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Aids for the management of incontinence

A critical review

BERNADETTE RYAN-WOOLLEY

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BERNADETTE RYAN-WOOLLEY

King's Fund Centre

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Foreword

Incontinence is at last becoming recognised as a real social, medical and nursing problem affecting many people of all ages. Over the last 10 years a series of initiatives in the UK has brought this to public notice and a series of responses has followed. Prominent among these has been the emergence of continence nurse advisers – now a full-time or part-time appointee in most health districts. Many such advisers act as local resource persons spreading information among their colleagues in the community and hospital. The English National Board of Nursing Midwifery and Health Visiting has authorised a certificate course on 'An introduction to the promotion of continence and the management of incontinence'. The King's Fund has published a policy document – *Action on incontinence* – arising from the work of the Incontinence Action Group. Medical schools are including teaching on the complex physiopathological background of incontinence in their curricula. And, very significantly, the Department of Health and Social Security has devoted funding from its Helping the Community to Care programme to the production of educational materials for professionals and for lay carers and patients themselves. These resources are channelled through Age Concern England (for the carers) and the University of Manchester Department of Geriatric Medicine (for the professionals).

This project paper provides detailed information on the main products available for the practical management of incontinence. There are many hundreds of these and without basic information of the type provided here no nurse or doctor can make informed decisions about which to use for individual patients. Bernadette Ryan-Woolley has brought together in a succinct and easily readable form all the essential facts. These include the theory underlying each type of product, differences in manufacture and presentation, costs, the research work published so far and that which still needs to be carried out.

Intended as an essential *vade mecum* for continence nurse advisers, community nurses and ward sisters, this review contains information which will be of practical benefit to general practitioners and all specialists who work among the incontinent.

The author has had advice and support from a distinguished advisory panel, the staff of the King's Fund Centre and many others involved in the manufacture, distribution and use of these products. Acknowledgement and thanks are due to them.

J C Brocklehurst
Manchester
1986

Contents

Glossary of terms

The following terms are used in relation to absorbent pads.

Absorption capacity
The ability of the absorbent core to accept and distribute the voided urine.

Functional absorption capacity
The maximum volume that the pad can hold when in position on a patient. If the weight of a 63 kilogram (10 stone) seated person is evenly distributed the mean actual weight in the crotch area is $40g/cm^2$.

Maximal absorption capacity
The maximum volume which the pad can hold without leaking. Both functional and maximal absorption capacities depend upon the urine flow rate – the urine volume per second.

Compression capacity
The capacity of the absorbent to continue to hold urine already contained when compression is applied, for example when sat upon. This will depend on many factors including the ability of the inter-fibre spaces to remain open and the integrity of the capillarity under compression.

Strike-through
The process whereby urine passes through the coverstock and into the pad core which is underneath and in direct contact with the coverstock.

Strike-through time
The time period (seconds) between urine actually arriving at the coverstock and starting to strike through it and into the absorbent core. Ideally this should be immediate.

Web strength
The web is the sheet structure formed by the fibres. Web strength refers to the resistance of the absorbent to breaking up when exposed to sheering forces while in use on the body. This is dependent upon the length of the pulp fibres and the inter-fibre friction. Web strength is often poor in high-yield mechanical pulp because the fibres are shorter in length. Conversely, long and slender fibres (2 - 3mm) which provide good web strength are present in chemical pulps.

Wet-back
The passage of urine from the absorbent core back to the skin surface. This is not a desirable feature. It is claimed that some coverstocks reduce this retrograde flow, so offering low wet-back.

Wettability
The interaction between the liquid phase (urine) and the solid (the pad). High wettability means the interaction is good since a wettable material is hydrophilic (water-attracting). This is not a desirable feature in a coverstock or facing material, but high wettability is desirable in the absorbent core.

Wicking
The transport of urine along the absorbent core. This refers to both horizontal and vertical movement and depends on several factors including the nature of the fibre surface, capillarity and the arrangement and density of the fibres.

1 Body-worn pads and pants

Description and use

Body-worn absorbent pads housed in close-fitting pants or fixed into waterproofed side-fastened garments are used as physical containment devices in patients with urinary and/or faecal incontinence.

Rationale

They are employed for social reasons to protect the patient's environment (clothes, bedding, furniture and so on) from excreta.

Indications for use

Long-term – for intractable incontinence which cannot be treated or more appropriately managed.
Short-term –
a) as a carefully monitored part of a habit retraining programme
b) for specific situations, for example during high stress activities or for long journeys.
They may offer physical separation for the patient with urinary incontinence where a good one-way pre-absorbent liner is used, but in many situations where large urine volumes or faeces are involved they may offer the patients themselves neither physical separation nor psychological protection.

Pants

These may be specially designed to accommodate particular pads or the patient's own underwear provided it will maintain the pad in a position conducive to its proper functioning. Commonly used materials for incontinence pants include PVC, nylon, polyester, paper, cotton, or any combination of these. The pants may be disposable, semi-disposable (short-life in use) or longer lasting (withstanding many washes). Although numerous design features are used to meet the individual needs and requirements of patients, four main types or categories can be described (Figure 1, page 9):
a) waterproof pants
b) lightweight open-knitted stretch pants
c) front/side fastening or drop-front pants
d) marsupial type pants.

a) Waterproof pants

The whole of the pants may be composed of a waterproof material placed in direct contact with the skin, or a large percentage of the garment may be waterproofed. These pants range from the simple traditional all plastic, to the more sophisticated waterproofed variety with an inner and outer layer of nylon polyester or similar material.

Where a large proportion of the waterproofed or moisture-impervious material is in direct contact with the skin, local heat loss and heat gain mechanisms (radiation conduction convection and evaporation) may be adversely affected. The net effect of some waterproof pants is to retain heat in summer making the patient feel hot, sticky and uncomfortable (skin

health may also be compromised) and to augment heat loss in the winter making the patient feel cold, wet and uncomfortable.

These pants may also be quite noisy so that their owners become conscious of wearing them. This may be less apparent once the material has warmed on the body but may become more troublesome with continued laundering particularly if high temperatures have been involved. In order to render PVC pants soft and pliable a plasticiser may be used (Malone-Lee 1984). This tends to leach out over time and the speed at which it is lost is directly related to the number of times the garment is laundered. Once it is lost the pants become hard, noisy, brittle and cracked. They will no longer offer any resistance to urine leakage. Moreover where plasticisers are employed there is a tendency to attract odourous molecules but not to neutralise them. In practice this means that smells stay on the pants. Some waterproof pants will readily stain and if this is the case high temperature during laundering may serve to fix the stain chemically into the material.

Waterproof pants may fulfil the needs of some patients, particularly where extra security is required. However, their long-term continued use would seem inappropriate. This category of pants is worn with a non-waterproof backed pad. They have elastic leg and waist bands which are commonly non-adjustable and are available in hip sizes 20 - 60 inches (51 - 150 cm).

b) Lightweight open-knitted stretch pants

These pants are made from a stretch material so that they conform to the various shapes and sizes of the lower torso and, to a lesser extent, cater for differences in upper thigh dimensions. The open-knit nature means that increased local heat loss may be a problem during the winter particularly in females who wear stockings. These pants are easily and quickly laundered. Their actual life in use depends on many factors including how they are applied and removed (some may ladder easily) and the method and severity of laundering (high washing or drying temperatures may adversely affect their structural and functional integrity). If hand laundered these garments may last for more than 100 washes (Journet 1983) though many regard them as essentially semi-disposable and this is reflected in their low purchase price.

Some of the pants in this category contain strengthening bands which run horizontally around the whole garment. Their purpose is to support the absorbent pad in the most appropriate position. The close body fit of this category of pants is an important feature in maximising the pad's functional capability. They are available in a range of sizes to cater for body weights from 20 to 110 kilograms, hip sizes 24 to 48 inches (61 - 102 cm) and greater and are worn with waterproof backed pads.

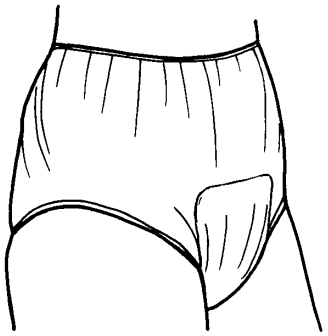
c) Front/side fastening or drop-front pant

These pants which are made of cotton and/or polyester were designed for users with limited dexterity. They open at the front or side and have Velcro or press stud fastenings. Some contain a waterproof layer or pouch in which case a non-waterproof backed pad is used. Others which do not incorporate any waterproofing are worn with a plastic backed pad. They are available in hip sizes 18 to 64 inches (45 - 160 cm).

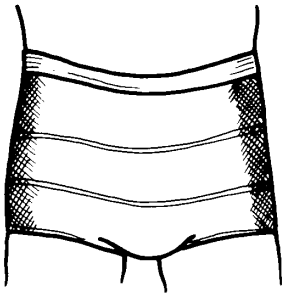
d) Marsupial pants

First developed by Willington in the late 1960s these pants contain an internal or external pouch in the crotch area into which an absorbent pad is inserted. The pouch compartmentalises the pad and to some extent the urine. The innermost layer of the pouch next to the skin is composed of a hydrophobic (water-repelling) material. In theory the fibres of this material do

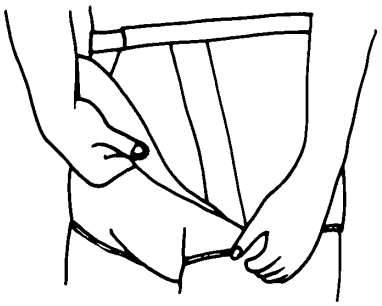
Figure 1 Pants (to be worn with absorbent pads) used in the management of incontinence



a) Waterproof pants

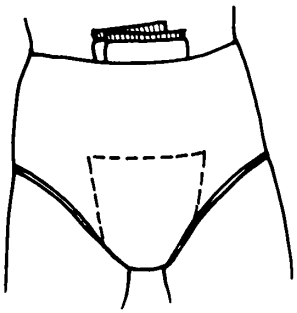


b) Lightweight open-knitted stretch pants



c) Front/side fastening or drop-front pants

External pouch



Internal pouch

d) Marsupial type pants

not absorb and hold urine but instead urine passes through the inter-fibre spaces into the absorbent pad beyond, which is hydrophilic (water-attracting).*

The innermost layer of the pants is often referred to as 'one-way' or 'stay dry' so that the patient's skin is said to remain dry. In practice, however, urine will pass in both directions and is only prevented from doing so if the maximal functional capacity of the pad is not reached and excessive pressure to the partially saturated pad is not applied. The outermost layer of the pouch nearest the patient's clothing is composed of a waterproof material.

This category of pants is quite robust and generally launders well though their actual lifetime in use will depend upon many factors including the method and severity of the laundering process. High temperatures may render the pouch stiff, brittle and prone to cracking so that leakage of urine may occur. Moreover this treatment may chemically fix any stains into the waterproof material.

Marsupial pants are available in a range of styles to suit the varying needs of males and females of all ages and include a fly-opening style for males. They are aimed at the ambulant/fairly ambulant self-caring patient. Carers may regard the removal of a wet pad from the pouch as a most disagreeable task. The 'one-way' pouch lining makes these pants suitable for urinary incontinence and unsuitable for faecal incontinence. They have adjustable leg and waist bands and are available in hip sizes 20 to 48 inches (51 to 122 cm) and greater.

Absorbent pads

These are soft packages composed of an absorbent core encased in an envelope of liquid permeable material known as the coverstock. They are worn against the body and retain urine which has been voided incontinently. A waterproof layer may be present on the side of the pad which is placed nearest the patient's clothing. Pads fixed into waterproofed side fastening pants are known as diapers or all-in-one garments. The absorbent material in most pads presently available originates from wood fibre. The final performance quality and cost of the pad is directly proportional to the number and intensity of steps in the processing chain and is also dependent upon the wood species used. The form in which the wood fibres are finally used is fluff pulp or tissue paper.

Fluff pulp

Pulping of the wood fibres involves the removal of lignin (the characteristic hardening material impregnating cell walls of woody tissues) and release of the cellulosic fibres. Pulping may be by mechanical or chemical methods (Malone-Lee 1984). Chemical and mechanical pulps are used in varying proportions to form fluff pulp.

Tissue paper

This is supplied in layers as a bundle (wadding). Bleached mechanical pulp is commonly used. Tissue paper layers may sometimes be used with fluff pulp to aid dispersion of the urine, improve utilisation of the whole pad and reduce sheering forces which might otherwise break up the fluff web.

Superabsorbents

Various chemical superabsorbents are available which are low in bulk while being high in

* The 100 per cent spun polyester has a water absorption capacity of approximately 0.5 per cent at 25°C and 65 per cent relative humidity. In comparison cotton has a value of approximately 15 per cent at the same temperature and relative humidity (Tam *et al* 1978).

absorption capacity. They are used as granules or laminate sheet in incontinence pads. Their use in adult pads is still limited because they do not absorb quickly enough to cope with high urine flow rates. Strike-through time* is lengthened so that leakage may occur. Once absorption of urine and solidification takes place these materials feel cold. Moreover urine may be prevented from spreading or leaking into the whole pad by the speedy solidification so that subsequent urine (leaked incontinently) may not be accommodated.

Coverstock

The skin is separated from the absorbent core by a non-woven facing material or coverstock which should be resistant to liquid penetration while permitting rapid urine passage through and into the absorbent beneath. A coverstock should also be resistant to retrograde urine flow from absorbent to skin. Other important criteria are that it should give a soft and dry feeling to the wearer and it must not contribute to skin irritation or to bed sores either in the dry or wet state (Malone-Lee 1984). Currently available coverstock is made of rayon, polyester, polypropylene or polyethylene.

Waterproofed layer

Where present on the absorbent pad this consists of polymers including PVC, polyethylene or polypropylene.

Factors or properties of importance with respect to the technical performance of the incontinence pad include:

absorption capacity
compression capacity
strike-through
web strength
wet-back
wettability
wicking.

For an explanation of these terms see the Glossary of terms on page 6. For greater detail on the technology of incontinence garment structure refer to Malone-Lee (1984).

Excellent technical attributes are of little relevance unless a good shape and fit of the pad in the crotch area is achieved. Absorbent pads are available in various shapes, sizes and capacities to contain urine and/or faeces under different conditions of activity and rest (Figure 2, page 13 and Figure 3, page 14).

