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Economics of Lower Urinary Tract Symptoms (LUTS) in Older People

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Contents

Abstract

Urinary incontinence is an area of clinical and social importance to older people and providers of care. This article provides an update on the 'symptom' of urinary incontinence and reviews the concept of lower urinary tract symptoms (LUTS). The challenges facing health services researchers working in this field are also discussed in terms of trying to quantify the size and extent of the underlying problem. Economic issues and work undertaken to evaluate the cost of LUTS are appraised and the common nonsurgical treatments for LUTS are described together with associated conditions and their cost implications. The cost to individuals and society of LUTS is generally underestimated and the importance of reducing its severity (if cure is not achievable) makes clinical and economic sense.

Present demographic changes in world populations will continue for some time with marked increases in the very old who consume more health resources than any other age group.

Urinary incontinence, whilst lacking the glamour of other medical conditions, is nevertheless a 'geriatric giant' and as such is an area of health needs in which fiscal policy will play a major role in future service provision. Indeed a recent television campaign in the UK by Pharmacia and Upjohn encouraged the public to seek help with regards to urinary incontinence,[1] ensuring that economic evaluation of incontinence will have a prominent role to play in health services research in the future.

In the medical model, incontinence is a symptom. It is, however, only one among several significant lower urinary tract symptoms (LUTS), a term first introduced by Abrams in 1994 in an attempt to critically evaluate the impact of individual urinary symptoms and to promote a more detailed enquiry as to the root of the patients urinary problems.[2-4] LUTS may have components of both storage abnormality symptoms and voiding abnormality symptoms (table I).

In terms of the classification of diseases, incontinence is no more of a disease of the lower urinary tract than cough is a disease of the lungs. In this review we will wherever possible encourage the use of the concept of LUTS. Unfortunately, to date, most of the work conducted in this area has not taken into account individual symptoms. This poses problems when performing economic evaluations. Addressing urinary incontinence alone does not produce the whole picture. There may be costs associated with nocturia and frequency which are not related to urinary incontinence. For example, the disruption caused by lost sleep due to nocturia and alterations in usual activities due to frequency are extremely difficult to evaluate. Therefore the cost of LUTS may be greater than the cost of urinary incontinence alone.

Table I. Lower urinary tract symptoms

Urgency
Frequency
Nocturia
Pain
Straining
Incomplete emptying
Hesitancy
Weak stream
Intermittency

This review provides a background to the problem of LUTS in older people. It covers epidemiology, economics, the cost of current practical treatments of LUTS in the older population (excluding surgical interventions) and suggests ideas for further research.

1. How Big Is the Problem?

One of the great challenges facing researchers working in the field of urinary dysfunction (particularly in older people) is the conflict in reporting of epidemiology. It is generally now accepted that whatever perspective is used, the problem is still underestimated and is big one.[5]

Indicators of prevalence are further complicated by researchers concentrating on incontinence rather than LUTS. Herzog and Fultz estimated the prevalence of urinary incontinence as 10 and 20% in men and women, respectively.[6] Later works by Diokno et al.[7] and Herzog and Fultz[8] have concluded that 19 and 38% of men and women, respectively, are more realistic figures for urinary incontinence.

Other important confounding issues in epidemiological research have been those of population demographics, namely the setting for the problem (community based or residential homes), gender, age and racial variations. All of the above points (and the lack of measures of disease severity) further compound the problem of what is the perception of need in the older population.

It is well known that the prevalence of LUTS is greater in the residential home setting than in the community. Ouslander et al.[9] suggested that approximately 50% of the nursing home population had incontinence problems. Peet et al.[10] reported that problems with incontinence in the nursing home population are are not only greater but also more severe.[10]

Studies of aging and incontinence have shown increases in prevalence with age from 15 to 35% between the ages of 65 and 90 years.[11] This increase may be due to the increased burden of mental and physical handicaps with aging rather than a true ageing phenomenon.[12] Bjornsdottir et al.[13] found that 50% of octogenarians had daily symptoms of urinary incontinence.

There is a relative dearth of studies in older males. Tsang and Garraway[14] suggested that benign prostatic hypertrophy (BPH), which commonly causes LUTS in men, may affect 40% of men over the age of 65 years.

