities

Because the performance of washables was generally poor (particularly for leakage) compared to disposables, the development of better washable products is a priority.

7. ABSORBENT PRODUCTS FOR MEN AND WOMEN WITH MODERATE-HEAVY URINARY INCONTINENCE

There are 12 absorbent product designs for men and women with moderate-heavy urinary incontinence (**Table VI-5**). The most commonly used products are disposable bodyworn inserts and diapers (**Figs VI-3 and VI-6**). More recently, modified diapers (T-shaped diapers, **Fig VI-7**) 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 VI-9**). Washable counterparts to most disposable bodyworn designs are available but they have a much smaller market, where they are available. They are made from a variety of natural and synthetic materials. Disposable and washable bedpads are used on the bed at night with or without the support of a bodyworn product. Disposable and washable 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 any leakage from the bodyworn. Both practices place an underpad on display and mark the individual as being incontinent and are therefore to be discouraged. Aspects of assessment that are particularly important regarding absorbent pads for moderate / heavy UI are frequency / severity of leakage, day / night incontinence, gender (some products are better for men/women than others), ability to change pad independently / need for carer, pad changing position (standing / lying), laundry / drying facilities, individual priorities (e.g. need for discreetness), personal preference for design / materials (washable / disposable) and lifestyle (at home / travel / work etc).

a) Quality of data

There have been two recent clinical trials comparing the main designs of disposable bodyworn pads (one also included washable designs). There have been no trials of underpads for the last 15 years. There have also been a large number of comparative studies of absorbent products for moderate-heavy incontinence but most are more than 10 years old and evaluated 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 (56) identified 30 studies of absorbent products published between 1965-1990. Some robust multi-centre international studies have examined the correlation between laboratory testing and the leakage performance of products clinically.

Product category	User characteristics / priorities / contexts which:		Notes
	FAVOUR use	DISCOURAGE use	
Disposable pouches	• Discretion is a priority (B/C) • Using a specifically male product is important (C)	• Penis is retracted (C) • Incontinence is heavy LIGHT (B/C)	
Disposable leafs	• In general (B/C)		
Disposable inserts	• Low cost is a priority (B/C) • Male specific product unimportant (C)		• Appropriate whether or not penis is retracted
Washables	• Incontinence is light LIGHT (B/C) • Low cost is a priority (B/C) • Design concept is acceptable / preferred (C) • User is mobile and active (B/C)	• Adequate laundry facilities are not available (B/C) • Design concept is unacceptable (B/C) • Carrying used pads when out is an issue (B/C) • Incontinence is heavy LIGHT (B/C)	

Figure VI-17: Designs of pads for men with light urinary incontinence. For definitions of light LIGHT and heavy LIGHT, see Section VI.4.

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

	Disposable (single use)		Washable (reusable)	
Type	Bodyworns	Underpads	Bodyworns	Underpads
Design groups	Inserts (Fig VI-5) Diapers (Fig VI-6) T shaped diapers (Fig VI-7) Pull-ups (Fig VI-9)	Bedpads (Fig VI-14) Chairpads	Inserts (Fig VI-4) Diapers (Fig VI-8) T shaped diapers Pull-ups (Fig VI-10)	Bedpads (Fig VI-15) Chairpads

b) Results

1. EVALUATIONS COMPARING DIFFERENT DESIGNS OF DISPOSABLE AND / OR WASHABLE BODYWORN ABSORBENT PRODUCTS FOR URINARY INCONTINENCE

Fader et al. [51] carried out two clinical trials of absorbent products for moderate-heavy incontinence; one involving subjects in the community and the other subjects in nursing homes. In the community-based trial 85 moderate / heavily incontinent adults (urinary or urinary / faecal) living in their own homes (49 men and 36 women) were enrolled, and tested three (or two) products from each of five design categories (total of 14 test products): disposable inserts (with mesh pants); disposable diapers; disposable pull-ups; disposable T-shape diapers; and washable diapers. All products were provided in a daytime and a (mostly more absorbent) night-time variant. Products were selected based on having similar scores for absorbency across the designs (Rothwell scores, (50) see below) and performance data from pilot studies. In the nursing-home-based trial 100 moderate / heavily incontinent adults (urinary or urinary / faecal) living in a total of 10 nursing homes (27 men and 73 women) evaluated one product from each of the four disposable design categories above. Products were selected on the basis of product performance from the community-based trial and, again, day and night-time variants were provided.

Product performance was characterised using validated questionnaires which asked the participants (in the community-based trial) or carers (in the nursing home based trial) to evaluate various aspects of pad performance (leakage, ease of putting on, discreetness etc) using a five point scale (very good – very poor) at the end of the week (or two weeks for the nursing-home-based trial) of product testing. In addition, participants / carers were asked to save individual used pads in bags for weighing and to indicate the severity of any leakage from them on a three-point scale (none, a little, a lot). These data were used to determine differences in leakage performance. Numbers of laundry items and pads used were recorded to estimate costs, and skin health changes were recorded by the participant or by the researchers. At the end of testing participants were interviewed and ranked their preferences (with and without costs), stated the acceptability of the design (highly acceptable – totally unacceptable) and recorded their overall opinion on a visual analogues scale (VAS) of 0-100 points (worst design – best design). A pad changing experiment was conducted with 12 women from the nursing home based trial to determine any differences between product designs. Under idealised conditions the different designs were applied (by the same carers) in random order for each patient and the speed of pad changing was timed using a stop-watch.

Findings from the community-based and nursing home trials were broadly similar. The leakage performance for the disposable inserts was worse than the other designs for day and night and disposable pull-ups were preferred over inserts for the daytime. The new T-shape diaper was not better overall than the traditional disposable diaper. But there were important differences in performance and preference findings between men and women from both trials and the men (in the community) had more severe urinary incontinence than the women - mean daytime urine mass 375 g for men and 215.g for women (difference148g, CI: 79.8, 217.7).

Pull-ups (the most expensive design) were better overall than the other designs for women during the day and for community-dwelling women during the night too. Although disposable diapers were better for leakage than disposable inserts (the cheapest), women did not prefer them, but for men (in the nursing homes and the community) the diapers were better both overall and for leakage and were the most cost-effective design. No firm conclusions could be drawn about the performance of designs for faecal incontinence and there was no firm evidence that there were differences in skin health problems between designs (Level of Evidence 1).

In the nursing home trial the carers found pull-ups and inserts significantly easier to apply (in the standing position) and significantly quicker in the pad change experiment (mean time 35.2 and 37.9 seconds for inserts and pull-ups respectively and 53.2 and 62 seconds for diapers and T-shaped diapers respectively) and ability to stand was associated with preference for pull-ups or inserts. Despite being designed for ease of changing the T-shape diaper was not found to be easier or quicker to change than the diaper.

The washable products (used in the community-based trial) gave diverse results. Two of the products were made from cotton terry-towelling (one a simple square, folded and pinned in a diaper shape; the other a shaped diaper-like design, both worn with plastic pants) while the third product had a felt absorbent core, with an integral plastic backing and was fixed by poppers. This third product performed significantly worse for leakage than the other two washables and was therefore excluded from the final data analysis. The terry-towelling washables were better for leakage at night than the other disposable designs, but were less popular overall for daytime use than the other disposable designs. Three quarters of the women (27/36) found them unacceptable, but nearly two thirds of men (31/49) found them highly acceptable at night. Findings from the community-based trial showed that there were many practical problems dealing with washable products particularly when out of the house, but that they were more acceptable at home.

Macaulay et al, [21] carried out a pilot study of 19

washable products with 14 community dwelling subjects. The products included a mixture of washable 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 washable products performed poorly for leakage, one washable product made of cotton towelling (used with plastic pants), scored better than both the other washable and disposable products (Level of Evidence 3).

Seven older trials have compared disposable with washable bodyworn products for moderate-heavy incontinence [57-63]. The trials varied in size and design from a large controlled trial with 276 subjects [57] to a small trial of eleven subjects [60]. In addition some trials have compared disposable and washable bedpads and body-worns. Brown [23] [64] undertook a large trial of this kind. The fact that no systematic method of product selection was used for these studies limits the utility of the results since particularly good or poor products may have been selected to represent the disposable or washable 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 [57] and Grant [58] both reported that they did not find statistically significant differences between their washable and disposable products in terms of an adverse change in skin condition. But Hu et al. [65] reported a statistically significant improvement in the skin condition of their disposable product users as compared to their users of washable products (See Section XIV).

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

Four studies attempted to measure costs [58, 59, 64,66]. Of these, three used statistical methods of analysis. Hu et al. [66] and Brown [64] reported that although there were *no* statistically significantly differences in terms of per-day product costs of washable 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 washable product (ie for laundering the products as well as soiled bed linen and clothes). Brown [64] found no significant differences between daily costs of the washable and disposable products. However, statistically significant differences were found between the groups in terms of incontinence-related laundry, with the disposable group producing less laundry than the washable group. Grant [58] reported that the cost

of washable products was significantly lower than that of disposables, but laundry costs were not taken into account. (see committee 22)

2. DISPOSABLE ABSORBENT PRODUCTS FOR URINARY INCONTINENCE: STUDIES OF SINGLE DESIGNS, LABORATORY TESTS AND STUDIES OF MATERIALS

Clancy and Malone-Lee [67] compared versions of the same pad experimentally engineered to have different combinations of fluff pulp and topsheet materials. Forty-five heavily incontinent older adults participated. The main valuable finding from this study was that pads were more likely to leak if they were not held in place by pants (p<0.0001) and that, if there was 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 [68,69], both carried out in nursing homes. A study of shaped insert pads involved 228 subjects from 33 nursing / residential homes who tested 20 ranges of insert pads (74 products in total). A similar study of diapers involved 192 subjects from 37 nursing / residential homes who tested a total of 36 products. These studies showed the wide range of product performance that can exist 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 XIV.

Because clinical evaluations are expensive and time-consuming, laboratory evaluation procedures are in widespread use. Few have been clinically validated but there is a clinically-validated International Standard relating to the leakage performance of disposable bodyworn pads for moderate-heavily incontinent adults in institutions [50]. 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 [70] 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, Sweden and other countries 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 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. [71]. 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 [72] 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).
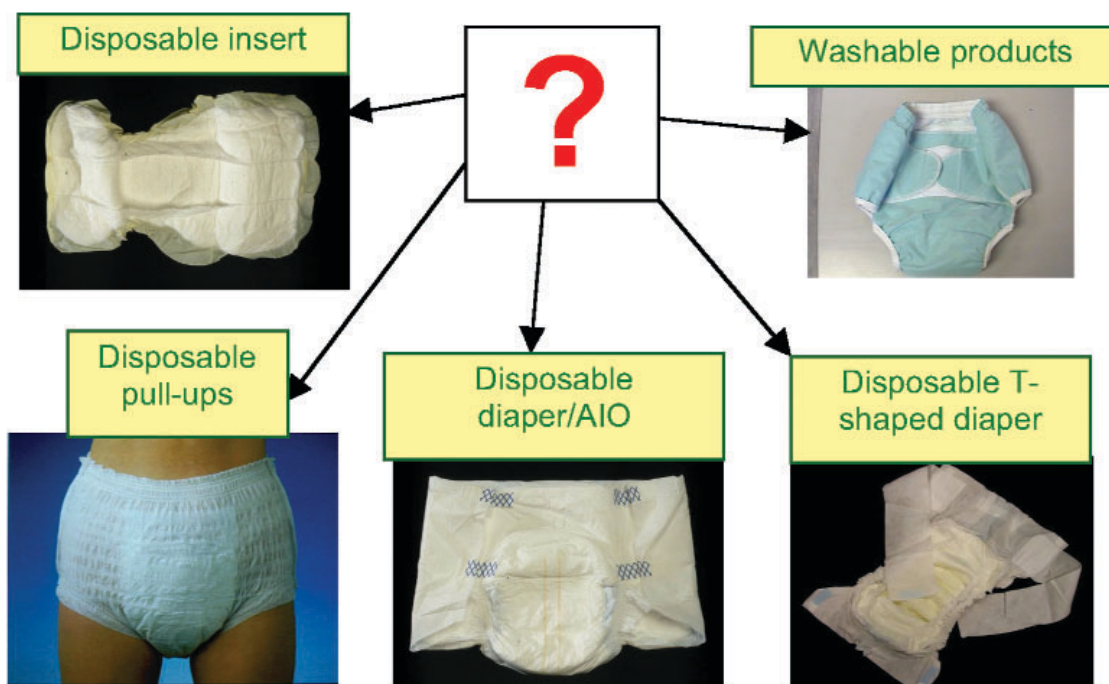
c) Summary

Results from these studies indicate that there is no single best design (i.e one design that is significantly better than all other designs for all users) (Level of Evidence 1). There is evidence that different designs are better for men and women, and that men leak substantially higher volumes of urine than women (Level of Evidence 1). Of the disposable designs, the more expensive pull-up and T-shaped diaper designs are not better overall than the cheaper diaper for men, indicating that the diaper is the most cost-effective design for men. For women pull-ups are better overall than the other designs (except for night-use in those living in nursing homes), but they are expensive (Level of Evidence 1). Unlike men, women in the community do not favour diapers over insert pads and of these cheaper designs, inserts may be preferred for women. There is also evidence that the leakage performance of inserts is worse than other designs, but that they 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 an international standard laboratory tests (Level of evidence 2). This test has been shown

to have very good repeatability and adequate reproducibility (Level of Evidence 2). Washable products are very varied in design and materials, and also in performance. There is evidence that terry-towelling products (used with plastic pants) have good leakage performance, however they have limited acceptability - confined mainly to some men at night. There is no firm evidence regarding the performance of different designs for faecal incontinence and no firm evidence that any particular design or type of material (washable or disposable) is better or worse for skin health.

The user characteristics, priorities and contexts which favour or discourage the use of the different product designs are summarised in Fig VI-18.

d) Recommendations

- Gender should be considered when products are prescribed / purchased for users. As men often have substantially higher incontinent urine volumes than women, men may require more products and / or more absorbent products than women (Grade of Recommendation B).

- Gender should also be considered when products are prescribed / purchased for users because men and women are likely to prefer different designs. Men generally prefer disposable diapers to inserts (Grade of Recommendation B).

- Women generally prefer disposable pull-ups to other designs, but these are expensive. Disposable inserts are a cost-effective alternative (Grade of Recommendation B).

- Caution is recommended if washable designs are being considered. Heavy bulk confines their use mainly to the night-time (where they may be particularly useful for users who lie on their side). They are unacceptable for most people during the daytime and for most women at any time and for this reason a blanket policy of health services providing washables alone is not recommended. If washables are being considered refer to points below (Grades 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, diapers should be selected in preference to inserts to minimise leakage (Grade of Recommendation B).

- *Carer application*: When products are applied by a carer to a patient who can stand for pad changing, disposable inserts or pull-ups are

| | Disposable insert | | Washable products |
| Disposable pull-ups | | Disposable diaper/AIO | Disposable T-shaped diaper |

| Product category | User characteristics / priorities / contexts which: | | Notes |
	FAVOUR use	DISCOURAGE use	
Disposable inserts	• Carer is needed for pad change and user can stand (B/C) • Discretion is a priority (B/C) • Ease of putting on is a priority (B/C) • Female (B/C)	• Incontinence is heavy HEAVY (B/C) • Mobile and active (C)	
Disposable pull-ups	• Carer is needed for pad change and user can stand (B/C) • Reliable containment of leakage is a priority (B/C) • Ease of putting on is a priority (B/C) • Discretion is a priority (B/C) • Female (B/C)	• Removal of clothing for pad changing is an issue (B/C) • Low cost is a priority (B/C) • Night time use, with a carer (B/C)	
Disposable all-in-ones	• Incontinence is heavy HEAVY (B/C) • User can not stand for a pad change (B/C) • Male (B/C)	• Discretion is a priority (B/C)	
Disposable T-shaped pads	• Reliable containment of leakage is a priority (B/C) • Male (B/C)		
Washable bodyworns	• At night, if incontinence is heavy HEAVY (B/C) • Male (B/C)	• Adequate laundry facilities are not available (B/C) • The concept is unacceptable (B/C) • Discretion and appearance are a priority (B/C)	

Figure VI-18: Designs of pads for adults with moderate-heavy urinary incontinence. For definitions of light HEAVY and heavy HEAVY, see Section VI.4.

easier and quicker to change than diapers or T-shaped diapers. If the patient is lying down (e.g. at night) pull-ups should be avoided (Grade of Recommendation B).

- *Combinations of designs for different situations* (e.g. disposable inserts for staying in, disposable pull-ups for going out, washable diapers at night) are likely to provide optimum management in terms of patient needs and cost-effectiveness (Grade of Recommendation B).

- See also the general recommendations relating to pad selection in Section VI.12 and recommendations specific to washable pads in Section VI.13.

e) Research priorities

- Comparison of absorbent products (disposable and washable) when used by carer-dependent users in the community.

- Development of more effective and aesthetically acceptable washable products, particularly for night-time use and for women.

- Development of more effective and acceptable disposable designs specifically for men.

8. DISPOSABLE UNDERPADS

There have been no published studies examining the use of bedpads during the last 15 years. This probably reflects the recognition of their limited role in long-term management of incontinence. Disposable underpads on chairs declare their user to be incontinent and require clothes to be pulled up (or absent) which is unacceptable for dignity. In the bed disposable underpads easily become displaced, folded and creased under the patient which inhibits their performance and comfort, and may potentially be a threat to skin health. Large disposable underpads with wings to tuck into the bed may have a role as bed protection 'back-up' to bodyworn pads. The main role of disposable underpads should be confined to temporary bed or chair protection such as during clinical procedures (e.g. enemas) or when using a urinal.

Published trials comparing different disposable bedpads are few [23] [73,74] 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 [75] has drawn attention to the risk of infection, particularly from products containing recycled paper. Leigh and Petch [76] and Sprott et al. [77] 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 [78]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. [70] 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.

a) 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).

b) Recommendations

- Disposable underpads should not be used for long-term management of incontinence, but have a useful role as temporary protection for chairs and beds during clinical procedures (Grade of Recommendation C).

- 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).

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c) Research priorities

Disposable underpads have a limited role in continence management but are known to be widely used. An exploration of patient views regarding their use may help demonstrate their limitations

9. WASHABLE UNDERPADS

Aspects of assessment that are particularly important regarding washable underpads are patient acceptability and preference, particularly with regard to willingness to be naked below the waist (if sole use intended) and availability of laundry and drying facilities.

Cottenden [79] has reviewed comparative evaluations of different washable bedpads up to about 1990. Leiby and Shanahan [80] 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 washable bedpads are commonly used by multiple patients and questions are often asked about the risk of cross-infection. Cottenden et al. [81] 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 71oC 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.

a) Summary

The literature contains insufficient robust data on which to base guidelines for choosing between washable 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).

b) Recommendations

- If considering using washable underpads for sole use (ie without a bodyworn product) the patient will need to be naked below the waist.

Patient consultation and approval will therefore be needed (Grade of Recommendation C).

- Personal preferences of users with regard to topsheet material, tuck-in flaps and integral waterproof 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 washable bedpads is low and not a contra-indication for their use (Grade of Recommendation B).

c) Research priorities

Comparison of washable underapds with bodyworn products when used at night.

10. ABSORBENT PADS FOR CHILDREN WITH URINARY AND / OR FAECAL INCONTINENCE

Most children are expected to achieve daytime dryness by the age of three [82]. 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. (see committee 9)

Aspects of assessment that are particularly important regarding bodyworn products for children are presence of faecal incontinence, day / night incon-tinence, level of independence with toileting, and use of aids (e.g. callipers).

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 (83). Sixty-one children with physical and / or learning disabilities tested five diaper products and five pull-up products, each testing each product for one week. The children were randomised to receive either the pull-up or diaper group first and individual products were tested in random order within each design arm. 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 generally, the diaper products performed similarly to each and so did the pull-up products, although there were some statistically significant differences between products within each of the two design groups. Overall diapers were preferred for night-time use by the majority of parents. By contrast, 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 and / or had faecal incontinence, and wore callipers or adapted footwear. The authors recommended that both diapers and pull-ups should be supplied for children, with pull-ups (which are about 50% more expensive than diapers) being provided for selected children during the daytime.

a) 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).

b) Research priorities

Comparison of washable and disposable bodyworn products.

11. PADS FOR FAECAL INCONTINENCE

Most absorbent products are designed for urinary incontinence. No studies comparing available absorbent products for faecal incontinence were found. Bliss et al. [84] reported preliminary findings of a survey of the use and evaluation and suggested modifications of absorbent products for faecal incontinence by 188 community-living persons with the problem. Forty-five percent of persons used an absorbent product for FI. Ninety-eight percent of those with UI and FI used the same type of product for both. Suggested improvements in product designs included having better odour control, fit, and ability to stay in place; a clearer distinction between the front and back of a pantiliner or pad; adding wings for greater absorbency; and making them flushable, cooler feeling, wider and longer in the rear and more absorbent but less bulky. For mild faecal incontinence, especially when faeces remain between the buttocks without soiling underwear, persons have used a small disposable gauze surgical dressing placed between the buttocks. This product was more acceptable than a pantiliner or pad to some men [84] (Level of Evidence 2).

a) Recommendations

• A disposable gauze dressing that can be placed between the buttocks maybe acceptable for men with light faecal incontinence (Level of Recommendation C).

b) Research priorities

• Better designs of products are needed for light and moderate FI (with and without UI).

12. GENERAL RECOMMENDATIONS ON PAD SELECTION

• *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).

• *Brand differences:* The individual product brands within a design group often exhibit a wide range of performance and acceptability for individuals, and it cannot therefore be assumed that pads of different brands but broadly similar design will be equally acceptable or effective (Grade of Recommendation B).

• *Combinations of designs:* Absorbent products vary greatly in price and performance and suitability for individual needs. Users may therefore find combinations of designs preferable and cost-effective. For example, women might use pull-ups (expensive, but discreet and good for leakage) for going out, and inserts (cheap, less good for leakage) for staying at home. Men might use disposable diapers for daytime, and washable terry-towelling products for night-time (Grade of Recommendation B).

• *Freedom from leakage*: In general, pads containing superabsorber should be selected in preference to those without (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). Robust, stretch (e.g. cotton / lycra) pants may also help to provide a snug fit and minimise leakage. 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.

13. RECOMMENDATIONS RELATING TO WASHABLE PADS

- *Laundry issues:* Access to good, reliable washing and drying facilities should be checked before washable 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 washable products needed per user depends on laundry turn-around times. Drying times for washables can be long and expensive, especially for bodyworns for heavy incontinence and for bedpads.

- *Personal preferences:* Personal preferences (of both users and caregivers) with regard to choosing between washable and disposable products should be taken into account carefully (Grade of Recommendation C). Some users prefer the chore of laundering washables to anxiety over whether their next consignment of disposables will be delivered on time. Washables generally require less storage space than disposables. Discreet disposal of disposables can be a challenge. The possibility of using a mix of disposable and washable products should be considered (Grade of Recommendation C).

Some users who choose disposables when at home prefer washables when travelling because of the space that disposables occupy in luggage and the possible inconvenience of disposal. Others use washables 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 washable products and sorting them after each laundry cycle should be considered before they are introduced (Grade of Recommendation C). Washable bodyworns 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. Washable bedpads are not usually personalised.

- *Staining:* Washable 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 washables too.

- *Costs:* Cost comparisons between washable 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 washables 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.

VII. SHEATHS

Close-fitting penile sheaths (sometimes called condom catheters, uridomes or external catheters) are commonly used male incontinence devices and they are used in combination with a urine drainage bag. They are suitable for males who are experiencing moderate to heavy urine loss, or have limited mobility and are experiencing frequency and urgency and may even be considered in combination with intermittent catheterisation (IC) for males who are leaking urine as a consequence of bladder emptying problems. Sheaths may not be suitable for males who are experiencing confusion, considered psychologically

vulnerable or have decreased sensation through spinal cord injury [85-87]. There is strong opinion expressed in the literature that suggests assessment, selection and use of penile sheaths and the accompanying urine drainage systems needs to be undertaken with the guidance, education and monitoring of health professionals who have a knowledge of continence products. Failure to do so, according to this expert opinion [86-87], may result in serious penile trauma, impaired penile skin integrity and leakage.of urine.

General guidelines on patient assessment for product selection are discussed in Section II. Aspects of assessment that are particularly important in relation to sheaths include: physical, mental, cultural, gender and socio-economic factors. This incorporates assessment of the cognitive and dexterous ability of the male or carer to apply the sheath and empty the drainage bag, the integrity of the penile skin, length and circumference of the penis and whether it is retracted, or retracts on sitting or bending down, history of latex or adhesive allergy and, most importantly, recognition that the assessment from the health professional needs to be ongoing. It is also important to assess factors known to encourage or discourage sheath usage. Expert opinion [86, 89,90] suggest factors that encourage usage include: level of reimbursement, cultural expectation, resonance with masculine image, and ability to keep urine off the skin when the skin integrity is at risk because of incontinence. Factors which they suggest discourage usage include: ignorance of product efficacy by professionals and consumers and embarrassment between carer and client.

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 urine drainage bag.

1. PRODUCT CATEGORIES AND FEATURES

Sheaths come with a variety of features (**Fig VII-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)
- 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.
- Transparency: some sheaths are transparent allowing for observation of the condition of the skin along the shaft and glans of the penis.

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 [91] found that 15% experienced side effects or complications when using sheaths. These were irritative, allergic or compressive in nature. Jayachandran et al. [92] 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. [93] 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
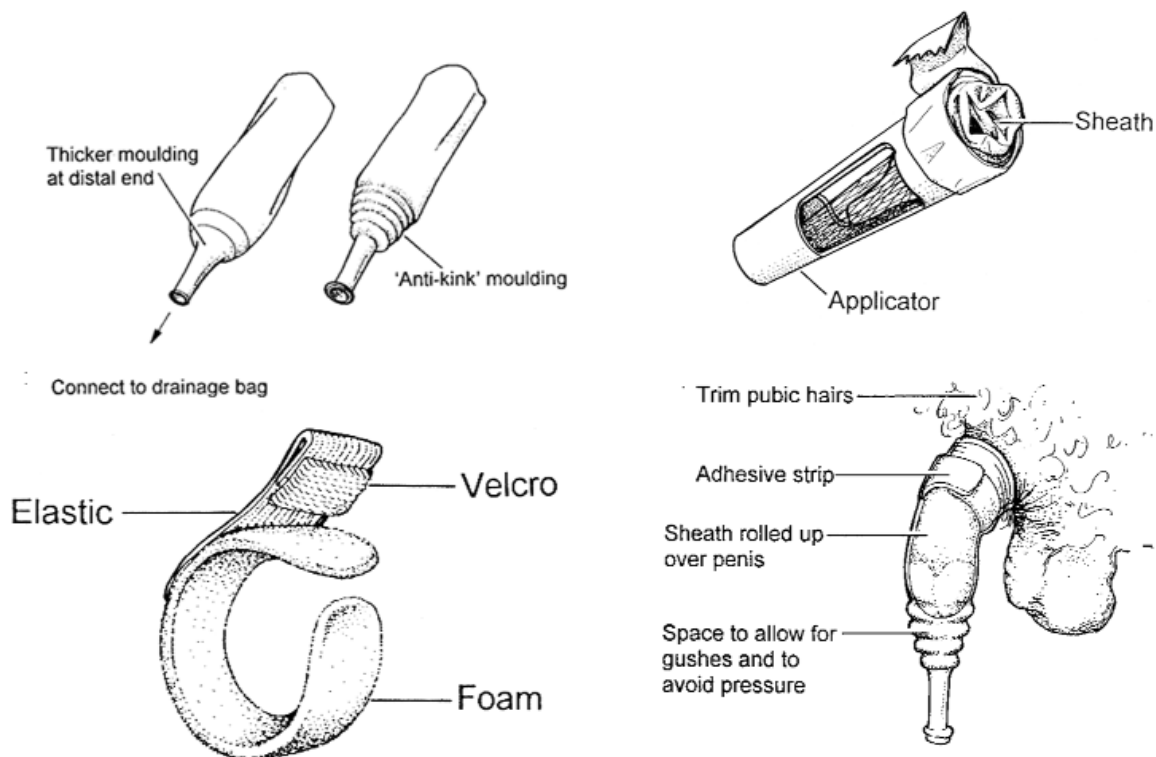
Figure VII-1: A variety of sheaths (top left and bottom right), a sheath applicator (top right) and an external fixation strip (bottom left).

developed UTI within a mean of 9.6 days. In a retrospective study, Johnson et al. [94] 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. [95] reported that 40% of 30 nursing home sheath users (mean period of use, 35.9 months) developed at least one UTI. The need for proper fitting of the sheath and regular monitoring of the skin integrity of the penile shaft, glans penis and prepuce of males who are regular sheath users has been highlighted in two articles that report a combined total of eight cases of fibropithelial polyps of the glans penis and prepuce of which six had a history of long term sheath use [88] [96].

A trial to compare sheaths and indwelling catheters in terms of infection, risk and patient satisfaction has been reported by Saint et al [97]. This was a prospective, randomised unblinded controlled trial which compared one type of sheath drainage with one type of indwelling urethral catheter using a small group of participants (N=75) across several locations in one hospital. There are important limitations of the study, including the low numbers drawn from a specific population, and the lack of comment on the changing / care routines associated with the sheaths and catheters. After making adjustments for age, mental

score, history of UTI and history of catheterisation the conclusions of the study were that for males without dementia the use of sheaths has the potential to reduce infection compared to indwelling catheters and is more acceptable to patients in terms of comfort and pain. For males with dementia no significant difference in infection rates was found.

Nichols and Balis [98] 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 [99] 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. In all 32 men were approached and

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20 consented, all experienced users of urinary sheaths. A questionnaire was developed to test the participants pre and post intervention. The new sheath – which was used for a week - proved more popular with the participants: it was judged to provide superior security (13/20 experienced increased dryness by day; 10/20 by night), and 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 [100] 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. [101] 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).