Safety and testing

Although there has been a massive upsurge in attempts to standardise the testing of absorbent incontinence products during the last few years there are at present no British Standards relating to these products. It is unlikely that any will be established for some time because of considerable variations in end-use conditions, for example the type of incontinence (frequency and amount of leakage), body posture, body fit and so on. Testing procedures for absorbent incontinence products may be either non-clinical or clinical.

Non-clinical reality

a) Laboratory or bench testing involving the application of specific tests which give consistent results, such as the total absorption capacity of a product under specific conditions – particular flow rates, pressures and so on.

*see Glossary of terms, page 6

b) Mannequin models – soft torsos which are manufactured to mimic the incontinent male or female. They incorporate the use of urine sensors so that urine flow (or wetting) patterns can be plotted using different pads, pants, flow rates, positions and fit.

Clinical reality – product trials

These will produce objective measurements of the volume of urine held in a particular pad before leakage occurs, skin health (inflammation or damage) and so on, as well as subjective measurements such as ease of fitting and removal and the user's opinion of the product.

Each major manufacturer of absorbent incontinence products follows his own testing procedures which are often confidential. Although these vary, most emphasis is placed on the non-clinical reality category of tests. Clinical reality product trials need to be expanded and standardised. This will help prescribers and users to select the most appropriate product, and introduce a degree of rationalisation into purchasing.

The coverstock or facing material is tested to ensure that it is non-toxic and does not cause skin or eye irritation. Many manufacturers compare their coverstock with B.P. gauze. The effects of coverstock on skin health are presently under investigation (Malone-Lee).

Supply and availability

Twenty-four UK-based companies are involved in the manufacture or supply of incontinence pants and twenty-six manufacture or supply body-worn pads. Prices for pants range from approximately 15p (for waterproofed disposable bikini tie pants) to £12.80 (for polyester mesh and vinyl marsupial type re-usable pants). Prices for pads range from approximately 3p (for a 25cm length of absorbent incontinence roll) to £9.96 (for a cotton-covered shaped re-usable pad). Pack sizes range from one to 200 (pants) and from one to 240 (absorbent pads).

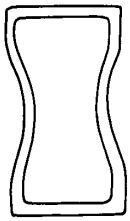
Absorbent incontinence products, pads and pants are not prescribable under the drug tariff provisions and are normally supplied via the community nursing services. In some areas the prescriber and patient are faced with an endless list of unspecified products to choose from, which makes selection difficult. In other areas rationalisation has meant that one or two alternatives may be available and patients whose requirements are not satisfied by these alternatives may find it difficult to obtain the product most appropriate to their particular needs. Absorbent incontinence pads and pants are now also widely available through mail order and it would seem that this market satisfies the needs of a growing number of self-caring, mobile people suffering mild incontinence.

Clinical trials

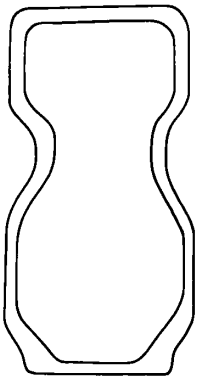
Watson (1980) reported an eight-week trial of Mölnlycke Maxi-Plus pads and stretch pants on 54 long-stay geriatric patients (39 female, 15 male) who had previously been managed with paper incontinence pads and plastic undersheets. A mean of 1.22 pairs of pants (mean life, 20 washings) and 2.36 pads were used per patient per day. A 90 per cent saving on incontinence pads and a 50 per cent saving on laundry costs was reported.

Bainton *et al* (1982) reported a four-week crossover trial of Kanga pants (standard) and pads and PVC Sandra (Henley's) pants and Bambi pads (Smith and Nephew). Fifty-one community-based females (aged 25 to 94 years) were admitted to the trial. Ninety-eight per cent preferred the Kanga pants and 55 per cent the Bambi pad. Both systems kept a similar proportion of patients (mean 63 per cent) dry during both day and night.

Figure 2 Body-worn absorbent pads



* † Shaped pad
Stress/light dribble



** † Shaped pad
Severe

* Single pad
Light to moderate

Coverstock

Tissue layers

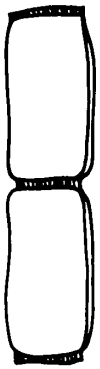
Pulp

Pad Section

Coverstock
Pulp

Waterproof

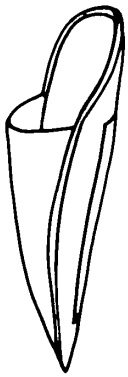
** † Light to severe



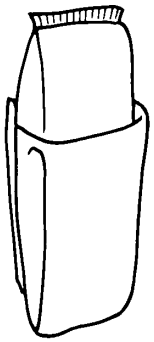
* Double pad
Light to moderate

* † Backed with adhesive strip
Light to moderate

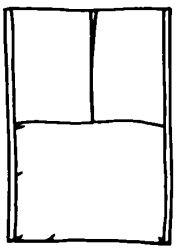
* Absorbent roll
Light to moderate



* † Adhesive strip backing
Light



* † Foam backed
Light



* † Light

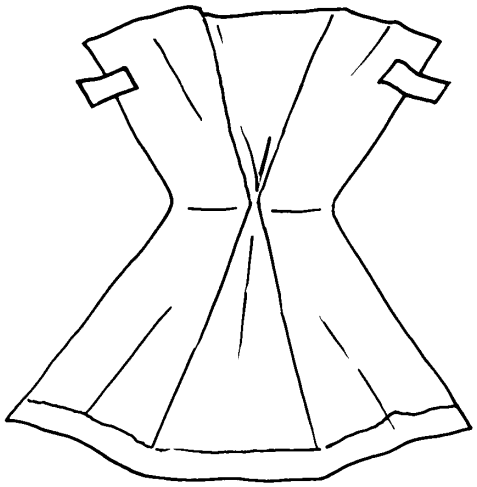
Key

Stress/light dribble – 0-50 ml/4 hours
Moderate – up to 200 ml/4 hours
Severe – 300+ ml/4 hours

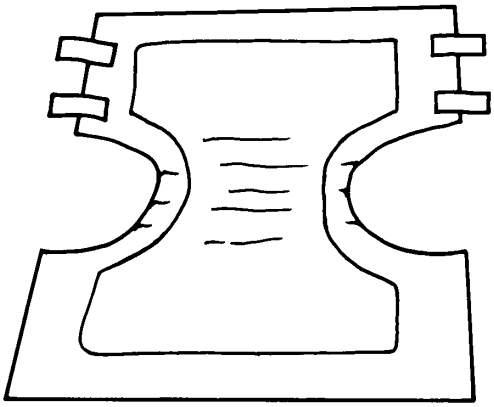
Use

* Urinary incontinence
** Urinary and faecal incontinence
† Waterproof backed

Figure 3 All-in-one disposable absorbent pad and waterproofed pant for urinary and/or faecal incontinence

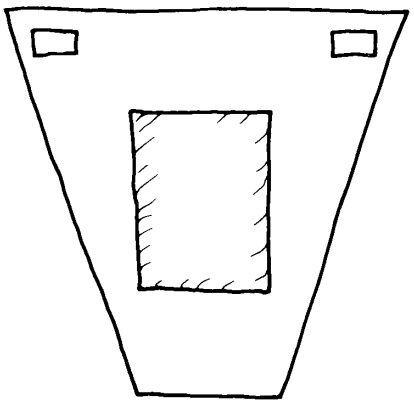


Wing folded
Moderate/severe
Also available without adhesive ties to be worn with pants



Elasticated legs
Moderate/severe

Adhesive
Absorbent
Waterproofing



Traditional shaped diaper
Moderate/severe

Key
Moderate – up to 200 ml/4 hours
Severe – 300+ ml/4 hours

Fader *et al* (1986) reported a trial of 27 garments (each used for one week) on 137 subjects. Patients (or their guardians) categorised themselves into three groups. Group 1, consisting of 34 ambulant, independent patients (33 female, 1 male) with light incontinence (mean daily pad use 2.5, mean urine volume per pad 52.5 cm^3), tried ten garments. Their needs were met by the Kanga single pad with either Kanga Lady or Henley's Sandralux pants. Group 2, 101 patients (79 female, 22 male) with heavy daytime incontinence (mean daily pad use 3.3, mean urine volume per pad 95.5 cm^3), tried twelve garments. Non-ambulant and dependent, this group required larger absorption capacities without leakage, and ease of changing was important. Mölnlycke Tenaform normal met this group's needs. The Peaudouce Slipad, while popular in a number of long-stay establishments, was not liked by some carers. Group 3, made up of 47 patients (39 female, 8 male) with heavy nocturnal incontinence (mean daily pad use 3.6, mean night pad volume 276.2 cm^3), tried four garments. Their characteristics and needs were similar to those of group 2. Mölnlycke Tenaform Super was the only garment which came close to meeting this group's needs.

Sanitary pads were considered inappropriate for incontinence management, wing-folded pads unsatisfactory and super-absorbency gels disappointing and expensive. Skin health was not considered to be at risk when good quality products were used. Some correlation between technical performance and clinical function was observed when assessing fluffed wood pulp performance in the laboratory.

Observations on clinical trials and suggestions for further research

During the last five years many of the published trials have concentrated on Kanga and Mölnlycke products. Fader *et al* (1986) have to a great extent rectified this situation. It is interesting to note that Kanga and Mölnlycke, in particular the latter, performed well when evaluated alongside numerous other products

The Fader *et al* study provides an excellent basis for the selection of functionally and structurally sound products. It is now necessary to expand upon this by carrying out longer-term trials (more than seven days) on the products which were found to perform well. Where similar products are competing for the same end-use conditions, cross-over trials will aid rationalisation.

Since there is great variation in end-use conditions (type of incontinence, frequency and amount of leakage, body fit) and absorbent incontinence product trials have a considerable subjective element, large population sizes are required to provide statistically significant viable conclusions. This is particularly important in view of the Fader *et al* finding that patient mobility and independence rather than symptomatology (other than nocturnal enuresis) determined whether low or higher absorption capacity products were chosen.

If prescribers have some knowledge of the industrial technology surrounding the production of absorbent pads and pants the large gap which exists between non-clinical and clinical reality testing may be reduced and more effective products result. Prescribers also need a good working knowledge of end-use conditions (type of incontinence, volumes and flow rates) so that they can select the most appropriate product.

It is evident that the trials discussed here have been greatly biased towards females and, while it is known that absorbent incontinence pads and pants represent the principal means of containing female incontinence, their use in males needs investigation. Absorbent pads are less likely to be accepted by males (except for the penile drip collector) and there are more alternatives available. None the less the use of absorbent pads and pants in males of all ages

requires clarification. Moreover, the whole question of the use of penile drip collectors needs to be investigated.

Research also needs to be directed towards the development of products which would cope more efficiently with large nocturnal volumes of urine. Since superabsorbents have the property of absorbing greater volumes than the corresponding amounts of cellulosic material and their high affinity for moisture reduces the chances of leakage, their development, acceptance and cost stabilisation may be of particular importance in the provision of products for this purpose.

In the adult it is the shape and fit of the absorbent pad in the crotch area which will determine whether or not leakage will occur, no matter what excellent features the product boasts in terms of absorption capacity. The shape and fit of the pad and pants therefore requires further consideration. While mannequin models have been used, clinical reality trials are lacking in this area.

Claims relating to the one-way nature of coverstocks have not been substantiated in clinical trials. This needs to be investigated.

Storage and disposal

Since absorbent incontinence pads are bulky and an individual patient may require several per day, storage may present problems. Storage space in hospital may be perfectly adequate, but large stores may cause inadequate stock rotation. This may result in a batch of pads eventually reaching the consumer which are unacceptable because yellowing has occurred. Exposure to sunlight will speed up this process. Storage problems are more likely in the community, particularly with infrequent deliveries of supplies which may also lead to unnecessary hoarding of stock.

In hospital absorbent pads (classified as clinical waste) are for the most part disposed of on site by incineration. Disposal, however, may present problems for the community-based patient. Some local authorities provide excellent collection services for used incontinence pads, supplying bags for the purpose and collecting usually on a weekly basis either along with the domestic refuse or separately. This special collection may be a source of embarrassment to some incontinent individuals – particularly if they reside in high-rise flats. Where no local authority collection service exists patients or carers may dispose of the absorbent pads in three ways:

1) placing them (wrapped) in the dustbin along with domestic refuse 2) burning (this usually requires a garden) 3) flushing down the lavatory may be appropriate for some absorbent pads, in which case the manufacturers will state this on their product literature. Unless the manufacturer's instructions are closely followed, this method may result in blocked drains. It usually requires removal of the plastic backing and breaking up of the pulp core into several pieces. This is not a pleasant procedure and may be totally unacceptable.

A recent consultation document published by the Department of the Environment recommends changes in disposal practices. It will require clinical waste to be regarded as industrial waste under Part 1 of the Control of Pollution Act 1974. Clinical waste is defined as waste which is a) composed of human or animal tissue or excretion or of drugs, medicinal products, swabs, dressings, instruments or similar substances, materials or things b) arising from any medical, nursing, dental, veterinary pharmaceutical or similar practice, investigation treatment, care, teaching or research c) poisonous, noxious or polluting. It is anticipated that the new regulations will be issued as a statutory instrument under the Control of Pollution Act

(Department of the Environment, personal communication) and since soiled absorbent pads will fit into all three of the above categories changes in disposal practices will be needed. In hospitals the regulations will mean that on-site incineration of absorbent pads will not be permitted but instead the newly categorised industrial waste will be incinerated at a municipal site. Community-based patients will require highly organised and widely available collection and disposal services.

Cost effectiveness

A considerable sum of money is spent each year – a recent mean estimate is £12 million (Health Service Supply Council 1984) – on absorbent body-worn pads and pants. Discussion of the trials and pad technology indicates that the cheapest products do not always possess good performance features. It would therefore be folly to choose the cheapest item as a cost saving exercise since larger numbers may be used. Non-measurable costs in terms of the patient's comfort, dignity, security and skin health may also be much higher when using a cheaper product. Cost should always be considered when choosing the most appropriate absorbent pad or pant. The patient with mild incontinence (50ml or less per 4 hours) may manage perfectly well with less costly products while severely incontinent patients or those with double incontinence need the more expensive products. Regular patient reassessment should also be undertaken.