Post micturition dribble can be severely bothersome to elderly males and is under-reported.[15] Beier-Holgersen and Brun[16] have suggested that, regardless of nature or severity, men more readily accept their urinary symptoms. However, with increasing health awareness, particularly with regards to prostatic cancer, a shift in reporting may be evident in the future.

Traditional thoughts as to why LUTS in females have a higher prevalence has centred around postmenopausal changes in hormonal status resulting in changes in detrusor, urethral and pelvic floor function. However, the exact mechanisms are not clearly understood (see section 5).

The vast majority of the above work has been undertaken across the continents of North America and Northern Europe. The problem of LUTS is significant and difficult to quantify in the older population in the developed world. To quantify the problem and the impact on a global scale is a difficult task, but there is no reason to suppose that that people in Third World countries suffer less than those in developed countries.[17,18]

2. How Much Can Lower Urinary Tract Symptoms (LUTS) be Corrected

By the time most older people receive clinical attention for their LUTS, cure may not be feasible. The aim should then be to reduce the severity of LUTS and improve the quality of life for these patients. Therefore, it is appropriate to seek underlying urinary problems in older people, both in terms of symptoms and causes, in a logical manner and to investigate them. This would also seem to make economical sense (see section 3).

3. The Economics of Untreated LUTS

At the core of the contribution of health economics to healthcare provision is the idea that markets fail to provide an adequate solution to the problems of how much healthcare to produce, what sort of healthcare to provide and who to provide it for. Therefore, decisions on these questions have to be made on behalf of society. In relation to LUTS, health economics can make contribution in 2 particular ways. The first is to quantify the size of the economic burden of LUTS. The second is to answer particular questions on the most efficient ways to provide particular services and to address particular problems.

Farrar and Donaldson[19] have provided examples of the above in relation to care of older people. At the macro level one question is whether the aging population is a growing burden that can be afforded by Western societies. They break this question down to 2 issues. First, is an aging population going to constitute an economic burden? Second, what does 'affordability' mean in relation to healthcare?

3.1 Burden

Economists can work with epidemiologists and social scientists to quantify the economic burden of LUTS so that a picture of current burden and possible future trends is formed. This may then be related to the cost of addressing these changing patterns so that estimates of healthcare costs and expenditure are made. This information can give an estimate of the burden and importance of a condition. It can also be used to estimate the effects of changes, such as an aging of the population, or an increase or decrease in prevalence. When doing this it is essential to include the costs borne by all relevant sectors regardless of budget demarcations (e.g. primary and secondary health services, social services, voluntary sector) as well as the public and wider society.

3.2 Efficiency of Healthcare

Efficiency can be thought of as producing healthcare so that the maximum benefits are produced for a given cost. Efficiency is a desirable aim as there is a fixed budget for healthcare so it is important to maximise the benefits produced by that fixed budget. Health economists address the issue of efficiency by looking at both costs and benefits, i.e. how much do you get from a particular cost outlay. If one intervention produces more benefits per unit of cost than another it will be preferred on an efficiency basis.

3.3 Quantification

Not surprisingly, attempting to quantify the health economics of LUTS is difficult. Many issues come into play, all of which need to be accounted for in an economic evaluation. Costs attributable to LUTS impose burdens on individuals, families, carers and healthcare institutions. LUTS are a cause for admission to hospital or nursing home.[12] Many individuals who experience LUTS pay for aids, such as pads, from their own pocket and also have to account for the cost of laundry of soiled clothing. The impact on the quality of life of the carer is a further issue. It is also difficult to quantify the benefits of an improvement in an individual's urinary incontinence.

Recently, 2 excellent reviews have addressed the issues of the economics of incontinence. The first study by Wagner and Hu[20] updated the work originally conducted by Hu[21] in 1984 and published in 1986.

They estimated the annual costs (in 1995) of urinary incontinence in the US for individuals over the age of 65 years as $US26.3 billion, or $US3565 per individual with urinary incontinence.