Pemberton et al [90] report a randomised prospective open crossover design trial to test user preference for an established one-piece silicone rubber self-adhesive sheath with a new one-piece silicone rubber self-adhesive sheath in a study sponsored by the distributor of both products. To be included the males had to be currently using at least one, one-piece urinary sheath, per day. Fifty three males from seven centres participated in the trial and were each given 10 sheaths of each product. Data from the 44 participants who had evaluated at least three of each product were analysed. No reason was given for why nine males did not complete the trial. The data shows that there were some problems with both products, however, it is difficult to understand why the new product was preferred, as the report does not mention any differences in the features of the two products.

Watson & Kuhn [102] describe a crossover study with six male participants that found the choice of leg bags may influence the performance of penile sheaths. Goldyn, Buck and Chenelly [103] 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. [104] 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, 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 confused elderly male – should be borne in mind (Level of Evidence 2). 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 2/3). Secure fixation 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. GENERAL POINTS FROM THE LITERATURE, INCLUDING EXPERT OPINION

- Prior to applying the sheath, ensure any remaining adhesive or barrier cream is removed from the penis and that it is thoroughly washed with soap and water and thoroughly dried.

- Trim long pubic hairs to prevent them being caught up in the adhesive.

- Protective skin wipes can be used to protect the skin, but make sure the skin has dried properly before applying the sheath.

- Leave a gap at the end of the sheath between the glans penis and the drainage tube to avoid trauma to the glans / prepuce. However, make sure the gap is not too large such as to cause kinking or twisting of the sheath [105].

- After the sheath has been applied, snip any reinforced ring or unrolled section of sheath sitting at the bottom of the shaft of the penis.

- Penile sheath removal should not be rushed and is made easier by gently rolling it off while bathing the penis in warm soapy water.

6. 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 in selecting products 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).

- When possible the external sheath rather than indwelling urethral catheter should be the urinary collection device of choice. (Grade of recommendation B).

7. PRIORITIES FOR RESEARCH

- 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.

- Comparison studies of the risks of complications between the use of sheaths, pads and catheters are required.

- 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.

VIII. 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 discreetness.

General guidelines on patient assessment for product selection are discussed in Section II. Aspects of assessment that are particularly important regarding urine drainage bags are patient / carer dexterity (86;106), and eyesight. Both are necessary to manage the urinary drainage bag system, including using the outlet tap to empty the drainage bag. It is also important to assess the patient's preferred and usual mode of dress (86;106); for example, a male whose preferred mode of dress is shorts will want a drainage system that is not visible and allows easy access for emptying,

1. PRODUCT CATEGORIES AND FEATURES

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 leg 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 to be

suspended around the waist. Some straps and suspension devices can be bought separately from bags, but they are generally not suitable for use with all bags (**Fig VIII-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 VIII-2**).

- Sampling port: bags may or may not have a sampling port in the drainage tubing 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.

- 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 infection for the self-carer and cross-infection between bag users by care givers. . Such features may include; a non return flap valve, designed to help reduce reflux of urine up the tubing when the bag is moved by users or carers, 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 drainage 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. Pre-sealed drainage systems to prevent breaking the closed system are also available.

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 VIII-3**). They usually have a capacity of 2000-4000 ml and come with a variety of design features many of which are similar to 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

a) Evaluations of urine drainage bags

Kennedy et al. [108] 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 [109] 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 [110] 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. [111] 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/
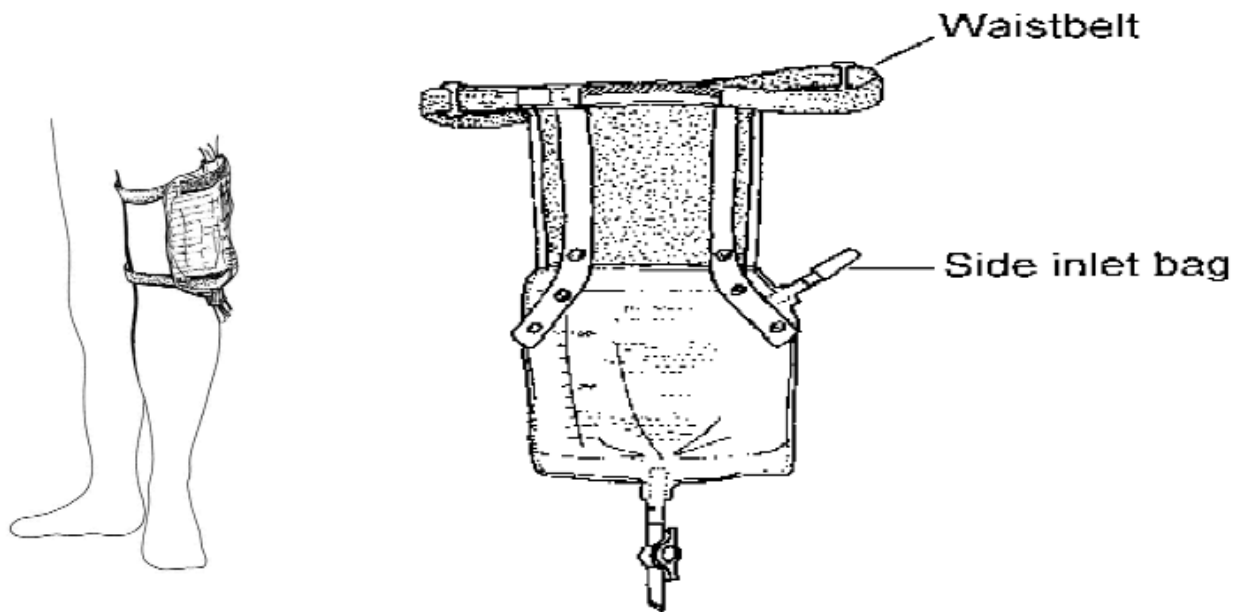
Figure VIII-1: Body worn urine drainage bags held in place using leg straps (left) and a waist band suspension system (right).
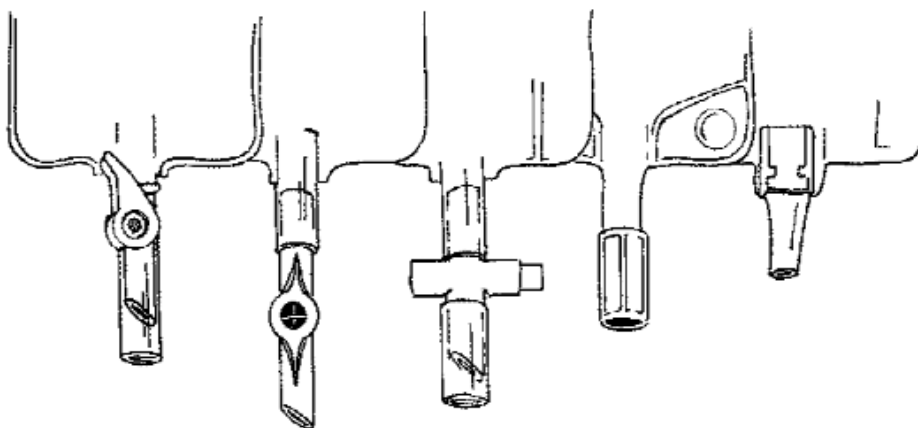

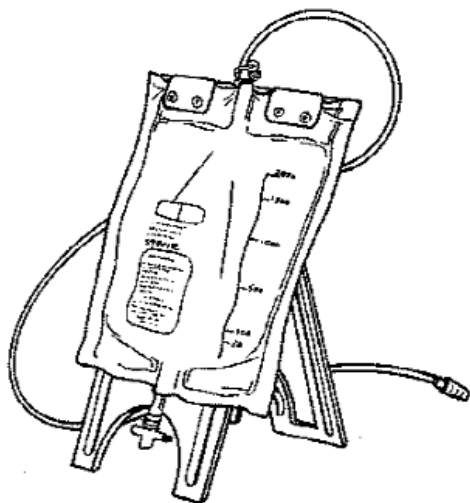**Figure VIII-2: A variety of urine drainage bag tap designs.**

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

nursing homes or long stay wards. Conclusions were substantially similar to those for the earlier MDA study.

Some international standards have been developed which provide general advice on bag performance and test methods [112]. These standards can be useful to laboratories asked to advise on bulk buying choices.

b) Urine drainage bag suspension systems

Little research has been undertaken on urinary drainage bag suspensions apart from a study by Thelwell et al. [113]. Thelwell et al. conducted a cross-over study using 52 subjects (20 men, 32 women). This study 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. Again, difficulty of application, comfort, discreteness and cost were key issues. However, there is suggestion in the literature that urinary drainage bag suspensions have an important role to play not only in the comfort and security of the wearer but in the prevention of urinary tract infection regardless of whether the drainage system is connected to a sheath or an indwelling catheter.

Munnings and Cawood [114] report the findings of a pilot study designed to evaluate the use of a belly bag of 1,000ml capacity and worn 24 hours a day, thus eliminating the need to use two separate bags and reducing the number of times the closed system is broken, Twenty-nine patients from a variety of areas from within an acute care setting who were using continuous catheter drainage systems were invited to participate, with 27 of the participants completing the study. All agreed to wear and then compare the belly bag with their previous leg and night drainage bag system. Worn around the waist, the belly bag is not positioned below the bladder: the manufacturers claim that the pressure of the bladder muscles is sufficient to ensure that urine flows through the catheter from the bladder into the bag. The residual pressure of the bladder is reported to be around 10-25cm H_2O, while the manufacturer asserts that a pressure of only 6cm H_2O is necessary to ensure the urine drains into the bag. Following education of how to use the drainage bag, users were given a questionnaire designed to facilitate comparison between the previous drainage system used and the belly bag. This was followed up with a telephone call. All agreed the belly bag was an improvement over their previous system of leg and overnight drainage bags, and found it more convenient, comfortable and less likely to cause pain with movement.

It has been suggested that current standard drainage tubing / bag designs evacuate the bladder sub-optimally, leading to retention of residual urine. Outflow obstruction can be caused by the development of air-locks in the dependent curls of tubing. A new drainage tubing design which incorporates a coiled downward spiral shaped configuration has been reported to eliminate air-lock obstruction (107) in experimental and clinical studies. However the importance of this in relation to infection requires further study.

There is opinion in the literature that positioning standard drainage bags below the bladder in a manner that averts kinking will prevent reflux of urine, and associated infection[115-117]. When doing so care must be taken not to increase traction or friction [106]. This can be achieved with the use of supports especially designed to divert accidental pulling on the catheter or sheath. When using these support systems allowance should be made for penile erection and tumescence [106].

The drainage system for indwelling catheters should be positioned off the floor to reduce the risk of cross infection[115-117]. Some sterile and unsterile leg bags come with a variety of tubing lengths or tubing that can be cut according to the needs of the individual, and leg straps that can be adjusted to allow positioning of the bag on the thigh or calf. Night bags - even if the tubing can be cut - rely on uniform stands or hangers to ensure that they are off the floor. Roe et al [118] raised the issue of poorly designed support systems for night bags. Expert opinion suggests that this still remains an issue.

c) Infection and cross-infection issues for management of urine drainage systems for indwelling catheters

Usage of urinary catheters and their drainage systems increases the risk of urinary tract infection and cross infection (See Section XII.2.h). There is evidence to suggest that catheter associated infections are reduced with the use of closed urinary drainage systems. A randomised controlled trial was reported by Platt et al [119]. This trial compared the incidence of infection (measured as 10^5 cfu/ml in catheter urine or drainage bag urine) between sealed junction catheters and unsealed junction catheters in a hospital setting with a median period of catheterisation of three days. For subjects not taking antibiotics, sealed junctions showed less infection than unsealed (p=0.01). For subjects taking antibiotics there was no difference in infection rates between sealed junctions and unsealed junctions. The infection rate appeared to be consistently lower in the subjects taking antibiotic than the ones not taking antibiotic but no statistical significance tests of this effect were reported.

There is little research to support the common practice of changing drainage bags every five to seven days (or any other particular change regime). The practice appears to be based upon expert opinion, anecdotal evidence and manufacturers' recommendations. Of interest is the study outlined by Keerasuntonpong et al. [120] which was a randomized 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 is no evidence to support the practice of adding *in situ* antiseptic agents to drainage bags to reduce catheter-associated infection. A paper by Thompson et al. [121] which was primarily looking at the effectiveness of hydrogen peroxide instilled into closed drainage bags in reducing infection in drainage bags and in catheters also raises the question of whether catheters are infected primarily via drainage bags or vice versa. This prospective randomised study in a hospital setting involved daily sampling for bacteriuria (See Section XII.2.h for further discussion of outcome measures for catheter-associated infection) in catheters ($>=10^5$ cfu/ml) and drainage bags ($>= 10^3$ cfu/ml) and identifying the infecting bacteria species.

In a sample size of 688, infection was found in 68 catheters and 78 bags. Although bag contamination was 8% in the H_2O_2 group and 16% in the control group (p<0.001) there was no significant difference in catheter bacteriuria (11% and 9%, respectively). One of the reasons given in the paper for questioning whether the drainage bag is the main source of catheter infection was that 77 % of the bags in this study were contaminated later than the catheters.

Best practice guidelines to prevent infections associated with short term indwelling urethral catheters are available. The most recent of these, the EPIC 2 guidelines, were revised in 2005 and reported by Pratt et al. [117]. Designed to prevent short term, indwelling urethral catheter associated infection in NHS Hospitals in England, the guidelines are based upon a series of systematic reviews that include the best available evidence (experimental and non-experimental research as well as expert opinion). These guidelines recommend a closed catheter system where drainage bags are changed according to the manufacturer's recommendations (5-7 days) or the patient's clinical need. The guidelines also recommend that antiseptic or antimicrobial solutions are not added to urinary drainage bags.

The quandary for health professionals involved in the education and support of clients, who are self-managing and often financing their long term indwelling catheter drainage systems while living at home, is that they are aware that many of them are leaving the bags on for much longer than the manufacturers recommend and are often washing the bags out with a variety of solutions and reattaching the bags directly to the indwelling catheter. There is a paucity of studies that have explored long-term self-management of urinary catheter drainage systems in a community setting

Madigan & Neff [122] undertook a literature review (50 studies) that explored the complications and long term management of long term indwelling catheters used for urinary retention and incontinence. Their recommendation in relation to management of drainage bags was that closed drainage systems were preferred best practice. However they also indicated that leg and bed bags may be used for up to four weeks if the system is broken daily to allow daily bag decontamination with a diluted (1:10) bleach solution This recommendation appears to be based on the following two trials, one of which involved 54 participants sampled from an acute care rehabilitation centre and one involving 14 community dwelling participants.

Dille et al [123] report a randomised group parallel study with a pre-test and multiple post-tests utilised to determine the safety of a four week re-use of vinyl leg and bed bags compared to the usual practice of one week when de-contaminated daily with a procedure that utilised dilute bleach (sodium hypo-chlorite). Set in an acute rehabilitation unit, 54 participants (18 female and 36 males) completed the four week data collection period. Randomised by the flip of a coin, 28 participants were in the experimental group and 26 in the control group.

All participants had an indwelling catheter and were using a leg bag during the day and a bed bag at night. Both groups received identical daily bag decontamination and weekly bag and urine cultures. A standard of 0 to 100 cfu/mL was used to measure bag decontamination effectiveness and the urine cultures were processed by the Associated Regional and University Pathologists Inc. No significant differences were found between groups and the authors concluded that it is safe and cost effective to reuse vinyl bags for four weeks as opposed to the previous practice of one week, if the protocol for daily decontamination described is used. This study does not compare the practice of washing out the drainage bags with the chlorine solution either weekly or for a period of four weeks with a closed urinary catheter system to determine if that would result in fewer UTI's.

Rooney [124] reported a study of 14 people with neurogenic bladders living at home. They changed from using daily sterile leg bags to non-sterile leg bags which were washed out after use each day with a dilute chlorine solution. Nine participants were on Foley catheter drainage and five were using sheaths. 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 study ran for three months including a preliminary baseline phase of one month. No comment was made on whether the non sterile bags were changed. There were no symptomatic UTI infections during the study and urine samples with bacteriuria ($>10^5$ cfu/ml) did not increase. However the sample was very small and no statistical tests were applied to the results.

d) Urinary drainage bag features intended to reduce the risk of cross infection

The cross-infection risks of leg bags (particularly via the tap or sampling port) have been studied by Glenister [125] and by Wilson and Coates [109]. In her study Glenister [125] 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 [109] studied sampling ports and contami-nation 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.

A small comparative study of two sets of closed system bags with a double non-return valve and two set of bags with a single non-return valve - all inoculated with Escherichia Coli and using simulated laboratory conditions in two separate microbiological laboratories blinded to each other - found that the colonisation of a simulated bladder was significantly delayed when the double non return valve was used [126].

e) Purple urine bag syndrome

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 [127] 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. There is no evidence to suggest detrimental effects on patients' health or functioning of the drainage system. However, the smell can be very distressing.

Studies which have compared leg bags and catheter valves are reviewed in Section XII.

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 suspension systems 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 high level evidence from studies – predominantly in acute care settings - to support the use of closed urinary drainage systems (Level of Evidence 2).

5. GENERAL POINTS FROM THE LITERATURE, INCLUDING EXPERT OPINION

Provision of clearly presented information based on the best evidence available is needed for clinicians, carers and patients as many aspects of caring for a urinary drainage bag system are supported by scant or conflicting evidence or by custom.

There is agreement that the hands must be cleansed and clean non-sterile gloves put on prior to caring for the urinary drainage bag system and that, on completion of handling the system, the gloves must be discarded and the hands cleansed again [117], [128] .

There is also mention of confusion arising for clinician, patient and carer because of the many different designs of urinary drainage bag taps, and the regularity with which such features are changed [129]. Manufacturers should ensure that the instructions and accompanying literature that they develop for their urinary drainage bag systems are clearly presented and easily understood [129] in a format which is convenient to retain and refer to.

6. RECOMMENDATIONS

- In making urinary 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 Recom-mendation B).

- The patient's individual needs and personal preferences should determine the use of leg / suspension / attachments and position of where the bag is worn (Grade of Recommendation C)

- Maintain closed urinary drainage system for indwelling urinary catheterisation where the system is only broken to change the sterile bag according to manufacturer's recommendation or in a shorter period of time if clinically indicated. (Grade of recommendation A).

7. PRIORITIES FOR RESEARCH

Jones, et al [128] identify many of the issues concerning the handling of urinary drainage bag

systems that require further research, including the issue that has already been discussed above, of how long a closed urinary drainage system can be left unbroken before the urinary drainage bag is changed. Jones et al [128] also suggest research is needed into:

- How often and how drainage bags should be emptied?

- If a closed urinary drainage bag link system is used, does the night bag that is connected to the leg bag need to be sterile or can it be a reusable one?

- If a reusable night urinary drainage bag can be used, how should it be cared for when not in use?

- What is a reasonable method to dry reusable bags after they have been washed?

- To establish whether the incidence of UTI is increased in hospital, community or residential aged care settings when urinary drainage bags in closed drainage systems are changed at different intervals (eg the time of catheter change rather than weekly).

- To determine in own home settings whether a closed catheter drainage system is more effective at preventing urinary tract infections than a reusable non-sterile urinary drainage bag washed out each day with soap and water.

- To determine in own home settings whether a closed catheter drainage system is more effective at preventing urinary tract infections than a reusable non sterile urinary drainage bag washed out each day with a diluted solution of chlorine.

IX. BODYWORN URINALS

1. FEMALE BODYWORN URINALS

Pieper [130] 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 AND DRIBBLE CONTAINERS

The urine collection devices most commonly used by men are sheaths (see Section VIII) 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 IX-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.

They should be fitted by a specialist: a good fit is crucial for comfort and to avoid leakage. It is also important that the wearer / carer understands how to use the device and the importance of skin care. The wearer / carer will need good manual dexterity to manage the device. Several urinals will be needed to use in rotation, allowing each to be properly washed and dried between periods of use.

Dribble pouches are also available for light incontinence (**Fig IX-2**) but there are no published evaluations of these products.

3. PRIORITIES FOR RESEARCH

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.

X. MECHANICAL DEVICES FOR WOMEN WITH URINARY INCONTINENCE

Female mechanical devices are designed to prevent urinary leakage in different ways and fall into three main categories: those that are applied over the urethra at the external meatus; those that are placed within the urethra (intraurethral devices) and those that are inserted into the vagina (intravaginal devices). Both designs of urethral device are intended to occlude the urethra and the intravaginal devices are intended to provide some support to the bladder neck and possibly some compression to the urethra. These devices are also known as occlusive devices and are primarily used for women with stress incontinence. There has been one Cochrane review of these devices [131].

General guidelines on patient assessment for product selection are discussed in Section II. Aspects of assessment that are particularly important regarding mechanical devices are high levels of motivation and acceptability of the concept of use, good cognition and good manual dexterity. They should probably be avoided by those with skin sensitivity or if avoidance of urinary tract infection is a priority.

1. DEVICES THAT OCCLUDE AT THE EXTERNAL MEATUS

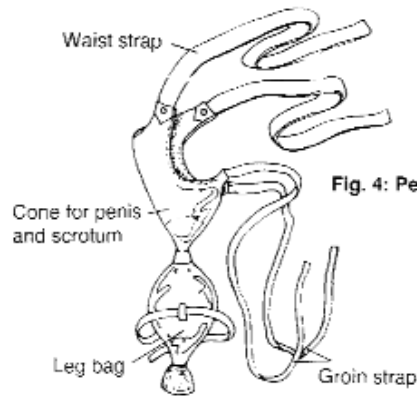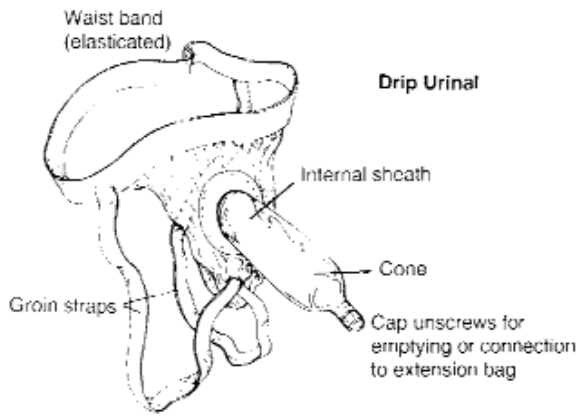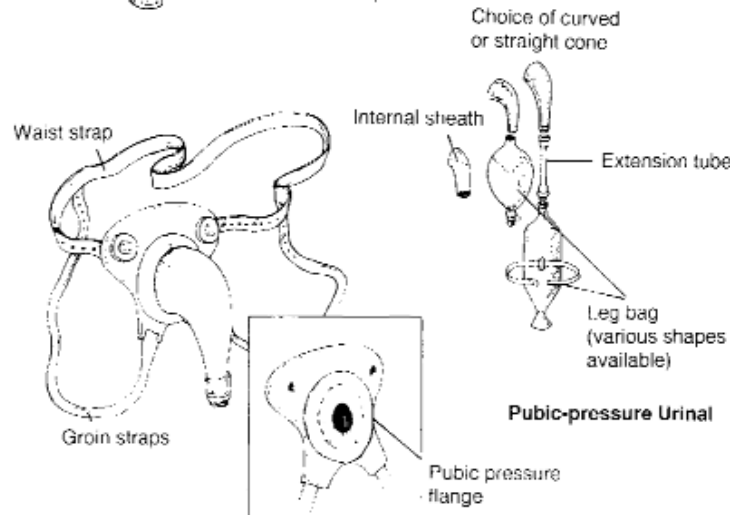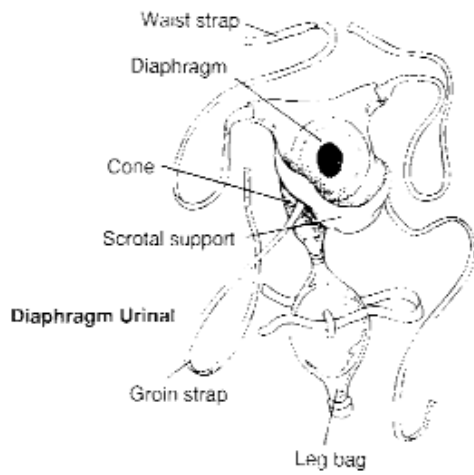Urethral occlusion devices have been developed to

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

Figure IX-2: A dribble pouch.

block urinary leakage at the external urethral meatus (**Fig X-1**). Several devices have utilized either adhesive or mild suction to achieve occlusion. 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 was reusable for one week. CapSure (CR Bard Inc., no longer available) was 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.
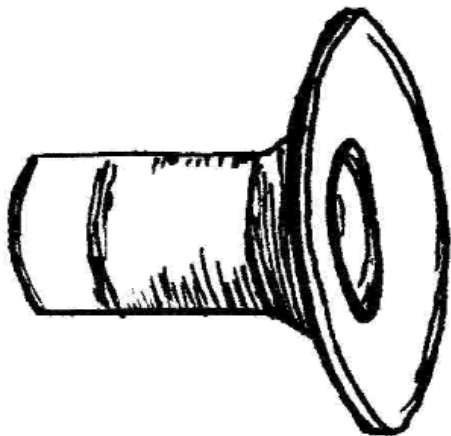
Figure X-1: A female occlusive device that occludes at the external meatus.

a) Quality of data and results

Miniguard: Eckford et al. [132] 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. [133] enrolled 411 women to their study; 390 used the device, and 346 completed the study. Results showed significant improvement in symptoms. The incontinence impact scores significantly decreased from a mean of 41.0 (out of 300 – high scores worse) to a mean of 10.5 at 17 weeks. Twelve hour pad test showed mean urine loss decreased significantly from 15.8 to 6.9 ml and

incontinence episodes from 14.2 episodes per week to 4.9 episodes at week 17. Symptoms of vulvar irritation or lower urinary tract discomfort occurred in a small percentage of subjects but it was generally transient, and only three women discontinued using the device for this reason. There were no statistically significant differences in the proportion of subjects reporting urinary tract infection during device use compared to beforehand. The authors concluded that the device was safe and effective (Level of Evidence 3).

FemAssist: Versi et al. [134] 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<0.0 1) for UDI (Level of Evidence 3).

Moore et al. [135] reported on 57/100 recruited women who completed a one-month trial. Reduction of incontinence was statistically significant on 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 as likely to respond as those with mild or moderate pad test loss. Women with stress, urgency 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. (136) 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.[137] later reported on 41 women recruited to use the device over a three month period, but 10 declined to participate, six withdrew before two weeks, 10 failed to attend two week follow-up and 11 did not attend three month follow-up. Only two 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 non-surgical management of stress incontinence (Level of Evidence 3).

CapSure: Bellin et al. [138] 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).

Shinopulos et al. [139] carried out a multi-centre study enrolling 100 women with stress incontinence who wore the device for 12 weeks. Eighty-four women completed the study. Mean pad weights reduced from 6.7g at baseline to 0.19 by week 12. Complications affected seven patients, including urethral / vaginal swelling and vulval abrasion, but none of the affected patients withdrew from the study. The IQOL tool showed significant mean improvement from 62.3 to 90.4.

b) Summary

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 two-thirds of patients improved, but this data is from open studies (typically pre-test / post-test with no control group) and there have been no randomised controlled trials. 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). The devices tested in these studies are no longer available and there are no external urethral devices currently on the market.

c) Recommendations

Although these devices have proved effective for some women (limited mainly to those with high motivation, manual dexterity and cognitive function), 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.

d) Priorities for research

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 is recommended. One half of patients utilizing these devices in monitored studies were dry and two-thirds 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, for occasional or intermittent use and/or for those who prefer to avoid pads or surgery.

2. 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 (140). These devices have 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 [141]. (**Fig X-2**)

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
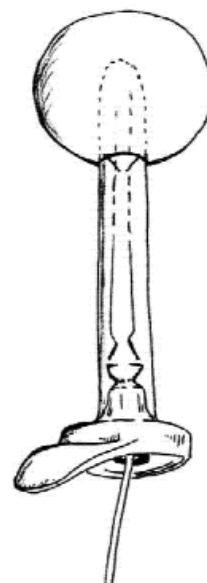

Figure X-2: A female intraurethral occlusive device.

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 [142], Reliance and other intraurethral devices mentioned in this sub-section, are not currently marketed.

a) 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. [142,143] and Peschers [144] studied the Viva device. Peschers et al. screened 53 patients with USI and 21 patients accepted treatment with the two sphere device. During a four month study, the investigators analyzed subjective improvement and performed pad-weight and cough tests. The authors reported that 67% of patients had improvement in symptoms. Nielsen et al. [142] studied forty women who tested two variants of the device (with one or two spheres) each for two weeks in a cross-over study . They then continued with what they judged to be the better plug in period three (two months). Only 45% (18/40) completed this period but almost all (17/18) were reported to be subjectively and objectively continent or improved. Six women developed urinary tract infections and two of these had retained a plug in the bladder.

Staskin [145] 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). Eighty subjects discontinued the device prematurely, mostly because of discomfort and inability or unwillingness to use the device. Miller et al [146] and Sand et al [147] 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 in the study by Staskin et al. [145], and 79% complete dryness and 16% significant improvement on objective pad weight studies consistent with the improvement in subjective diaries (p<.0001) for Miller et al. [146]. In the Miller study the patients reported improved comfort and ease of use over time. Sensation of device presence decreased from 35% at week one to 7% at 12 months. The volume of urine lost during exercise decreased from a median of 20g (range 4.9-80.2g) without the insert to 2.6g (1.3-6.8g) when the insert was worn (p=0.03). On a 5-point scale, in which 1 represented very comfortable and 5 very uncom-fortable, 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 [145]. One or more episodes of gross hematuria (24%), cystoscopic findings of mucosal irritation at four or at 12 months (9%) and asymptomatic bacteruria (30%) on monthly cultures were also documented [146].