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2 Underpads for bed and chair

Description and use

Underpads are placed beneath incontinent patients to protect their immediate environment – bedding and upholstery – from contact with urine or faeces.

Rationale

Unlike body-worn pads, underpads do not contribute to prevention or cure and they do not enable incontinent patients to achieve social continence. They represent an unfortunate but sometimes necessary part of the management of the immobile and dependent incontinent patient.

Disposable underpads

The type of disposable underpad often referred to as a 'draw sheet' is commonly a one-piece construction formed from a waterproofed layer which has been bonded throughout to a tissue or non-woven cover. They may also be composed of three material layers as described below. The length of these products ranges between 128 and 190cm and their width between 64 and 80cm (Figure 4a, page 20).

A second type of disposable underpad contains a waterproofed outer covering, an absorbent centre, usually composed of cellulose wadding (with a variable number of layers ranging between four and 20) or fluff pulp, and a top non-woven liquid permeable cover. The length of these products ranges between 40 and 90cm and their width between 30 and 75cm (Figure 4b, page 20).

Re-usable underpads

The fleece-like, stay-dry or urine permeable products are said to present a warm and dry barrier to the skin. They are composed of a hydrophobic (water repelling) material. In practice the fibres of this material do not absorb and hold urine, but instead urine passes through the inter-fibre spaces into a conventional disposable underpad (Figure 4 b), page 20) which is placed beneath the product. These underpads are available in sizes ranging from 51x45cm for a chair to 104x170cm for a double bed (Figure 5d, page 21).

Absorbent re-usable underpads may consist of two or three material layers. The 'Kylie' is a two-layer product comprising an upper brushed polyester or 'drier' layer which is quilted to a needled rayon absorbent or 'soaker' layer, reinforced with liquid carrier threads. Sizes are 50x100cm (chair cover) and 100x100cm (bed sheet). Attached to the latter are two polyester tuck-in flaps. A waterproofed sheet is used beneath this product (Figure 5a, page 21). There are also three material layer products, commonly containing a waterproofed outer covering.

Safety and testing

In 1972 a specification was drawn up for disposable underpads – TSS/D/300000 (Department of Health and Social Security 1972). This gives the minimum performance requirements for a 15-ply disposable incontinence underpad. At that time the five-ply underpad had not been introduced. The specification referred to underpads measuring 40x60cm and contained three

tests relating to the waterproofness of the backing, the water retention capacity of the absorbent and the absorbency of the total product. This specification is regarded by many as inadequate and out of date since the three laboratory tests do not relate to clinical reality. In excess of 80 per cent (measured by volume) of the disposable underpads bought by the NHS are of the thin five-ply type (Health Service Supply Council 1984) but no specification for these products exists. Moreover it is common practice to take the minimum acceptable absorbency of 44ml per $100cm^2$ of the surface area applicable to the 15-ply underpad (Department of Health and Social Security specification TSS/D/300000) and simply to divide it by three to arrive at an absorbency level for the five-ply product of 15ml per $100cm^2$. Unless it can be shown that a linear relationship exists between ply numbers and absorbency this approach is invalid.

Misuse of the DHSS specification also occurs if total pad absorbency rather than absorbency per $100cm^2$ is considered. While one would expect an underpad measuring 75x75cm to have a higher absorbency than one measuring 30x40cm this may have no bearing whatsoever on the functional capability of the product.

The microbial content of fluff pulp products is very low but cellulose wadding made from reprocessed pulp may present a hazard because of high microbial content. Non-pathogenic and pathogenic micro-organisms (in particular bacteria and fungi) may adopt the role of opportunistic pathogens in debilitated or 'at risk' patients. For this reason it is advisable to use fluff pulp products (preferably sterilised) in critical areas such as theatres and maternity and in any situation where a wound exists or the primary defence barrier (the skin) has been breached. Safety Information Bulletin Number 19 (84) 64* draws attention to the distinction between 'clean' and 'sterile' products for clinical use and indicates that textile or paper/pulp products may contain substantial numbers of micro-organisms. The choice between sterile and non-sterile products in vulnerable patients is a matter for professional judgement.

No performance standards exist for disposable draw sheets or re-usable underpads, other than those relating to flammability (B.S.3121; B.S.5438/test 3; B.S. 5722/1984). Performance standards need to be established for all categories of underpads (chair, bed, disposable and re-usable). The present specification for the thick (15-ply) disposable underpad needs to be updated. If research into the use of the thin (five-ply) underpad indicates that it has a part to play in the management of incontinence then a standard for this product would also need to be established.

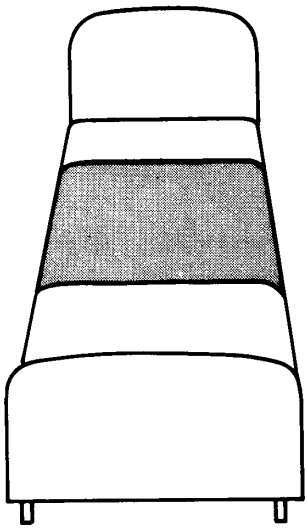
Supply and availability

Twenty-four UK-based companies are involved in the manufacture or supply of underpads, 20 of whom are involved in disposable products (19 conventional disposables and six in the draw sheet type) and six in re-usable products. Prices range from 3p each for a 40x60cm five-ply conventional disposable underpad to £22.55 including VAT for a Kylie bed sheet (the price for a grade A product when nine or less are purchased). Pack sizes range from one (Kylie) to 200 (five-ply conventional underpad).

Underpads (disposable and re-usable), are not prescribable under the drug tariff provisions and are normally available via the community nursing services. They are also available through mail order. Cost containment policies favour the use of thin (five-ply) unspecified disposable underpads because they are cheaper. The more costly and perhaps more suitable products (the 15-ply

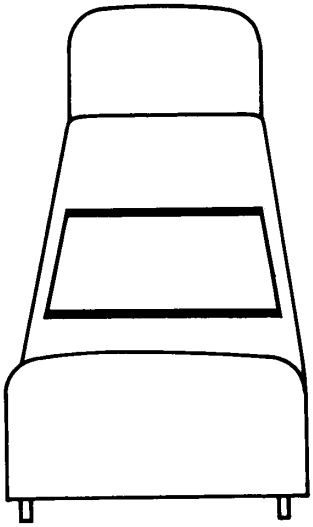
* Enquiries related to the bulletin (in England) should be addressed to Miss M N Duncan, Department of Health and Social Security, Scientific and Technical Branch, 14 Russell Square, London WC1D 5ET

Figure 4 Underpads for bed and chair

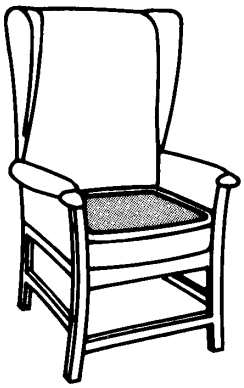


a) Draw sheet type
Side flaps tucked beneath mattress to hold product in position

Bed underpads



b) Conventional type
Not secured to underlying bedding



Chair underpad

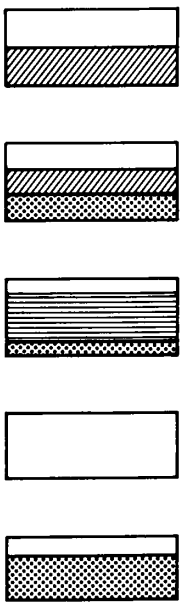
disposable underpad, re-usable underpads and so on) may not be available. Patients may be forced into purchasing more appropriate products for their particular needs from chemists or via mail order.

Clinical trials

Thomas and Hubbard (1979) compared the laboratory performance of two disposable (the Polyweb 12-ply and the Kanga five-ply) and one re-usable (the Kylie) underpads. The Kylie performed best, having the greatest absorptive capacity and the Kanga gave the worst performance. The barrier effect of the surface layer was quantified. The Kylie was found to have an effective hydrophobic dry layer. The Polyweb and the Kanga failed to provide a dry upper surface.

Smith (1985) reported a nocturnal trial of the Kylie bedsheet (two weeks), the hygi Everdri (with hygi 10-ply disposable bed pad for one week and Polyweb 14-ply disposable bed pad for one week) and disposable bed pads (hygi for one week, Polyweb for one week) on 15 patients. The Everdri was subject to shrinkage. Patients' skin was frequently wet and they were restless. Pads from beneath the Everdri were found to break up when wet. Disposable underpads alone were found unsatisfactory from a patient and nursing view point. The Kylie bed sheet performed best. No staining occurred, shrinkage was minimal and it did not adhere to patients' skin. Skin dampness was greatly reduced because of the product's large absorbency capacity. Patients were comfortable hence slept undisturbed. The Kylie was found to have the lowest running costs at 36p per night and the Everdri with Polyweb the highest at 56p per night.

Figure 5 Variations in the composition of underpads



a) Hydrophobic 'drier' layer
Absorbent 'soaker' layer
(Re-usable)

b) Cotton layer
Absorbent layer
Waterproof backing
(Re-usable)

c) Non-woven layer or coverstock
Absorbent centre, 4 to 20 layers
Waterproof backing
(Disposable)

d) Fleece-like hydrophobic
(Re-usable)

e) Tissue or non-woven layer often bonded to waterproof backing
(Disposable)

Observations on clinical trials and suggestions for further research

Many trials, published and unpublished, have used inadequate sample sizes. Since the results are largely subjective it is essential to include large numbers of patients in future trials. Multi-centre trials would be useful in assessing any regional differences or bias. The statistical significance of future trials would also be improved if products were evaluated over longer periods (in excess of two weeks).

More disposable underpads are purchased by the NHS than any other single item for the management of incontinence. Although more than 80 per cent of these are of the thin (five-ply) type no rationale for their use in nursing practice has been developed. This needs to be investigated. If the thin underpad is found to have a place in the management of incontinence the microbial aspects associated with reprocessed cellulose wadding must be investigated. The effect of underpads, in particular the covering or facing material, upon skin health also needs to be assessed. Although some six companies manufacture or supply disposable draw sheets there have been no significant trials of these items. This should be rectified. Comparative trials using these items and the widely available plastic draw sheet would be valuable.

Storage and disposal

Storage of disposable underpads may present problems because of their bulky nature. This may be particularly apparent in the community and exacerbated where unrealistically large numbers of pads are being used. When infrequent delivery of stock occurs, unnecessary hoarding of underpads may also result. Disposable underpads will readily burn (in the dry and wet state); therefore their storage presents a fire hazard. Storage of the re-usable underpads should not present any particular problems and their low flammability potential means that they are not a fire hazard.

For disposal of disposable underpads, see the section on disposal of body-worn absorbent pads (page 16). Re-usable underpads can be disposed of as one would household linen or blankets provided the products have been properly laundered first. A microbiology report on the hospital laundering of the Kylie states that a 25-minute foul wash programme with a maximum temperature of 89°C (for five minutes) was sufficient to eradicate in the region of 10^8 *streptococcus faecalis* from full thickness test discs of the Kylie bed sheet.

Cost effectiveness

Although the trials conducted to date have been small-scale it is apparent that the cost effectiveness of the Kylie bed sheet has been properly assessed. This product is cost effective provided adequate numbers are available and laundering is not a problem. These criteria are satisfied in the hospital setting but may be a problem for home-based patients.

Where re-usable underpads are compared with disposables it is important to include disposal costs of the latter (special collection, incineration and so on). This has not been done hitherto. The proposed changes in disposal practices (see page 16) will increase disposal costs and the re-usable products will be rendered even more cost effective.

The total NHS market for disposable incontinence underpads was estimated to be 140 million items per annum with a total value of £7 million in 1983 (Health Service Supply Council 1984). A forward view of the market indicates that the number of disposable underpads will continue to rise and there will be an even greater rise in the use of body-worn absorbent pads. Their cost effectiveness needs urgent and careful examination by properly conducted trials including cross-over trials with body-worn absorbent systems.

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3 Urinary catheters

Description and use

A urinary catheter is a hollow tube designed to be passed into the bladder to drain it of urine either intermittently (into a receiver) or continuously (within a closed system into a bag). With intermittent catheterisation the bladder retains its reservoir function to a greater or lesser extent. This is not the case with continuous catheterisation although a small but variable volume of urine may be maintained at the base of the bladder. There are two types of urinary catheter. Urethral catheters are passed into the bladder via the urethra (mean length 3.5cm and 20cm in the adult female and male respectively). Suprapubic catheters are passed directly through the anterior abdominal wall in the mid-suprapubic region.

Rationale

Indications for urinary catheterisation are: to relieve urinary tract obstruction; to permit urinary drainage in patients with bladder outlet obstruction or other causes of neurogenic bladder dysfunction; prior to and following pelvic surgery; to measure urinary output accurately in very ill patients; to obtain urine for examination in patients with impaired communication or who are otherwise unable to cooperate fully; to empty the bladder during labour; to introduce fluids into the bladder for irrigation purposes or as direct therapy, as in the use of cytotoxic drugs; other reasons including the facilitation of bladder healing.

The suprapubic route may be indicated after pelvic surgery, for acute urinary retention, or where there has been urethral trauma, urethral or bladder neck surgery and repair of vesical or urethral fistula (Hilton *et al* 1980).

The decision to catheterise should involve medical, nursing and, where possible, patient input. Urethral catheterisation is a frequently used technique performed by adequately trained staff: for the female patient a nurse, and for the male a doctor or a suitable authorised nurse. In cases of urinary incontinence catheterisation should be the final option, in view of its complications (see Figure 6 opposite and Figure 7, page 27).

Catheter types

Urinary catheters are made of polyvinyl chloride (PVC), latex, latex coated with silicone or Teflon and silicone treated, or all silicone.