They used the principle of cost of illness as first described by Hu.[21] This involved aggregating individual level data pertaining to the average cost of treatment and the average amount of healthcare use in order to form population estimates. Combining these aggregated estimates with disease prevalence they provided the above fiscal estimates.

For their estimation, costs were described as direct (those associated with providing a healthcare intervention e.g. diagnosis, inpatient services, outpatient care, cleaning of laundry, medications) and indirect (those arising because of the intervention but not a direct consequence of the healthcare being provided e.g. lost productivity due to time off work). Intangible costs (the monetary value of the pain and suffering resulting from urinary incontinence) were not included in their analysis. For the purposes of prevalence they used the estimates of Diokno et al.[7] for community-based incontinence and Dey[22] for institution-based incontinence.

Using Hu's original data from 1984 and updating this with national hospital discharge surveys, Wagner and Hu[20] assumed that 2% of individuals with incontinence in the community and 5% of those living in institutions sought treatment. Their framework for direct costing incorporated features such as diagnostic costs, treatment costs (behavioural, pharmacological, surgical), routine care costs, and incontinence consequence costs [skin irritation, urinary tract infections (UTIs), falls]. These were all considered at the community and institutional level.

The authors assumed that 30% of those aged >65 years incurred indirect costs. By combining direct and indirect costs they came to the figure quoted above ($US26.3 billion) the vast majority of which was due to direct costs (US$25.6 billion) i.e. 97%. However, their study gave no information on whether or not this is money well spent. It says nothing about the health benefit of this spending or whether more benefit could be created by different patterns of spending. This limitation was discussed by the authors.

As uncertainty existed around prevalence, numbers of patients treated, different treatments, average cost of treatments and supplies, they used a sensitivity analysis. This involved the systematic variation of key parameters to determine the impact on total costs.[23] Each of the important parameters was adjusted one at a time in the sensitivity analysis. The parameters that they emphasised were prevalence, proportion of individuals seeking treat-

ment, proportion of different treatments (behavioural, pharmacological, surgical), the average annual cost of these treatments and cost of supplies of routine care. The sensitivity analysis revealed that total costs were minimally affected by most of the above – all except prevalence (by taking a very conservative estimate of 9% prevalence rate for community based incontinence, as opposed to 18%, the total cost decreased from US$26.3 billion to US$16.1 billion). This cost of illness study showed the size of the problem but did not assess the effect of treatments.

3.4 Willingness to Pay

The above study was descriptive in nature, which is invaluable in providing basic information for policy makers but it is also necessary to have comparative studies using alternative economic evaluation techniques which allow us to answer the question: what is the best way to do something?[24]

Methods of economic evaluation include cost minimisation, cost effectiveness, cost utility and cost benefit. In cost benefit analysis, both costs and benefits are assigned a monetary value. The benefits of any intervention can then be compared directly with any costs incurred. One way to do this is to determine the 'willingness to pay'.[25] This is based on observed trade offs between resources and states of ill health. Respondents are asked what is the maximum amount of money they are prepared to pay for the commodity (in this case, an improvement in incontinence).

Willingness to pay for a reduction in the number of micturitions and leakage episodes was used in a Swedish study where frequency of micturition and involuntary loss of urine were combined as an outcome measure.[26]

To see if combining frequency and leakage was an appropriate outcome measure, quality-of-life (QOL) scores together with scores from the EuroQol instrument[27] were correlated with frequencies and incontinence both individually and together.

This qualitative and economic health study was undertaken in the form of a questionnaire. The sample consisted of 541 patients of whom 461 (85%) replied.

Patients were asked about their willingness to pay for a hypothetical treatment and 2 levels of improvement were offered (25 and 50% improvements in their symptoms). Patients were willing to pay approximately twice as much for a 50% improvement compared with a 25% improvement. Patients with greater severity of incontinence were also prepared to pay more.

The baseline QOL scores of these patients were lower than those of the general Swedish population and the scores correlated significantly with the combined symptoms ($p < 0.001$). The EuroQol scores also correlated with combined symptoms ($p < 0.001$). When scores were taken for individual symptoms and correlated both symptoms had approximately the same weight. The authors concluded that the severity of symptoms expressed as frequency and incontinence is correlated with QOL, health status and willingness to pay for a given percentage reduction in their symptoms.