Robinson et al [148] carried out a small randomised controlled trial comparing the NEAT device (intra-urethral device with expandable tip) with the Reliance device. Twenty-four women (mean age 51 years) entered the study and there were eight withdrawals. Devices were randomly allocated and tested for four months. Improvement was reported for 6/8 women (NEAT) and 5/8 women (Reliance) when compared to baseline. There were no significant differences in the number of women improved, in mean reduction in urine loss, or in leakage scores between the two groups.

Boos et al. [149] 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 the FemAssist and 49 to the 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. [140] measured pad weights during four standardized aerobics sessions during which six subjects were randomly assigned to exercise twice with the insert and twice 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 three 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 versus 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).

b) 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 [133] 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 clinician acceptance of this form of therapy has also been limited and there is currently only one intraurethral device on the market. High cost is also a factor that probably precludes more widespread application but 'occasional' use, for example during exercise may be helpful and affordable for some

patients. Good hand dexterity is necessary to use the device (Level of Evidence 3).

c) 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).

d) Priorities for research

It is important that new devices - particularly invasive ones - are 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. In particular assessment of their cost-effectiveness and effects on quality of life, when used intermittently or for particular activities, is recommended.

3. INTRAVAGINAL DEVICES

Support of the bladder neck to correct urinary stress incontinence has been achieved, with varying success, utilizing traditional tampons, pessaries and contraceptive diaphragms, and intravaginal devices specifically designed to support the bladder neck.

a) Quality of data and results

1. TAMPONS / PESSARIES

Nygaard [150] 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).

2. DIAPHRAGMS / PESSARIES

Realini et al, [151] 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 the amount of urine lost during pad tests, number of leaks per week, and overall assessment response (Level of Evidence 3).

Suarez et al. [152] 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%) but two of them 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. [153] 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, three 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.

3. 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. Single-use disposable devices: (i) 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 urethrovesical junction (originally called the Conveen Continence Guard, now known as Contrelle Activgard); (ii) A version of the expanding polyurethane design, with similarities to a tampon, (Conveen Continence Tampon, Coloplast, Denmark (no longer available) (**Fig X-3**); (iii) An expanding polyvinyl alcohol sponge (Ladycon, Home Care Engros, Norway); (iv) a simple surgical foam cylinder with drawstring e.g. Rocket stress incontinence device (Rocket Medical PLC)

4. Reusable intra-vaginal ring (Introl)

A pilot laboratory study was carried out by Biswas [154], the developer of the device, employed a straining cystogram. Eighty-six percent of the patients were continent with the device in place on cystogram. Following this study, the number of device sizes was increased from eight to 25. Evaluation studies followed examining efficacy, safety and satisfaction. Davila
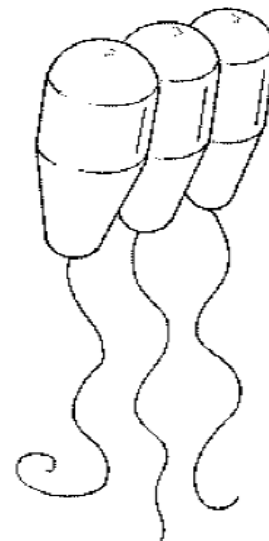
Figure X-3: A female intravaginal occlusive device.

[155] initially demonstrated that 83% of patients were dry on pad weight test. Later [156] the researchers enrolled seventy women (53 completed) aged 24-76, 29 with stress, and 24 with mixed incontinence in a one 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 included five urinary tract infections and 23 cases of vaginal soreness or mild irritation (Level of Evidence 3).

Moore et al. [157] 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 19g to 2g (p<0.001), 62% were continent, and 15% were >50% improved, and wished no further therapy. Moore et al. 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.[135], 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. [158] 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).

5. DISPOSABLE INTRA-VAGINAL DEVICES

Thyssen et al. [159] tested the Continence 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. [160] reported on 19/22 women with stress incontinence, subjectively 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. [161] 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

Hahnet al. [162] 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.[163] reported on 94 women recruited in a cross-over study, which compared two versions of the same device; the Conveen Continence Guard (CCG) and the Contrelle Continence 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 [164] 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 7g (range 2-18g) during exercise. With the vaginal sponge *in situ* there was no leakage.

There has been a recent report of a novel disposable intravaginal device (ConTIPI ltc. Israel) which may come to market. This device has a resin core with support 'poles' covered with a soft nylon mesh that stretches between the arms of the poles to act as a suburethral sling. Ziv et al. [165] recruited 60 women with severe stress incontinence to test the product. A seven day 'control' period was followed by a 28 device usage period.

There was no control arm or comparison product. Pre-weighed pads were used during the test period and the primary end point was the percentage of women achieving at least a 70% reduction in pad weight gain from the control period to the last 14 days of usage. Ten women withdrew from the study during the test period, four for device related reasons. Using intention to treat analysis 85% of women achieved at least 70% reduction in pad weight gain. The most common adverse events reported were mild and included genital tract discomfort, pain and spotting with blood; the only report of a moderate event was of candidiasis. The authors conclude that the device is easy to use, well-tolerated and effective. Further evaluation will be needed.

b) 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, but the evidence is limited. (Level of Evidence 3).

Studies performed in the acute setting, regardless of the device type, demonstrate better performance than diary based studies performed over time. Efficacy appears to be 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, but may also indicate limitations in product efficacy, difficulties in application or other factors such as discomfort (Level of Evidence 3).

c) Recommendations

Vaginal support devices may be considered as a 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).

d) Priorities for research

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

4. OVERVIEW OF MECHANICAL DEVICES WOMEN

a) Overall summary

The recent Cochrane review of mechanical devices for urinary incontinence in women [131] review found only six trials that met their criteria and concluded that the role of such devices is questionable. The authors state that there are indications that using mechanical devices might be better than no treatment but that the evidence was weak and that there was insufficient evidence to recommend any specific device or to show that mechanical devices are better than other forms of treatment.

In this section we have attempted to review all available evidence including many trials that did not meet Cochrane criteria. Most trials were open pre-test post-test trials with no comparators and the strength of this evidence is relatively weak. Although most trials showed positive effects on symptoms, this was often combined with relatively high drop-out rates and unwanted effects, such as discomfort, skin irritation or urinary tract infection.

Although many products have appeared on the commercial market, few have stood the test of time and are currently marketed – there are no external urethral devices available and there is only one intra-urethral device. There are at least two intra-vaginal devices available on the market and these may have potential to be more acceptable to women because of their similarities to familiar tampons. The relative lack of market success for these products may indicate low efficacy and unwanted effects, but may also reflect their relatively high cost compared to pads which are the main alternative.

b) Overall recommendations

It is possible that some of the mechanical devices currently marketed are effective and acceptable to a minority of women and, given that they are relatively non-invasive (with the exception of intra-urethral devices), they may be suggested to patients for consideration and testing, particularly for short-term or occasional use.

c) Overall priorities for research

The substantial withdrawal rate and the frequency of unwanted events indicates that that there is a need to establish efficacy of these devices (compared to no treatment) over longer time periods (more than a year), with careful identification of unwanted effects.

There is also a need to compare devices with simple, cheap devices. The Cochrane review recommends an intravaginal tampon as a suitable comparator.

There are indications that the devices may best be used occasionally or intermittently for specific activities and there is a need for this type of use to be tested, possibly compared to the most common alternative - an absorbent pad.

As these devices aim to prevent urine leakage there is also potential for testing their efficacy compared to other treatments such as pelvic-floor exercises or surgery.

XI. MECHANICAL DEVICES FOR MEN WITH URINARY INCONTINENCE

Male mechanical 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 XI-1**). Such devices have the potential advantages of low cost and simplicity compared with a sheath and drainage bag. However there is potential for tissue damage and these devices should be used with caution.

Careful assessment is necessary for use of these devices because there is potential for damage to the penis from ischaemia (restriction of blood to the penis).
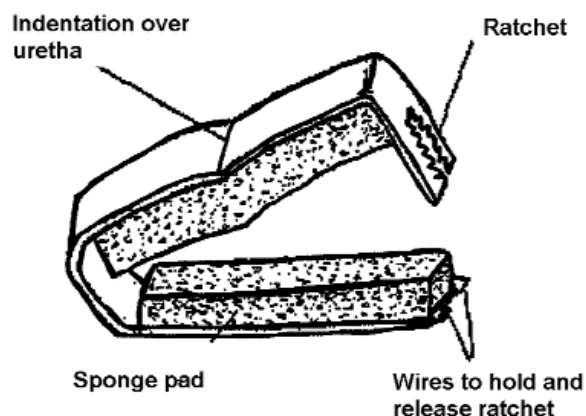
Figure XI-1: A penile clamp.

Such devices should be fitted by a trained health professional and subject to regular review. Use should be limited to men who are assessed as being cognitively intact, are aware of bladder filling, have normal genital sensation and intact penile skin, have sufficient manual dexterity to open and close the device (Moore 2004) and are motivated and willing to use such a device.

1. QUALITY OF DATA

The use of penile compression devices is described only rarely in the literature (166); (167) 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 (168).

2. RESULTS

Moore et al. [168] evaluated three different devices (Timms C3 penile compression device; Cunningham clamp; and U-Tex 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 Moore et al. concluded that, used correctly, the Cunningham clamp can be an effective method of controlling urinary incontinence (although it should be noted that complete control i.e. no leakage, was not achieved) 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.

Expert opinion and anecdote suggest that penile clamps may be more successful when used for short periods, for example when undertaking activities such as swimming or jogging. Such activities may not only exacerbate incontinence but also preclude the use of bulky and / or absorbent products.

3. SUMMARY

Male mechanical devices can partially control urinary leakage (but not eliminate it at comfortable levels of use) but are 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).

4. RECOMMENDATIONS

- Male mechanical devices may 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 (B).

- The devices should be fitted by a trained health professional and reviewed regularly (Grade of Recommendation C).

- The devices may be considered for short-term use when undertaking sport or other activities, as an adjunct to management with other products (Grade of Recommendation C).

5. PRIORITIES FOR RESEARCH

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

XII. 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, where alternative strategies are unsuitable or unsatisfactory. However, indwelling catheters are rarely completely trouble-free and the risk of catheter-related complications is high, with substantial detrimental impact on patients, carers and healthcare services. It is generally agreed that catheter use should be avoided wherever possible and only adopted for those in whom alternative strategies are unsuitable or unsatisfactory, after careful assessment of the patient and their particular problem [169].

This section examines the characteristics of urinary catheters, and provides a critical review of existing evidence to guide decision-making on choice of catheters, equipment and management strategies to minimise associated risks. Specific issues relating to short-term catheterisation are addressed, but the main focus of the section is on long-term management of bladder dysfunction, by intermittent catheterisation (least invasive) or indwelling catheterisation (most invasive). An overview of factors influencing choices of catheterisation strategy is provided in **Table XII-1**. Detailed discussion of key issues is provided under the following headings: user characteristics, catheter characteristics, associated risks / problems, catheter management.

The bulk of research evidence on catheter use relates to short-term catheterisation. In particular there are numerous trials which focus on catheter-associated urinary tract infection since this is well recognised as a major source of healthcare associated infection. The quality of data is very variable and many studies are limited by being underpowered and by other design issues, including poorly defined outcome criteria and highly selected study populations. Much less research has addressed intermittent or long-term indwelling catheter-related issues and guidance to healthcare practitioners remains largely based on expert opinion. Some of the difficulties in conducting research on use of continence products are discussed in Section III. Further discussion related specifically to catheters is provided within the following sections (**Table XII-1**).

1. INTERMITTENT CATHETERISATION

Intermittent catheterisation (IC) is the act of passing a catheter into the bladder to drain urine via the urethra, or a catheterisable channel such as a Mitrofanoff diversion. The urine can be drained into a toilet, urinal, plastic bag, or other reservoir. The catheter is removed immediately after drainage. This technique avoids many of the problems associated with indwelling catheters. Intermittent catheterisation may be carried out using a sterile technique in some care settings, but clean intermittent catheterisation (CIC) or clean intermittent self-catheterisation CISC [170] is widely accepted as a safe technique for people who are self-caring in their own homes. Since some studies do not distinguish between CIC and CISC, the term CIC has been adopted to cover both throughout the following section. CIC provides much greater convenience than urethral catheterisation, without unacceptable increases in infection rate, and has become a method of choice for management of bladder drainage for neurogenic and non-neurogenic bladder dysfunctions where urinary retention is a significant symptom and not easily remedied by other relatively simple means, eg TURP for prostatic obstruction. CIC can be taught to people of all ages, including the very elderly and children as young as four years old, with parental supervision [171,172] CIC

can also be taught to carers, where this is an acceptable procedure to both patient and carer.

a) Quality of data

The majority of research evidence on intermittent catheterisation relates to catheter-associated urinary tract infection (CAUTI) and catheter materials and coatings. The most frequent complication of CIC is urinary tract infection (UTI) but it is unclear which catheter types, techniques or strategies, affect its incidence. There is wide variation in practice and important cost implications for using different catheters, techniques or strategies. Two relevant Cochrane reviews were identified; 'long-term bladder management by intermittent catheters in adults and children' [173]; and 'urinary catheter policies for long-term bladder drainage' [174]. The objective of the first review was to examine which intermittent catheter types, techniques or strategies, affect the incidence of UTI. Fourteen trials were included but sample sizes were small and attrition of participants was problematic. Definitions of outcome variables and follow-up periods differed, making it difficult to draw clinically useful conclusions. Several of the trials were more than 10 years old and were typically less rigorous in design and analysis. The authors concluded there is insufficient evidence to state that incidence of UTI is affected by use of sterile or clean technique, coated or uncoated catheters, single (sterile) or multiple use (clean) catheters, self-catheterisation or catheterisation by others, or by any other strategy. The objectives of the second review [174] were to determine if certain catheter policies are better than others in terms of effectiveness, complications, quality of life and economics. Comparisons included type of catheterisation (intermittent, indwelling urethral and indwelling supra-pubic) and antibiotic prophylaxis. Seven trials were included but all were small and confidence intervals were wide. There was limited evidence which indicated that prophylactic antibiotic therapy was associated with reduced episodes of bacteriuria (asymptomatic and symptomatic) in subjects using intermittent catheterisation. In both reviews, the trials which met the inclusion criteria were limited by small sample sizes and methodological weaknesses. A third review on 'catheter policies for management of long-term voiding problems in patients with neurogenic bladder' [175], which aimed to assess the effects of different types of urinary catheter (IC): in managing the neurogenic bladder, found there were no trials that met the inclusion criteria. Other research in this area is dominated by retrospective reviews of bladder management outcomes of patient cohorts. Long-term follow-up studies are almost exclusively of patient groups with neurogenic bladder disorders. Small scale, comparative studies of new products are common and are often industry-sponsored. Quality of life issues are vitally important for continence product users but studies are often limited by outcome

Table XII-1. Catheter choices. Catheters should only be considered where there is no satisfactory, non-invasive alternative to manage bladder drainage.

| Product category | User characteristics / priorities / contexts which: | | Notes |
	FAVOUR use	DISCOURAGE use	
Intermittent catheters (IC)	• If more than 100ml retained in bladder (C) • Concept of IC acceptable to user (or carer) • User has sufficient dexterity and cognitive ability to manage regular drainage	• In general (as with all catheters), where alternative, non-invasive management is satisfactory • If user lacks motivation or unable to cope with regime	• See Section XII.1 • Greater independence for users • No need for urine collection bags • Reduced risk of catheter-associated complications • Greater freedom for sexual activity.
Long-term indwelling catheters (LTC): general	• Only for voiding problems which cannot be managed satisfactorily by other strategies (pads, other products or IC) (A) • User or carer able to empty drainage bag regularly	• In general (as with all catheters), where alternative, non-invasive management is satisfactory • Avoidance of UTI is a priority (A) • Cognitive impairment (danger of interfering with catheter) (C) • High risk of recurrent catheter encrustation & blockage (B)	• See Section XII.2 • May be required: (i) to drain the bladder where there is urinary retention; (ii) to improve care of for those with severe incontinence who cannot manage otherwise, are terminally ill, or need secure urine drainage to heal skin lesions / wounds affected by the presence of urine
LTC: urethral insertion	• Concept is acceptable	• History of urethral trauma • Haematuria of unknown origin • High risk of catheter being expelled (bladder spasm)	
LTC: supra-pubic insertion	• Concept is acceptable	• Haematuria of unknown origin, • Bladder tumour • Small, contracted and fibrotic bladder • User is obese	
Short-term indwelling catheter	• Post-operative controlled drainage • To monitor urine output • To irrigate the bladder • To instil medication • To relieve retention of urine	• In general (as with all catheters), where alternative, non-invasive management is satisfactory • Avoidance of UTI is a priority (A)	

measures predominantly based on user satisfaction, in the absence of clear criteria. Few studies have directly compared CIC with other methods of bladder drainage.

b) User characteristics:

CIC is a commonly recommended procedure for people with incomplete bladder emptying not satisfactorily managed by other methods. CIC can be appropriate for post-void residual urine volumes of 100ml or more in:

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

- Patients with difficulty emptying the bladder after surgical procedures, if outflow obstruction occurs either in the short or long-term.

- Patients who accumulate a build up of residual urine caused by detrusor overactivity and inadequate bladder emptying.

- Acute urinary retention (most commonly in men).

- Management of urethral stricture.

- Emptying the bladder following continent urinary diversions such as a Mitrofanoff diversion.

CIC may be a practical option for patients who are:

- Sufficiently motivated to manage their 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 [176].

- 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.

- Unable to perform the technique themselves but willing to accept the procedure from a carer.

Most men require some form of lubrication to aid catheterisation, which can be on the catheter surface or instilled into the urethra [177] (Level of Evidence 3). For those with preserved urethral sensation, a local anaesthetic gel may be needed. Many female patients also use a catheter lubricant / anaesthetic gel although some choose not to. In developing countries, where resources are limited (or sometimes through patient choice), patients sometimes use plain water as lubricant [178] (Level of Evidence 4).

Regular bladder drainage is important to avoid potential damage to the upper urinary tract from urine reflux and raised intravesical pressure from build up of residual urine. Patients require individualised care plans to help identify appropriate catheterisation frequency, based on discussion of voiding dysfunction and impact on quality of life, frequency-volume charts, functional bladder capacity, and ultrasound bladder scans for residual urine. Some people need to catheterise several times per day, others less frequently. Catheterising frequently enough to avoid residual urine greater than 500ml is a general rule for adults but further guidance is also provided by urodynamic findings, detrusor pressures on filling, presence of reflux, and renal function. 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 [176]. Lack of motivation is the most common reason for failure, often linked to difficulty managing the technique or adhering to the required regime.

Children at school need a multi-professional assessment which may include a continence advisor, paediatric community nurse or school nurse, 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 [179]. Intermittent catheterisation has also been shown to be an effective technique for elderly patients with post-void residuals more than 50% of the bladder capacity, resistant to other treatment [180]. In a group of 21 patients (mean age 76.5 years), 12 mastered the technique of CIC, with the remainder catheterised by their partners or nurses. Urinary continence was restored, urgency, frequency and nocturia decreased and UTI rate diminished, resulting in improved quality of life.

Advantages of intermittent over indwelling catheterisation include:

- Greater opportunity for individuals for self-care and independence.

- Reduced risk of common indwelling catheter-associated complications.

- Better protection of the upper urinary tract from reflux.

- Reduced need for equipment and appliances e.g. drainage bags.

- Greater freedom for expression of sexuality.

- Potential for improved continence between.

c) Catheter characteristics

Types and characteristics of catheters used in intermittent catheterisation vary considerably so evaluation and selection of products is complex [173].

Plain uncoated catheters (typically clear plastic PVC) are packed singly in sterile packaging. As per industry standards, all disposable catheters are intended for one time use but PVC catheters are frequently cleaned and reused by individual users because of cost or concern about environmental issues. 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 limited period of time, such as one week). Where products are used in ways which differ from manufacturers' guidance, both patients and health care professionals should recognise their personal, professional / legal responsibilities. In some countries, including the US, there are very clear governmental directives that catheters identified as single-use devices should not be re-used in any setting. US patients should be provided with an adequate number of catheters to use a sterile catheter for each catheterisation, and patients and carers must be informed that catheters are identified for single use only.

Most uncoated intermittent catheters are used with separate lubricant, although this is a matter of personal choice. Cleansing for re-use (where this occurs) varies from being washed with soap and water, boiled, soaked in disinfectants, or microwaved. Cleaned catheters are air dried and then stored in a convenient container (often plastic containers / Zip loc bags or paper bags). Metal catheters made from silver or stainless steel can be sterilized by heat or chemicals and may be used repeatedly for longer periods than other reusable materials.

Coated catheters are single use only (they are not currently suitable to be cleaned and reused) and are designed to improve catheter lubrication, ease of insertion and convenience. Coated catheters may reduce urethral trauma and CAUTI although good quality research evidence remains limited. The most common coatings are hydrophilic (which require the addition of water to the catheter to form a lubricious layer) or pre-lubricated (whereby the catheter is supplied pre-packed with a coating of water soluble gel). There are also several pre-lubricated products with an integrated collection bag (all-in-one) which gives flexibility for the user and are efficient for hospital use.

Intermittent catheters range in size from 6-20 Ch, with most common sizes being 10-12 for females and 12-16 for males (**Fig XII-1**). Intermittent catheters are generally around 40cm long (male length) and are more rigid than indwelling catheters to aid insertion. A variety of aids to assist catheterisation are available (**Fig XII-2**).

Some women find a stiffer catheter easier to handle and some designs are slightly curved and made only in female length (around 18cm) to accommodate their
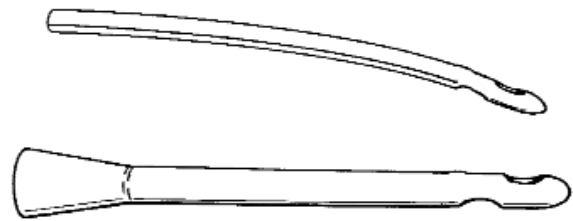
Figure XII-1: Examples of catheters for intermittent catheterisation: Scott (top) and Nelaton (bottom).
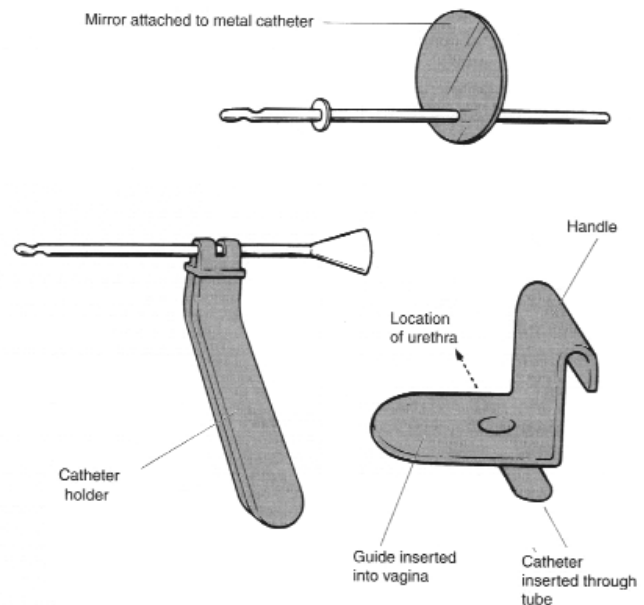
Figure XII-2: Examples of catheters for intermittent catheterisation: Scott (top) and Nelaton (bottom).

requirements. 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. Catheter designs may include a protective tip to help reduce the transfer of bacteria from the distal region of the urethra further into the bladder. Patients should have the opportunity to try different catheters and choose which best suits their needs and lifestyle. Different catheters / packs may be appropriate at different times e.g. when added convenience for quick and efficient use and disposal is important, such as going to work or on holiday.

An effective intermittent catheter should have the following characteristics:

- Smooth for comfort, but sufficiently firm for easy insertion and maintenance of lumen patency.

- Minimal friction on insertion or removal.

- Smooth 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.

Although there is an increasing range of intermittent catheter types on the market - including many pre-lubricated products with integrated collection bags - the quality of evidence for clinical benefit is poor. De Ridder et al [181] conducted a prospective, randomised, parallel, comparative trial of a hydrophilic coated catheter with an uncoated PVC catheter with 123 male spinal cord injured (SCI) patients. Only 57 completed the 12 month study but fewer patients with the coated catheter experienced one or more symptomatic UTIs (p=0.02). There was no difference in haematuria, leukocyturia and bacteriuria. However a recent Cochrane Review [173], concluded that overall current research evidence is weak, most studies are underpowered and conclusions are limited by serious design issues. An earlier literature review (182) also indicated the wide variety of materials and techniques used for intermittent catheterisation. It 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.

d) Associated risks / problems

Urinary tract infection is well-recognised as the most frequent complication of intermittent catheterisation [173;182]. The accumulation of urine in the bladder provides a reservoir for infection, but it has also been proposed that the increased intravesical pressure reduces the vascular supply to the bladder tissue rendering it more susceptible to bacterial invasion [183]. A post-void residual urine volume of 150ml has been demonstrated to be an independent risk factor for the development of UTI, in stroke patients [184] (Level of Evidence 2).

In Wyndaele's review of complications of intermittent catheterisation (82 studies), prostatitis was identified as a risk in men but epididymitis and urethritis were relatively rare [182]. Trauma from catheterisation, measured by haematuria, 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 review concluded that the most important preventative measures are good education of all involved in CIC, good patient compliance, use of an appropriate catheter material, good cathe-terisation technique and the avoidance of bladder over-filling. Similar findings were reported by Campbell [185] in a follow up of children with spina

bifida who had used intermittent catheterisation with uncoated PVC catheters for at least five years. The incidence of urethritis, false passage, or epididymitis was very low whilst adherence to the protocol was excellent. However, Ku et al [186] found a higher incidence of epididymitis in their cohort review of 140 male, SCI patients followed over 16 years.

1. Urinary tract infection

It is difficult to know the prevalence of UTI associated with intermittent catheterisation as reports vary widely and definitions of UTI are inconsistent, sometimes based on bacteriuria alone (asymptomatic) and sometimes on symptomatic UTI (with or without clearly defined criteria). Other variations include the evaluation methods used, catheterisation techniques, frequency of urinalysis / culture, administration or not of prophylactic antibiotics, and the patient group studied (including gender, functional ability, behavioural and personal hygiene factors). In a prospective study of 128 SCI patients, where the incidence of UTI was calculated as the number of episodes per 100 person-days, the overall incidence of UTI was 0.68. The rate for males using CIC was 0.41, compared to 2.72 for those using an indwelling catheter [187]. Biering-Sorensen et al. (188) 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 per year. The technique of intermittent catheterisation used does not seem to be a risk factor and despite different catheterisation techniques used, the number of episodes of clinically significant nosocomial urinary infections and the mean species turnover remains similar [189] (Level of Evidence 2).

In the Cochrane review cited above [173], the primary outcome measure was catheter-associated infection (definition of infection as used in the trial reports). Fourteen trials met the inclusion criteria but too little data could be entered into a metanalysis to produce meaningful data summaries. Based on the available data, the authors concluded that there appeared to be no clear difference between various methods of catheterisation (sterile catheterisation techniques, clean catheterisation with a single-use sterile catheter, or clean catheterisation with a clean reused catheter). Whilst the outcomes of this review raise questions over efficacy and cost-effectiveness of expensive coated catheters it is clear that further robust research is needed. All sample sizes in the trials were small and only two included statistical power calculations, although they were unable to achieve their predicted sample sizes. Most studies suffered from high attrition rates and several reports were more than 10 years old.

The challenges of obtaining sound data in this clinical area continue to hinder the accumulation of evidence to help guide healthcare practitioners. A common difficulty is in the establishment of robust outcome

measures. UTI remains the most clinically important primary outcome variable but bacteriuria/ positive urine culture is not clinically relevant unless accompanied by symptoms. Symptoms themselves may present in vague and imprecise ways, especially in elderly and/or SCI patients where symptoms can be masked or unclear.

A Cochrane review on urinary catheter policies for long-term bladder drainage [174] reported limited evidence that prophylactic antibiotic therapy was associated with reduced episodes of bacteriuria (asymptomatic and symptomatic) but all trials were small and confidence intervals were wide. The authors caution that possible benefits from prophylaxis must be balanced against possible adverse effects such as the development of antibiotic resistant bacteria.

In order to improve rigorous clinical evaluation of current and innovative products for CIC, more epidemiological data on user populations and characteristics of catheter use is needed. A recent Canadian national survey of intermittent catheterisation practices following SCI [190], reported on 912 responses to a 36-item self-report postal questionnaire. Fifty five per cent of respondents used intermittent catheterisation regularly, with users forming a significantly younger group than non-users (P=0.001). The majority of users (73%) used a clean technique. The remaining 27% reported using a sterile technique. Uncoated catheters were used most commonly; 74% only used uncoated catheters; 15% used hydrophilic coated catheters; and 11% reported using both types. These notable differences may be partially related to patient education, costs to patients and health insurance funding constraints. The majority of uncoated catheter users used their catheter only once (53%) but a further 30% used their catheter more than nine times. The mean frequency of self-reported CAUTIs in the past 12 months (symptomatic but not necessarily confirmed by laboratory evidence) was 2.6, with females experiences significantly more infections than males (P=0.003). Although the use of hydrophilic coated catheters was associated with a lower rate of CAUTI (2.46 v 2.62 for those using uncoated catheters), this difference was not reported as statistically significant. However UTI rates are multi-factorial and are unlikely to be fully accounted for by the variables investigated. A significant relationship between number of catheterisations per day and CAUTI rates was identified, with those who catheterised only once a day having the highest rate of infections (P=0.03). This is consistent with previous suggestions that increasing the time that colonised urine is present in the bladder is associated with increased infection rates [181]. It is interesting to note that, while extra fluid intake was positively related to reduced rate of CAUTI (P=<0.001), catheter re-use, catheter disinfection and antibiotic prophylaxis were not significantly associated with CAUTI rate. Clearly

there are potential limitations in this study as with any which employs self-report methodology. These include self-selection of respondents, accuracy of recall and quality of information provided, but the large number of respondents and the degree of internal consistency reported by the researchers provide creditability to these results.