Plastic catheters

The integrity of PVC is such that very thin-walled functionally sound catheters may be produced. In practice this means that of all the catheter materials presently available, PVC provides the widest internal diameter (lumen) compared to overall catheter diameter. Since these catheters absorb less than 1.5 per cent of their own weight in water the internal and overall catheter diameters will remain unchanged throughout their lifetime in use. Plastic catheters are quite hard at room temperature and though more pliable at body temperature their rigidity makes them uncomfortable to sit on. In Foley catheters the balloon is made from latex which is prone to encrustation associated with trigonal irritation and bladder spasms. This

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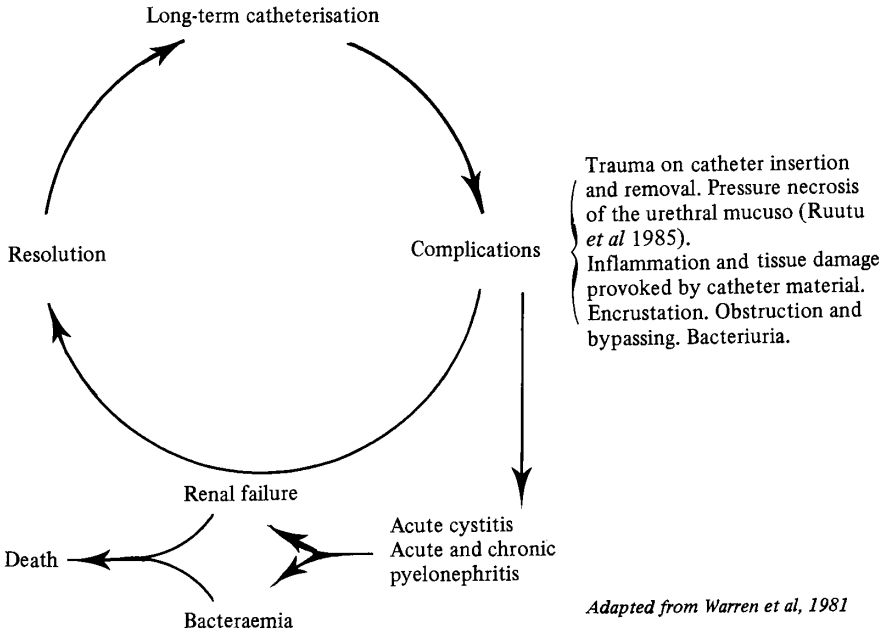
Figure 6 Complications associated with long-term catherisation



may result in catheter expulsion (Blannin and Hobden 1980). PVC catheters are commonly used post-operatively and for intermittent catheterisation. The mean recommended time *in situ* is up to 14 days.

Latex catheters

The composition of these catheters is commonly 94 per cent latex rubber and 6 per cent chemical additives. (Clay, for example, will provide a cheaper end product but such additives are potentially toxic.) Latex changes over time because it absorbs water and body moisture and for this reason it is often referred to as a living material. The chemicals contained within latex catheters may well leach out during their lifetime in use and cause irritation and tissue reaction. Another disadvantage of the so-called living nature of this material is that latex absorbs up to 40 per cent of its own weight in water. Swelling of the catheter may then lead to a reduced internal diameter and/or increased overall diameter. Latex catheters are more flexible, somewhat stronger and less expensive than others. They are, however, prone to encrustation and blockage by urinary deposits. These catheters are for short-term use and may be left *in situ* for up to 14 days.

Coated latex catheters

These are generally latex catheters coated with either Teflon (a fluorocarbon polymer) or silicone, both of which are said to be inert. It is claimed that the coatings:

a) do not absorb water as does the latex material beneath. Therefore swelling of the catheters and changes in diameter should not occur
b) provide for a smoother surface than is possible with the 'all-latex' catheter
c) compartmentalise the latex thereby reducing the likelihood of chemical leaching to the surface and subsequent irritation and tissue damage.

A roughened surface will result in microscopic 'nooks and crannies' which favour collection of debris (Wilksch *et al* 1983). This may be associated with the build-up of urinary deposits which are excellent sites for bacterial attachment. A roughened surface will provide a larger surface area on which these undesirable processes occur. A smoother surface and the resultant smaller surface area may be important in providing some degree of resistance to encrustation.

Coated latex catheters are better tolerated than the all-latex varieties. These catheters may be left *in situ* for four and 12 weeks respectively for the Teflon- and silicone- coated varieties. The silicone coating process is said to result in a variable but reduced internal diameter in some products (Blannin 1983). Moreover, the Teflon-coated catheters are said to have a smaller outer diameter for the same drainage capacity when compared to the silicone-coated latex catheter (Urwiller and Thistle 1971). The silicone treated or siliconised latex catheter is treated to provide for easy insertion and to give some degree of lubrication.

All-silicone catheters

These catheters are made by an extruding process. The silicone mix is pumped into a mould and the balloon is bonded into position. This method of manufacture results in catheters with thin walls providing a larger drainage lumen compared to that found in the silicone-coated latex variety of the same size (Kennedy 1984). The smooth surface of these catheters together with their inert nature and relatively large lumen means that encrustation and tissue irritation or damage are minimised. They are generally well tolerated by patients though some females find them rather hard to sit on. These catheters are said to be suitable for long-term drainage – up to 12 weeks.

Catheter structure

The French (Charrière) catheter gauge (FG or CH) is internationally used to size catheters. The numbers or sizes CH 8 to 30 refer to the external circumference of the catheters in millimetres. Mean internal catheter diameters (lumen) range from 0.9 to 5.5mm and mean external catheter diameters range from 3 to 10mm. The usual size of catheter for an adult with clear debris-free urine is CH 12 to 16 and where the urine is thick, gritty or slow-flowing CH 16 to 18. Only where haematuria is present or blood clots are expected (for example, post-operatives) should a catheter in excess of CH 18 be used (Blannin 1983, Kennedy 1984).

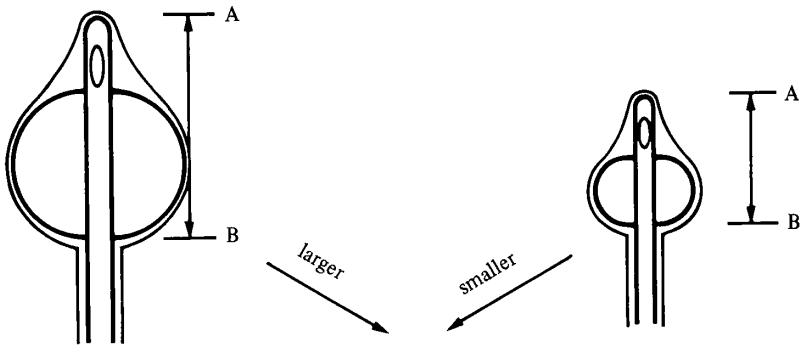
Two-way Foley catheters have two internal channels – the larger for urine drainage and the smaller to inflate the balloon once in the bladder, by the aseptic introduction of water. The capacity of these balloons ranges from 5ml to 30ml, while 50ml is also available for specialist surgical procedures. The mean weights of catheters with 5ml and 30ml of water in their balloons is 17 grams (0.6ozs) and 48.2 grams (1.7ozs) respectively. Quite obviously the 30ml balloon should never be used routinely for long-term catheterisations but instead only considered in specific situations such as post-surgical, since the overall area occupied by a 30ml balloon in the bladder together with the weight would certainly irritate and damage the bladder walls and neck, induce bladder spasm and lead to bypassing (Figure 7, opposite). There may also be a greater residual volume of urine since the catheter eyes (or inlet channels) will be situated at a higher level in the bladder. The variations in catheter inlet channels or eyes are illustrated in Figure 8 (page 29). Three- and four- way catheters have extra channels to irrigate the bladder or instil solutions into it.

Safety and testing

A British Standard has been established for urinary catheters – B.S. 1695 (1981): Specification for sterile urinary catheters for single use – which is presently under review. Draft standards

Figure 7 Benefits of Foley catheters with small (5 ml) retention balloons

The bladder of the continuously catheterised patient will collapse around the balloon.



Residual urine volume

Mean weight in trigone imposed by catheter with 30ml balloon 48.2 grams (1.7 ounces) approximately.

Greater residual urine volumes to support bacterial growth.

Larger balloon tends to be associated with a longer catheter tip (length of catheter beyond the balloon) and length A-B is greater. This has a greater traumatising effect on the bladder mucosa which may lead to ulceration and cystitis.

Mean weight in trigone imposed by catheter with 5ml balloon 17.0 grams (0.6 ounces) approximately.

Smaller residual urine volumes to support less bacterial growth.

Smaller balloons tend to be associated with a shorter catheter tip and length A-B is smaller.

Rationale

↑ balloon size and weight → ↑ irritation → ↑ bladder spasms → ↑ bypassing (episodes and volume)

relating specifically to Foley catheters have been formulated and it is expected that a standard will be established in the near future. For a discussion of the sterility of urinary catheters see the section on safety and testing of urine collection bags, page 35.

Because urinary catheters are passed through a body orifice and into an organ the various materials from which they are composed are examined for any toxicological characteristics. Recent workers (Graham *et al* 1983 and Ruutu *et al* 1985) have established a good correlation between the cytotoxicity of some catheters and human tissue irritation or damage. Manufacturers endeavour to achieve as smooth a catheter surface as is practicable, desired or required and although no direct relationship between roughness of the external catheter surface and acute or chronic tissue damage has been established (Wilksch *et al* 1983) it is generally agreed that a roughened catheter surface might induce or enhance irritation and tissue damage.

Supply and availability

Some 20 UK-based companies are involved in the manufacture or supply of urinary catheters. Urethral catheters range in price from 50p each for a PVC nelaton (for intermittent catheterisation) up to £7 for a silicone-coated Foley for long-term use. Suprapubic catheters range from £3 to £25.

In October 1983 a supplement to the drug tariff was published by the Department of Health and Social Security – the Advisory list of urinary incontinence appliances. This represented the first attempt at drawing together the products in this field which were on the market and selecting those which were regarded as providing value for money (Department of Health and Social Security, personal communication). The list was made mandatory for FP10 (prescription) from July 1985. It categorises prescribable incontinence appliances and indicates some basic product information to help the prescriber calculate the patient's requirements, including the name, address and telephone number of the manufacturer or supplier, the mean life in use of the product, the pack size and the price. Urinary catheters are prescribable under the drug tariff provisions.

Clinical trials

Blannin and Hobden (1980) examined the physical characteristics of various catheters and the factors responsible for patient comfort to determine suitability for long-term drainage. Considerable variations in internal and external diameter were found for a given catheter gauge. Exposure of latex to urine resulted in severe deposition of debris. PVC catheters were found to be stiff and inflexible and were considered suitable for short-term use only. Silicone catheters (solid or latex with silicone coating) were found to be equally comfortable for the majority of patients, though early results indicated a reduced drainage potential for silicone coated catheters. A catheter size 16FG with 10ml of water in the inflation balloon was considered most suitable for long-term catheterisation. Latex catheters were found appropriate for patients requiring frequent changes and silicone catheters for patients who were able to tolerate them for longer than two months.

Kennedy and Brocklehurst (1982) reported a study on nursing management of 107 elderly patients (68 hospital- and 39 home-based). CSU showed a wide range of organisms. These were only obtained for culture and sensitivity when there were obvious symptoms of infection such as pyrexia or malaise. Antibiotic treatment was found to be unimportant. Solid silicone, silicone-coated latex and Teflon-coated latex male length catheters were found in general use. Nurses were not able to recognise which catheter they were using. Catheter bypassing was a problem for 40 per cent of patients. Many procedures were adopted to cope with bypassing. The need for better policies for the management of long-term catheters was emphasised.

Figure 8 Variations in catheter tip structure

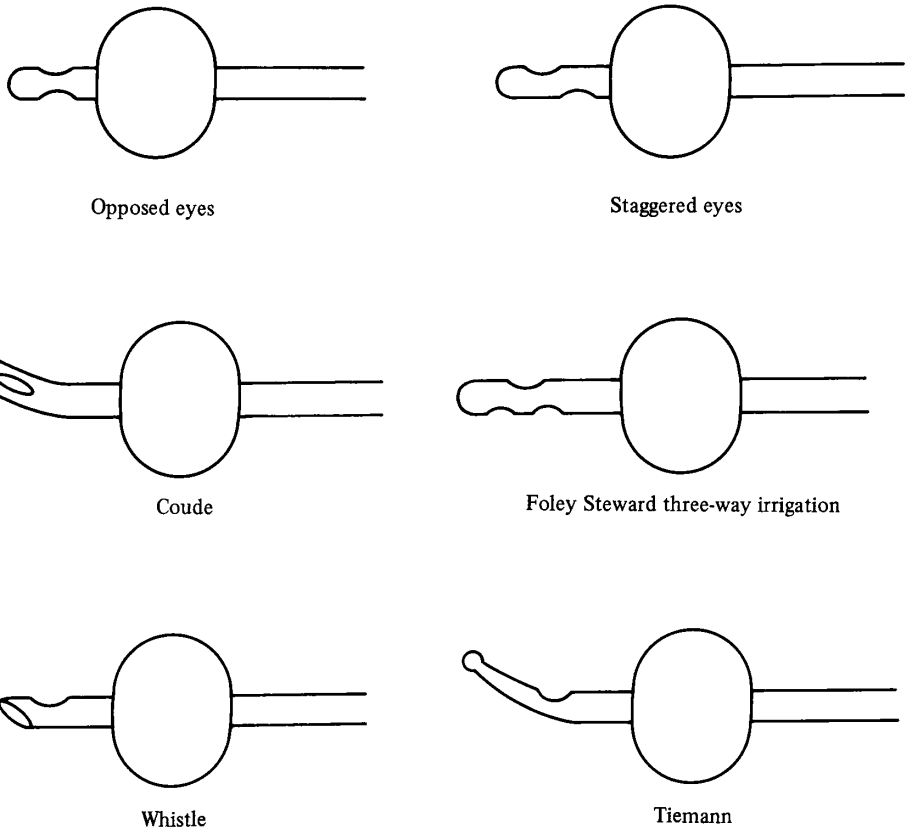
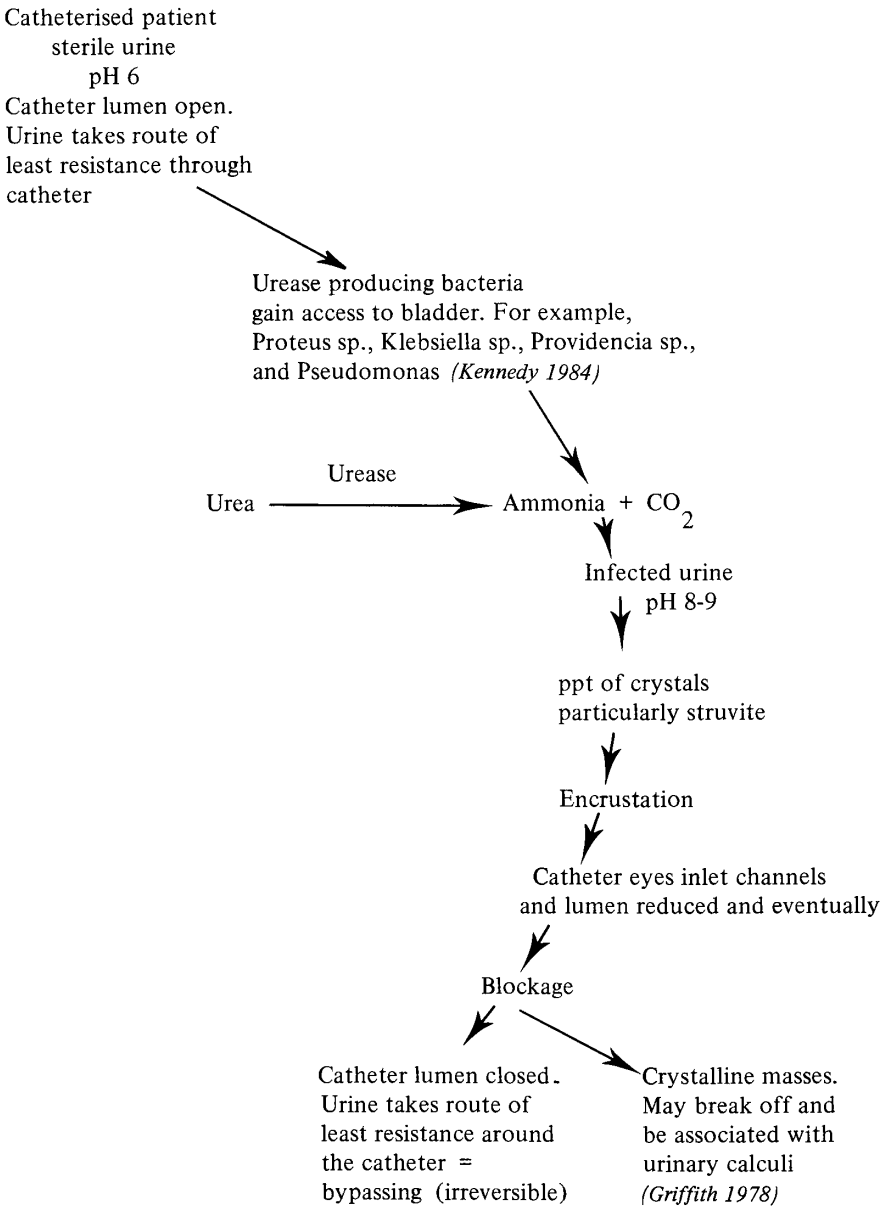