This study (using 1996 prices and the exchange rate of £1 = 11.5 Swedish Krona) produced median willingness to pay of between £12 and £57 per month. These values do not correspond to any purchases of services so would not appear in most evaluations or cost of illness studies. This would mean that estimates of the burden of incontinence are likely to be biased downwards as reported by Drummond.[28]

4. Treatment of LUTS, Associated Conditions and its Costs

4.1 Drug Treatment of Urinary Tract Infections

The incidence of UTI is high in older people and is the most common cause of acute bacterial sepsis in those aged >65 years. It can also be the basis for LUTS in older people. Asymptomatic patients must have a urine culture threshold of 1×10^5 c.f.u/ml of a single species for diagnosis but this is lowered to 1×10^2 c.f.u/ml in symptomatic patients.[29] Asymptomatic bacteriuria is more common in

Table II. Cost of common antibacterial treatments for urinary tract infections in the UK (year 2000 prices)

Antibacterial and dose	Cost of 7-day treatment (£)
Amoxicillin 500mg tid	1.05
Cefalexin 250mg qid	2.02
Erythromycin 250mg qid	0.82
Trimethoprim 200mg bid	0.54
Nitrofurantoin 50mg qid	1.96
Nalidixic acid 1g qid	12.83

bid = twice daily; **qid** = 4 times daily; **tid** = 3 times daily.

older people but it is not clear if treating it is cost effective or cost beneficial, especially if the adverse effects of antibacterials are also considered.[30]

Table II provides the cost of common antibacterial treatments for UTIs in the UK. The above costing is based on non-proprietary tablet preparations. Costs increase with capsular and liquid preparations.

Bacterial resistance, especially to ampicillin (to which approximately 50% of *Escherichia coli* are now resistant), has increased the importance of urine culture prior to therapy.[31] The principle that treatment of symptomatic UTIs is cost effective is not challenged. What is questionable is which antibacterial should be used to achieve the desired effect at the lowest cost.

4.2 Drug Treatment of the Overactive Bladder

Drug treatment for LUTS in older people primarily centres around the treatment of the unstable or overactive bladder (the urodynamic diagnosis being detrusor instability or detrusor hyperreflexia).

Whilst the use of drugs requires careful consideration in older people this must be weighed against the possible benefits that certain medications may provide. These medications should be given in combination with bladder re-education.[32-34]

Table III compares the cost of medications used to treat overactive bladder. It is not clear what the response rate with each drug is i.e. how many patients must take the drug to have a certain number improved or cured. The duration of treatment and how long patients are likely to continue or comply with treatment is also not clear. Larger, well constructed, randomised, controlled clinical trials need to be performed to answer these questions.

4.1.1 Imipramine

Imipramine[35,36] is a tricyclic antidepressant with central and peripheral anticholinergic effects, sedative and antihistamine properties, local anaesthetic properties, calcium antagonist properties, adrenergic properties and a nocturnal effect in reducing urine production.[37] It is the latter property that can make this an attractive drug for treating nocturia. However, caution is needed especially when given with other antidepressants, antipsychotics, alcohol, anticoagulants and cimetidine.

Postural hypotension is a potentially dangerous adverse effect of imipramine. Its long half-life (3 days) means titration should be a slow process starting with 25mg once a day. The average recommended dose is 50mg daily, but up to 150mg may be used.

4.1.2 Oxybutynin

Oxybutynin is a tertiary amine with powerful anticholinergic, local anaesthetic and papaverine-like properties.[38]

It is renally excreted and has a half-life of 3 hours.[39] Adverse effects include dry mouth, constipation, reflux oesophagitis, dry skin, visual accommodation problem and minor ankle swelling. These adverse effects cause poor compliance. A low dose regimen of 2.5mg twice daily is recommended in older people initially with upwards titration depending on desired and unwanted effects.[40,41]

Table III. Cost of drugs used to treat the overactive bladder (year 2000 prices)

Medication	Cost for 1 month's treatment (£)
Imipramine 75 mg/day	0.42
Oxybutynin 5mg tid	12
Tolterodine 2mg bid	32
Propiverine	32

bid = twice daily; **tid** = 3 times daily.