Several studies have sought to determine whether the antibacterial effects of cranberry extract will reduce or eliminate bacteriuria and pyuria in patients using intermittent catheterisation, particularly in SCI populations [191,192]. In a randomised, double-blind, placebo-controlled study of 48 SCI patients living in the community and using intermittent catheterisation or external urine collection device, participants ingested 2g concentrated cranberry extract in capsule form or placebo daily for 6 months [192]. There were no differences between groups with respect to number of urine specimens with bacterial counts >10^4cfu/ml, types and numbers of different bacterial species, numbers of urinary leukocytes, urinary pH, or episodes of symptomatic infection.

2. TISSUE TRAUMA, STRICTURES AND OTHER COMPLICATIONS

Long-term follow-up studies have examined other complications associated with intermittent cathe-trisation and found urethral trauma to be common [193,194]. Urethral bleeding is frequent in new patients and has been noted to continue to occur in up to 30% on a long-term basis [194,195], however risks of tissue trauma may be reduced with newer catheter products which are designed to reduce friction. Consequently the outcomes of older studies need to be considered with caution. The withdrawal frictional force was compared between two hydrophilic coated catheters and one uncoated catheter in a prospective, randomised, participant-blinded, crossover trial by Stensballe et al [196]. Forty participants completed the study and it was interesting to note that while one coated catheter (SpeediCath) exerted a lower mean withdrawal force than the other catheters, the second coated catheter (LoFric) exerted a significantly higher mean friction force than both the other catheters. Both hydrophilic coated catheters were associated with less microscopic haematuria than the uncoated catheter. Similarly, there was a lower incidence of microscopic haematuria reported in two of the coated catheter groups compared to uncoated catheters in trials included in the Cochrane review [173]; 0.31v 0.65 [197]; 6/14 (43%) v 11/14 (78%) (198). Trauma of the urethra, especially in men, can cause false passages. Treatment for false passages in SCI patients by six weeks indwelling catheter use and five days antibiotics, has been reported to be effective [199] (Level of Evidence 3). The false passages had disappeared on cystoscopy and CIC could be restarted.

It has been claimed that the long term risk of urethral

stricture formation may be less when hydrophilic coated catheters are used [200]. The degree of urethral inflammation, measured by urethral cytology in two groups using CIC (one using ordinary PVC catheters with lubricant; the other using hydrophilic coated catheters), showed significantly less urethral inflammation in the hydrophilic coated catheter group. Although this data suggests some benefit in using hydrophilic coated catheters to minimise stricture formation in the long-term comparative studies are limited. One recent follow-up study of 31 females with spina bifida, using CIC for a median of 15 years, examined risk of urethral lesions. There were few problems reported (only on 20 occasions in a total of 459 patient-years), despite long-treatment periods and use of non-coated PVC catheters [201].

The relative importance and cost-effectiveness of hydrophilic catheter coatings has not been adequately addressed in large scale studies to date. Hedlund et al. [202] in their review of 28 CIC studies, called for a prospective, randomized, long-term, multi-centre study to address clinical benefit and cost effectiveness. Data on patient characteristics should include age; gender; diagnosis of bladder dysfunction; reason for CIC; physical and mental disability; manual dexterity; and previous treatments. Effect parameters should include number of catheterisations; urinary tract infection (symptomatic or asymptomatic); early and long-term urethral complications; patient satisfaction, preferences; and drop-out rates. Robust studies of this nature are still awaited.

3. Other complications

Formation of bladder stones has been found to be associated with long-term use of CIC in a number of studies [203] (Level of Evidence 2). Barroso et al. [204] 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). A retrospective study of 140 SCI patients, followed up from 1987 to 2003, identified 27.9% of patients diagnosed with epididymo-orchiditis. This problem was more common in patients using CIC compared to indwelling catheterisation (42.2% v 8.3%, P= 0.03). Multivariate analysis showed CIC to be an independent risk factor for epididymo-orchiditis, with SCI patients in this study subject to a 7-fold higher risk (OD 6.96; 95%CI, 1.26-38.53 [186].

e) Catheter management

1. Education, support and quality of life (QoL)

Good education of all involved in CIC, good patient compliance, use of an appropriate catheter material, and good catheterisation technique have been identified as the most important measures to prevent adverse complications [182]. Factors affecting adherence to self-catheterisation procedures have been explored, addressing both initial mastery of technique and both short-term adherence and long-term adherence [205,206]. Time taken to build confidence is variable and may range from days to years [206]. General determinants of adherence related to knowledge, complexity of the procedure, misconceptions, fears, shame, motivation, quality and continuity of professional care. Integration of the CIC regime into everyday life was a recognised difficulty and for younger patients, in particular, availability of materials, physical impairments and resistance to 'sickness role' were factors which could also compromise adherence. Qualitative research studies using a grounded theory approach have identified similar factors influencing variations in quality of life (see also Section XII.4).

These include sex; lifestyle; frequency of duration of carrying out CIC; technical difficulties; type of catheter; co-morbidities; and individual predispositions [207]. In the large scale Canadian survey above (190) 71% reported that CAUTIs had negatively impacted on their QoL score (a 10-point scale). Severable significant variables associated with CAUTI and QoL were determined. Interestingly, time lost from social activities was more strongly associated with compromised QoL than actual number of infections or days lost from work.

2. Catheter cleaning for re-use

Where catheters are cleaned for re-use they may continue to be used many times, up to weeks or even months. However, health professionals and users need to recognise their personal responsibilities and liabilities in supporting this approach since manufacturers' guidance will normally relate to single use only (see also Section XII.1.3). Questions over how long the same catheter may be safely reused require further examination, and may be particularly important in developing countries, where access to new supplies may be limited [208].

Methods of cleaning or re-sterilising include soaking in a variety of antiseptic solutions or boiling water or microwave sterilisation. In a study which compared three home cleaning methods used by patients performing CIC, all of the following were found 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 [209]. None of the cleaned catheters showed detectable bacterial growth for 48 hours after the cleaning procedure was performed (Level of Evidence 4). Lavallee et al. [210] 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.

Table XII-2. Intermittent catheterisation

Patient education & support:

- Discussion of individual bladder dysfunction and reasons for CIC.

- Personal anatomy and identification of urethral orifice.

- CIC technique – comfortable position, frequency, observation of patient's technique.

- Hygiene.

- Discussion of any psycho-sexual anxieties (body image, sexual function etc).

- Single use versus reusable catheters (cleaning, storing, re-use, disposal). NB including awareness of personal / legal issues.

- Difficulties and what to do.

- Dietary advice and avoidance of constipation.

- Obtaining supplies.

- Follow-up visits and consultations.

Guidance for common problems:

- Catheter will not go in at first attempt – relax for a while and try again a bit later; lubricate catheter (eg dipping in water or gel); if necessary seek professional guidance.

- Catheter inserted into vagina by mistake – withdraw, wash and re-insert.

- Catheter will not come out – leave for a few minutes, relax and try to 'let go', cough gently and withdraw catheter.

- UTI – report changes in urine (eg blood, sediment, smell). Know how to recognise signs of symptomatic infection and seek treatment and review of CIC technique.

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. [211] 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 a high setting for six minutes on a rotation table was recommended together with a heat sink – a cup of water in a microwave-safe container 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. If microwaving is to be accepted as an appropriate sterilization method then users must be provided with a standardised, evidence-based, protocol to follow. A recent study reported the development of titanium dioxide-coated catheters for CIC which were easily sterilized under certain light sources and were shown to be safe in experimental studies [212]. Preliminary clinical analysis with 18 volunteers was also promising.

f) Comparisons between intermittent and indwelling catheterisation

A systematic review of risk factors for UTI in adults with SCI reported evidence of fewer infections in patients using intermittent catheterisation compared to indwelling catheterisation (213). Twenty two studies met the inclusion criteria for evaluation but the authors noted that many had important methodological deficiencies. Intermittent catheterisation has also been shown to be associated with fewer UTIs compared to indwelling catheterisation in elderly patients after surgical repair of hip fractures [214] and in a comparative study of patients at a hospital department of urology [215].

Patel et al.[216] examined the outcomes of different forms of urinary drainage for men with acute urinary retention. After a short period of indwelling urinary catheterisation 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.

In a recent 2-week prospective study of intermittent catheterisation versus indwelling urethral catheterisation in older female patients in a rehabilitation setting, 81 females >65 years with post-voiding residual volume persistently >300 ml were randomized to one of two groups[217]. Both groups demonstrated similar success in regaining bladder function and similar rates of bacteriuria. The authors concluded that intermittent catheterisation was justified in managing this patient group, particularly since indwelling catheters were deemed to hinder rehabilitation and adversely affected quality of life.

In a prospective RCT of CIC versus supra-pubic catheterisation (SPC) for post-operative bladder care following hysterectomy in 40 women there was no significant difference in the length of bladder care between the two groups[218]. Bacteriuria was higher

in the CIC group at days 3 and 5 (p=0.05 and 0.004 respectively) although it is unclear whether there was evidence of symptomatic infection. However, there was a higher incidence of symptoms / problems arising from the SPC site, of which 23% were shown to have a positive wound swab. The authors concluded that despite a higher rate of bacteriuria, the high incidence of site problems with SPC could be avoided by CIC. The technique of CIC was seen to be more acceptable to patients (p=0.009); allowing fewer disturbances at night (p=0.006); greater freedom to lead a normal life during the day (p=0.000); and less anxiety / embarrassment (p=0.005) compared to SPC.

g) 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. 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 and support, use of an appropriate catheter material and good catheterisation technique. Difficulties in carrying out the procedure such as physical and technical difficulties, embarrassment, time involved and lack of appropriate public facilities may deter users from adhering to the regime. 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.

The available data on intermittent catheterisation does not provide convincing evidence that any specific technique (sterile or clean), catheter type (coated or uncoated); method (single use or multiple use), person (self or other), or strategy is better than any other for all clinical settings. This reflects lack of reliable evidence rather than evidence of no difference. Currently clinicians will need to base decisions about which technique and type of catheter to use on clinical judgment, in conjunction with patients. Differential costs of catheters / techniques may also inform decision making.

In particular, CIC has been shown to have benefits over indwelling catheterisation in the following ways:

- Avoidance of common problems associated with LTC use such as catheter leakage and / or practical management of drainage systems

- Avoidance of complications linked to bacterial biofilm formation, including catheter encrustation and blockage. Strong evidence for reduced risk of CAUTI is less clear.

- Maintenance of some level of bladder capacity and muscle tone by allowing the bladder to fill periodically, compared to free drainage by indwelling catheter.

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

- Lower incidence of bladder calculi than indwelling catheterisation (Level of Evidence 2/3).

2. INDWELLING CATHETERISATION

Indwelling catheters (**Fig XII-3**) may be used in the short-term to manage an acute need for controlled bladder drainage or as part of a long-term management strategy (**Table XII-1**).

Catheters may be inserted into the bladder urethrally (UC) or suprapubically (SPC) through an incision in the abdominal wall. The continued requirement for indwelling catheterization should be reviewed at regular intervals and the catheter removed promptly if no longer necessary, since catheter use is associated with a number of risks. The major complication associated with short-term, indwelling catheters used in acute care, is nosocomial (healthcare acquired) catheter-associated urinary tract infection (CAUTI), which can lead to life-threatening bacteraemia in vulnerable groups and may also contribute to reservoirs of antibiotic resistant microorganisms [169] [117] [219]. Long-term catheters (LTC) are also associated with increased risk of CAUTI and a further range of problems including: recurrent blockage due to encrustation by mineral deposits; meatal tissue damage - often caused by excessive weight from heavy drainage bags; frequent bladder spasm with potential expulsion of the catheter; formation of bladder calculi; and potential for long-term neoplastic changes
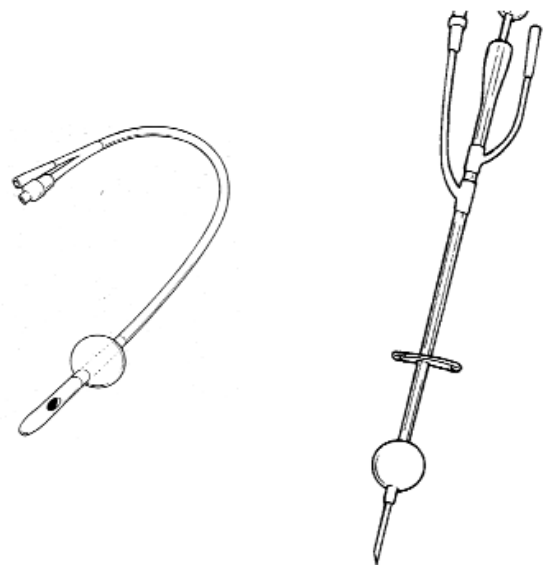

Figure XII-3: A Foley catheter (left) and a suprapubic catheter with a sharp trocar for introducing the catheter (right).

in the bladder (although further long-term studies are needed to establish this risk). Although for some patients an LTC 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. Intermittent catheterisation (See Section XII.1) is less invasive and is generally associated with fewer risks.

a) Quality of Data

Seven Cochrane reviews relating to short and long-term indwelling catheter use were identified. Reviews on short-term (<14 days or other temporary short-term use as defined by triallists) catheter issues included: types of urethral catheters for management of short-term voiding problems in hospitalised adults (220); policies for bladder management [221]; the role of prophylactic antibiotics [222]; and policies for removal of short-term indwelling catheters [223]. The objective of the first review [220] was to determine the effect of type of indwelling urethral catheter on the risk of UTI. Twenty-three trials - comparing different types of standard catheters or a standard catheter with an antiseptic catheter (silver alloy or impregnated with silver oxide), or an antibiotic impregnated catheter (either minocycline and rifampicin, or nitrofurazone) - met the criteria. The reviewers concluded that currently available evidence suggests that silver alloy catheters prevent asymptomatic bacteriuria in the short-term catheterised patient, although trials are generally of poor quality (Level of Evidence 2/3).

They also recommended that further economic evaluation is required to confirm that reduction of infection compensates for the increased cost of the silver alloy catheters. Catheters impregnated with antibiotics were also beneficial in reducing bacteriuria in hospitalised adults catheterised for less than a week but data were too few for those catheterised longer. However, it is important to note that although bacteriuria is a commonly used outcome measure in CAUTI studies there is much debate over the clinical utility of this measure. Many studies fail to distinguish between asymptomatic bacteriuria and symptomatic infection. This is discussed further in Section XII.h.2.

The second review [221] included 14 trials which reported on comparisons between SPC and UC for short term (up to 14 days). Higher relative risks scores were found for UC related to more bacteriuria (RR 2.60; 95% CI 2.12 to 3.18), more frequent re-catheterization (RR 4.12; 95% CI 2.94 to7.56) and increased discomfort (RR 2.98; 95% CI 2.31 to 3.85) (Level of Evidence 1). The third review [222] included six parallel group RCTs and reported weak evidence that antibiotic prophylaxis reduced the rate of symptomatic UTI in female surgical patients, compared to antibiotics given when clinically indicated. The review of policies for catheter removal reported suggestive, but inconclusive,

evidence of benefit from midnight removal of the catheter (larger volumes at first void) and shorter hospital stay after early rather than delayed removal. There was little evidence on which to judge other aspects of management such as catheter clamping, prior to removal.

Of the three Cochrane reviews relating to long-term catheter use, a review of comparative methods of using catheters for neurogenic bladder management [175] failed to find any trial that met the inclusion criteria. A second review [224] to compare types of indwelling catheter for long-term use (defined as >30 days) found only three trials which met the inclusion criteria. One trial compared antiseptic impregnated catheters with standard catheters and two compared different types of standard catheter. The authors reported 'an astonishing lack of evidence for this clinically highly relevant problem'.

Since the included studies were very small and showed methodological weakness, the authors concluded that the available evidence was insufficient as a reliable basis for practice and catheter choice remains largely based on clinical experience. In the third Cochrane review on 'urinary catheter policies for long-term bladder drainage'[174], seven trials met the inclusion criteria. All were small, with wide confidence intervals. No appropriate trials addressed comparisons between: indwelling UC and SPC; UC and intermittent catheterisation; or SPC and intermittent catheterisation.

Evidence pertaining to whether antibiotic prophylaxis is better than antibiotics given when clinically indicated, was insufficient as a basis for clinical practice. A Cochrane review *protocol* for washout policies for the management of long-term catheters in adults has been published [225] but there is little published clinical evidence to review, to date. Overall long-term catheter care practices remain poorly supported by research evidence. This is at least partially due to difficulties in conducting trials in long-term catheterised populations for a variety of reasons, many of which have been discussed in earlier sections.

The impact of long-term catheters on users' quality of life (QoL) is a very important issue which has not been studied adequately. No Cochrane reviews have dealt with this topic directly, although several reviews have included issues with an impact on QoL such as catheter related complications and comfort. One RCT addressed education needs of catheter users. Other studies include a small number of prospective cohort studies, with the remainder being retrospective studies and case series reports, providing evidence at Level 3. Much relevant research uses qualitative research methodologies, aimed at understanding the nature of long-term catheter-related issues and patient concerns. Measures of QoL used commonly rely on a single question of quality of life or satisfaction on a 3- or 10-point scale.

Validated QoL instruments, such as SF 36 are not only infrequently used, but are likely to lack sensitivity for the specific issues which concern catheter users. There are currently no device-specific measures as advocated by ICS (226), although work in this area is continuing.

b) Prevalence of indwelling catheters use

Short-term catheterisation is common in acute care settings, with up to 25% of patients receiving a catheter during their hospital stay [169,227]. The prevalence of LTC use in home care or community care settings varies widely and can be more difficult to determine. A large scale survey of 4010 older people (>65 years) receiving home care in 11 European countries, found a mean prevalence of LTC use of 5.4%, ranging from 0% in the Netherlands to 23% in Italy [228]. In another large study of 1004 frail older women living in the community the reported LTC prevalence rate was 38.1% [229].

There is evidence that older patients aged 65 years or more are often catheterised inappropriately [230-232]. Gokula et al. [231] surveyed a 10% random sample of patient charts from 2845 elderly patients who received an indwelling catheter during hospital admission in one year. Less than half the selected charts recorded an appropriate indication for catheterisation. An explicit reason for catheter insertion was documented in only 13% of charts and there was no written order for catheterisation in 33% of the charts. Only 18% had documented care plans for catheter removal.

Expert opinion and experience suggests that even when there is an appropriate clinical reason for initial catheterisation, patients may remain catheterised unnecessarily if medical and nursing staff fail to review ongoing need (Level of Evidence 3). Problems of inappropriate catheter use may be compounded when patients are transferred from one clinical setting to another without adequate information on why the person was catheterised [233]. Wald et al [234] reported that 32% of patients catheterised during treatment for hip fracture in their study were discharged to nursing homes with the catheter still in place.

The prevalence of catheterized patients in nursing homes is generally higher than in people living at home and has been reported to be around 9% in the UK [235], but there may be considerable variation between homes [236]. In nursing homes in the US, it has been estimated that between 7-10% of the residents have an LTC [237], although figures vary from state to state. More recent data from analysis of a US National Nursing Home Survey [238] and a point prevalence study of nursing home-associated infections in the Department of Veterans Affairs nursing home care units [239] demonstrated similar prevalence. Tsan et al. [239] reported a prevalence of

10.7% for indwelling urethral catheters and 2.46% for suprapubic catheters amongst a nursing home population of 11,475 in 133 care home units. There is some evidence of decreasing rates of urinary catheterisation in some places. A retrospective cohort study of the use of urine collection devices in skilled nursing facilities (SNFs) in five US states examined the characteristics of 57,302 patients who remained in an SNF for one year in 2003 [240]. The prevalence of indwelling catheterisation was 12.6% at admission and 4.5% at annual assessment (P<0.001). Paraplegia, quadriplegia, multiple sclerosis and comatose state were strongly associated with LTC use. Male residents were more likely to use a catheter at every assessment, as were obese patients; individuals with diabetes mellitus, renal failure, skin conditions, deep vein thrombosis, aphasia or end-stage disease; and those taking multiple medications.

Duration of catheter use in home settings varies widely, with a median of 3-4 years and some individuals using them over 20 years [241-243]. Management regimes for continence problems in older people continue to demonstrate a predominance of containment strategies, using pads and catheters [244] and consequently unwarranted use of LTCs for incontinence continues in many places despite known catheter-associated risks.

c) User characteristics

Short-term catheterisation (usually defined as up to 14 days) 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 indwelling catheters - routinely changed and replaced, often over many months or years - may be required to aid those who have difficulty emptying their bladder due to obstruction or neurological disorders, where intermittent catheterisation is not a satisfactory option. LTCs may also be used to provide supportive care for those with severe incontinence who cannot manage otherwise, are terminally ill, or need treatment to heal skin lesions or surgical wounds affected by the presence of urine.

Long-term catheterisation is most commonly used to help manage:

- Bladder outlet obstruction (BOO), where patients are unsuitable for - or waiting for - surgical relief.

- 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 (as a last resort when alternative non-invasive approaches are unsatisfactory or unsuccessful).

d) Routes of catheter insertion

For some patients the insertion of an indwelling catheter suprapubically (SPC) into the bladder, through the abdominal wall, offers advantages over the urethral route (UC). SPC may be necessary following urethral or pelvic trauma but also offers advantages in acute and long-term care. In frail elderly men, and / or those prone to infection e.g. diabetes mellitus, SPC can be preferable to a urethral insertion to avoid urethritis, orchidoepidydimitis and prostatitis [245]. Strategies to support the SPC may be required (e.g anchoring to the abdominal wall with a BioDerm tube holder) to prevent traction and potential displacement of the catheter or balloon [246].

Advantages of SPC compared to UC are:

- Avoidance of risk of urethra trauma to men and women during catheter insertion and withdrawal.

- Avoidance of 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.

- Reduced risk of contamination where faecal incontinence is a problem.

SPC insertion is generally contra-indicated in patients with haematuria of unknown origin, bladder tumour, or small contracted or fibrotic bladders which may have resulted from long-term urethral catheterisation on free drainage. In obese or immobile patients the traditional SPC 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. SPC is an effective and well-tolerated method of bladder management for many SCI patients [247-249]. In Sheriff et al's study [247] the general level of satisfaction with SPC was very high with 70 % of patients awarding a satisfaction score of 9/10 and 95% awarding 7/10 or more. It is of interest to note that in 18% of cases, an SPC was inserted following the request of the patient, having heard about this form of bladder management from others. A review of current literature on SPC in the neuropathic bladder, by Feifer & Corcos [249] identified some notable differences between early studies and more recent reports. Problems and complications of SPC identified in earlier studies of SCI patients were less common in the more recent investigations, in which patients were managed with anti-cholinergics, frequent catheter changes and volume maintenance procedures. Recent studies demonstrated similar morbidity profiles to clean intermittent catheterisation.

Although SPC has gained 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 [247] [250]. Other complications of initial SPC insertion include misplacement [251-253] and incisional hernia [254,255]. There are a number of SPC techniques for insertion described in the literature and training models have been developed to facilitate teaching [256]. Some modern catheter insertion kits employ the initial introduction of a guide wire into the bladder, to facilitate accurate positioning of the catheter introducer. 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), some authorities recommend introduction of the SPC by percutaneous technique using intraoperative ultrasonography combined with flexible cystoscopy [257,258]. In low risk patients nurse specialists may undertake first insertion of an SPC, according to agreed policy and protocols [259]. Subsequent SPC changes can be competently managed by skilled nurses [260].

e) Catheter characteristics

An effective indwelling catheter should have the following design characteristics:

- Retained in the bladder effectively, yet easily removable without trauma to tissue.

- Soft 'tip' within the bladder to avoid pressure damage to the mucosa.

- Effective drainage while minimising risk of bladder mucosa being 'sucked' into drainage channel.

- Conforms to shape of urethra.

Despite some notable efforts to improve catheter design, the original Foley design has changed very little over the years and remains the most common. However traditional drainage systems may fail to drain the bladder to completion, due to potential outflow obstruction caused by air-locks within the curled, redundant drainage tubing segments. A novel, spiral-

shaped, drainage tubing design has recently been reported which appears to optimize flow and minimize residual urine [261]. Further evidence of efficacy is awaited.

f) Catheter materials

An ideal catheter material requires the following properties:

- 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.

Catheters are made of a variety of materials including polyvinyl chloride (PVC or plastic), latex rubber with or without a coating, silicone 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). 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 by mineral deposits from the urine and the implication of latex allergic reactions in the development of urethritis and urethral stricture [262-267] or anaphylaxis [268].

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 materials known to cause least friction and tissue reaction are silicone elastomer and hydrophilic polymer-coated catheters, or all-silicone catheters [269] (**Table XII-3**). These materials are therefore recommended for long-term use (i.e. expected to remain in situ for 14 days or more, and changed regularly for a new catheter as part of a long-term strategy of care). LTC materials are also less vulnerable to rapid colonisation by bacteria and encrusting by mineral deposits than short-term catheter materials. There is evidence that silver-alloy coated catheters can help to reduce risks of CAUTI in the short-term (where bacteriuria is used as the outcome measure) (See Section XII.2.h), but no currently available material or surface coating is completely immune to microbial colonisation.

Inflation of silicone catheters with water can sometimes lead to water loss from the balloon over time, with an associated risk of the catheter falling out [270]. Consequently some manufacturers recommend filling the balloon with a 10% aqueous glycerine solution.

Most catheter materials are suitable for either UC or SPC, however not all UC catheters are also licensed for SPC. Suprapubic catheter removal is sometimes associated with trauma of tracts or stoma site where overgranulation has occurred, with bleeding and patient discomfort [260;271]. This can be 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 [272,273]. Management of this and other catheter-related problems is considered below in Section XII.2.k

The main finding of a recent Cochrane Review of types of indwelling urinary catheters for long-term bladder drainage in adults [224] was a remarkable

Table XII-3. Catheter materials

Duration of catheterisation		Catheter material
Intermittent	Removed immediately after urine drainage.	Plastic: with or without hydrophilic polymer coating. Metal (silver, stainless steel).
Indwelling, short term use	Catheter expected to be *in situ* for < 14 days.	Latex or plastic PTFE-coated latex. Silver-alloy coated (catheter materials recommended for long-term use may also be selected).
Indwelling LTC	Catheter expected to be in situ for 14 days or more (recommended time between catheter changes depends on local catheter policy - may be up to 12 weeks).	Silicone elastomer-coated latex. Hydrophilic polymer-coated latex. All silicone

lack of evidence for this clinically, highly relevant problem. Despite consideration of 11,000 abstracts and 74 full papers, only three trials met the inclusion criteria. Since these were very small and showed methodological weakness, the authors concluded that there was insufficient evidence to provide a reliable basis for clinical decision-making and catheter choice remains largely based on clinical experience.

g) 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 is measured in Charriere (Ch) – also called French gauge (Fr) - which refers to 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 related 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 [274]. Although larger sizes may be needed following urological procedures where blood clots and other debris are a problem, large catheters are generally associated with increased bladder irritability and spasm [108], and with potential blockage of para-urethral glands and tissue damage, including urethral strictures. Therefore large catheter sizes should be avoided wherever possible. Small balloon sizes are recommended for all patients (10ml for adults and 2.5-5ml for children) to minimise the risk of discomfort and bladder irritation. Larger balloons tend to sit higher in the bladder with potential for increased residual urine volumes to collect below the catheter eyes. Larger balloons are also associated with increased risk of meatal tissue damage caused by bladder spasm and possible expulsion of the catheter with a fully inflated balloon.

The most common sizes of SPC catheters for adults are also 12-16Ch. Some SPC kits provide a specific catheter in the kit and therefore dictate the sizes available; others allow the insertion of a range of Foley catheters. Since the catheter is inserted into the bladder via an artificial stoma it is possible that slightly larger sizes may be better tolerated than for UC although there is no research evidence to support this.

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.

h) LTC–associated risks / problems: catheter-associated urinary tract infection (CAUTI)

The urinary tract is recognised as the commonest site for nocosomal infection in hospitals and nursing homes, accounting for between 21% and 45% of all healthcare-associated infections [239;275-278]. National nosocomial infection surveillance systems monitor CAUTIs and provide guidance for benchmarking [279]. The presence of an indwelling catheter is a key risk factor in around 80% of nosocomial UTIs. The risk of bacteriuria increases by 5-8% per day of catheterisation [280-282] and all LTC 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 [169].

Access is gained in two ways: (1) extraluminally during catheter insertion or via the periurethral space; (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) [283]. However, clinical studies have shown that colonisation will occur even when strict infection control practices are adhered to [284].

Indwelling catheters rapidly become colonised by micro-organisms which form a strongly adherent biofilm on catheter and drainage equipment surfaces. Biofilm formation begins by deposition of a conditioning layer of proteins, electrolytes and other organic molecules from the urine [285] which may then mask catheter surface properties designed to inhibit colonisation. Micro-organisms attached to catheter surfaces divide to form micro-colonies, ultimately developing a complex three-dimentional structure, including fluid filled channels through which the biofilm members receive nutrients, diffuse away wastes and send chemical signals to each other [286].