Figure 9 Association between catheter blocking and leaking



Joiner *et al* (1982) reported a study of 24 women (aged 16 to 65 years, mean age 36 years) who were trained in the use of self intermittent catheterisation (SIC). 92 per cent had previously relied on continuous urine drainage via Foley catheters. 83 per cent successfully completed training. Following discharge 15 per cent gave up SIC, 5 per cent returning to the use of diapers, 10 per cent electing to go back to continuous Foley catheter drainage. During SIC infection rates were low. Most patients welcomed the freedom from drainage apparatus and diapers. SIC was found to be an excellent solution for well-motivated, independent women and it prevented urinary tract infection.

Hukins *et al* (1983) examined catheters from 10 female patients (aged 50 to 91 years) for encrustation by X-ray defraction. The catheters had been *in situ* for a minimum of 5 days. Solid silicone, latex treated with silicone or Teflon- and silicone-coated latex catheters were examined. Encrustation was observed in all four types of catheter. With the solid silicone this was slight and restricted to the external surface. In all cases encrustation was greater at the proximal end.The only detectable compound present was ammonium magnesium orthophosphate hexahydrate which occurred naturally as struvite.

Kennedy (1983) reported a nine-month study of 18 elderly catheterised females, using three types of catheter. Each type of catheter was to remain *in situ* for three months and was only changed if problems such as bypassing developed. In fact the mean time *in situ* was only 35 days for the solid silicone, 30 days for the siliconised latex and 12 days for the Teflon-coated latex catheter. Only 19 per cent of the silicone, 7 per cent of the siliconised and 2 per cent of the Teflon-coated latex catheters were routinely changed at three months. Silicone catheters were found to be uncomfortable, however, bypassing and blocking were rare. Siliconised latex catheters were better tolerated, though bypassing caused by bladder spasms and blocking due to encrustation were common. Teflon-coated catheters gave the worst performance: bypassing and blocking were common. The largest number of urease-producing bacterial species (associated with encrustation) were isolated from urines of patients with Teflon-coated catheters *in situ.* No one catheter was considered ideally suited for long-term use in the elderly catheterised female.

Anderson *et al* (1985) reported a study of 92 female patients with pre-operative sterile urine undergoing pelvic surgery who were randomised to either suprapubic or urethral post-operative catheter drainage. Significant bacteriuria (10^4 ml of urine or more) on the fifth post-operative day was statistically significantly lower when using a suprapubic catheter (20.8 per cent) than with a urethral catheter (45.5 per cent). Post-operatively impaired bladder emptying also tended to be reduced when using suprapubic catheters. One year post-surgery the initial post-operative bacteriuria was closely correlated to increased rates of both cystitis and asymptomatic bacteriuria. Suprapubic bladder drainage after colposuspension and vaginal repair was recommended in an effort to avoid an increased risk of urinary infection.

Ruutu *et al* (1985) reported a study of all brands of latex catheters in Finland. The catheters were investigated for cellular toxicity by making an eluate from them after an epidemic of severe urethral strictures in patients following cardiac surgery. Four out of seven brands (57 per cent) including the one involved in the stricture cases showed marked cytotoxicity inhibiting almost all cell growth in several human cell cultures when a 30 per cent catheter eluate was used. Four silicone catheters did not influence cell growth, nor did they cause any new strictures after they were inserted into patients who had previously had latex catheters. The conclusions of the study were that all medical personnel should be made aware that adverse urethral reactions in connection with catheterisation can be induced both chemically and mechanically.

Observations on clinical trials and suggestions for further research

Manufacturers state that silicone catheters should last for up to three months *in situ.* The trials discussed here indicate that they do not last for this length of time. Blannin and Hobden (1980) quote 70 per cent of silicone catheters lasting for two months (wide age range). Kennedy (1983) reported a mean lifetime in use of 35 days (elderly patients) with only 19 per cent actually lasting for three months. Silicone catheters were also described as hard and uncomfortable although these comments came from females in female-biased trials. The main advantage of these catheters is a reduced tendency for debris to be deposited and therefore a reduction in encrustation and blocking. Lower rates of tissue irritation and inflammation associated with the use of silicone catheters were also observed. These findings together with their non-toxic nature make silicone catheters the most inert presently available. The silicone-coated latex catheters have the same attributes as the all-silicone variety. However, since the coat reduces the internal diameter (lumen) it follows that deposits of debris will more readily lead to blocking in these catheters.

Latex catheters are cheap, soft and comfortable for the patient for short-term use. However, the data on their cytotoxic nature and the fact that exposure of latex to urine results in encrustation are matters for grave concern. Ruutu *et al* (1985) state 'Urologists should advise hospital staff to switch to silicone or plastic catheters despite their higher cost until better quality control of latex catheters has been established'. Although Teflon-coated catheters were not found to be cytotoxic (Ruutu *et al* 1985) and indeed, Teflon as a material is said to be inert, as a coating on a latex catheter it appears to be reactive since elderly female patients were unable to tolerate these catheters. They blocked readily and bypassing was common (Kennedy 1985). It is said that thin layers of silicone as found in the siliconised latex catheters may melt away within a few hours of use, so exposing the urethra and bladder to the latex beneath (Ruutu *et al* 1985). It is apparent that both Teflon-coated and silicone treated latex catheters need further investigation. PVC catheters appear to have established a post-operative or intermittent use niche.

Statistically significant comparative trials need to be carried out on all the catheter varieties discussed here. An investigation into individual patient tolerance to a particular catheter material would also be helpful. It is necessary to determine how long a long-term catheter needs to last *in situ.* Research into extending the life of catheters should also be undertaken since the risks to the catheterised individual, in particular that of bacteraemia, are increased with each re-catheterisation. An investigation into how best to reduce the incidence and degree of bacteriuria needs to be carried out and the correlation between bacteriuria and catheterisation complications needs to be established. The place of catheter teams (involving a bacteriologist) to increase awareness of the hazards of bacterial contamination should be considered.

Finally, catheter blocking and leaking are serious problems still requiring solutions. Figure 9 (page 30) indicates the association between blocking and leaking. This is not applicable to all cases of blocking. Individuals react differently to the presence of a catheter and some will tend to block their catheters very quickly while others may not block at all. Individuals may also bypass their catheters without a blocked lumen due to kinked tubing, large catheters or constipation (Kennedy 1983b) and bladder spasms (Blannin and Hobden 1980).

Other pertinent questions which may warrant consideration are:

Does urinary tract infection make blocking and bypassing worse?

What effect does the catheter size and balloon inflation volume have?

Is there some method of reducing blocking and bypassing, for example by maintaining an acid urine (refer to Figure 9, page 30)?

Would periodic clamping and resultant release of larger volumes of urine (in appropriate patients) lead to a less contracted bladder with better muscle tone and in turn to fewer bladder spasms and less leaking or bypassing?

The effect of a 30ml balloon on the integrity of the bladder trigone and urethra needs to be critically assessed. Cystograms may be useful in determining whether or not the 'fit' of the balloon in the base of the bladder is associated with leakage.

Storage and disposal

Urinary catheters are sterilised by gamma irradiation and theoretically they should remain sterile indefinitely because of their packaging. However, there are problems associated with storage which tend to limit their life. Packaging may be inadvertently damaged so rendering the product non-sterile. Removal of packaged catheters from the box may precipitate this, particularly if they are crammed into drawers. If catheters are bunched together with elastic bands this may damage the integrity of the packaging but also, and equally important, the lumens (drainage and inflation) may be compressed. The inflation channel with its diameter of 0.5mm to 2mm may be imperceptibly affected such that inflation of the balloon is possible but deflation may not be because the compression may cause the channel to behave as a flutter valve, thus closing down the lumen once inflation has taken place.

British Standard 5750 (1981) relating to Foley catheters states that if the known shelf life of a product is less than five years then the manufacturer should state this. Prefilled catheters are subject to a two-year use-by date. This is to ensure that at the end of the two-year period there is still sufficient water in the product to inflate it properly. After this time, however, the effects of osmosis and evaporation may reduce the water volume to an inadequate level. For disposal of urinary catheters, see storage and disposal of body-worn pads and pants (page 16).

Cost effectiveness

Generally speaking the catheters which are employed for short-term or intermittent use (PVC, latex, Teflon-coated or siliconised) are cheaper than those used for long-term catheterisation (all-silicone and silicone-coated latex). Of the two varieties currently used for long-term drainage, however, the silicone-coated catheter is the more expensive. In terms of patient comfort these are said to be superior to the all-silicone. However, the coating on top of the latex is said to reduce the internal diameter, thus apparently lowering drainage potential when compared with the all-silicone product. The increased level of patient comfort alone may be sufficient to make the silicone-coated latex catheter cost effective. Comfort may be an important issue in preventing costly side effects (irritation, bladder spasm, encrustation, by-passing or infection). A cost effective comparison for all-silicone and silicone coated catheters would be useful. In view of the problems associated with the short-term use of inexpensive latex catheters (Sutherland *et al* 1983; Ruutu *et al* 1985) these products do not appear to be cost effective.

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4 Urine drainage bag assemblies

Description and use

A urine drainage bag assembly consists of a wide-bore clear plastic tube which collects urine from another body-worn appliance (an indwelling urethral catheter or penile sheath) and is integral with a bag (often opaque and graduated) which has an outlet tap for emptying and reclosure. A non-return or anti-reflux valve is commonly present in the bag to prevent or minimise urine back flow. There are two types of drainage bags, body-worn and night drainage.

Body-worn drainage bags

These generally have a small capacity of 350 to 1000ml. Plastic varieties may be used for five to seven days and sometimes longer. The rubber ones may last up to six months if properly washed, dried and cared for (Department of Health and Social Security Advisory list of urinary incontinence appliances 1985). These bags are normally worn during the day. They must be provided with a suitable method of attachment to the patient's thigh, knee or calf or be suspended from the waist. Males often prefer a long connecting tube and calf attachment so that the outlet tap is easily accessible below loose trouser legs. For females this is not suitable unless they wish to wear trousers. The inner aspect of the thigh may be a suitable attachment site for those who wear long, loose skirts. However, women's thighs are notoriously ill-shaped for attachment, being conical with the apex downwards. For some, a waist belt with attachment similar to a suspender belt may be the preferred alternative. It is important to find a satisfactory and discreet method of collecting urine for all individuals. Body attachment is achieved by straps made of fabric, latex, elastic or foam with Velcro or button fastenings. The bags may also be placed in pants, pocket, sporran or holster garments (Figure 10, overleaf).

The larger capacity bags may be adequate to cope with overnight volumes of urine and may be suitable for some patients. The inlet tubing length varies from 3cm to 52cm and there are ten main outlet tap types (Figure 11, pages 38 and 39).

Night drainage bags

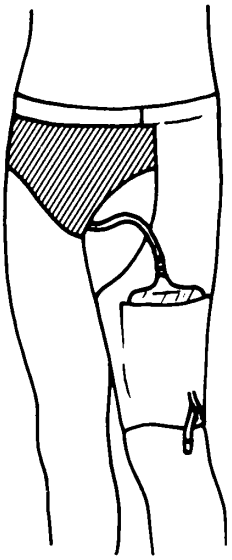
These bags have a large capacity to accommodate overnight urine volumes of 1500ml to 2000ml. They may be used for up to seven days (Department of Health and Social Security Advisory list of urinary incontinence appliances 1985) and are attached to the bed or a stand on the floor. The inlet tubing length varies from 90cm to 106cm and there are eleven main outlet tap types, although some models for once-only use do not have outlet taps (Figure 11, pages 38-39). Figure 12 (page 41) indicates the variations in shape, inlet and outlet facility in urinary drainage bags.