4.1.3 Tolterodine

Tolterodine is a more specific muscarinic receptor antagonist. It is as effective as oxybutynin in reducing urinary symptoms but may have a significantly improved tolerability profile, with a lower incidence of dry mouth.[42-44]

4.1.4 Propiverine

Propiverine has both anticholinergic and calcium channel antagonistic actions.[45] It has a documented beneficial effect in the treatment of detrusor hyperreflexia.[46,47]

5. Estrogen Replacement Therapy in Women

The female lower urinary tract is estrogen sensitive. Falling estradiol levels after menopause lead to reduced vascularity of tissues, particularly of the vagina. This, together with a decreased glycogen content of the cells, leads to a fall in lactobacilli levels and an increase in vaginal pH. This environment encourages the growth of certain bacteria, including coliforms and streptococci, and predisposes to urinary tract infections. The fall in estrogen has also been implicated as a factor in the development of peri- and postmenopausal stress incontinence by affecting the integrity of the urethra and possibly bladder neck.[48,49]

On the whole, the clinical trials addressing incontinence and the role of hormone replacement therapy have not produced conclusive evidence for the role of estrogen in the management of incontinence (stress or urge). There are, however, major methodological problems with most of these studies. These problems have centred around the type of estrogen used (e.g. estriol, estradiol) and the route of administration (topical or systemic).

Many of the studies consisted of a heterogeneous group of patients both in terms of menopausal status, the numbers treated and reported symptoms. Fantl et al.[50] undertook a systematic review of systemic oestrogen for treatment of incontinence in postmenopausal women. This analysis consisted of 6 controlled trials and 17 uncontrolled studies and showed that there was a significant subjective improvement for all patients and those with genuine stress incontinence. However, objective measures showed no improvement in the amount of urine lost. Trials investigating detrusor instability and estrogen are limited.[51,52] These have shown an improvement in subjective symptoms, such as urgency, but no objective improvement in incontinence. Work is ongoing in assessing the benefits of topical localised estrogen and LUTS.

Topical estrogen may, however, be beneficial in treating vaginal atrophism and the accompanying symptoms of frequency, urgency, nocturia and dysuria. Although objective changes in incontinence states may not be noticed, the QOL for some older women maybe improved.

Table IV enumerates the types of local/topical preparations available in the UK, duration of recommended use and costs. Note that long term unopposed estrogens in women with a uterus is contraindicated due to the risk of endometrial hyperplasia and endometrial carcinoma. However, the risk of such pathologies developing with short term topical treatments is negligible.

All manufacturers recommend that topical treatment be discontinued periodically and the need for further treatment be reassessed. Many older women do not like to apply vaginal creams which are messy and stain clothes. They may be cheaper than other forms of estrogen but also ineffective because they are not used as prescribed.

6. Treatment of Voiding Disorders

It is now recognised that older people of both sexes can have high post-void residuals of urine, with or without coexisting pathologies (such as detrusor instability).[53,54] It can be particularly problematic in older patients with underlying neurological disease.

The technique of clean intermittent self-catheterisation achieves good results in bladder emptying. A residual volume of urine of >150ml (in the absence of an obstruction) can be considered as threshold for treatment. Patients (or their spouses/carers) can be taught this technique and a twice daily regimen is usually sufficient to improve post-void residuals. However, there can be practical dif-

Table IV. Topical estrogens used to treat lower urinary tract symptoms in the UK (year 2000 prices)

Estrogen preparation	Type	Duration of use	Cost per month (£)
Ortho Dinoestrol®	Cream	3-6mo	2.61
Ortho Gynest®	Intravaginal cream	3-6mo	2.72
	Pessaries		5.29
Ovestin®	Intravaginal cream	2-3mo	5.21
Premarin®	Intravaginal cream	1mo	2.19
Tampovagan®	Pessaries	3wks	7.00
Vagifem®	Tablets	3mo	14.62
Estring®	Vaginal ring	2y (replace every 3mo)	32.90 per 3 mo

ficulties and patients and their families may need an initial intense period of support before the technique is mastered. The schedule suggested by Sheri and Barnes[55] is suitable for use in community and hospital based environments.