Catheter biofilms commonly comprise mixed communities of micro-organisms embedded in a matrix of host proteins and microbial exopolysaccharides [287,288] (**Figs XII-4, XII-5 and XII-6**). Microorganisms growing as a biofilm are less susceptible to antimicrobial therapies than free-living organisms and are a major source of resistant, nosocomial pathogens [169] [219,289]. Decreased susceptibility arises from multiple factors including; physical impairment of diffusion of antimicrobial agents, reduced bacterial growth rates; and local alterations of the micro-
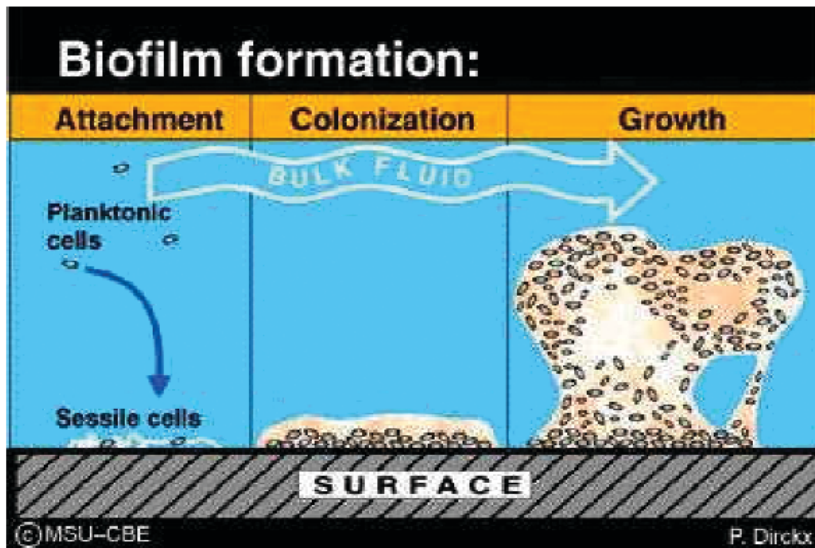
Figure XII-4: Biofilm - 'pillars, mushrooms and water channels' (Reproduced with the permission of Montana University Centre for Biofilm Engineering).
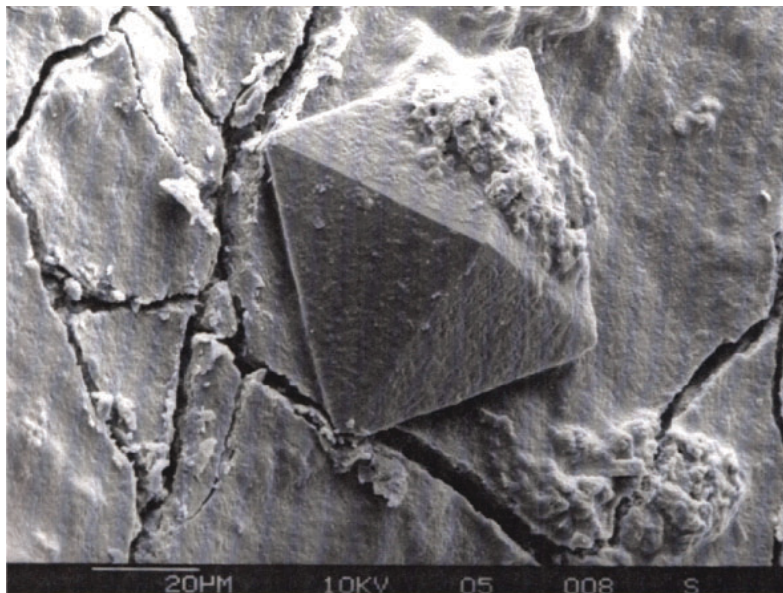

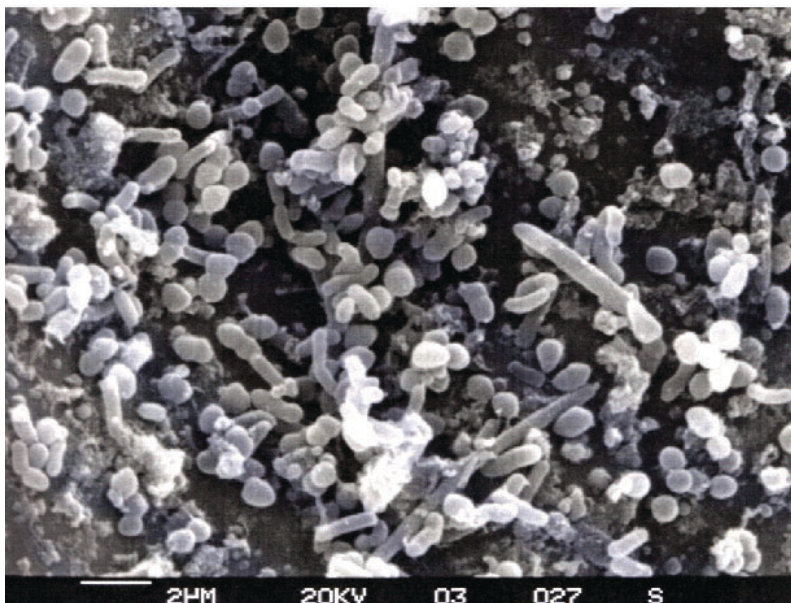*Figure XII-5: Scanning electron micrograph of biofilm.*

Figure XII-6: SEM of bacteria colonising catheter surface – Proteus mirabilis, Enterococcus faecalis, lactobacillus sp.

environment that may impair activity of the antimicrobial agent [286]. The close proximity of cells within a biofilm can facilitate plasmid exchange and the spread of antimicrobial resistance [285].

1. PREVALENCE OF CAUTI

The majority of research on the risks of CAUTI has been conducted in acute care settings where catheters usually remain in place for less than 14 days and many patients' health is already compromised by co-morbidities [290]. Less is known about the prevalence of CAUTI in long-term and home care settings or about the potential for reduction of CAUTI and improved cost benefits in the LTC population [282]. In the multi-national survey of 4010 older people (>65 years) receiving home care in 11 European countries, the risk of a UTI was found to be 6.5 times greater for catheterised individuals than for non-catheterised [228]. Prevalence of a UTI amongst 1004 frail older women living in the community was 21% in catheterized women compared to 10% in non-catheterized subjects (P>0.001) [229]. Furthermore, catheterised subjects were more likely to die within a year (RR1.44; 95% CI 1.01-2.07). Tsan et al's point prevalence survey [239] of Nursing Home acquired infections found 13.2% of 11,475 residents had an indwelling urinary catheter. Of those, 13% of residents with a UC and 9.5% of those with a SPC had a UTI. In catheterised SCI populations the overall rate of urinary tract infection has been quoted as about 2.5 episodes per patient per year [291]. Although randomized trials are lacking there is some evidence of reduced rates of bacteriuria and CAUTI with SPC, condom catheters and intermittent catheterisation compared to UC [239;245;291].

Bacteraemia resulting from CAUTI invariably represents a serious complication which may occur in approximately 4% of catheterised patients with bacteriuria in acute care settings [290;292;293]. In their review, Saint et al. [292] statistically pooled results from several prospective studies on short-term indwelling catheterization (in which the definition of bacteriuria varied between studies, ranging from >=10^3 cfu/ml to >=10^5 cfu/ml) and estimated (Level of Evidence 2) 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.

- 72% of patients developing bacteriuria will remain asymptomatic and not require treatment.

- 24% of those developing bacteriuria will develop a symptomatic UTI without bacteraemia.

- 4% with bacteriuria will develop bacteraemia.

This data is interesting since it provides supporting evidence that bacteriuria remains asymptomatic in a majority of catheterised patients. However, it can be difficult to generalize such data from acute care contexts to other practice settings. Unfortunately, few epidemiological studies or comparative catheter evaluations are conducted on long-term catheterised patients in community settings.

2. OUTCOME MEASURES AND CRITERIA FOR CAUTI

Interpretation of the literature on CAUTI is often confused by the range of definitions and outcome measures used. In this chapter, the terms symptomatic infection and asymptomatic bacteriuria have been employed to distinguish as clearly as possible between symptomatic and asymptomatic conditions. However many studies make little or no distinction between these states, referring to both as infection. This can be particularly confusing when attempting to interpret results in terms of the magnitude of infection-related problems, clinical importance and implications for services and individuals.

Bacteriuria is commonly used as a surrogate outcome measure for the clinically more important outcomes of symptomatic UTI. Although symptomatic infection is far less common than asymptomatic bacteriuria, the frequency of catheter use produces considerable overall morbidity for patients and high costs to healthcare services [294], often including unnecessary antibiotic drug therapy which may then become a major source of antibiotic resistant pathogens. Asymptomatic bacteriuria can lead on to symptomatic infection, but not necessarily. Questions about the significance of long-term asymptomatic bacteriuria in its own right (e.g. effects of chronic tissue inflammation) are currently unanswered.

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 [169]. Most definitions of symptomatic UTI (e.g US Centres for Disease Control [295] are based on those used for non-catheterised patients and include significant bacteriuria. For catheterised patients, these include presence of pyuria (>10wbc/mm^3) plus one or more clinical signs and symptoms for which no other aetiology is apparent: fever, suprapubic or flank discomfort, bladder spasm. For SCI patients signs and symptoms may also include increasing spasticity and / or worsening autonomic dysreflexia (usually manifested by increase in blood pressure, headache, sweating above the SCI lesion, flushing below the SCI lesion) [296].

However, commonly used criteria for symptomatic urinary infection have been questioned by Tambyah and Maki [290] 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 was predictive of infection (p=0.14) (Level of Evidence 2). The criterion for bacteriuria (catheter-associated infection) in this study was >= 10^3 colony forming units (cfu/ml urine). This finding raises further questions over the selection of the most appropriate outcome measures in studies of CAUTI. Indeed concerns have also been raised over current UTI criteria for non-catheterised populations, particularly for elderly groups, including nursing home residents. Consensus criteria (e.g. Loeb criteria 2001) have been found to be limited in terms of sensitivity, specificity and predictive value by Juthani-Mehta et al. [297] and these authors have called for clearer identification and evaluation of evidence-based clinical criteria associated with laboratory evidence of UTI. A further complication to difficulties in confirming 'best criteria' for UTI and CAUTI is the variation in the clinical and scientific definitions required for specific populations, for research purposes or to meet stipulations for reimbursement from governments and medical agencies. It is important that efforts to resolve these issues are progressed as quickly as possible to provide greater clarity in the interpretation of existing research, the design of new studies and the application of clinically important findings.

3. REDUCING THE RISK OF CAUTI

Risk factors which are independently predictive of increased risk for CAUTI have been identified in a number of large prospective studies of short-term catheterised patients [169] (**Table XII-4**). There is evidence that females have a substantially higher risk than males (relative risk: RR 2.5-3.7) but the greatest risk is associated with prolonged catheterisation > six days (RR 5.1-6.8). A recent retrospective cohort study of 35,904 undergoing major surgery reported that 86% of patients had a perioperative indwelling catheter [298]. Multivariate analysis showed that postoperative catheterisation for longer than two days was associated with increased risk of UTI.

Although there is some evidence to suggest there may be a reduced risk of CAUTI when SPC is employed compared to UC, the data is limited, studies are often small and most catheterisations are for post-operative care in acute care settings. One large scale point prevalence study of nursing home acquired infections in >11,000 residents [239] reported that 9.5% of residents with a SPC had a UTI compared to 13% of those with a UC. These data just fail to demonstrate a statistically significant difference between UC and SPC (one-sided, Fisher's exact test; P= 0.066). A review of five published RCTs comparing SPC with urethral catheters following colorectal surgery [299] reported that sample sizes were small, catheters were used short-term and there was no apparent

Table XII-4. Risk factors for catheter-associated infection based on prospective studies and use of multivariate statistical modelling (adapted from Maki & Tambyah 2001 [399].

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

difference in the duration of catheterisation between the two techniques. Significant UTI was defined in different papers as bacteriuria with either =>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 concluded that the results favoured SPC over urethral catheterisation as UTIs are reduced, particularly in females, and the ability to attempt normal voiding is facilitated, particularly in males (Level of Evidence 2).

Much of the recent research on reduction of risk of CAUTI has centered on the development of catheters with antimicrobial surfaces, such as silver. Silver ions are bactericidal [300], non-toxic to humans when applied topically, and have been used successfully in other areas of infection control such as burn wounds. Silver is also purported to have broad spectrum activity against Gram-positive, Gram-negative, aerobic and anaerobic organisms. Early silver-coatings incorporated silver oxide into the external surface of the catheter material only, but efficacy against CAUTI was limited [301]. Subsequently, silver-alloy coatings were developed to provide an integral coating on both internal and external surfaces and promote a slow release of silver ions. Other developments have been directed towards impregnation of catheter materials with antibiotic or antiseptic agents such as nitro-

furazone [302-305]; minocycline and rifampicin [306]; chlorhexidine, silver sulfadiazine, triclosan [307] and others. Although a large number of studies (both laboratory models and clinical studies) have attempted to examine the potential benefits of antimicrobial catheters, most have used bacteriuria - rather than symptomatic UTI - as a surrogate end-point. Most reports were either prospective cross-over studies [308] or prospective surveillance of outcomes associated with introduction of new catheter types, in comparison with historical or baseline outcomes associated with previously used catheter types [309-311]. Almost all have examined short-term catheter use in acute care settings.

A recent Cochrane review [220], designed to determine the effect of type of indwelling urethral catheter on the risk of UTI, examined 23 trials, comparing different types of standard catheters or a standard catheter with an antiseptic catheter (silver alloy or impregnated with silver oxide); or an antibiotic impregnated catheter (either minocycline and rifampicin, or nitrofurazone). The reviewers commented that trials were generally of poor quality but concluded that current evidence suggests silver alloy catheters prevent asymptomatic bacteriuria in the short-term catheterised patient (Level of Evidence 1). They recommended that further economic evaluation is necessary to confirm the extent to which reduction of clinically important infection compensates for the increased cost of the silver alloy catheters. Catheters impregnated with antibiotics were also found to be beneficial in reducing bacteriuria in hospitalised adults catheterised for less than a week, but data were too few for patients catheterised longer.

An earlier systematic review of antimicrobial urinary catheters to prevent CAUTI in hospitalized patients [312] identified 12 randomised or quasi-randomised trials of silver-alloy coated (n=9) or nitrofurazone-coated catheters (n=3) compared to standard silicone or latex catheters. Pre-post study designs were excluded. No study addressed symptomatic UTI and therefore analysis was based on bacteriuria. Although all studies indicated some benefit in prevention or delay of onset of bacteriuria the effect size varied substantially between studies. Variations were related to catheter type, patient characteristics, control group bacteriuria rate and year of publication (i.e prevailing clinical conditions at the time of the study).

Post enrolment exclusions, absence of intention to treat analysis, highly selected study samples and lack of data on clinically meaningful end-points, all limited the ability to draw definitive conclusions on efficacy. The authors concluded that, according to fair-quality evidence, antimicrobial catheters can prevent bacteriuria in hospitalized patients during short-term catheterisation (Level of Evidence 1), but trial results are highly context dependent. The relevance of results to other institutions or patient groups depends on the similarities between settings with respect to a range of variables, including: background bacteriuria rate, baseline catheter type, local catheter use and maintenance practices, patient groups and patterns of antimicrobial usage. The authors cautioned that older data may lack current relevance, particularly where background rates of bacteriuria have changed notably in the intervening period. Although there is evidence that antimicrobial-coated catheters prevent bacteriuria during short-term catheterisation, there is a lack of corresponding data to demonstrate clinical benefit [313]. Further well-designed and adequately powered randomised trials, with clinically relevant endpoints are needed to clarify comparative clinical utility and economic value.

In contrast to the majority of trials of silver-coated latex catheters Srinivasan et al [314] found no significant reduction in bacteriuria with silver-impregnated, silicone catheters despite similar performances in vitro. However, outcomes may have been affected by notable differences in the study groups in this prospective, cross-over study. The authors drew attention to the fact that not all silver products are the same and clinical trials of new products remain critically important. Any potential advantages of silver alloy catheters (or other antimicrobial catheters) for LTC patients remain uncertain, although clinical experience suggests some benefits for individuals with frequent symptomatic infections. It is not known whether argyria (deposition of silver in the skin) may be a potential problem for long-term care patients or whether silver-resistant mutants may be selected by repeated exposure [315, 316].

A common concern over the use of antimicrobial impregnated catheters is that elution of sub-inhibitory levels of the antimicrobial agent into the urine may induce resistance in resident organisms with prolonged catheter use [317]. 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. Alternative approaches to inhibiting biofilm development include development of catheter surfaces which reduce protein absorption [318]; inflation of the balloon with a biocide solution, such triclosan, which then diffuses throughout the catheter material and into the surrounding area [319;320]; or efforts to disrupt matrix or glycocalyx components with agents such as heparin [321].

Relatively few studies have examined the cost benefits of different catheters. Those that have tend to rely heavily on assumptions that a certain proportion of patients with bacteriuria will develop the clinically important outcomes of symptomatic UTI or bacteraemia. The focus of economic studies generally falls on acute care settings and, as discussed earlier, it can be difficult to generalise results from one practice setting to another. Practitioners and/or institutions

who are considering introducing a new product (e.g. catheter type) for a majority of their patients on the basis of claims of improved cost-effectiveness from clinical research studies, are advised to look carefully at the similarities and differences between their own local practice (and patient groups) compared to that described in the research. Economic studies are frequently required to make assumptions about certain data (e.g. increased length of hospital stay for CAUTI) which is then applied to an economic model. (Cross ref to economics chapter). Such assumptions may or may not be applicable in local settings.

Numerous trials of oral antibiotics, antimicrobial bladder washes, drainage bag solutions and topical disinfectants all lead to the common conclusion that bacteriuria and UTI may be suppressed temporarily at best, but resistant organisms are highly likely to emerge [287]. The application of devices to secure catheters in place, to prevent a 'to and fro' pistoning effect that could favour invasion of catheter tracts by microorganisms, has been shown to reduce the incidence of catheter-related blood stream infection in central venous catheters. Only one prospective, randomised trial has examined a similar device for urinary catheters (StatLock) [296]. Although the study in 118 SCI patients failed to achieve statistically significant results the authors reported a clinically important reduction in the rate of symptomatic UTI of 45% and called for further larger scale trials. They also noted the polymicrobial nature of infections including the presence of a Candida species in more than 20% of infections.

4. TREATING CAUTI - ANTIBIOTIC USE

Some studies have suggested that methenamine hippurate may have a beneficial effect in preventing bacteriuria in patients requiring short-term catheterisation during and post-surgery. However, a Cochrane review [304] designed to address this issue concluded there is not enough reliable evidence to conclusively support its use for urinary prophylaxis and identified a range of methodological limitations in existing studies. Caution is needed in translating research on reducing CAUTIs in short-term catheters to LTCs but treatment of asymptomatic bacteriuria is not recommended in either for either group. Urine cultures should be obtained before initiating treatment to permit selection of specific therapy for the infecting organism and the extensive use of broad spectrum therapy should be avoided [322].

Studies of LTC patients can be difficult given the relatively high proportion of disabled or elderly patients, many of whom are very frail. However, routine use of prophylactic antibiotics in LTC patients is not supported by research evidence and has been shown to favour the emergence of resistant organisms. In a double-blind, cross-over study of 34 elderly nursing home patients with urethral catheters [323] subjects 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°C for two days in the absence of other clinical sources of infection or (ii) flank pain or unexplained mental disturbance or abdominal discomfort.

Only 23 patients completed the study and although norfloxacin failed to reduce asymptomatic bacteriuria, there was a significant reduction in symptomatic UTIs (1 v 12, p<0.02) and a decrease in catheter-associated complications of obstruction and leakage (p<0.05). 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 prevent bacteriuria in long-term catheterised patients and favoured the emergence of quinalone-resistent 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. One RCT in which 70 residents in a long-term care home were allocated to a treatment group (1gm IV meropenem given 30 minutes before re-catheterisation) or control group (no antibiotics) showed no significant differences in urine cultures at 3, 7, 14 or 28 days [324].

When catheterised patients are prescribed a course of antibiotics for symptomatic infection a common question from healthcare practitioners is whether the catheter should be changed to a new one prior to starting antibiotics. There are concerns that this may allow time for a new biofilm to become established on the catheter within a few hours (and provide a source of re-infection) before the antibiotics have taken effect. There is little research to guide practice but in one RCT of 54 nursing home 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 [187].

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 (Level of Evidence 2).

Replacement of the catheter, in patients suspected of having a UTI, prior to collecting a urine sample for culture and sensitivity testing has also been shown to reduce the number of pathogens identified, the number of antimicrobials prescribed and laboratory costs [325]. There is evidence that certain bacterial strains may be particularly difficult to eradicate. In a prospective study of infection in catheterised nursing home patients a single genotype of P.mirabilis was shown to persist in the urinary tract despite many changes of catheter, periods of non-catheterisation and antibiotic therapy [326].

Cranberry juice has long been advocated as a treatment for urinary tract infection and there is some evidence of decreased symptomatic infections in some study populations [327]. However current evidence to date is limited to non-catheterised patients and caution needs to be applied in extrapolating results to catheterised patients (see also Section XII.2.9).

i) LTC-associated risks and problems: recurrent catheter blockage

Recurrent catheter encrustation by mineral deposits, leading to catheter blockage occurs in up to 50% of LTC users, with resultant increased costs to services and patients [328-331]. 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) (**Figs XII-7 and XII-8**) which precipitate from the urine, most commonly under alkaline conditions.

The precipitation of different ionic species (ie Ca^{++}, Mg^{++}, and phosphates) is influenced by their ionic concentrations in the urine. In addition, the urinary pH at which different ions precipitate from the urine varies, not only for different ions, but also between individuals and at different times[332,333]. These factors contribute, at least in part, to individual variability in terms of susceptibility to catheter encrustation and time to blockage. Catheterised patients can usually be classified into 'blockers' or 'non-blockers' [328,329] where 'blockers' are those individuals who experience recurrent catheter blockage within a few days to a few weeks.

Early recognition of recurrent 'blockers' facilitates proactive care through appropriate catheter change regimes [329]. Urine from recurrent blockers tends to have a very narrow 'safety margin' between 'voided' urinary pH and the pH at which crystallisation (or nucleation) occurs. This margin is much wider in non-blockers [334]. Precipitates occur most commonly under alkaline conditions caused by the presence of urea-splitting micro-organisms such as Proteus mirabilis, in the catheter biofilm [329,334-336].

Figure XII-7: Section of catheter showing encrustation and blockage.
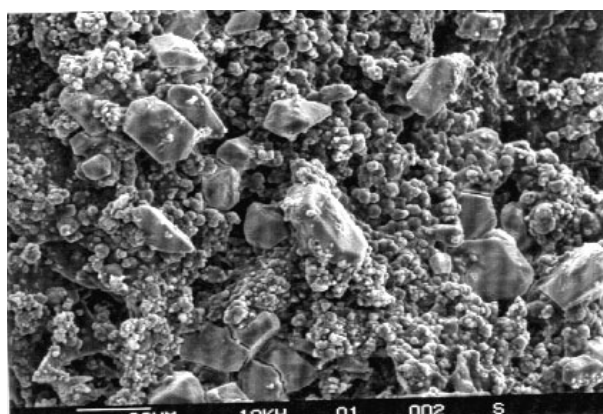
Figure XII-8: SEM of encrusting material - struvite and calcium phosphate.

1. REDUCING CATHETER ENCRUSTATION – CATHETER MATERIALS

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. Encrustation may sometimes take place in the absence of infection [337] and is influenced by catheter surface properties, including roughness and irregularity, hydrophobicity and wetability, charge, polymer chemistry and coatings. None of the currently available long-term catheter materials is resistant to biofilm formation and encrustation. In a series of laboratory studies of 18 types of catheter materials,

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using a model of the catheterised bladder, none resisted biofilm formation by a clinical strain of P.mirabilis [338,339]. Relative times to catheter 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).

Although it is not possible to examine the effects of polymer surface properties on microbial adhesion and formation of catheter encrustation in detail here, recent studies have shown that strongly electron donating surfaces are less prone to adherence by P.mirabilis than more hydrophobic materials [340]. Some copolymer, polyurethane blends are associated with less microbial adherence and improved resistance to encrustation in an artificial bladder model [341]. The effect of iontophoresis produced by passing an electric current through silver electrodes attached to catheters has also been shown to inhibit bacterial growth [342]. Another potentially promising innovation is the use of the antiseptic agent triclosan in the catheter balloon [319,320,343]. In laboratory models of the catheterised bladder infected with P.mirabilis, silicone and latex-based catheters, with balloons inflated with triclosan, 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. However, latex-based catheters required a higher concentration of triclosan (>1mg/ml) than silicone catheters to produce similar inhibitory effects on P. mirabilis. Diffusion through the latex balloon occurred but the latex-based catheter did not become impregnated with triclosan throughout. The potential benefits of triclosan in catheter balloons now needs to be tested in clinical trials but it is also important to note that not all microbial species responsible for CAUTIs are sensitive to this biocide and emergence of resistant strains is a common concern [320].

2. REDUCING CATHETER ENCRUSTATION - INTERVENTIONS

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 good evidence from laboratory studies that increased fluid consumption (leading to lower concentration of encrustation components) increases the time to catheter blockage [344]. Increasing citrate concentration in fluid intake and urinary output (eg through drinking orange juice or other fruit juices such as lemon or lime) has also been shown to increase time to catheter blockage (see below). Cranberry juice has frequently been advocated to reduce UTIs, microbial

adherence and biofilm development but an in vitro study by Morris and Stickler [345] drinking cranberry juice did not produce urine which was inhibitory to the development of P.mirabilis biofims and catheter blockage, although increased fluid intake was beneficial. Although some studies have claimed drinking cranberry juice can decrease urinary pH in healthy volunteers [346], this is unlikely to be accomplished in catheterised patients, in the presence of continued ammonia production by the action of urease-producing micro-organisms [347].

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 [339]. Significant reductions in precipitation of calcium and magnesium salts were also noted but the impact of possible side-effects remains unclear, and therefore clinical potential is uncertain. Clinical studies on the prevention or management of catheter encrustation are extremely limited and only two relevant studies addressing the use of urease-inhibitors were identified. One early clinical study [348] examined oral administration of a urease inhibitor (acetohydroxamic acid) to five patients who required frequent catheter changes (=>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 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. A subsequent double-blind, RCT of acetohydroxamic acid in the palliative treatment of infection-induced urinary calculi, demonstrated lowered urinary pH in urine infected with P.mirabilis but the side effects were unacceptable to patients [349] (Level of Evidence 1).

An alternative approach to reducing catheter encrustation, aimed at increasing the 'safety margin' between urinary pH and the nucleation pH (pHn) (i.e. the pH at which crystals of calcium and magnesium are formed in the urine) warrants further clinical investigation). In laboratory studies using models of the catheterised bladder, the pHn of the urine was shown to increase when urine concentration was decreased and also by addition of citrate to the urine [350]. In models supplied with urine containing citrate at 1.5mg/ml or above, catheter drained freely for the 7 day experimental period. Drinking 500ml pure orange juice per day can achieve concentrations of citrate of up to 1.2mg/ml urine [333] and further clinical evaluation of the effects of increasing a patient's fluid intake with citrate containing drinks is awaited. Viable cell counts of P.mirabilis in the model suggest that results were unlikely to be due to direct effects of citrate on the growth of metabolism of P.mirabilis in

the catheter biofilm, but rather on the process of mineral crystallization.

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 recurrent blockage are difficult and / or unacceptable to patients. Solution G (Suby G) and Solution R (**Table XII-5**) have been shown to be effective in *in vitro* models of the catheterised bladder [351-353] and *in vitro* models of struvite stone chemolysis [354]. In response to concerns over potential damage to the bladder mucosa from acidic catheter maintenance solutions, Getliffe et al. [352] advocate the use of small volumes of solution so that less enters the bladder. Under controlled laboratory conditions smaller volumes of acidic solutions (Suby G) (50ml), retained in the catheter for 15 minutes, were shown to be as effective as the commonly available commercial standard of 100ml. Getliffe et al. also showed that two sequential washouts with 50ml were more effective than a single washout.

There is relatively little clinical evidence to draw on in this area and outcomes remain to be tested in well-controlled clinical trials. Most clinical studies are small-scale and descriptive although both Getliffe[355] and Kunin et al. [328] compared groups of 'blockers' and non-blockers' to identify characteristics of recurrent 'blockers'. One small-scale, comparative trial of Suby G, Solution R and saline catheter 'washouts' in 14 older female patients [356] reported 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 suggesting this was at least partially related to the physical process of administration. This issue was previously raised by Elliot et al. [357] who also demonstrated increased uroepithelial shedding following washouts with up to 60ml saline 0.9%; chlorhexidine 0.02% or noxythiolin 2.5%.

A more recent RCT, which aimed to compare weekly catheter flushes with saline or an acidic solution, with no flushes, reported the mean time until catheter removal was very similar between groups. Importantly, there was no evidence of detrimental effects, such as increased risk of symptomatic infection, from breaking the closed system in order to apply catheter flushes. However the study was underpowered and subjects were only followed for a maximum of eight weeks. There were considerable difficulties with recruitment of patients and target numbers fell short within each group (Level of Evidence 2) [358]. 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 [359] but potential benefits may be outweighed by the greater risk of inflammatory tissue reactions when used as a catheter maintenance solution. Renacidin solution is approved for kidney stone disintegration in the US but although it may be

Table XII-5. Catheter maintenance solutions.

Suby G or Solution G[1]	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.
Solution R[1]	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.
Renacidin[R2]	A citric acid solution, pH 3.5-4.2, containing glucono-delta-lactone to minimise tissue irritation and magnesium carbonate, aimed at reducing encrustation.
Mandelic acid 1%[1]	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
Saline 0.9%[1,3]	A neutral solution, pH 7, recommended for flushing of debris and small blood clots. Neutral pH solutions will not dissolve catheter encrustations.
Chlorhexidine 0.02%[1]	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 the UK pre-packed in a sterile delivery devices designed for instillation into a urinary catheter.

[2]Renacidin® is approved in the USA for kidney stone disintegration only. Although it may be effective in certain situations for persistent catheter blockers, there are no supporting studies.

[3] Saline is widely available

effective for recurrent catheter blockers, there is no published research evidence of its use in this group.