Safety and testing

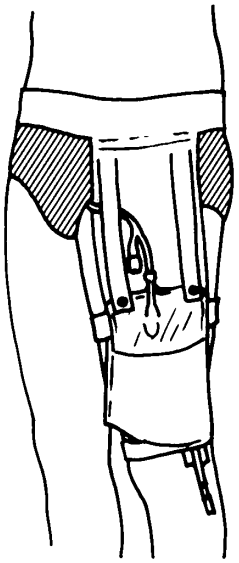
There is at present no national surveillance system for checking the quality of individual products. Since 1982 the Department of Health and Social Security in conjunction with the Health Service Supply Council has operated a voluntary manufacturers registration scheme for the quality assurance of certain sterile products, including urine drainage bags.* Manufacturers are inspected to ensure that their quality control systems are good in respect to sterility.

* Guide to good manufacturing practice for sterile medical devices and surgical products. B.S. 5750, 1981.

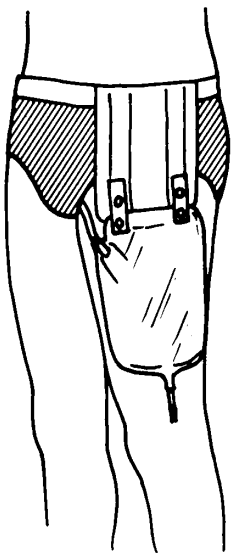
Figure 10 Urine drainage bag support systems



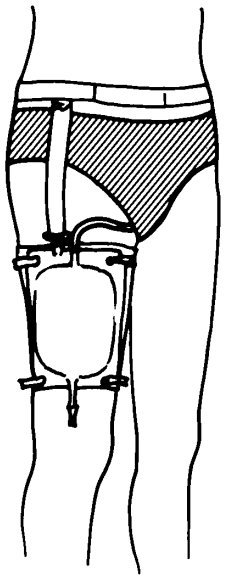
One-leg pant garment with pocket on outside aspect to hold bag



Holster garment suspended from waistbelt and attached to thigh by straps



'Sporran' type garment Waistband with apron to suspend bag from



Waistbelt with elastic suspender to support, and straps to hold bag onto thigh

Although there are at present no British Standards for urine collection bags the Department of Health and Social Security is cooperating with the British Standards Institute and the International Standards Office in formulating draft proposals. This work is a long way from completion, however. Manufacturers are asked to submit details of their product, including toxicological characteristics. Any problems relating to the construction or use of urine drainage bags should be reported to the Department of Health and Social Security.*

Supply and availability

Some 20 UK-based companies are involved in the manufacture or supply of body-worn drainage bags and some 10 in night drainage bags. Price ranges are 69p to £2.80 (body-worn) and 14p to £2.10 (night drainage) approximately. Pack sizes range from one to 50 bags, each individually packed or sealed. Ten UK-based companies manufacture or supply body attachments for drainage bags. Prices range from £2.14 (for a pair of elastic and Velcro leg bag straps) to £10.70 (for a sporran type garment). Body-worn (leg bags) and night drainage bags together with attachment devices including straps, sporran and holster suspensory systems are prescribable under the drug tariff provision (see supply and availability of urinary catheters, page 28). Leg bag garments are not prescribable. They may be supplied via community nursing services and are also available through mail order.

Clinical trials

Daschner *et al* (1981) reported a study of 10 closed urine drainage systems with urimeters and 13 systems without urimeters which were subjected to comparative experimental and bacteriological tests. Characteristics investigated included:

sterility of the single pack product
fluid tightness at maximum capacity and independent of position
presence or absence of Pasteur drip chamber
possibility for sterile urine sampling
integrity of the non-return valve
outlet tap, ease of opening and reclosure using one hand
bed attachment capabilities.

None of the systems met all the hygienic and clinical requirements, only a few systems could be recommended and most were said to require further substantial improvements before they could be recommended for clinical use.

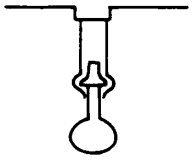
Kennedy *et al* (1983) reported a trial of drainage taps in 10 different drainage bags (six body-worn and four night drainage). Forty participants, including medical staff and inpatients, were asked partially to empty and re-close the drainage taps on bags filled with water. The overall best performer was the Dover Searle leg bag with its crocodile snap clip and the worst was found to be the Portex leg bag which had a bung. The implications of the survey were:

future bag designs should have medical and nursing input
simple sound valves with easy opening and closing mechanisms should be incorporated
consideration should be given to one-handed emptying
bungs and caps should be avoided
designs which prevented urine contact with operators' fingers should be encouraged.

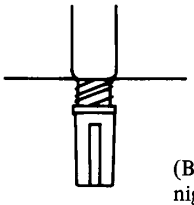
Kennedy (1984a) reported a trial of the Lic Tribag, a body-worn bag with a night connector which obviates the need for breaking the closed system. Sixteen elderly catheterised patients (eight female and eight male) used the Lic Tribag for two weeks and comparisons were made

* Contact Mr W H Walmsley, Department of Health and Social Security, Government Buildings, Warbreck Hill Road, Blackpool, Lancashire.

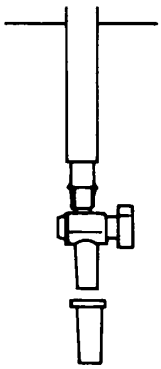
Figure 11 Variations in urine drainage bag outlet valves



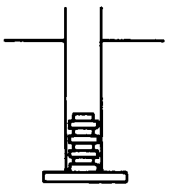
(Body-worn and night drainage)



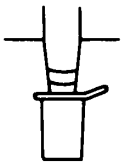
(Body-worn and night drainage)



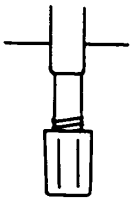
(Body-worn and night drainage)



(Body-worn)



(Body-worn and night drainage)



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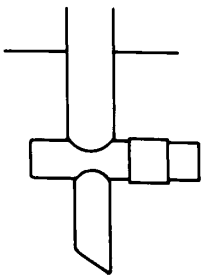

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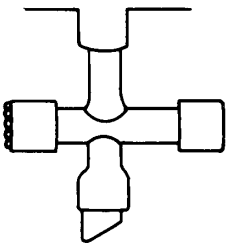

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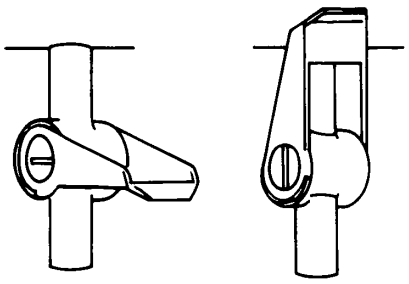

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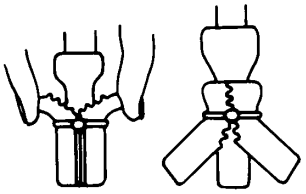

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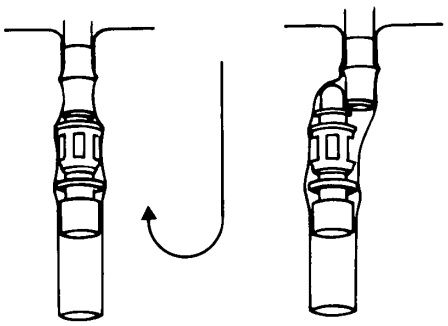
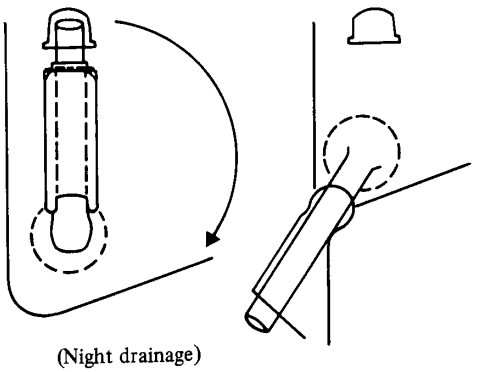
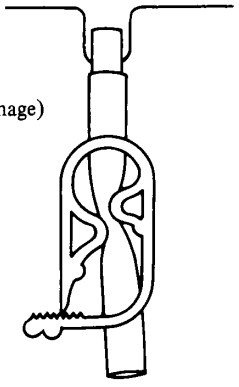


(Body-worn)



(Night drainage)

(Night drainage)



with previously used leg bags. The Tribag is held in place on the thigh, calf or lower leg by fixing it to a material bag holder and strapped to the leg with Velcro ties. For thigh attachment there is a special belt to which the bag holder is clipped. It was anticipated that the bags would last for seven days but in practice they lasted two to four days (mean). The night connector functioned well. The nursing staff felt that the Lic system was fiddly to fit and slow to empty but was nevertheless very comfortable for the patient.

Kennedy (1984b) reported a nocturnal assessment of 40 elderly patients. 57.5 per cent were found with a leg bag *in situ* (commonly the Wallace 350ml capacity) lying in bed, 35 per cent with a two-litre bag on the bedside and 7.5 per cent with a two-litre bag lying on the floor. Only 12 per cent of the patients with the two-litre bag attached were known to have had leg bags during the day although 24 per cent of these patients were not bedridden. Of the 30 per cent of patients who bypassed large volumes of urine at night, 92 per cent had leg bags lying in the bed.

Observations on clinical trials and suggestions for further research

No outlet valve tap in use at present is fully satisfactory since none strikes a balance between simplicity of use and avoidance of operator contact with urine.

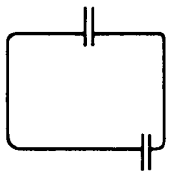
Body-worn urine drainage bags were commonly reported as uncomfortable to wear. The majority incorporate straps for limb attachment. These do not actually support (hold up) the urine bags but serve only to attach (hold on) to the moving part (the limb). This means that the downward seeking (gravity induced) attitude of the bags (proportional to the contained fluid volume) can only be counterbalanced by increased local pressure – tightening the straps. This results in pinching of the skin which may be so marked as to produce a tourniquet effect. Where bags have an additional attachment to a waist belt or are housed in pants or a pocket garment ultimately suspended from the waist they are more comfortable and do not migrate downwards. Such migration may well lead to trauma of the urethra and trigone where the body-worn appliance is a urethral catheter.

Two types of urine sampling ports have been observed – puncture chambers commonly in the catheter attachment or drainage tube and latex cuffs on the drainage tube. These urine sampling sites require further investigation for several reasons. Micro-organisms must not be able to gain access to the urine pathway as a consequence of sampling at the site. Some bacterial species commonly found in the infected urinary tract are of the order of one micrometer in diameter. Thus resealing has to be at least that good. The term resealable therefore needs to be defined and the resealable nature at these sites needs to be quantified.

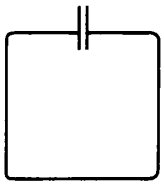
Some latex cuffs are freely moveable along the drainage tubing and when moved may leave on the tubing beneath a visible entry site for micro-organisms to gain access. Moreover, misinterpretation of bacteriological results and subsequent inappropriate management may result because of local microbial activity in the zone between the tubing and latex cuff. Some information on the most appropriate needle size to use at these ports and an indication of the number of times one could safely sample at one port would be helpful. It would seem that inadvertent excessive pressure might result in the needle passing through the opposite side of the tubing thus injuring the sample collector.

The integrity of non-return or anti-reflux valves should be investigated and leaks or reflux quantified. A decision should then be made on what is and what is not acceptable. Some non-return valves protrude into the graduated area of the bag and so may favour the spread of bacterial infection. These valves should therefore be situated above the maximum fluid level.

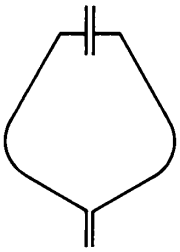
Figure 12 Variations in shapes and inlet and outlet facilities of urine drainage bags



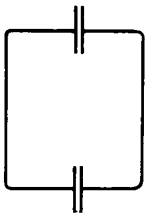
(Night drainage)



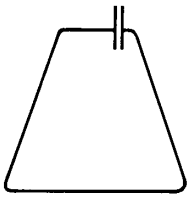
(Night drainage)



(Night drainage)



(Body-worn and night drainage)



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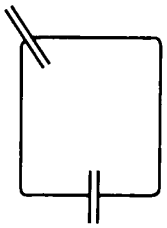

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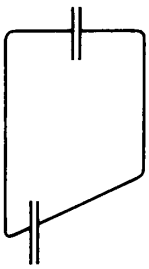

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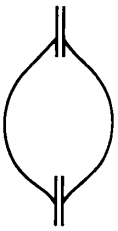
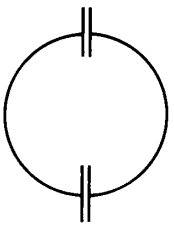
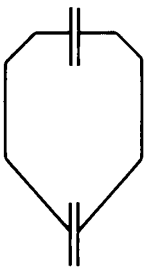


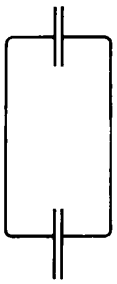
(Body-worn)



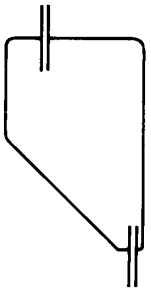
(Night drainage)



(Body-worn)



(Body-worn)



(Body-worn)

Since graduations of 25ml upwards are present on drainage bags, an investigation into how accurate they are should be undertaken. Once accuracy has been quantified a decision should be taken on what is and what is not acceptable.

The mean internal diameter of urinary drainage tubing is 6mm and that of the average urethral catheter 3.4mm. Smaller bore drainage tubes may certainly be adequate for some patients provided they are firm enough to prevent kinking. They would therefore represent an aesthetic improvement.

The benefits of direct connection of body-worn bags to larger volume urine drainage bags for nocturnal use requires investigation with particular reference to the bacteriological aspects.

Since the majority of hospital acquired infections are urinary tract infections (Garibaldi *et al* 1982, Jenner 1982 and Crummy 1985), a greater teaching input for nurses on the bacteriological aspects associated with closed urinary drainage systems is desirable.