7. Incontinence Products

It is beyond the scope of this review to describe the various products and designs available on the market. Excellent reviews exist elsewhere.[56-59]

Wagner and Hu's estimates in 1995 considered the cost of these products as part of the direct costing strategy.[20] This was calculated to be $US10.5 billion dollars. The true figure may be much higher.

The use of pads and their cost to health resources and patients themselves is extremely difficult to quantify.[60] Quite often, the cost of these is borne by the patients themselves. Smith suggested that £24 million was spent per annum on pads and pants alone in the UK.[61]

The use of catheters and pads has become an integral part of the management of LUTS in older people, however wrong this approach might be. Crow et al.[62] reported that 10 to 12% of patients admitted to hospital in the UK have an indwelling urethral catheter *in situ*. Catheters are available on prescription from the National Health Service in the UK.

Unfortunately, all too often clinicians and continence advisers are faced with problems arising from the long term use of these devices which may have been instigated with the carer in mind rather than the needs of the individual patient. Chronic urethral catheterisation predisposes to infections, bypassing, encrustation and stone formation and trauma to the urethra. All catheters are expensive in terms of the time needed to change and manage them.

Pad use is invaluable in patients whilst a cure is being sought, and in some with dementia and progressive disability. However, it may be inappropriate in the long term and lead to inertia in locating an underlying cause for the patients symptoms and condition.

The products currently available and their cost in the UK can be found in the Association of Continence Advisers' Directory of Continence and Toileting Aids.[63]

8. The Future

Any meaningful economic evaluation of LUTS first requires the development and instigation of interventions that have beneficial, quantifiable and validated outcomes.

Fonda et al.[64] succinctly comment on the problems plaguing research in this area. They highlight that research of older patients suffering LUTS is different from those of younger patients and that studies should aim to reflect this. They advocate a 'back to basics' approach where researchers should concentrate on cure and preventative measures to combat the problem.

Another problem is what actually constitutes a continence service within a particular community. A study of 3 locations in the UK showed wide variations in the range of services available to patients and their families.[65] We are currently evaluating a new continence service in the community. Health

economic analysis will play an integral part in the overall evaluation of this novel model of care. Our model will, however, approach economic evaluations from a new perspective.

We aim to provide a quantitative estimate of the level of expenditure by health and social services, and by individuals themselves, on the management of LUTS. The problem with previous studies is that they obtained estimates of the cost of incontinence (not LUTS) by extrapolating the results of smaller surveys and samples to the whole of the population.

We are collecting economic data on a subset of 800 patients who have been identified as having LUTS from a large epidemiological prevalence study in which 55 000 men and women, based in the community and aged >40 years, have reported their LUTS in a postal questionnaire. These 800 patients, together with 800 non-LUTS patients, have undergone face-to-face home interviews. Respondents were asked a range of questions to elicit any National Health Service and private costs they bear as a result of their LUTS. These were covered in a number of areas:

- medications – bought or prescribed;
- complications arising from catheters;
- use of pads, aids or appliances and their costs;
- tests (urine, urodynamics, urinary diaries);
- treatment or advice given;
- loss of paid employment;
- laundry costs;
- household adaptations;
- effects on daily activities;
- willingness to pay.

We hope that our work will provide a true reflection and comparison of what actually happens to individuals with LUTS in our community from a health economic point of view. In addition, from our larger epidemiological prevalance study we have identified patients who have severe LUTS to warrant further investigations and the opportunity for treatment within various randomised controlled clinical trials. Economic evaluations will also play an important role in the final analyses of these studies. We hope to report and publish all these findings in a series of papers in 2001.

It is hoped that this practical framework for estimating the cost of LUTS will be applied to the residential and nursing homes within our regional setting.

At best, present cost evaluations are flawed, probably an underestimate and little better than a 'guesstimate' with a few notable exceptions. What is agreed is that the cost is large because the problem is so common. What is also agreed is that the cost to those with LUTS and society is high and that despite the current costs of treatment, they are not universally acceptable or effective.

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