Overall, methodological issues make it difficult to draw robust conclusions on the effectiveness of acidic solutions in managing catheter blockage. It is unlikely that any currently available strategies will completely prevent catheter encrustation and a more practical aim is to extend catheter life to a period which is acceptable to users and manageable by healthcare professionals (see Section XII.2.k below). Early detection of impending blockage by determination of usual length of catheter-life [355] or by application of a sensor device designed to detect early stages of P. mirabilis biofilm formation [350] are likely to remain the main stays of management.

j) LTC-associated risks and problems: urethral trauma, bladder calculi and bladder cancer

1. URETHRAL TRAUMA

Urethral trauma and discomfort can occur during catheterisation but may be minimised by using a sterile lubricant or anaesthetic gel [360] (see also Section XII.2.k), however clinical practice remains variable. More studies have considered the use of lubricants for male catheterisation but few have considered the procedure for women or for supra-pubic catheterisation [361]. A recent randomised, double-blind study with 62 alert, cooperative females requiring urethral catheterisation, demonstrated that the group receiving lignocaine gel had a significantly lower median procedural pain score compared to the group receiving a water-based lubricating gel [362]. Supra-pubic catheterisation can sometimes lead to urethral leakage which may require surgical closure of the urethra, especially in women.

2. BLADDER CALCULI

Most long-term follow up studies of LTC use have addressed SCI populations. Indwelling catheters (UC and SPC) have been significantly associated with increased risk of bladder calculi formation in SCI patients, compared to intermittent catheterisation [203,363]. In a retrospective cohort study of 457 patients, controlled for variable follow up times by regression analysis, both UC and SPC were significantly associated with increased risk of bladder calculi formation compared to intermittent catheterisation IC (hazard ratio 10.5; p<0.0005 and 12.8; p< 0.0005) respectively [364]. This increased risk was independent of age, sex, level and degree of injury but calculi were no more likely to form with SPC than UC (hazard ratio 1.2, p=0.6). Another case series of SPC in 118 patients with neurogenic bladders [365] found 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.

Where SPC has been compared to CIC the main difference appears to be in a lower incidence of bladder calculi in the CIC group. A prospective comparison of long-term outcomes between 34 quadriplegic patients managed by SPC (mean period 8.6 years) and 27 paraplegic patients managed with CIC (mean period 9.9 years) reported no significant difference between groups in respect of symptomatic UTI, renal stone, degree of bother and overall satisfaction [248] but there was a significantly increased incidence of bladder stones in the SPC group. However a recent review of current literature [249] (56 studies), concluded there were variations between older and more recent studies. More recent studies showed morbidity profiles to be similar for SPC and CIC, where patients were managed by anticholinergic medications, frequent catheter changes and volume maintenance procedures (Cross reference Neuro Chapter). A dedicated catheter clinic established to aid the management of patients having problems with LTC, reported the majority of patients were elderly with chronic disabilities. A significant proportion of those with catheter encrustation and blockage (45% of 147 patients) were shown to have formed bladder calculi [366].

3. BLADDER CANCER

A number of retrospective, cohort reports of SCI patients have linked bladder cancer with long-term indwelling catheterisation [367-369]. The reported incidence of squamous cell and transitional cell carcinoma associated with chronic indwelling catheterisation varies widely between studies but Groah et al. [369] in their follow-up of 3670 subjects, calculated that patients with SCI and an indwelling catheter were 25 times more likely to develop bladder cancer than the general population (Level of Evidence 3). For SCI patients without an indwelling catheter, the risk of bladder cancer was 15 times that of the general population. Since SCI patients are already at increased risk of developing bladder cancer compared to non-SCI groups, the influence of an indwelling catheter on bladder cancer requires further clarification, including the potential relationship between duration of catheterisation and cancer development. Bladder calculi have been identified as an independent risk factor for bladder cancer by some authors [367].

Most reports have grouped UC and SPC together as indwelling catheters but a small number of case study reports have drawn attention to long-term risks of carcinoma within the cystostomy tract with SPC, with or without further extension into the bladder [370-372]. However, in a retrospective analysis of screening biopsies for bladder malignancy in 36 patients with SPC for more than 12 years, Hamid et al.[373] found no tumours in the screened group although histological findings were frequently abnormal (Level of Evidence 2). These authors raise concerns over the interpretation of screening cystoscopy and biopsy in this population

and note the importance of the distinguishing between histological changes and confirmed cancers when interpreting study results. Recently published guidance on management and prevention of catheter-associated urinary tract infection, based on an extensive survey of the literature, includes a recommendation that patients with urethral catheters in place for 10 years or more should be screened annually for bladder cancer [374] (Grade of Recommendation C).

k) Catheter management strategies

Although guidelines and protocols for catheter-care practices are abundant, relatively few practices are supported by research evidence and even fewer 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 [375], 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.

1. Catheter change procedures and catheter comfort

Indwelling catheters can cause substantial patient discomfort but 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. Further investigation and guidance to practitioners is needed. Catheter-related pain or discomfort can occur as the catheter is passed, in situ and on removal. Local anaesthetic lubricant gels are commonly used to aid the insertion of indwelling catheters in males and protect the sensitive urothelium from trauma [376]. Similar use of anaesthetic gels is generally recommended for females although the procedure may be less consistent in some places and where only small amounts of lubricant are applied to the catheter tip this may be insufficient to coat the urethra adequately. There is little research evidence to underpin clinical practice in this area although the NICE guidelines on infection control [375] recommend: 'an appropriate lubricant from a single–use container should be used during catheterisation to minimise trauma and infection'. The choice of lubricating gel is usually left to practitioners but not all gels containing anaesthetic agents (eg lidocaine) are suitable for both urethral and suprapubic use. One prospective, randomized, double-blind, controlled trial of plain lubricant versus lidocaine gel prior to female catheterisation in an accident and emergency department found no significant differences in pain ratings, based on lubricant type or catheter size amongst 100 women recruited to the trial [377]. Anaesthetic gels may be contraindicated in patients with damaged or bleeding urethral membranes and

should be used with caution in those with cardiac conditions, hepatic insufficiency and epilepsy [378]. Lubricants which contain chlorhexidine have been reported to trigger anaphylaxis in a small number of patients during catheter insertion and consequently a careful history is required to screen for sensitivities [92;379].

Catheters can be painful when in situ. In one study at a US Veterans Affairs Medical Centre, 42% of catheterised patients reported it was uncomfortable, with 48% complaining it was painful, and 61% stated it restricted their activities of daily living[104]. If bladder spasm is the cause of pain when a catheter is *in situ* a low dose of an anticholinergic medication can help [380]. Other helpful approaches include treating constipation if present, ensuring that the catheter is the smallest size to provide adequate drainage, and ensuring that the drainage bag is well supported to prevent dragging on the catheter. Bladder discomfort related to an indwelling catheter can exacerbate post-operative pain by mimicking overactive bladder syndrome that is resistant to conventional opioid therapy. Sub-lingual oxybutinin has been shown to be an effective treatment for pain after radical retropubic prostatectomy, with significant reduction in other pain relief requirements [381]. Cuffing of the catheter material on balloon deflation (see below) and / or encrustation of the catheter by mineral deposits may cause pain during catheter removal. Encrustation is discussed further in Section XII-.2.i and management of these problems is also discussed below.

Protocols on indwelling 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. SPC changes can be compe-tently managed by skilled nurses [260], 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 [382]. 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 [383]. Dressings around the stoma site are not normally required unless there is excessive discharge, causing staining and / or sticking to clothing.

Urinary catheter 'deflation cuff' formation can be a problem in both SPC and UC, causing difficulty in removal and great discomfort to patients. Evidence suggests deflation cuff formation can be a particular

problem for all-silicone SPCs. 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 [384]. 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 [272]. It has been suggested that slow deflation may enhance the probability of the silicone balloon returning to its pre-inflation shape [273]. 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 has been well-tolerated by patients and produced virtually no trauma.

2. Personal hygiene and infection control

Meatal cleansing by simple washing with soap and water during routine bathing or showering is recommended (Level of Evidence 1) [385;386]. No consistent reduction in bacteriuria has been demonstrated by any other meatal cleansing regimes, using povidone-iodine solution or cream, chlorehexidine, polymicrobial creams, 1% silver sulfadiazine or antiseptic lubricating gels, compared to routine bathing or showering [117;245]. Effective handwashing by healthcare professionals, carers and patients, before and after handling catheters and drainage equipment is generally accepted to be the most important component of any infection control strategy. Healthcare professionals and formal carers should also wear gloves. Catheters and drainage equipment are commonly supported in position by tapes, Velcro and other securing devices (eg CathSecure, StatLock) but the importance of these in reducing risks of CAUTI and the mechanism involved are not well-established [296] (See also Section XII.2.h).

3. Urine collection – catheter valves

Urine may drain continuously from the bladder into a drainage bag attached to the catheter (See Section VIII) or intermittently via a catheter valve. 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 than continuous drainage into a bag. Valves are available in a variety of designs (**Fig XII-9**) ranging from simple inexpensive types used for up to a week, to more expensive, complex, forms which last longer and which may permit one handed action. However, valves are not available or licensed in all countries.

Most valve designs can be attached to a drainage bag at night to allow free drainage while the patient sleeps. A valve can provide a discreet alternative to conventional urine drainage bags and may offer improved maintenance of bladder tone and capacity
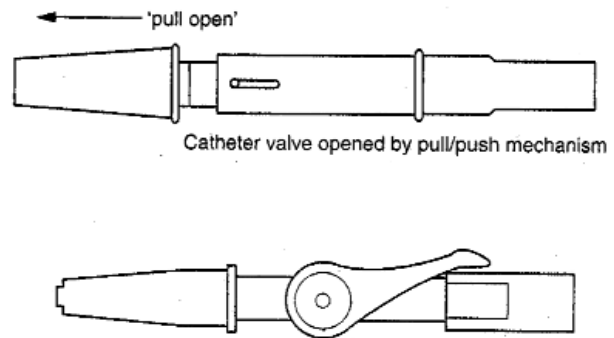
Figure XII-9: Example catheter valves.

for appropriate patients. 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 mechanism 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. 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, clinical 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 were cross-over designs, with 28, 16 and 18 subjects respectively [387-389] (Level of Evidence 3); two randomized their sample of 100 subjects to either catheter valve or standard drainage[390,391] (Level of Evidence 2). 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.

Several studies have evaluated a single valve design [392,393] but only one has compared a broad range

of valve designs [394]. 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). A more recent development concerns the design of a prototype, novel, automatic valve system for LTC patients [395] which may be helpful for patients who lack sufficient dexterity to manage a manual valve. In 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).

4. MAINTAINING EFFECTIVE CATHETER DRAINAGE

Use of urinary catheters is rarely completely trouble-free. 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 XII-10 to XII-12** combine current evidence-based knowledge and expert opinion to provide some guidance on trouble-shooting common problems.

5. RECURRENT CATHETER ENCRUSTATION AND BLOCKAGE

Factors affecting persistent catheter encrustation leading to recurrent blockage have been discussed earlier in Section XII.2.i. The day to day management of recurrent catheter encrustation and blockage is largely a nursing responsibility but there are few options available. Maintenance of dilute urine by a suitably high level of fluid intake has been shown to reduce encrustation in laboratory studies [344] and increased urinary citrate concentration produced by drinking orange juice or other fruit juices may also be beneficial [344] (see Section XII.2.i above). However the amounts required may be relatively high and clinical studies are needed to assess benefits and possible detrimental side effects e.g on bowel behaviour. Use of a catheter valve in suitable patients

may also help reduce build up of encrustation by facilitating periodic flushing but clinical evidence is currently unavailable. In a majority of patients a characteristic pattern of 'catheter life' can be identified with careful record-keeping of three or more catheter episodes [237;329;396]. 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 [330].

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 term. A range of commercially available catheter-maintenance solutions is indicated in **Table XII-5**, although these are not necessarily available in all countries. Support for irrigations is strongly divided between those claiming benefit for specific patients who experience very frequent blockage and those who consider any break to the closed system to increase risks of infection. Research evidence is primarily derived from laboratory models of the catheterised bladder, as considered above in Section XII.2.i. The few clinical studies which have addressed this issue have been limited by methodological deficits and small sample size.

I) Levels of evidence relating to catheter-associated risks and complications

- All currently available catheter materials are subject to bacterial biofilm formation (Level of Evidence 1).

- Silver alloy coated catheters are associated with a 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 infection (Level of Evidence 4). Silver oxide coated catheters are not associated with a statistically significant reduction in bacteriuria (Level of Evidence 2).

- Antimicrobial catheters can prevent bacteriuria in hospitalized patients during short-term catheterization (<30days) (Level of Evidence 1). Trial results are highly context dependent and the effectiveness of specific antibiotic preparations may be limited to specific groups of microorganisms. Potential toxicity and / or antibiotic resistance is unknown (Level of Evidence 2).

- There is little evidence to guide the precise timing of catheter change when antibiotic cover is required for a particular patient. One study has shown that clinical outcomes (i.e. reduction in polymicrobial

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URINE DOES NOT DRAIN

PROBLEM

ACTION

Drainage bag > 2/3 full ? — Y → Empty bag

N ↓

Check position of drainage bag and tubing: - is bag below the level of the bladder? - is tubing kinked or twisted? — Y → Adjust position of bag and /or drainage tubing

N ↓

Bladder mucosa obstructing catheter eyes (suction pressure) ? — Y → Raise the bag above the level of the bladder briefly to relieve suction pressure

N ↓

Catheter blockage by mucous, cellular or bacterial debris and/or mineral deposits ? — Y → Try to relieve blockage and ascertain its cause:
- 'milk' the catheter gently along its length
- Change the catheter, observe the nature of the blockage and any external deposits (cut the catheter open if necessary to view the lumen)

N ↓

Catheter blocked by pressure from faecal loading in lower bowel ? — Y → Change catheter and treat constipation

N ↓

Catheter blocked by bladder calculi ? — Y → Change catheter and perform cystoscopy and removal of stones

N ↓

Unexplained problem ?
- change catheter and record details

Recurrent catheter encrustation & blockage:
- identify recurrent 'blockers' by monitoring catheter changes for a characteristic pattern of 'catheter life' (over a minimum of 3 catheters - ie time to blockage) and by direct observation of encrustation
- plan to change catheter before likely blockage

Aim to extend 'catheter life' where necessary by:
- using an all-silicone catheter (larger lumen)
- encourage production of a dilute urine
- consider use of an acidic 'catheter maintenance solution'
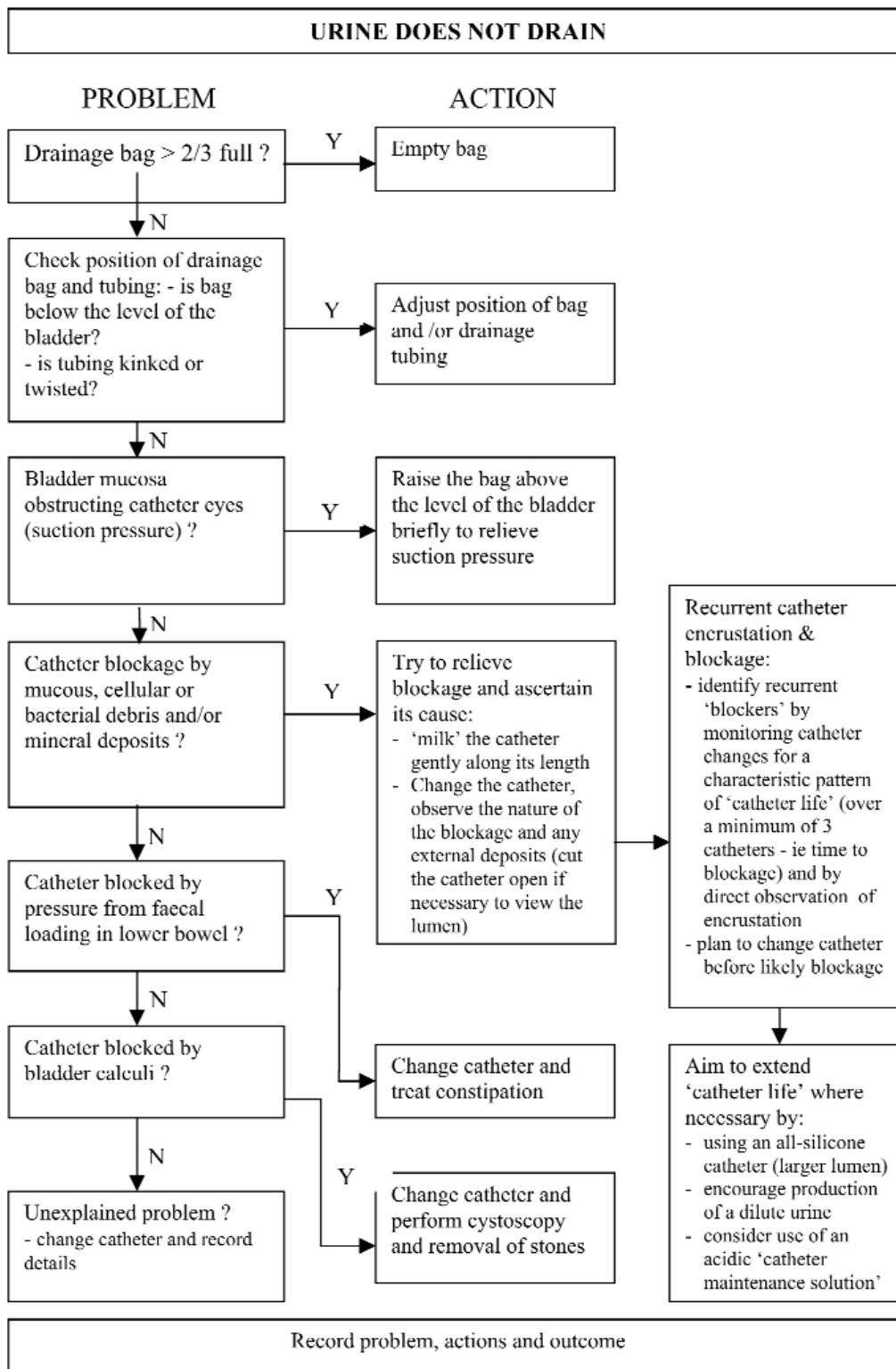
Record problem, actions and outcome

Figure XII-10: Troubleshooting long-term catheter problems: urine does not drain (N = No; Y = Yes). (Always have a spare catheter available)

URINARY BY-PASSING

PROBLEM	ACTION
By-passing may be caused by the catheter being blocked –	see Algorithm in Fig 12-10
Is the catheter the correct size ? – large sizes are associated with irritation and leakage	change catheter to a smaller size 12-14 Ch is appropriate for most adults for long-term drainage
urinary tract infection?	check for signs & symptoms of systemic infection. Treat as required
bladder irritation / spasm ?	consider: • concentrated urine promote increased fluid intake to dilute urine • check for bladder calculi by X-ray or ultrasound treat as required • consider anticholinergic medication • if persistent urethral leakage occurs with SPC it may be necessary to consider surgical closure of the urethra.

Record problem, actions and outcome

Figure XII-11: Troubleshooting long-term catheter problems: urinary by-passing.

counts, time to achieve afebrile status and clinical status at 72 hours) are significantly better among subjects randomised to catheter change immediately before institution of antibiotics (Level of Evidence 2).

- A majority of health services have clear policies on the use of antibiotics, designed to limit unnecessary use. Current evidence does not support routine use of antibiotic cover during catheter changes unless the patient's condition renders them particularly at risk (Level of evidence 4).

- Meatal cleansing by simple washing with soap and water (i.e. not with antimicrobial agents) during routine bathing or showering is recommended (Level of Evidence 1).

- 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).

- Evidence from in vitro models of the catheterised bladder indicates that i) dilute urine; ii) high urine citrate content (> 1.5mg/mL) reduce risk of blockage (Level of Evidence 2).

- Evidence from *in vitro* models of the catheterised bladder indicates that acidic 'catheter maintenance' solutions may have a role in dissolving encrustations in persistent blockers (Level of Evidence 2). There is insufficient evidence from RCTs to assign an *in vivo* level of evidence.

THE INFLATION BALLOON DOES NOT DEFLATE

PROBLEM

ACTION

Blocked deflation channel?	• try to remove or dislodge debris blocking the deflation channel by gently 'milking' the catheter along its length • try to remove or dislodge debris by inserting a few drops of sterile water into the inflation channel (no more than 1-2ml) with a sterile syringe
Faulty valve or syringe	• try a different syringe, withdraw water very slowly or leave syringe in place, the water may seep out over a period of time • insert the needle of a sterile 10ml syringe into the balloon drainage channel just above the inflation valve. If the valve is faulty the water may be withdrawn gently via the syringe
? constipation, present - may cause pressure on the inflation channel	try to relieve constipation
consult local policy for further advice or seek medical help	**do not cut the catheter** • it may recoil inside the urethra **do not cut the inflation valve off** • if the balloon does not deflate it will no longer be possible to try alternative simple methods **do not attempt to burst the balloon by over-inflating it** a cystoscopy will be required to remove fragments! remaining fragments may result in formation of calculi

Record problem, actions and outcome.
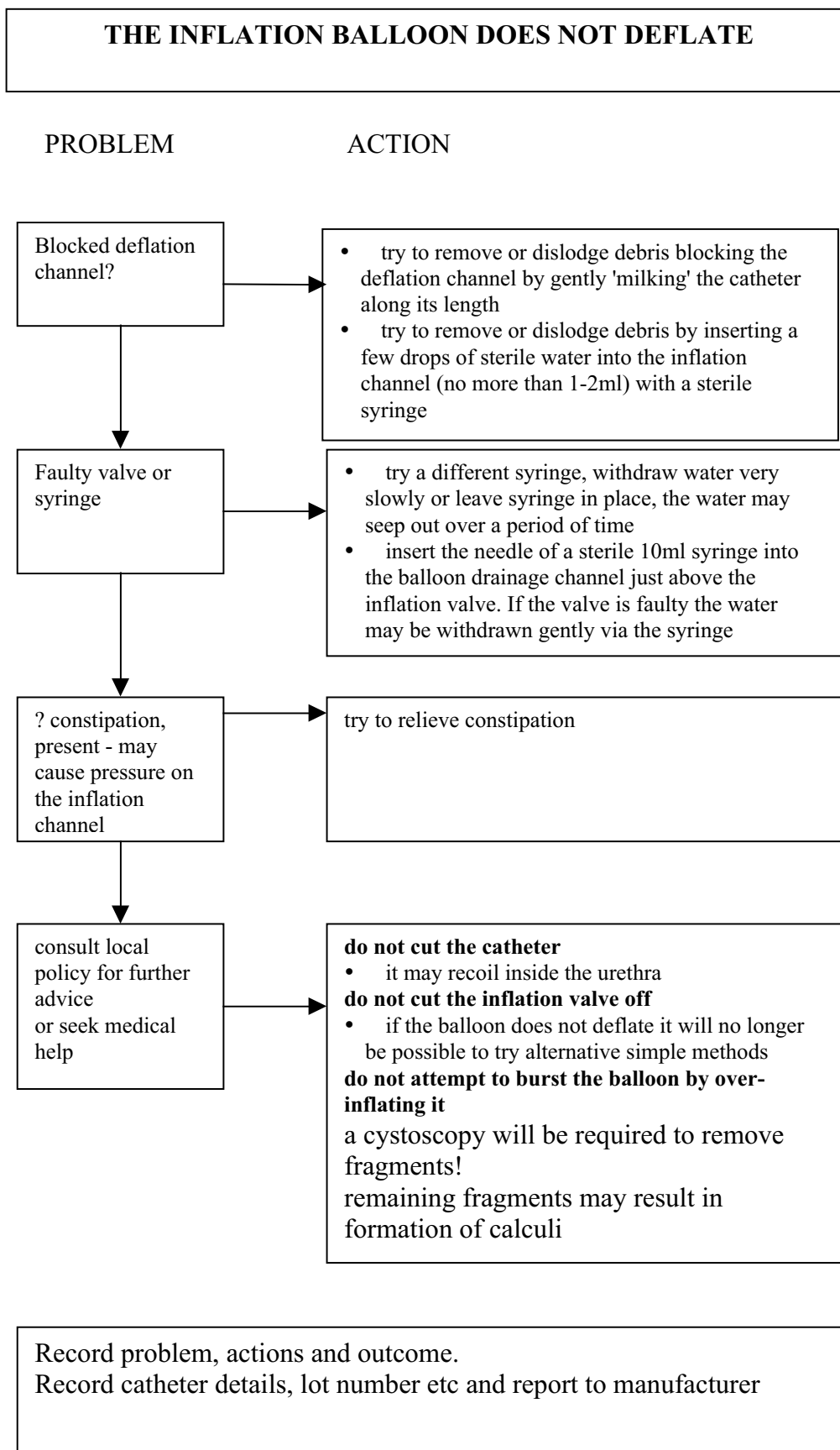Record catheter details, lot number etc and report to manufacturer

Figure XII-12: Troubleshooting long-term catheter problems: the inflation balloon does not deflate.

- Suprapubic catheterisation (SPC) is an appropriate alternative to urethral catheterization for many patients following appropriate risk assessment (Level of Evidence 1).

- There is some evidence for a reduction in catheter-associated infection in SPC use during short-term catheterisation (Level of Evidence 2), compared to urethral catheter insertion. However, there is no corresponding evidence for long-term catheterisation.

- Patient comfort, quality of life and satisfaction with SPC is generally good compared to urethral catheters (Level of Evidence 1).

- 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).

m) Urinary catheters versus other care strategies

Very few studies have compared urinary catheterisation with other strategies to manage urinary incontinence, not least because of the difficulties in recruiting to and conducting robust trials. For male patients who do not have problems with retention of urine external urine collection systems are an option (See Sections VII, VIII and IX). One recent prospective, randomized, unblinded, controlled trial on men >40years in a US Veterans Affairs Medical Centre reported that the use of condom catheters was less likely to be associated with bacteriuria, symptomatic UTI or death than the use of indwelling catheters (97). Patients reported that condom catheters were more comfortable (P=0.02) and less painful (P=0.02) than indwelling catheters.

A small number of studies have attempted to examine preferences for different urinary incontinence treatments in long-term care. In a descriptive, comparative study of preferences for treatments for frail older adults, residents in long-term care facilities were interviewed and groups likely to serve as proxy decision makers were surveyed (family members of residents and nursing staff) [397]. Forced choice comparisons of continence treatments were measured. Although there was wide variation within and between groups, most preferred non-invasive strategies (diapers and prompted voiding) to invasive strategies including indwelling catheterisation. Older adults stated they would choose a treatment based, in part, on feeling dry, being natural, not causing embarrassment, being easy, and not resulting in dependence. Similar results, showing urinary catheterisation as the least favoured

choice, were found in a study of 117 medical inpatients aged 80 years or over, their physicians, nurses and family members [398].

3. CATHETER-RELATED QUALITY OF LIFE

Use of a LTC is often a last choice for bladder management when other options such as CIC, for males a sheath (condom) catheter, or other voiding treatments like Crede procedure, are either unsatisfactory or no longer practical. Catheter users must deal with a variety of problems that disrupt their daily activities and negatively affect QoL, such as CAUTI, blockage, leakage and catheter dislodgment. In addition, the visibility of a catheter or drainage bag can contribute to shame or stigma, and urine odour can be embarrassing. A catheter can also be a reminder of vulnerability associated with illness / mortality and a symbol of a loss in control of bodily function. Yet catheter users also acknowledge catheter-associated benefits of freedom from wetness, convenience, and utility in promoting urine drainage. While this section focuses on long-term catheter use, even short-term catheters can have a detrimental impact on QoL. For instance in a study of short term catheter use prior to surgery for acute urinary retention, leaking, blocking, urgency, and pain at the penis or during erection were all reported [399].

Studies of QoL issues commonly utilise qualitative research methodologies, such as phenomenology or grounded theory approaches (see also Section XII.1.e). In-depth interviews with catheter-users and carers provide important insights into aspects of 'living with a catheter' and contribute research based evidence to support development of effective care strategies. Measurement of QoL and the impact of factors which may affect it is complex. Most validated QoL instruments fall into one of two groups: i) generic measures designed to encompass domains including physical, mental and social wellbeing; ii) disease specific measures designed to measure change in QoL resulting from treatment (Cross reference QoL chapter). For those people whose urinary symptoms are managed by products or devices, including catheter users, it is particularly difficult to assess the impact of the product on QoL (see earlier in this Chap). This is partially because changes are more likely to be related to improved management of ongoing symptoms rather than actual change in symptoms, and partially because QoL is also dependent on the underlying disease process.

Much of the literature on LTC use involves people with neurogenic bladder, particularly those with spinal cord injury (SCI) or multiple sclerosis (MS). Thus, QoL in catheter users must be considered from a perspective of how the disease and the device affect the individual's life. For instance, in one postal survey of 230 people with SCI, the factors which had most impact on QoL were social activities and accom-

plishments, including employment, attending school, and other activities. There was no association between QoL and different bladder drainage methods [400]. A particular problem for people with spinal cord injury or disease is autonomic dysreflexia (AD), an autonomic nervous system syndrome causing symptoms which include severe hypertension, headache and sweating. A blocked urinary catheter can be a common cause. AD can be a serious problem requiring emergency medical attention, but lack of knowledge and awareness of the risks by some health care providers can cause high levels of anxiety for SCI patients [241;401] (Level of Evidence 3).

There are currently no validated instruments measuring quality of life in people with urinary catheters, though these are being developed in the US [243] and in the UK (Level of Evidence 3).