Storage and disposal

Sterilised urine drainage bags have been subjected to gamma irradiation or ethylene oxide (gas). Gamma irradiation has the advantage of passing straight through the product though it does tend to discolour PVC. Discolouration is not a problem with ethylene oxide. However, the whole system must remain open during the sterilisation process. Since each bag is individually sealed they should theoretically remain sterile, but because of the risk of damage to the packaging or inadequate storage, many manufacturers suggest a five-year shelf life. High storage temperatures will adversely affect the integrity of the bag thereby shortening shelf life, as will the ultra-violet in sunlight if the products are left on windowsills.

For disposal of urine drainage bags, see storage and disposal of body-worn pads and pants, page 16.

Cost effectiveness

Costs must be seen in relation to the benefits. The cheapest design features (such as cap outlet valves and latex sampling sleeves in the drainage tubing) may well prove the most expensive in terms of overall cost effectiveness, since they may lead to patient discomfort and urinary tract infections.

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5 Penile sheaths and external catheters

Description and use

Penile sheaths or external catheters are expandable tubes designed to fit over the penis and along the penile shaft. They are attached by a small integral drainage tube to a urine bag assembly (Figures 13 and 14 opposite). These devices are used to protect the male from episodes of incontinence and to afford collection of the urine when spontaneous or stimulated (as in the case of patients with spinal cord lesions) voiding occurs.

Rationale

Urine is conducted into a drainage bag by gravity so the drainage bag assembly must be situated below the level of the sheath. Most of the sheaths currently available are composed of soft latex. There are two main penile sheath outlet types: a reinforced funnel composed of thicker latex, and a gathered base with or without a strengthening flange or disc immediately prior to the drainage tube (Figure 15, page 46).

A penile sheath may be appropriate if the following six criteria are satisfied:

1) incontinence is moderate or severe;
2) the penile shaft is long enough (4cms minimum) to achieve proper attachment of the sheath and fixation (where this is used);
3) the patient or carer is able to manage the sheath and urine drainage bag assemblies;
4) sensitivity to latex is not present;
5) the patient does not repeatedly pull off the sheath; and
6) urinary retention is not a feature.

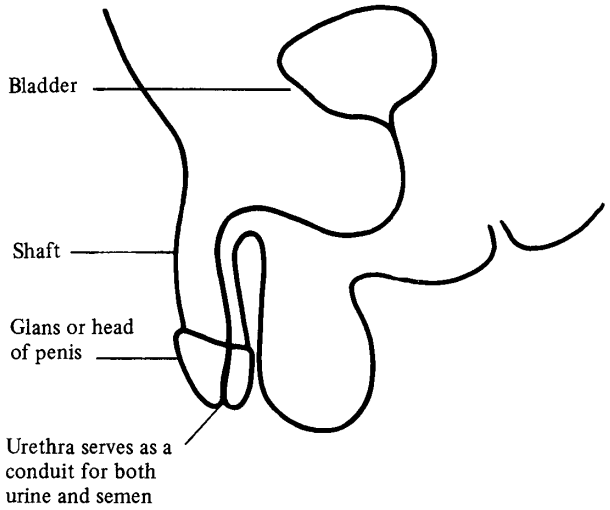
Safety and testing

Since penile sheaths are worn on the body and not inserted into it (as are urinary catheters) no apparent stringent controls relating to their safety and testing exist. There are no British Standards for penile sheaths – neither for the materials of which they are composed nor for their dimensions. Manufacturers are asked to submit details of their product which would include any potentially toxic characteristics. However, from time to time penile sheaths which prove to be highly irritant do enter the market. Because latex comes from different plantations in the tropics, the types and quantities of chemical additives may vary. Thus there can be considerable variation in the composition of the finished product. Exact formulations are not readily given out by the manufacturers and unlike pharmaceutical products, the precise composition of latex can be kept secret. Since latex can be an irritant to many skins, and since each sheath may be worn for one to three days before changing, it would seem sensible to establish standards for these incontinence products.

Supply and availability

Twenty-four UK-based companies are involved in the manufacture of penile sheaths and external catheters and 19 in the manufacture of sheath fixatives. Sheath prices range between 20p and £5.90 each, in pack sizes of one to 100. Penile sheaths and fixatives (where applicable) are obtainable on prescription under the drug tariff provision. (See supply and availability of urinary catheters, page 28.)

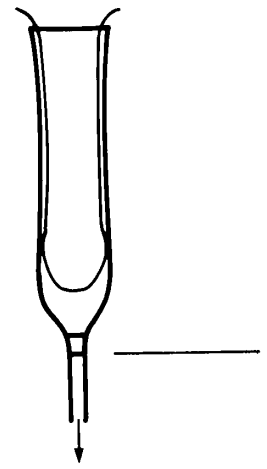
Figure 13 Review of the male anatomy



The penis is a cylindrical erectile organ, predominantly sexual with an incidental urinary function

Penile skin is non-hair bearing, thin and extremely loose to permit distension *(Lich and Howerton 1970)* These are important features with respect to skin health in the patient using an external catheter

Figure 14 Penile sheath application



Fixative:

a) none

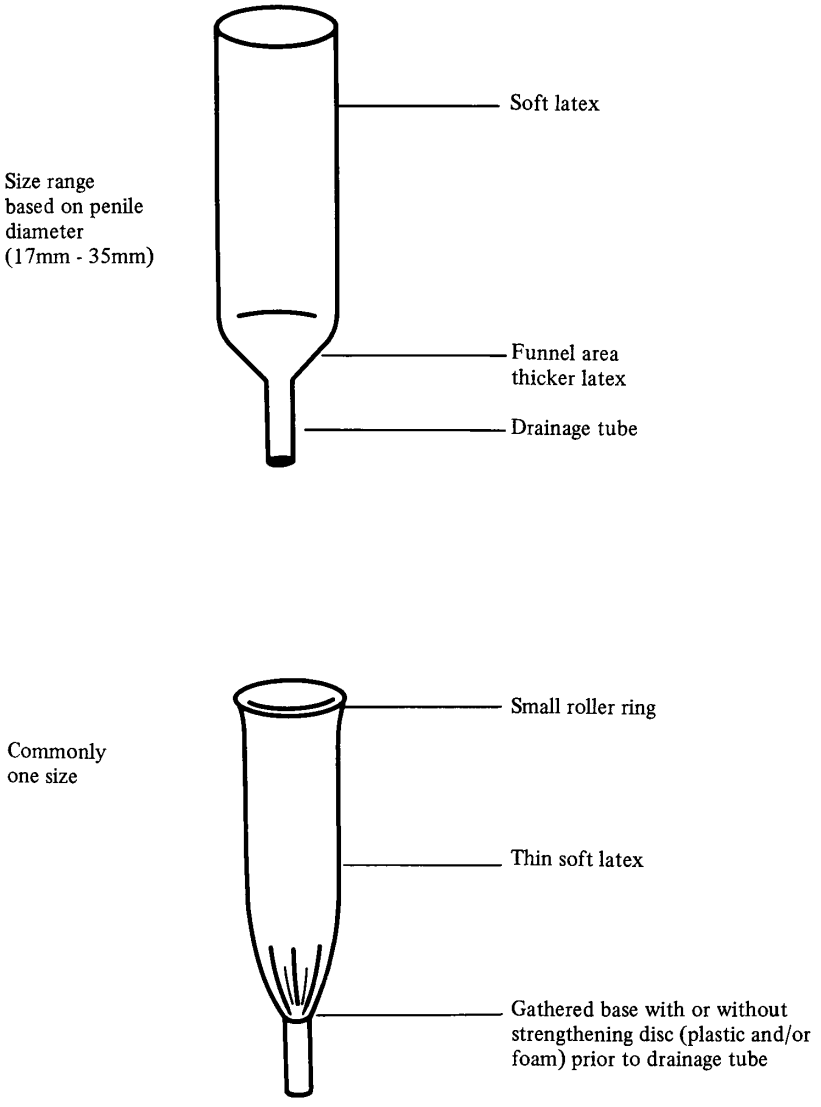
b) internal adhesive strips, sprays or paint-on products

c) external – latex straps, adhesive foam or Velcro and elastic wound around the shaft or applied in spiral fashion

The drainage tube must be 2-3cm below the end of the penis to prevent friction, irritation and tissue damage and to ensure adequate urine drainage This gap also provides for a pre-drainage reservoir.

Urine drainage bag assembly

Figure 15 Types of penile sheath



Clinical trials

Although penile sheaths are frequently used in the management of incontinent males and some 16 million were purchased in 1983 (Health Service Supply Council 1984, personal communication), no major trials describing their use have been published. Many problems associated with penile sheaths relate to their application. Some commonly expressed problems include the following.

Where the sheath must be fixed this may not be carried out according to the manufacturer's instructions. Anxious patients or carers, eager to avoid embarrassment, may fix the sheath too tightly and impede the blood supply to the penis. Many patients using penile sheaths suffer from sensory loss below the level of a spinal lesion and therefore are unable to appreciate the discomfort and pain which would otherwise be felt. Oedema, ischaemia, urethral obstruction and tissue breakdown may then occur (Jayachandran *et al* 1985).

Twisting of the sheath at the site of the drainage tube attachment or positioning the device too close to the glans may lead to obstruction of urine flow. This can result in backflow and incomplete emptying of the sheath. Urine leakage may follow and if the pressure is great enough complete sheath detachment by 'blow-off' may occur.

If inadequate drainage occurs the constant bathing of the thin penile skin with urine may result in dermatitis:

$$\text{urea (in urine)} \xrightarrow{\text{urease}} CO_2 \text{ and ammonia} \longrightarrow \text{ammoniacal dermatitis.}$$

Suggestions for further research

An investigation into patients' and carers' knowledge about the application and management of penile sheaths would seem appropriate since most complications result from improper or prolonged application (Golz 1981, Steinhardt and MacRoberts 1980) and are entirely preventable.

The effects, if any, of the various sheaths on skin health need to be clarified (a particularly important consideration in view of the fully adhesive sheath now available) as do the effects (both mechanical and skin health aspects) of the fixatives used.

A study of how penile sheaths cope with varying urine flow rates would be helpful and may aid in selection of the most appropriate device for particular patients' needs and indicate any need for design improvements.

The whole topic of connection to urine drainage bag assemblies and subsequent body attachment needs to be investigated. The optimal lifetime in use for a sheath needs to be established. While it is known that many patients change their sheath every one to three days, this may not be adequate, particularly if pooling of the urine and obstruction to outflow occurs, since these factors may encourage the passage of bacteria into the urethra. Moreover, the question of perineal care needs to be considered, and the incidence of urinary tract infection associated with the use of penile sheaths examined.

Storage and disposal

Penile sheaths are not sterile devices although sterile urine drainage bag assemblies may be used. There is a considerable problem in the storage of latex. Under any conditions, latex products have a finite shelf life which is very much reduced as storage temperatures increase. The fixative

materials (adhesive strips, sprays and liquids) are said to be heat stable. For disposal, see storage and disposal of body-worn pads and pants, page 16.

Cost effectiveness

This cannot be discussed since significant comparative product trials are lacking. The very large variation in individual sheath costs emphasises the need for studies of cost effectiveness.

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6 Enuresis alarms

Description and use

Enuresis alarms are used to train enuretic individuals – persons who lack bladder control after reaching an age at which one would normally expect control to be established (Meadow 1980). When the condition occurs during sleep at night (bedwetting), with a frequency in excess of one episode per month, it is referred to as nocturnal enuresis (Schmitt 1982).

Rationale

Enuresis alarms make use of the electrical conductivity of urine. When urine is voided and detected by the appropriately placed electrically conducting sensors (mats or pads) a battery driven circuit is completed, causing an output stimulus which may be light, sound, vibration or any combination of these. The most commonly used output stimulus is sound (Figures 16 and 17 overleaf).

The principle behind the use of enuresis alarms is response training. The frequently used 'buzzer' or 'bell and pad' alarm is intended to induce a slight 'start' producing a contraction of the pelvic floor muscles (Morgan 1983) thereby shutting off the urine stream, and awakening the individual so that urination may be completed in the toilet. Initially, the enuretic wakes after voiding is completed, but after two to four months an alarm-perceptive individual will wake because of the sensation of bladder distension rather than the sound of the alarm (Figure 18, page 53).

Who benefits from the enuresis alarm?

Enuresis alarms are most commonly used in the management of children 7 to 14 years of age and young adults of 15 to 24 years. They may also be used by children aged 5 to 7 years provided they are sufficiently mature, cooperative and able to use the apparatus (Meadow 1980). Personal or body-worn enuresis alarms may also be used in the toilet training of mentally handicapped children (Azrin *et al* 1971, Smith *et al* 1975, Dixon and Smith 1976). Patients at risk of developing bed sores due to incontinence might also benefit from an enuresis alarm which utilises light as its output stimulus (Hunt, 1985, personal communication. The nursing staff would be alerted quickly and the patient benefit from rapid changing.

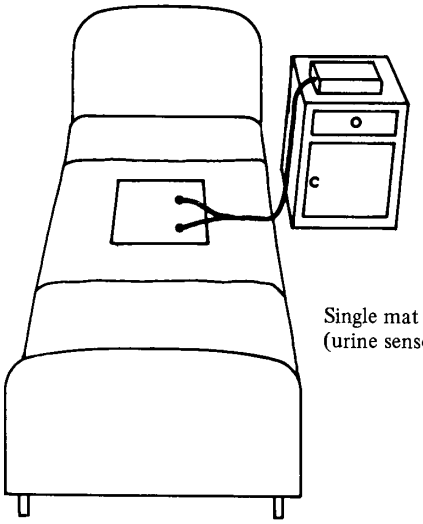
The use of an enuresis alarm may precede, follow or complement the following forms of treatment:

- Simple supportive measures
  - fluid restriction
  - rewards
  - star charts
  - early and late waking
- family and child counselling
- drugs
- dry bed training programmes
- bladder and toilet training
- pelvic floor exercises.

Figure 16 Traditional enuresis alarms and hints on setting up

Alarm unit to be placed out of reach of bed.