The published literature addressing QoL in catheter-users is small, and is commonly limited to reports addressing levels of satisfaction with a device. Studies which include a broader perspective of QoL are discussed below under the following headings: changes in bladder management, embarrassment, sexuality, catheter-related pain, catheter adjustment, and self-management.

a) Changes in Bladder Management

Changes in bladder management are often made to promote QoL but there are trade offs that require weighing up the pros and cons of various methods. People sometimes switch from CIC to an indwelling catheter - despite the inherent problems with an indwelling catheter -because quality of life might be improved. In particular, women with cervical spinal cord injury (SCI) may need an indwelling catheter because of difficulties in transferring to the toilet, limited hand dexterity, or dependence on caregivers [402]. Moreover, many people have used different bladder drainage methods over time. In one study, of 30 long-term catheter users, 80% of the sample had used another form, and 33% had used two or three different types [242]. In another small study with a sample of 11, 100% had used another method, and 27% had used two or three other types [243]. Reasons for non-compliance with CIC in relation to QoL or satisfaction have been addressed in Section XII.1.e and in some studies comparing drainage methods (Level of Evidence 3).

Two studies provided additional evidence of how changes in bladder drainage methods are made to improve their quality of life. In a retrospective study assessing compliance with bladder management, 50 new spinal cord injury (SCI) patient records were reviewed after admission, discharge, and follow up from 1994-1997 [402]. Of 38 patients on IC at hospital discharge, 20 (52%) were back to UC at follow up. Six of 10 females on IC had resumed UC. Reasons for

not continuing with IC were: the need to depend on caregivers, poor hand functioning, spasticity, incontinence (despite anticholinergic drugs), and for females with cervical injury, toileting inconvenience (Level of Evidence 3). In contrast, a retrospective chart review and follow up questionnaire was used with 236 SCI injured people (at least 10 years post injury) between 1956-1990 [403]. An 85% response rate was achieved in the sample, with 82% males who had tetraplegia (47%) or paraplegia (53%). Although 46% changed their bladder management method over time and 28% considered the method a problem, in 58% of those who had tetraplegia, the use of CIC went up from 11% at discharge to 36%. Suprapubic tapping decreased from 57% to 31% and Crede increased from 5% to 19%. CIC alone, or with other methods, was the most common method (Level of Evidence 2).

b) Embarrassment

Embarrassment and a sense of lack of bladder control are two major catheter-related issues that are ongoing problems for many people. In one study at a US Veterans Affairs Medical Centre, 30% of catheterised patients surveyed found the indwelling catheter embarrassing, and 61% stated it restricted their activities of daily living [104]. The catheter is placed in a position in the body normally considered 'private', yet health care providers frequently need access to the site to provide care. Also, the force of urine flow is something that catheter users must deal with on a daily basis. In a qualitative phenomenological study of 14 people with long-term catheters, people told stories of how getting wet in public was embarrassing and how the force of the urine was like water that had built up pressure [404]. They used the metaphor of "flowing water" to describe the force of urine flow, the weight of the drainage bag, and the sound of urine sloshing around in the bag.

Living with the catheter was described in one qualitative study [241] 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. Individuals used planning and great care when going out (e.g. mapping out the toilets) to prevent urine accidents. They were bothered also by their lack of bodily control, the monotonous care, and how it was a reminder of their condition and mortality (Level of Evidence 3).

Catheter related embarrassment is a common experience stemming from exposure to the opposite sex, the visibility of the urine bag, and unpredictability of urine accidents[(405,406) [241]. Breeches in privacy were identified in two qualitative studies of the lived experience of catheter use [407] [241;408;409]. To

care providers, catheters may seem commonplace, but male / female sensitivities may occur during catheter care, particularly catheter changes, including men who are embarrassed by a female care provider [405]. Embarrassment can be minimized by providing privacy during catheter changes and same sex care providers when possible [241] [407,408]. Acknowledging the embarrassment that exists if the nurse is of the opposite sex paradoxically may diminish the vulnerability [241]. Humour is often used by care providers, catheter users, and caregivers, and a professional approach by the health care provider may help the catheter user accept the situation [241] [407,408](Level of Evidence 3).

A few studies have examined QoL issues related to practical aspects of living with the catheter, such as managing the drainage bag (See Section VIII). While most people who are self-caring cope with the management of their catheter drainage system, many find them restrictive and report a negative impact on QoL. In a small pilot study based on a postal questionnaire to LTC catheter users (n=59) [410], almost 25% of respondents stated that wearing a bag had a major negative affect on everyday living. Concealment of the bag was one of the most important concerns raised (89%). Keeping the urine drainage bag covered and its visibility minimized can help reduce embarrassment and the stigma related to using a catheter. The visibility of the bag can be considered demeaning and it exemplifies a loss of bladder control; [241,408]. Moreover, if a bag is unreliable, and springs a leak for instance, it contributes to vulnerability. Even using a catheter for a short time can be an assault to one's dignity. In a study in post-operative short-term catheter use, people complained about feeling "on display" and objectified [407] (Level of Evidence 3).

c) Sexuality

In a study of experiences of 25 men with prostate cancer, many of whom were treated with a urinary catheter, subjects reported the catheter contributed to feelings of shame, excess hospital visits for complications, and with other treatments for cancer, an end to sexual activity [411]. Men viewed healthcare professionals as having responsibility for medical decisions and they alone felt responsible for the catheter, micturition, and sexual life (Level of Evidence 3).

Issues related to sexuality were dominant in several other studies. Using a catheter compounded changes in sexual life caused by illness or injury [406,409]. In one study, catheter users complained that care providers did not provide enough information about sexuality and how to adapt to a catheter [409]. Despite some care provider's reluctance to address these issues, sexual health should be a part of assessments [412], and information about sexual activity should be provided proactively, while recognizing that some catheter users will wish to engage in sexual intercourse and others will not (Level of Evidence 3-4).

The underlying disease may also impact on sexuality. For instance, a urinary catheter complicates sexual activity in people with spinal cord injury (SCI). Moreover, men may have changes in sexual performance related to ejaculation, erectile function, and arousal [413]. For females with SCI, experimenting with positions, lubrication, and preventing spasticity may be helpful in sexual activity [414] (Level of Evidence 2). For people with SCI, sex-related autonomic dysreflexia (AD) occurs most often in people who suffer from AD during bladder or bowel care (415) (Level of Evidence 2). Autonomic dysreflexia is an autonomic nervous system syndrome that occurs in people with spinal cord injury or disease. Symptoms include severe hypertension and excruciating headache as well as sweating and goosebumps. It can be a serious problem—even life-threatening—requiring emergency medical attention, yet it is sometimes ignored or disregarded by health care providers [401]. A blocked catheter is also a frequent cause of AD. In a qualitative study (409), several people complained that care providers did not know much about AD and often dismissed their anxiety and concerns (Level of Evidence 3).

d) Catheter-related Pain

Pain related to catheter use is not always recognized although anecdotal information suggests that many people find a urethral catheter uncomfortable (see also Section XII.2.k on catheter comfort and catheter change procedures). In Saint et al's study [104] 90% of catheterised patients surveyed reported they found the indwelling catheter uncomfortable or painful. Sometimes women complained about the pain because of sitting on the catheter or sores in the vaginal area [401], however it is unclear whether sores or skin irritation are related to latex sensitivity, friction, or wetness or a combination. Bladder spasms, CAUTIs, blockage, and dislodgement can all contribute to catheter-associated pain, as well as insertion and removal procedures[401,408,416] (Level of Evidence 3). Pain arising from AD in SCI patients can result from catheter blockage and has been discussed above.

e) Adjustment to a Catheter

Adjusting to living with a catheter may take a considerable time. In Roe's study [417] participants reported it had taken them up to a year. Similar lengths of time are commonly reported in anecdotal evidence. An educational booklet for catheter wearers has been shown to significantly improve knowledge and acceptance of the catheter [418]. Though the implications for this type of intervention are positive (Level of Evidence 1-2), the sample was small (n=45)

and the study has not been replicated. The core category identified in a study using a grounded theory approach to examine older people's experiences of living with a LTC was 'all about acceptance'. Two further categories defined as 'at ease' and 'unease' reflected the extremes of their experience and these were mediated by 'interaction with others'[419]. The presence of a catheter can affect the individual's view of their own body and such shifts in body image can cause some people to exclude themselves socially. New catheter users (both urethral and suprapubic) may resist the "intrusion of the catheter" prior to acknowledging the need for it [420]. Qualitative studies have shown that although some people felt ill prepared for a catheter, and even viewed it as distasteful, most learned to accept the device over time [408,420]. Catheter-users have described their changed perceptions of the body and of how they learned to pay attention to urine flow to prevent catheter related problems. Though most acknowledged feeling vulnerable because of disruptions caused by the catheter, they noted also that keeping urine flowing was critical to their well being [404] (Level of Evidence 3).

Health care providers need to provide proactive support and education about the catheter and its care, particularly since some catheter users are uncomfortable in asking for help or support. Male / female sensitivities can interfere, for example, a woman might be disinclined to talk about her catheter with her son [408,420] (Level of Evidence 3).

Guiding and supporting an individual's adjustment to living with a catheter involves promoting dignity, supporting the changed body image so that the catheter becomes a part of self (and almost not noticed), and learning self-management and self-care, and in planning for active life in the community. It is essential that catheter users know how to select suitable equipment. Simple advice such as not using a coloured catheter in the summer when white clothing would allow it to show can be very helpful. Knowing where toilets are and planning for outings (rehearsing) can prevent urine accidents [401] (Level of Evidence 3). Ambulatory females who use a belly bag need to face the toilet when emptying the bag. Since this position is associated with male toileting rather than female it can sometimes cause embarrassment. Some women may prefer to use a unisex toilet where possible.

While adjustment takes time, emotional distress with the catheter can swing back into the picture at any time if problems develop. Depending on whether the device is working well or not, people can move back and forth between acceptance and estrangement from the catheter [241] when the problem in the background emerges and brings the issue once again to the foreground [421] (Level of Evidence 3). Learning to live with a catheter involves recognizing that the benefits can outweigh the problems (409), watching for signs of problems, and adjusting to the interpersonal and sexual changes [420] (Level of Evidence 3).

f) Self-management

Self-monitoring, a component of self-management, involves awareness of what to notice and related measurements or observations [422]. Self-monitoring urine flow was found to be helpful in preventing or minimizing catheter-related problems in a pilot study with 11 community-based individuals over a six months' time[243]. In this study, a 3-day urinary diary of intake and output was combined with an educational program, individualized to the interests of participants. Most participants said they learned to pay attention to urine flow, through observing continuous drainage into the drainage bag, increased awareness of the urine colour, position of the catheter, and by monitoring the consistency of their fluid intake [243]. Health care providers can help catheter users to learn to manage their catheter themselves, (i.e., self-care) by identifying where they are in the process of learning self-care and by working with them [420] (Level of Evidence 3).

g) 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 (asymptomatic) is commonly employed. However, there are important questions over the appropriateness of this as an outcome measure. 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 there are relatively fewer studies based on community dwelling patients. RCTs may not be the most appropriate or pragmatic design for these groups. Although there are now a number of Cochrane reviews relating to long-term catheter use it is clear that the quality of studies available frequently precludes drawing robust conclusions.

The published literature on SPC use 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. Overall the risks associated with short and long-term use of indwelling catheters are common to both urethral and SPC insertions, including CAUTI, tissue trauma, catheter encrustation leading to blockage, formation of bladder calculi and histological changes.

Quality of life measures, including evaluation of psychometrics, need to be developed further and tested in this population, which may have different needs than others with incontinence. Studies of incontinent people that include catheter users should present data in ways that give the reader information about this sub-population. Sensitivity and a proactive stance from care providers could prevent or minimize some of the stigmatizing effects of the catheter, including those related to privacy needs, dignity, and sexuality. Further product development may help catheter users attain a higher quality of life. Additional research on the effects of self-management/self-care may provide direction for teaching that could contribute to a higher quality of life for catheter users.

4. OVERALL RECOMMENDATIONS RELATING TO CATHETERS

a) Intermittent catheters

- Clean intermittent catheterisation (CIC) is a treatment of choice for those with ongoing bladder emptying problems and residual urine > 100ml who are able to manage the technique (Grade of Recommendation A).

- CIC technique can be taught to all ages of people with appropriate motivation and manual dexterity (or to a carer where this is acceptable to both parties). Appropriate education and ongoing support is needed (Grade of Recommendation C/D).

- Frequency of catheterisation needs to be based on individual need, to prevent over-filling of bladder (Grade of Recommendation C).

- An external lubricant or lubricant-coated catheter is recommended to minimise urethral trauma (Grade of Recommendation C).

- CIC users may benefit from access to different catheters or catheter-packs for different purposes (eg ease of use may be particular important when at work or in public) (Grade of Recommendation C)

b) Indwelling catheters

- Indwelling catheters should only be used after alternative management strategies have been considered and rejected as unsatisfactory (Grade of Recommendation A).

- Duration of catheterisation should be minimal (Grade of Recommendation A).

- A closed drainage system should be maintained to reduce risk of catheter-associated infection (Grade of Recommendation A).

- Asymptomatic bacteriuria should NOT be treated with antibiotics (unless urological instrumentation is planned) (Grade of Recommendation B).

- Routine urine culture in an asymptomatic patient is not recommended (Grade of Recommendation C).

- Silver-alloy catheters should be considered for short-term catheterised patients to reduce the risk of catheter-associated infection (Grade of Recommendation A) but further economic evaluations are required to determine cost-benefit to institutions.

- Catheter materials designed for long-term use (all-silicone, silicone or hydrogel-coating) should be used where a catheter is expected to be used long-term (i.e. >14days) (Grade of Recommendation B).

- Meatal cleansing with plain soap and water (not with antimicrobial agents) is recommended (Grade of Recommendation A).

- Addition of disinfectants to drainage bags, bladder irrigation and antibiotic prophylaxis are NOT recommended as routine infection-control measure (Grade of Recommendation A).

- If an indwelling catheter 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).

- UC and SPC catheters and drainage bags should be adequately supported to prevent meatal or cystostomy damage from traction (Grade of Recommendation C).

- In patients with recurrent catheter encrustation and blockage, careful monitoring should be undertaken to identify of a characteristic pattern of 'catheter life' and instigate pre-emptive catheter changes prior to likely blockage (Grade of Recommendation C).

c) Catheter valves

- 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).

5. PRIORITIES FOR RESEARCH

a) General

- Despite much published research (primarily on short-term catheter use in acute care settings), 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 and its clinical/research usefulness (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 post catheter removal.

- A standardised definition of UTI should be adopted as the primary outcome variable. At present the most recent CDC/NHSN surveillance definition of health care-associated UTI is recommended [295]. Although criteria for both symptomatic UTI and asymptomatic bacteriuria are defined by the CDC, it should be recognised that definitions are applicable to non-catheterised populations and specific to acute care settings.

- Better adherence to CONSORT guidelines [423]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 differences in clinically and economically important endpoints in preference to (or 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 patients' comfort, satisfaction and quality of life measures.

- Further research on the development of biomaterials that resist microbial adherence and biofilm formation and /or prevent catheter-associated bacteriuria in both long-term and short-term catheter users.

- Further efforts aimed at reduction of LTC use, particularly in nursing home populations. Targeted areas to include evaluation and management of skin problems, and alternative measures for people with diabetes mellitus, obesity and communication problems.

b) Intermittent catheters

There is lack of evidence demonstrating the effectiveness of any particular catheter type, technique or strategy. Variations in clinical practice and growth in the use of single-use catheters (particularly coated catheters) with associated increased costs mean that large, well-designed, parallel group RCTs are needed. RCTs are difficult to conduct in this area and must focus on the most important pragmatic questions, for both clinical and cost-effective reasons. Key issues are identified below.

- What evidence is there that coated (single-use) catheters are superior to uncoated (multi-use) catheters and in what ways (e.g infection, comfort, convenience)? Further studies are needed on the risks / benefits of single use catheterisation (new catheter used at each insertion) versus single patient use (patient cleans, stores and re-uses the same catheter for several days) for patients whose long-term bladder management is by CIC.

- To assist assessment of cost-effectiveness, it is recommended that patient acceptability / satisfaction with procedure and a measure of health state utility are measured for different situations (e.g. at home and when away from home) as a secondary outcome variable.

c) Indwelling catheters

- Epidemiological studies of CAUTI in LTC use in community care settings.

- Better prospective data on long-term sequalae of indwelling catheter use, eg ongoing symptoms, strictures, calculi, bladder cancer.

- Studies comparing catheterisation techniques eg CIC, suprapubic and urethral catheters, on CAUTI and other risks or potential benefits

- Studies to determine whether the frequency of regular re-catheterisation make a difference to CAUTI and other complications

- Studies to ascertain if there are detrimental effects on bladder tissue from persistent asymptomatic bacteriuria in long-term catheterised patients.

- Clinical evaluation of strategies to reduce recurrent catheter encrustation and blockage, including maintaining a dilute urine, increased level of urinary citrate, role of acidic 'catheter maintenance' solutions.

- Further development of catheter materials resistant to microbial biofilm formation, new approaches to disruption of the biofilm, or alternatives to catheterisation.

d) Catheter valves

- Clinical 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, including factors such as: frequency of catheter blockage, catheter-associated infection, hospitalization, unplanned catheter changes, adequacy of equipment, knowledge about self care, interaction with caregivers in catheter management.

- Case study analyses to maximise evidence gained through clinical experience and expert opinion, particularly where opportunities for formal research are likely to be unrealistic.

XIII. PRODUCTS FOR PREVENTING OR CONTAINING FAECAL INCONTINENCE

The broader issues of conservative management of faecal incontinence are dealt with comprehensively in chapter 16 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 offensive 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 XIV and XV, respectively, while products for preventing or containing faecal incontinence are covered in this section (apart from absorbent pads, which are included in Section VI).

1. 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 VI).

An anal plug (**Fig XIII-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 [424,425]. 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 community living people, both adults and children, who are independent in managing faecal incontinence and toileting. Another type of experimental anal plug consists of a balloon at the end of a catheter connected to a notification device. The catheter is intended to be inserted into the rectum by the user and the inflated balloon acts as the anal plug; there are also vent holes on the distal tip of the catheter (**Fig XIII-2**). The disposable, double lumen, balloon-cuffed rubber catheter has an infra-red photo-interrupter sensor that is connected to a pager [426]. When faeces enter the rectum, a photosensor signal is sent to the pager which then notifies the person to inflate the balloon. Before a bowel movement, the balloon is deflated and the catheter is withdrawn. To prevent ischemic bowel damage, patients are advised to deflate the balloon for 10-15 min every 3-4 hours.

By contrast, devices for channelling faeces from the rectum to a storage container are used primarily by people who are acutely ill, critically ill, confined to bed, or in long-term care institutions and receive assistance in incontinence management and toileting by caregivers [427-431]. 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.

Rectal tubes and catheters are inserted into the rectum and drain faeces through openings at their proximal end into a collection bag (**Fig XIII-3**). 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 tube during defaecation [428]. This arrangement works best with liquid stool which is most likely to be able to flow without blocking the drainage lumen [431,432]. Bowel management programs often include daily saline irrigations through the rectal catheter to maintain liquid consistency of stool and catheter patency. Differing amounts and frequency of irrigation have been reported (300 to 900 ml). Cutting the tip of the catheter off at an angle to facilitate drainage of stool of thicker consistency has been reported [433]. A rectal tube / catheter is contraindicated in patients who have intestinal mucosal disease, immuno-
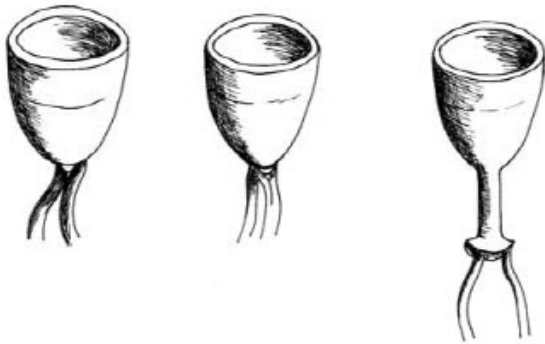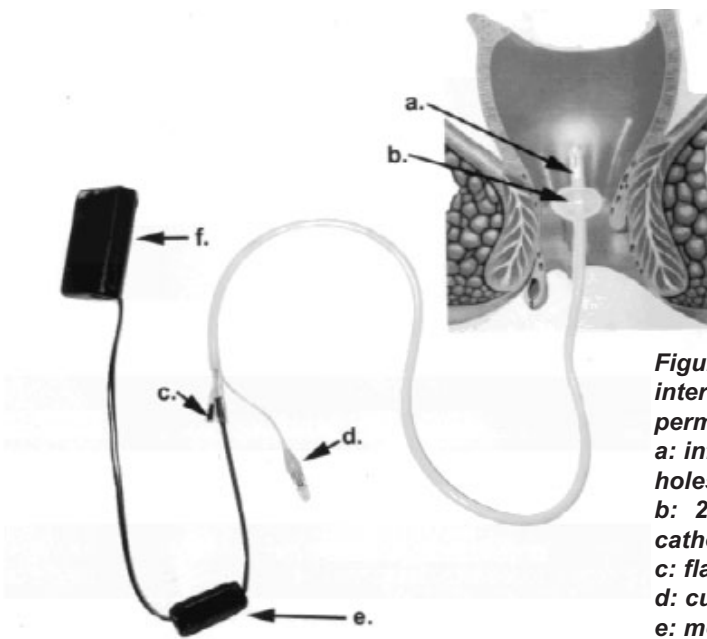
Figure XIII-1: Anal plugs.

Figure XIII-2: Procon anal plug with infra-red photo-interrupter sensor and pager. (Reproduced with the permission of Wiley-Blackwell Publishing)
a: infrared photo-interrupter sensor and flatus vent holes incorporated into the catheter
b: 20 cc air cuff (similar to a regular bladder catheter)
c: flatus venting charcoal filter
d: cuff fill valve
e: monitor connector
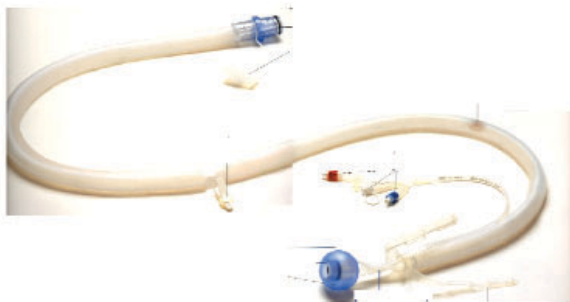*f: monitor that resembles a "beeper" or pager*

Figure XIII-3: Rectal catheters; Flexiseal Fecal Management System, Convatec (Nordic Capital Fund VII and Avista Capital Partners); Princeton, NJ (top); and Zassi Bowel Management System, Hollister, Inc. Libertyville, IL (bottom).

suppression, gastrointestinal bleeding or bleeding tendencies, recent myocardial infarction or prostate surgery [433,434]. 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 [432,433,435]. 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 [436] (**Fig XIII-4**). 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 [436]. Nasopharyngeal airways that can be used as a rectal trumpet are produced by several manufacturers.

An external anal 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 (**Fig XIII-5**). 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 [436,430].

An intra-anal stool bag is composed of a latex bag (20 cm non-extended, to 26 cm extended) that is inserted into the anus and an adhesive attachment (10 cm in diameter) applied perianally [437] (**Fig XIII-6**). There is a cut-out on the ventral urinary side of the adhesive wafer.

Aspects of patient assessment that are relevant to products to prevent or contain leaked stool include the following: a) physical characteristics (e.g., some anal plugs may be too large to fit smaller sized children),
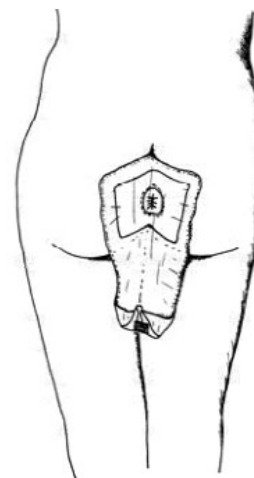

Figure XIII-4: A rectal trumpet.
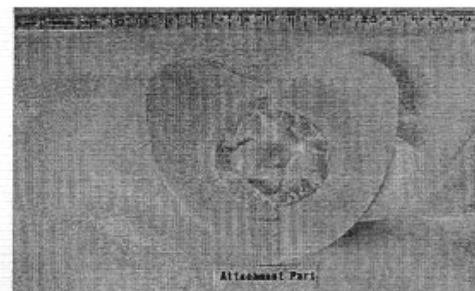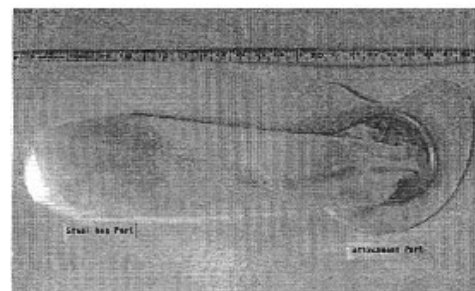

Figure XIII-5: An anal pouch.

Figure XIII-6: Interanal stool bag (left) and Outer attachment wafer of Interanal stool bag (right). (Reproduced with the permission of Wiley-Blackwell Publishing)

b) dexterity (e.g., some degree is needed to insert or remove an anal plug), c) mobility (e.g., rectal catheters are mainly used for patients who are in bed vs. ambulatory), d) nature of incontinence (e.g., bowel catheters will require irrigation when stool consistency is not loose or liquid in order to remain patent; and e) personal priority and lifestyle (e.g., some persons will wear an anal plug on certain occasions such as when swimming, despite discomfort).

2. QUALITY OF DATA

There have been eight published evaluations of anal plugs for controlling faecal incontinence and one of the anal catheter plug (Procon, AnaTech, El Paso, TX). Five reports included children of which two studied children exclusively [438,439]. The study designs were one randomized clinical trial, four repeated measures (cross-over), one pre-post design, one cross-sectional survey, one case series, and one case report. All of the studies of anal plugs except one evaluated products from the same manufacturer (Coloplast, Denmark). One study in children [438] compared the Coloplast device with one by Med.SSE-System, Germany. There has also been one published evaluation of a rectal trumpet using a case series design [436] and one each of an external anal pouch and an intra-anal stool bag in which no comparison group or pre-post measures were included.

3. RESULTS: ANAL PLUGS

Most evaluations of anal plugs have involved relatively small cohorts of ambulatory subjects. The largest sample had 48 subjects and 26 of 31 persons in the intervention group who wore the anal plug completed the study [440]. The aetiologies of faecal incontinence varied across studies and included spina bifida, imperforate anus, spinal injury, post-surgical incontinence, sphincteric injury, and obstetric trauma. Faecal incontinence was measured by self-report using a daily stool diary in six studies [424-426;439-441]. A questionnaire /survey was used in one descriptive [442] and one repeated measures study [438]. 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 [424]; the number of patients experiencing no faecal incontinence [425,438,439,441] or improved faecal incontinence [425] while using the plug; the number of patients able to retain 150 ml of viscous fluid while using the plug [441]; and the change in a faecal incontinence severity score [426,440]. The percentage of participants lost to follow-up ranged from 10% [424] to 80% [441].

The effectiveness of the plug in preventing faecal incontinence in adults ranged from 83% [441] to 38% [439] (Level of Evidence 3). Bond et al [440] conducted a randomized clinical trial of the effectiveness of an anal plug that included 31 adults and children with spina bifida in the treatment group and 17 adults and children in a control group; 84% of the treatment group and 100% of the control group completed 12 months of follow-up. There was no statistical difference in the faecal incontinence severity score between the group wearing an anal plug and the one that did not; however, the study was determined to be underpowered to detect differences. Norton and Kamm [425] compared two anal plugs for two weeks each in random order in a cross-over design. Of the 20 adults (16 female) participating, 10 (50%) were continent, and 9 (45%) withdrew after trying the first plug. Three anal plugs were compared by 10 adults for one week each in a cross-over design in an earlier study by Mortensen and Humphreys [424]. Continence was achieved in 83% of anal plug uses overall. Faecal incontinence occurred in 18%, 19% and 15% of uses when Plug 1, 2 or 3 were worn, respectively. Only one subject withdrew from the study. In a pre-post comparison of an anal catheter plug, seven of 18 adults (39%) with various aetiologies of faecal incontinence and a Cleveland Clinic FI severity score >7 completed a 14-day wear period [426]. The mean (standard deviation (sd)) faecal incontinence score during wear of the anal plug (5.2 (3.0)) was less than half that before its use (12.7 (3.6)). Christiansen & Roed-Petersen [441] reported that 86% of persons were able to retain 150 ml of viscous fluid while an anal plug was inserted.

In the study of children only, 38 children (ages six to 15 years) after anorectal malformation repair compared two anal plugs (one made of polyurethane and one of polyvinyl alcohol) for three weeks each in random order in a cross-over design. Approximately two-thirds (61%) completed the study. Twelve children (32%) were completely continent using either plug and five (13%) reported "total failure." Two or fewer soiling accidents occurred in 74% using the polyurethane plug, and in 65% using the polyvinyl alcohol plug [438].

A survey of adults and children showed that a higher percentage of children tolerated using an anal plug over a longer period of time [442]. Five of eight (63%) adult survey respondents who had faecal incontinence of various aetiologies stopped using an anal plug immediately while three used it periodically for 12 to 20 months. Two of seven child respondents stopped anal plug use immediately while five (71%) used it weekly for an average of 2.5 years. The most common reported problems associated with wearing an anal plug included discomfort and failure to retain the plug. Despite efficacy, approximately two-thirds of the subjects in two studies [425;441] said they would not continue to wear the plug due to discomfort. Discomfort occurred in 10% to 12% of times one of the three anal plugs were worn in another study [424]. In more recent studies, three of 23 subjects (13%) reported discomfort [440], and 25% of 16 withdrew from another study because of pain [439]. Two of the children who

withdrew from the paediatric study had complained of discomfort [438]. There was no association between comfort of the plug and anorectal sensitivity during anal-rectal physiology tests in adults [425]. Approximately 20% of children reported that insertion of the polyvinyl alcohol plug was painful while 17% found removal of the polyurethane plug to be painful; one child experienced bleeding on removal of this second plug. Rectal bleeding also occurred in adults but infrequently [424].

Failure to retain the anal plug was reported by 13% of subjects in two studies [439,440] and was noted by one child in the paediatric study as a reason for withdrawal [438]. The size of any plug tested was too large for six children in one study [438]. Other tolerance problems were fairly uncommon. In one study, adults rated all three anal plugs that were evaluated as relatively easy to insert. Two plugs were difficult to remove in only 5% and 6% of uses, respectively, while the third was difficult to remove in 23% of uses [424]. Other reported problems were feeling a need to defecate [425], inconvenience or difficulty in managing [425,426], and local irritation [442].

4. RESULTS: RECTAL TRUMPET

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 (436). 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).

5. RESULTS: RECTAL CATHETER SYSTEMS

Closed rectal catheter and collection bag systems specifically designed for extended use and diversion of faeces are commercially available primarily for acutely-ill or bed-ridden patients (Flexi-Seal® Fecal Management System, Convatec A Bristol Myers Squibb Company; Princeton, NJ; Zassi® Bowel Management System, Hollister, Inc., Libertyville, IL). The catheters of these systems typically contain a retention cuff that collapses to assist with insertion (US FDA approved for up to 29 days) and a port for irrigation. In one system (Zassi) there is also a collapsible zone below the cuff that resides in the

anus to allow normal anal sphincter function during use and a second port for sampling intestinal fluid. A third catheter has an inner balloon that can be inflated to serve as an anal plug to promote retention of an enema, for instance (Kim, US Patent 5 569 216, apparently not currently commercially available).

Six studies evaluated use of a rectal catheter system. Three studies used one type of catheter while the other three studies used three different types of systems. One study was of children [443]. The designs included a prospective single cohort in four studies [427;428;443, 444], a pre-post descriptive design [445], and a retrospective case-matched pre-post design [446]. The largest sample size was 106 in the retrospective chart review whereas sample sizes in the prospective studies were relatively small, ranging from 20 to 42 subjects. In the studies of adults, subjects were burn patients in two studies [444;446] and acutely or critically-ill patients in three studies [427;428;445]. In three studies, irrigation of the catheter with saline, a combination of lactulose and saline irrigation or use of an enema was used to keep the stool liquid and the rectal catheter patent [428;444;446].

In only two studies was the effectiveness of the rectal catheter system in reducing faecal incontinence reported (Level of Evidence 3). In the one paediatric study, 31 children (11 females) participated. Eight families refused to stop using the rectal catheter to complete an incontinence diary without use of a catheter. Two children had balloon extrusions and three were noncompliant resulting in their study withdrawal. The mean number of daily faecal incontinence episodes as reported on a daily diary decreased from 3 to 1.5 in males and from 1.6 to 1.1 in females (p<.05 for both) [443]. Three children experienced no improvement of faecal incontinence. In the one adult study, 39 of 42 subjects (62% female) with diarrhoea in intensive care units in seven hospitals completed the study. There was up to 29 days of follow-up. Varying degrees and types of leakage around the rectal catheter were reported in 71% of 198 assessments; 35% of these leakages extended to pads on the bed or beyond [427]. Seven (17%) of subjects had difficulty retaining the rectal catheter. Section VI.k discusses use of a small gauze dressing for absorbing small amounts of stool leakage and a moisture barrier as skin protective strategies that might also help prevent damage from stool leakage around a rectal catheter. Skin damage from the tape holding the catheter in place and rectal bleeding are other reported but uncommon complications [427;444].

The effect of a rectal catheter on various outcomes associated with stool leakage has also been studied. One study reported that the number of bed linen changes in burn patients with diarrhoea decreased eight-fold and dressing changes in hospitalized or burn patients decreased in half after a bowel system was introduced [444].

Other outcome measures of rectal catheter use included urinary tract infections, incidence of skin / soft tissue damage or infections, prevalence of pressure ulcers, and number of linen changes (Level of Evidence 3/4). In a retrospective review of medical records, approximately twice as many burn patients had skin / soft tissue or urinary tract infections before a bowel catheter system was introduced than after (p<.01) [446]. A prospective study of acutely and critically-ill patients showed that 41% who had normal skin in the perineum or buttocks at baseline maintained normal skin during use of the bowel catheter, 44% with some degree of skin damage improved, and 8% had worsened skin condition [427]. The percentage of intensive care unit patients with a stage II or greater pressure ulcer was observed to be less at nine months after use of a bowel catheter was introduced. The total number of patients observed was not reported. The length of time during which the prevalence of pressure ulcers was determined prior to catheter use was also not reported [445].

The condition of the rectal mucosa was observed endoscopically in 40 patients total across three studies; the evaluations were not blinded or independent and did not use a rating scale [427,428;444]. All endoscopic observations were reported as being normal after rectal catheter use. Few complications associated with use of the rectal catheter system were reported. Leakage around the rectal catheter seemed to be the most frequent problem. Catheter expulsion occurred in a small number of patients and skin damage from trying to secure the tube occurred only in one patient. Altered rectal sphincter function occurred using one of the catheters [428] (Level of Evidence 3).

6. RESULTS: ANAL POUCH

One case series study evaluated the use of an external anal pouch (Technoline, Concordia, Moderna, Italy) in 120 nursing home or hospitalized patients (65 men, 55 women, ages 45-96 years) [447]. The nursing home residents (n = 92) were bedridden and had faecal and urinary incontinence or were treated for constipation for rectal enemas that drained into the pouch. Ten had a pressure ulcer. They used the pouch for four weeks or more. Acute care patients (n = 28, of which 10 were in the intensive care unit) had diarrhoea and were temporarily bedridden. Forty-five patients who had surgery of the perineal area received a pouch to collect post-surgical drainage for up to three days. In the nursing home residents free of pressure ulcers, no new ulcers developed. In those with a pressure ulcer, healing occurred in five residents, ulcer diameter was reduced by 50% in three residents, and there was less than 50% reduction in two residents. Of the nursing home and acute care participants, 77% found the pouch comfortable and 75% thought it was better than a sanitary napkin. Seventy-seven percent of the nurses thought the anal pouch was easy to apply and 78% thought is easy to

remove. Reported complications included moderate pain on removal in 18 (15%) patients in the nursing home or acute care (Level of Evidence 3).

An internal anal stool bag (Terumo Corp., Tokyo, Japan) was applied to five bedridden patients (3 female, 2 male) aged 68-90 years [437]. Persons were administered a biscodyl suppository prior to insertion of the stool bag into the anus to control excretion of faeces. The bag was successful in collecting stool 50% of the time (Level of Evidence 3). The bag was removed after each stool was collected.

7. SUMMARY

- An anal plug can successfully prevent faecal incontinence but it is associated with high levels of discomfort, especially in adults (Level of Evidence 3).

- A rectal catheter system diverts faeces to a collection bag and promotes healing of damaged perineal skin but requires liquid stool consistency to remain patent. Some catheter systems enable irrigation of the rectum to maintain liquid stool consistency. Non-blinded and non-independent endoscopic observations suggest the catheter does not cause rectal mucosal damage during the recommended length of use (≤ 29 d in the US) (Level of Evidence 3).

- A rectal trumpet can successfully channel faeces to a collection bag and there is some evidence that it can thereby enable damaged perianal skin to recover but it has been associated with discomfort and its safety has not been determined (Level of Evidence 3).

- An external anal pouch and an internal anal bag can be used to collect stool (Level of Evidence 3) but the adhesive wafers used to adhere them can cause skin damage upon removal. The internal anal bag has been primarily used when a bowel movement is induced using a suppository.

8. RECOMMENDATIONS

- Anal plugs may be tried but many patients are likely to use them on a limited basis or reject them due to discomfort (Grade of Recommendation C).

- The use of a rectal trumpet (i.e. a nasopharyngel tube inserted into the rectum) 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 safety of the rectal trumpet has not been determined, but it suggests a lower risk due to its shorter length than a standard, longer rectal tube (Grade of Recommendation C).

- Use of a standard rectal tube with and without an inflatable balloon for faecal diversion is indicated primarily for non-ambulatory patients with liquid stools (Grade of Recommendation C).

- Use of an anal 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 skin is already damaged or the need for faecal diversion is less acute (e.g. where stool is more formed) (Grade of Recommendation C).

9. PRIORITIES FOR RESEARCH

- 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 (e.g., for assessing health of the rectal mucosa) over longer periods of use.

- Development and evaluation of an external anal 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. Further evaluation of an internal stool bag with similar adherent properties (as recommended for the external anal pouch) is needed.

XIV. SKIN HEALTH AND CONTINENCE PRODUCTS

1. BACKGROUND

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. In adults the term perineal dermatitis (PD) has commonly been used, but more recently it has been proposed that incontinence-associated dermatitis (IAD) is a better term because affected skin areas are not confined to the perineum [448]. The more inclusive

label 'Incontinence-associated skin damage' has also been applied [449] and may be preferable when describing skin problems on the buttocks, hips and sacrum where erythema or skin surface damage may also be caused by pressure, shear or friction.

a) The role of urine and faeces in skin irritation

Prolonged exposure to water alone has been shown to cause hydration dermatitis [450;451] and prolonged occlusion of the skin (as within a continence product) has been demonstrated to reduce skin barrier function [452] and significantly raise microbial counts and pH [453,454]. Repeated wetting and drying makes the skin more vulnerable to substances that are usually innocuous, e.g., bile salts [455;456]. 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 [457] 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 [458].

A similar mouse model was used by the same researchers to examine the role of urine in the aetiology of diaper dermatitis [456]. 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 [459]. Zimmerer [460] 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 [461]. Therefore, it is thought that bacterial or fungal infection is secondary to alterations in the skin barrier that allow penetration of the microorganisms [462].

Zimmerer et al. [460] 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 significant 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 [463] 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 [464].

Berg [465] analysed the aetiological factors contributing to infant diaper dermatitis and developed a model (**Fig XIV-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[466;467] within the pad area. In the largest study of assessment records of more than 59,000 residents in 510 nursing homes located in 31 US states, Bliss et al. [449] reported a prevalence of perineal dermatitis of nearly 6%. In studies with smaller sample sizes and other populations, perineal dermatitis (**Table XIV-1**) has been shown to affect about a quarter to a half of patients.

There is no widely accepted, valid or reliable tool for the assessment of PD / IAD although three instruments have been published [475-477]. One of these tools, the Perineal Assessment Tool, despite its name, appears to be an instrument primarily for assessing the *risk* of PD (versus assessing skin health) and it has been described and used by its developer as such [478]. Most researchers have reported ratings of colour changes (degree of erythema) based on visual inspection, which may be confounded by the

Table XIV-1. Studies reporting the prevalence of perineal dermatitis

Authors	Sample	Prevalence of dermatitis
Lyder et al. 1992 [716]	15 older people: hospital psychogeriatric wards	33%
Keller et al. 1990 [717]	95 older people: long stay	53%
Brown 1994 [718]	166 adults (acute medical wards)	35%
Bale et al. 2004 [719]	79 nursing home residents	25% baseline prevalence
Zehrer et al. 2005 [720]	398 nursing home residents on a skin damage prevention regimen	4% baseline prevalence
Bliss, Savik et al. 2006 [721]	59,558 nursing home residents	5.7%
Bliss, Zehrer et al. 2006 [722]	1,918 nursing home residents on a skin damage prevention program	3.5% baseline prevalence
Ehman et al, 2006 [723]	45 adult intensive care unit patients	36%
Junkin et al, 2008 [724]	698 paediatric and adult hospitalized patients	20%

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

Healthy skin

Compromised skin

Diaper dermatitis

Aetiological factors
Faecal enzymes
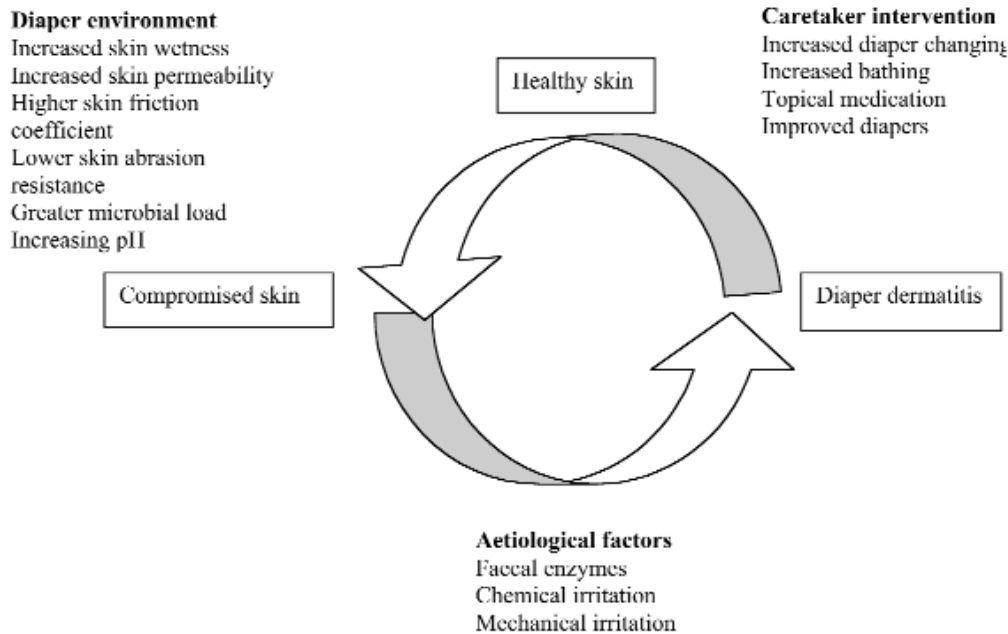Chemical irritation
Mechanical irritation

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

presence of reactive hyperaemia on areas subject to pressure (particularly the buttocks, hips and sacrum). In some studies (mainly those finding higher proportions of PD) trained staff or researchers have been utilised to carry out skin inspections at pre-specified times and in others (mainly those finding lower proportions of PD) the usual care staff have been asked to report skin problems or written records have been used; this may explain the wide range of prevalence reported.

Bliss et al. [479] 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. The prevalence of PD appears to be influenced not only by the type of patient (nursing home versus hospitalized) but also by the type of incontinence and whether or not a skin damage prevention program is followed.

Few studies report the severity of PD. In a prospective surveillance study of 981 nursing home residents with incontinence of urine and/or stool over six weeks, the most common anatomical locations of PD were the buttocks (73% of those with PD) and perianal area (70%) followed by the genitalia, scrotum and groin (36%) and thighs (24%) with the smallest percentage near the sacrum (9%). Approximately one-third of residents had PD in more than one location. Mild PD was by far the most common (69% of residents); severe PD affected only 8% of residents [472].

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 [480,481-483], but some studies have only found faecal rather than urinary incontinence to be a risk factor [484,485]. 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.

Some researchers have used pressure ulcer classification systems, such as those published by the National Pressure Ulcer Advisory Panel (NPUAP) or the European Pressure Ulcer Advisory Panel (EPUAP), to measure skin health. The validity and reliability of most of these tools have not been established. Doughty et al [486] and Bethell [487] described numerous other limitations of pressure ulcer staging systems and despite recent revisions of the NPAUP and EPUAP staging systems, many of the shortcomings still apply. The reliability of the EPUAP staging score (which is a modified version of the NPUAP score) has been tested recently in three studies using photographs of pressure ulcers. These photographs included 'moisture lesions' (defined as lesions resulting from prolonged exposure of the skin to excessive fluid because of urinary or faecal incontinence, profuse sweating or wound exudate). A high degree of reliability for classification of moisture lesions was found amongst 44 pressure ulcer experts

(Kappa =0.80) [488]. However, inter-rater reliability was found to be much worse (Kappa = 0.37) when photographs were viewed by 473 non-expert nurses (489) and subsequently in a European study of 1,452 non-expert nurses from five European countries (Kappa = 0.36). The authors concluded that better descriptors needed to be incorporated into the EPUAP system and more education was needed.

To investigate the validity of classifying moisture lesions, Houwing et al. [490] examined the histology of 14 biopsy samples of damaged patient skin. Skin damage was classified using the EPUAP system: 12 were moisture lesions, one was a grade 4 pressure ulcer (extensive tissue destruction / necrosis) and one was a combination of a moisture lesion and a grade 1 pressure lesion (non-blanchable erythema). Both pressure ulcers had a histological pattern suggesting ischemic pathology; the histology of the moisture lesions, however, was either of an ischemic or irritation pattern. Because of the overlap in histology patterns of some of the moisture lesions and the pressure ulcers, the authors concluded that there is no justification for classifying moisture lesions separately from pressure ulcer lesions. This finding requires further study as there are several limitations of their study. First, the true aetiology of the skin damage and the veracity of the EPUAP classification were not determined; some moisture lesions seem to be partially over a bony prominence so that a mix of pressure and moisture damage cannot be ruled out, which might explain the mixed histology patterns. Secondly, the moisture lesions and the pressure ulcer were both described as having blanchable erythema. Identification of moisture lesions as distinct from pressure ulcers is sought as a way to solve the tension between inadequate prevention / treatment of a pressure ulcer and inappropriate use of costly prevention relieving devices / measures.

Fader et al. [491], examined the effects of absorbent continence pads on mattress 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 / mattress. 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

In the 1980s, product manufacturers introduced diapers with super-absorbent polymers (SAP), 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 the 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 INFANT DIAPERS

Campbell and colleagues[492] 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., [493] randomised disposable diapers without SAP and disposable diapers with SAP to 149 newborn infants and assessed their skin condition seven 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 [494] 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 [495] 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 [496] found significant differences between products within each of the three product groupings but not between groupings (Level of Evidence 2). Grove et al. [497] 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).

3. 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 (64). This study included 166 incontinent patients (urine, faeces or both) from three acute care facilities who were divided into the five 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 six 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. (61) 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 five 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 [498] but it is known that repeated exposure to anionic surfactants (common in soaps) results in skin irritation [499;500]. In addition, the action of washing is also considered likely to contribute to mechanical damage of the stratum corneum.

Cleansing of skin soiled with urine and / or faeces should occur immediately if possible or promptly after episodes of incontinence [448;501-504]. In addition, an individualized schedule for cleansing the perineum according to patients' needs or preferences [505;506] or at routine intervals, such as daily or at bath time [448;501,507;508] has been recommended (Level of Evidence 3).

The practice of cleansing or wiping the perineum front to back is recommended as standard practice in the literature - particularly for women [509-513]; this recommendation is based on the physiological rationale of lowering presumed risk of contaminating the urethra with fecal bacteria and subsequent urinary tract infection [513]. One retrospective study of pregnant women found a significantly higher association of urinary tract infections in women who self-reported they wiped back to front (25.8%) than among those who wiped front to back (18.5%) [514](Level of Evidence 2).

To minimize friction damage of the skin during the perineal cleansing process, gentle cleansing and patting dry the skin [515,516] rather than rubbing or using a soft cloth is recommended by clinical experts [472,517,448,503,504;518] (Level of Evidence 4).

However there is some evidence that drying the skin

by patting may be less effective than gentle towel drying or drying with a hair dryer [519]. Damp skin is more vulnerable to friction damage and special care may therefore be needed to ensure that the skin is dry. For already damage skin, there are clinical anecdotes of using a small hand-held hair-dryer set on a low and cool setting rather than drying with a cloth. Further research into cleaning and drying techniques and products is encouraged.

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 [520].

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 reducing 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 [521]. 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.

The application of skin barriers is recommended on areas that would come in contact with leaked urine and / or faeces. In general these areas include the buttocks and perianal area, groin, and inner thighs. Community-living persons report leaking small amounts of faeces that remain between the buttocks. Clinically, nursing staff have observed seepage of faeces around a rectal catheter in hospitalized patients. In both groups, perianal skin protection is important, and skin barriers are recommended (Level of evidence 4).

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. [521] showed that barrier recovery (measured by TEWL) on experimentally irritated skin was accelerated by the application of petrolatum and De Paepe K et al. [522] showed similar results using a different moisturising cream. Hannuksela and Kinnunen [523] showed that treatment with moisturisers prevented the development of irritation in an experiment involving frequent skin washing with liquid detergent. However, Gabard [524] 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 [525] 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 [526] 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. In a later study, Hoggarth et al. [527] investigated the barrier function and skin hydration properties of six skin protectants when applied to the volar forearms of 18 healthy volunteers. The researchers found that each had different performance properties with the water-in-oil products containing petrolatum performing better than the oil-in-water products containing dimethicone for protection against irritation or maceration. However the dimethicone products had higher hydration properties compared to the petrolatum products. Overall the water-in-oil petrolatum-based product was the only product to be efficacious for all performance variables. A limitation of some petrolatum-based moisture barriers compared to a non-alcohol barrier film for individuals wearing absorbent pads or briefs is that the petrolatum-based products have been shown to transfer from the skin onto the absorbent product and reduce fluid update by 54% to 90%. [471]. However this has not been tested in clinical trials and the effects of different topical products on the leakage performance of absorbent pads is unknown.

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 [465] Level of Evidence 4.

a) Quality of data

Several studies of skin cleansing and / or moisturising / barrier products to prevent perineal dermatitis have been limited by being uncontrolled [528-531] and of small size and lacking adequate power calculations [532,533; 468], or not including any clinical outcome

measures [532]. Measurement of dermatitis may also have been compromised by reactive hyperaemia on skin areas subject to pressure. Only three randomised controlled trials of a skin cleansing regimes to prevent perineal dermatitis could be found, and two RCTs of products to treat dermatitis. Two trials focused on the costs of barrier products use. In addition there was one randomised crossover trial of pad changing frequency.

b) Results

1. Skin cleansing / moisturising products to prevent dermatitis

Byers et al. [532] 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).

i) Cleansing products

Cooper and Gray [534] 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 et al. [518] 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 and care costs may be made [478,518,532,533] and that staff opinion was favourable towards cleansers rather than soap and water.

ii) Costs of barrier products to prevent dermatitis

Zehrer et al. [471] compared the cost and efficacy of three incontinence skin barrier products in 250 nursing home residents from four facilities. A polymer-based barrier film was used either once daily or three times weekly, and one of two petrolatum ointments was used after each episode of incontinence. Residents were monitored for skin damage for six months. There were no significant differences in effectiveness among the various barrier film and ointment protocols of care.

Time and motion measures were used to determine the costs of the products and associated nursing labour. Daily cost of barrier product ranged from $0.17 for the barrier film applied three times per week to $0.76 for a petrolatum ointment applied after each incontinent episode. When nursing staff labour to apply the barrier products was included in the cost analysis, costs increased from $0.26 per day for the less frequently applied barrier film to $1.40 per day for the more frequently applied petrolatum ointments (Level of Evidence 3).

Bliss et al. [472] randomly selected 16 nursing homes to compare the cost and effectiveness of four skin damage prevention regimens. In three of the four skin prevention regimens, a moisture barrier ointment or cream of different compositions (43% petrolatum; 98% petrolatum; and 12% zinc oxide + 1% dimethicone) was applied after each episode of incontinence, while in the fourth, a polymer-based alcohol-free barrier film was applied three times per week. All regimens used a pH-balanced, moisturizing cleanser of the same manufacturer as the barrier. Time and motion measures were documented for the amount of skin care products used, the number, type, and time of caregivers performing IAD prevention care, and the number and type of supplies used. Compared to the three regimens in which a barrier was applied after each episode of incontinence, the use of a regimen in which a barrier film was applied three times weekly had significantly lower costs for the barrier product, labour associated with barrier application, and total cost which included products, labour, and supplies. There were also savings in total product (cleanser and barrier) and total labour costs. The total cost was lowest for the regimen using the barrier film compared to the other regimens in which a barrier needed to be applied after each episode of incontinence. The total cost savings ranged from $0.40 to $0.85 per episode of incontinence (Level of Evidence 2).

Although both these studies demonstrated cost savings when using barrier-film products such savings are dependent on relatively infrequent application of the barrier-film product. This may be achieved by assigning product application to care staff on particular shifts but uncontrolled use of such products may be expensive.

2. Skin products to treat dermatitis

In a double blind controlled trial of 64 subjects, Anthony et al. (535) 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 between 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).

Baatenburg de Jong & Admiraal (536) determined the cost of treating moderate to severe IAD in 39 nursing home patients in the Netherlands randomly assigned to treatment with a non-stinging barrier film or zinc oxide oil. The barrier film was applied every 48 - 72 hours for less severe skin damage and 24 - 48 hours for more severe damage. Zinc oxide oil was applied twice per day and after each episode of incontinence. Both barriers reduced IAD but the no-sting barrier film was significantly associated with reduced severity of skin redness and skin loss, although skin assessments were not blinded. The cost per day of the nursing staff labour in the regimen using the barrier film was €68.58 (sd = € 23.61) compared to €88.20 (sd = €22.88) in the regimen using the zinc oxide oil The total cost (including barrier, labor and supplies) per day of the regimen using the barrier film (€76.13, sd = €25.48) was also less than for the regimen using the zinc oxide oil (€102.96, sd = €23.25) (Level of Evidence 2).

3. PAD CHANGING FREQUENCY

Fader et al. [491] 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. Blinded 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, five 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 overhydrates skin and potentiates the effects of other irritants (Level of Evidence 2).

- Faecal incontinence is more irritating than urinary incontinence, but the combined effects of urine and faeces are 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).

- Bodyworn 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 (Level of Evidence 3) 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).

- A regular and structured skin care regimen using topical preparations such as moisturisers or barrier creams is associated with a low incidence of perineal dermatitis (Level of Evidence 4).

- 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 skin wetness (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).

- Skin barrier products should be applied to areas that potentially come in contact with leaked urine and / or faeces (Grade of Recommendation D)

- Barrier products 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).

- Cost effective approaches such as those that save nursing time and labour costs are recommended (Grade of Recommendation B).

6. PRIORITIES FOR RESEARCH

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.

XV. 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 [537,538] (5). 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. (19) 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. [539] 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. [540] 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 [540]. 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 [539] and [540].

There are several commercially available devices that are designed to absorb the odour of flatus. One such product originally called the "Toot Trapper" and renamed the "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 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). Pads comprising fabric covered activated charcoal that can be worn next to the anus or attached to a brief (GasMedic underair pad by Dairiair and Flat-D, Flat-D Innovations, Inc., Cedar Rapids, IA) . There is also underwear (briefs) entirely made of covered activated carbon cloth (Underease protective underwear (UltraTech Products, Inc., Houston, TX). Ohge at el. [541] compared the effectiveness of 11 devices containing activated carbon in six normal adults (50% female) under controlled conditions in absorbing odoriferous rectal gases. Five types of seat cushions, four types of pads, and two types of briefs (one that held a pad next to the anus and one made of activated carbon fiber fabric) were tested. A mixture gas comprising 100 ml of nitrogen with traces of hydrogen sulphide (40 ppm), methylmercaptan (40 ppm) and hydrogen (5,000 ppm) was instilled into the rectum of the subjects via a rectal tube. Since hydrogen does not react with charcoal, the amount of unabsorbed sulphide was determined from the ratio of sulphide to hydrogen collected from the pantaloons relative to the ratio in the instilled gas. The subjects wore mylar pantaloons that were sealed at the thighs and waist with elastic bandages to reduce convection to the air.

The subjects' clothing, apart from any device, absorbed approximately 22% of sulphide gas. The cushions absorbed an amount comparable to usual clothing, 20%. The various pads and the brief with an attached pad held near the anus absorbed 55-77% of the rectal gas. The underwear made of charcoal fabric was the most effective and removed nearly all (95-99%) of the sulphide gas. The charcoal fabric briefs are reusable and the charcoal is allegedly regenerable with heat. There are no reports of any odour absorbing devices being evaluated in persons with faecal incontinence. In vitro studies showed that each device had the capability of absorbing the rectal gases and that their performance efficiency depended on contact between the charcoal element and gas. Briefs entirely made of activated charcoal fabric appear to provide the greatest surface area for contact with malodorous rectal gas. The absorption of odorous gas by clothing suggests that washing outer clothing as well as underwear is important to reduce odour.

Some products aim to reduce the amount of malodorous flatus that is produced. Administration of the probiotic, _Lactobacillus plantarum_, (5 x 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 [542]. Although administration of charcoal, yucca and zinc acetate reduced the percentage of episodes of malodorous gas [543], there are inconsistent findings about reductions in flatulence from ingesting activated charcoal in humans [544,545]. Two clinical trials involving small sample sizes (19 and eight persons, respectively) showed that the over-the-counter product, Beano, which contains α-galactosidase, reduced flatus frequency in normal persons following the ingestion of beans (546;547). A significant reduction in cumulative breath hydrogen excretion over an 8-hour period after α-galactosidase vs. placebo suggests α-galactosidase reduces flatus production [547]. Although Ganiatas et al., 1994 reported a significant decrease in flatus using 240 galactosidic units (GalU), Di Stefano reported that effects of 1200 GalU but not 300 GalU were significantly different from placebo. One GalU is the amount of galactosidase that releases 1 μmol of galactose from its substrate in one minute [547]. Differences in the test diet or lack of adequate statistical power may explain these differences since neither study reported a power analysis. 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.

3. RECOMMENDATIONS

- Briefs made of activated charcoal fabric are recommended over pads or cushions containing activated charcoal for absorbing odoriferous rectal gas (Grade of Recommendation C).

- Since some pads absorb up to 75% of gas, there may be value in offering patients who have smaller amounts of gas the opportunity to compare pads and briefs for themselves. (Grade of Recommendation D).

- For those persons experiencing stool leakage due to flatus, over-the-counter ?-galactosidase containing products, which reduce flatus frequency, can be tried in an attempt to reduce FI frequency (Grade of Recommendation B).

- Washing of outer as well as under clothing after flatus is recommended to reduce odour due to absorption of gas by clothing (Grade of recommendation of C).

4. PRIORITIES FOR RESEARCH

- 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.

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