Output stimulus:
a) noise
b) light
c) vibration (from unit beneath pillow)

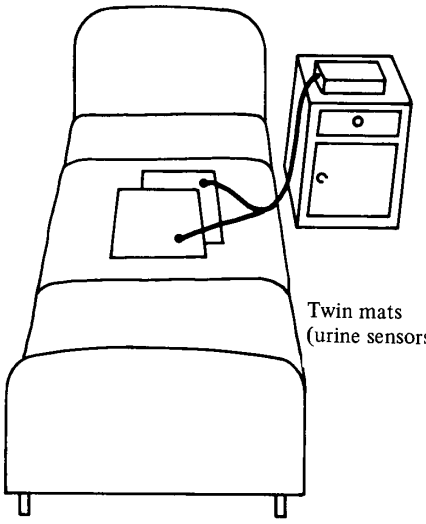


Single mat (urine sensor)

Single mat responds more quickly to urine as there are fewer layers to be negotiated before the circuit is completed

Waterproofed sheet is placed below enuretic mat

Draw sheet or top sheet is placed on top mat. This should be made of a non-conducting material such as cotton



Twin mats (urine sensors)

Waterproof sheet is placed below enuretic mat

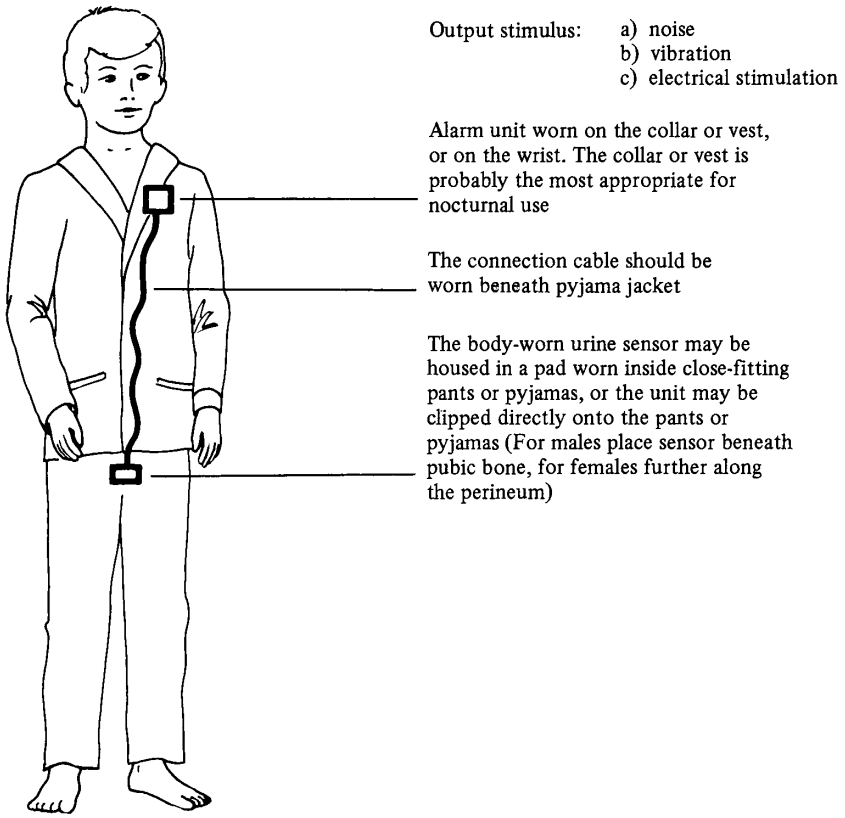
A piece of old sheet is placed between the bottom and top mat (cotton)

A draw sheet or top sheet is placed on top of mats (cotton)

Where a biological washing powder has to be used, dry bedding outdoors or use a fabric conditioner to reduce static electricity build-up, which is associated with false triggering of the alarm. This may present problems where polyester/cotton mix bedding is used.

NB Do not use nylon or other synthetic fabric as they are relatively impervious to urine; they also encourage perspiration and may therefore trigger false alarms

Figure 17 Personal enuresis alarm and hints on setting up



Success with the enuresis alarm will depend upon the counsellor as well as the patient's ability to respond to the alarm and will to become continent. If no maintained improvement is apparent at the end of three months, use of the alarm should be discontinued and recommenced after a rest period of three to six months. If a second course of treatment using an alarm is not successful another form of therapy is indicated.

Prevalence of childhood enuresis

It has been estimated that 15 per cent of 5-year-olds, 7 per cent of 10-year-olds and 1 per cent of 15-year-olds suffer from enuresis (Meadow 1980). The results of a postal survey looking into the prevalence of incontinence (Thomas *et al* 1980) indicated that 18 per cent of boys and 16 per cent of girls aged 5 to 14 years reported occasional (less than twice per month) or regular

(more than twice per month) incontinence, of which 90 per cent of the males and 60 per cent of the females were 'bedwetters'. In 1981 there were 1,343,464 seven-year-old children in England and Wales (Department of Education and Science, London and the Welsh Office, 1981). Hunt and Long (1982) estimated that up to 10 per cent of this age group might be enuretic – some 130,000.

Safety and testing

The construction and use of enuresis alarms is covered generally in the British Standard specification for safety of medical electrical equipment (B.S. 5724) Part 1, 1979. This is very lengthy (236 pages), very technical and is written in legal English. A supplement specification sheet for enuresis alarms has been published by the DHSS, and will appear in revised form in due course (R/E 1004/03).

In August 1984 a hazard notice was issued (Department of Health and Social Security 1984) concerning the Eastleigh AIP enuresis alarm along with others. The notice advises of the potential hazard associated with the passage of excessive current between the bed mats which may cause burns or ulceration in the user. Two cases of burns to children using the Eastleigh AIP alarm were reported to the Department of Health and Social Security. The department recommended that the following alarms should not be used: the Eastleigh API, D.1, Dri-Nite and DC301, Notsilk K1 and Notsilk Kliston A1. (The Eastleigh AIP can be updated to meet the DHSS requirements for approximately £13). Some Gullivar alarms are also unsafe and these, together with homemade and unbranded models, should be tested to ensure they meet the DHSS requirements. The hazard notice also names eight UK manufacturers who are known to supply safe enuresis alarms complying generally with R/E 1004/03 and B.S. 5724. Technical enquiries and reports of incidents should be made to the Department of Health and Social Security.*

Supply and availability

Thirteen UK-based companies are involved in the manufacture of enuresis alarms. Prices range from £15 to £72 (approximately). Enuresis alarms are not prescribable under the drug tariff provisions and are normally supplied through the community nursing services. They may also be purchased direct from the manufacturers.

Clinical trials

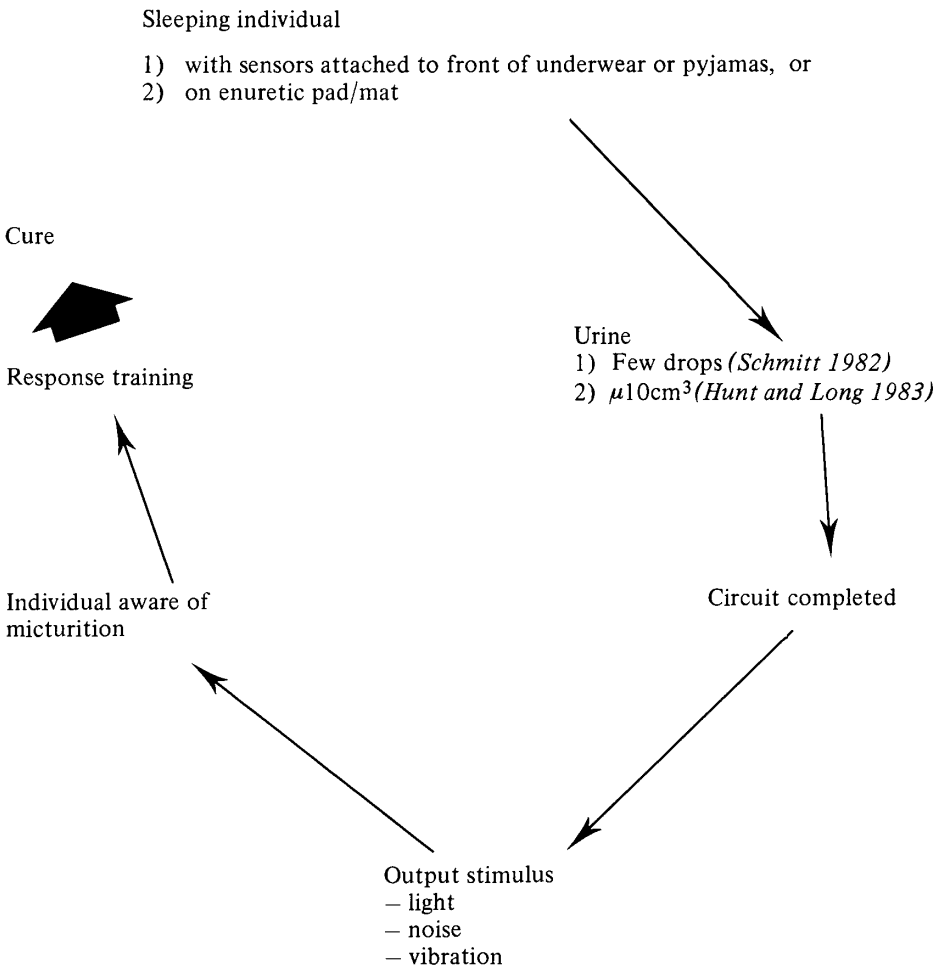
Hunt and Long (1983) have produced a very comprehensive 170-page compendium of information. The document includes an assessment of about two dozen enuresis alarms. Safety and technical attributes are analysed and other properties such as ease of repair, therapeutic effectiveness and reliability are evaluated. Advice is given on how to run an enuresis alarm service and a statistical method for evaluating the degree of success of issued treatments is described. No attempt was made to suggest a 'best buy' as too many variables were said to exist to make this valid. Many alarms in widespread use were found to be easily capable of producing ulceration.

Goel *et al* (1984) evaluated nine enuresis alarms. One hundred enuretic children were admitted to the trial for a period of 16 weeks and technical attributes were analysed. A 'best buy' was not attempted because of the small number of children using each of the alarm systems. However, the Eastleigh and Urilarm De-luxe models were found to have distinct advantages in terms of false alarms, breakdowns and durability of pads.

* Address all enquiries to Mr N H Richardson, Department of Health and Social Security, Scientific and Technical Branch, 14 Russell Square, London WC1 5EP.

Figure 18 Enuresis alarms: rationale

If successful the individual is awakened by the sensation of bladder distension rather than the sound (output stimulus) of the alarm and ultimately, with a normal bladder capacity, learns to inhibit the micturition reflex so does not have to wake during the night.



Observations on clinical trials and suggestions for further research

Limited observations may be made on wet detector mat and pad models as a consequence of the two clinical trials described above. Since children using an enuresis alarm are likely to require it for three to six months, durability of the mats and pads is most important. The available data indicates that some aluminium foil mats and pads lasted considerably less than this time (μ = 5 weeks (Wessex);μ = 7 weeks (Astric);μ = 5 to 13 weeks (Headingley)). However, replacement costs are low (Wessex £1.50 per pair; Astric £3.00 each; Headingley £4.50 each). Only Wessex regarded the mats and pads as expendable and recommended the purchase of two pairs. The plastic and aluminium foil mats (Wessex, Astric and Headingley) were generally reported as pliable and subject to wrinkling (leading to false alarms) and difficult to clean and dry properly after a wetting incident. The wire mesh type mats and pads (Eastleigh), though subject to fewer false alarms, did tend to rust and inadequate cleaning resulted in deposits forming on the mesh which prevented the alarm from functioning.

The Wessex alarm mean battery life was quoted as 12 weeks and the battery would need to be replaced during the course of one patient treatment time. Moreover, battery life was not directly proportional to cost. Astric batteries cost 76p and lasted 20 weeks while Wessex batteries cost £1.29 and lasted 10 weeks (1983 prices). Although the batteries may be changed quite quickly (one to four minutes) this does represent yet another chore for the parents. Wessex Medical claim that updated circuitry in the MK III Wessex enuresis alarm means that battery life has been extended to 12 months.

The alarm systems incorporating a single mat or pad responded more quickly to urine voiding (laboratory testing) than did the twin mats or pads. This is to be expected since the single system has fewer layers.

Faults such as broken connections were common and the stud type fasteners were frequently criticised for being easily damaged and not efficient. Although trivial these faults meant that the alarm was out of use until a repair was undertaken or a spare obtained.

The quoted mean 'cure' rate for nocturnal enuresis with an alarm is 70 per cent (Meadow 1980, Dische 1971) although some investigations quote figures as low as 17 per cent (Close 1980) and as high as 93 per cent (Hunt and Long, 1983). Since confidence in the equipment and its overall reliability is a most important factor in ensuring parent and child compliance further evaluations are needed. These should include particularly the newer personal alarm systems which will surely supersede their larger, more cumbersome predecessors. These body-worn alarm systems are lightweight, portable, cheaper to run (since they utilise a hearing aid battery) and easy to set up. It would also appear that they respond to smaller volumes of urine (a few drops rather than a few ml). They also allow underwear or snuggly fitting pyjamas to be worn, maintaining the individual's dignity. One disadvantage may be the fact that the alarm is inactivated without the necessity of getting out of bed.

Storage and disposal

Storage does not present problems with enuresis alarms. When not in use the batteries must be course be removed. There is no apparent risk of cross infection (Hunt and Long 1983) but the cheaper varieties with their minimal life expectancy will probably need to be replaced after one or two patient treatments. There are no special collections for these items, as they do not contain organic matter, and no guidelines relating to their disposal, probably because they are not hazardous in nature. Most of the manufacturers and suppliers suggested that obsolete systems should be disposed of along with general domestic wastes, although some operate a generous new-for-old part exchange scheme and others would re-purchase the alarms in any

condition for a few pounds, presumably disposing of the majority.

Cost effectiveness

The mean cost of two individual successful six-month treatment programmes is £40 for the alarm plus £5 to £10 for the batteries. This of course does not take into consideration maintenance, repair or replacement costs or the fact that the alarm may function for a much longer period.

It is apparent that a high cure rate – 70 per cent (Meadow 1980, Dische 1971) – is possible with a comparatively small expenditure on equipment and staff.

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