

The Schleswig-Holstein problem was thought to be understood by three people, two of whom were mad. Similar mind-bending problems not amenable to simple souls crop up in medicine. They occur particularly in the field of alternative and complementary therapy. As an example, *Bandolier* introduces the grapefruit seed extract problem.

## Grapefruit seed extracts

The BBC health site has an "Ask the doctor" section. One question was about Candida and grapefruit seed extract. Dr Trisha Macnair said that she could find no evidence that it had any therapeutic effect, and suggested seeing a complementary therapist. That is the grapefruit seed extract problem in a nutshell - we can't find evidence that it works.

But hang on a moment. That doesn't mean there is *no* evidence. Analysis of six commercial grapefruit seed extracts [1] showed five had antimicrobial properties, and were active against a strain of Candida. In all extracts with antimicrobial activity the chemical benzethonium was found, and, in some, triclosan and methyl parabene. The only extract without antimicrobial activity contained no chemicals. The chemicals detected are those used to preserve grapefruit. The only antimicrobial property came from synthetic chemicals. Organic grapefruit would have no effect.

## Problem

*Bandolier* will have its comprehensive alternative therapy website ready in a few months. We have identified about 100 systematic reviews, but need to know what questions you have about "alternatives" - your grapefruit seed extract problem. Questions you want answered, please, by email (andrew.moore@pru.ox.ac.uk) or fax (+44 1865 226978).

- 1 von Woedtke et al. Aspects of the antimicrobial efficacy of grapefruit seed extract and its relation to preservative substances contained. *Pharmazie* 1999 54: 452-456.

### In this issue

Saw palmetto and prostate problems .....	p. 1
Hospital acquired infection .....	p. 3
Preventing medical error .....	p. 4
Computers to prevent medication error .....	p. 5
After prostate cancer surgery .....	p. 6
Influenza vaccines / Student websites .....	p. 8

*The views expressed in Bandolier are those of the authors, and are not necessarily those of the NHSE*

## SAW PALMETTO AND PROSTATIC HYPERTROPHY

An extract of the fruit from the American saw palmetto plant has been used by native American Indians for hundreds of years to treat a variety of men's problems, and prostate gland swelling since the 1800s. Does it work? Systematic reviews [1,2] say that it does.

## Search

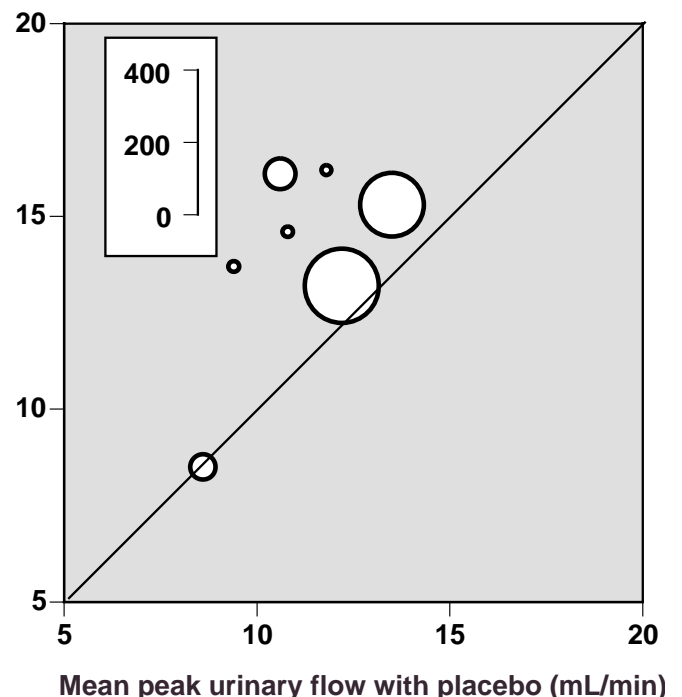
The search for randomised controlled studies of Saw palmetto (using all those peculiar botanical names that plants have) against placebo or other treatments was thorough. It found 24 studies, 18 of which met the inclusion criteria. The mean age of men involved was 65 years and the mean duration of the studies was nine weeks.

## Results

Compared with placebo, Saw palmetto improved peak urinary flow rate by an average of 1.9 mL/second and mean urinary flow rate by 2.2 mL/second (Figure 1). Saw palmetto did not decrease prostate size.

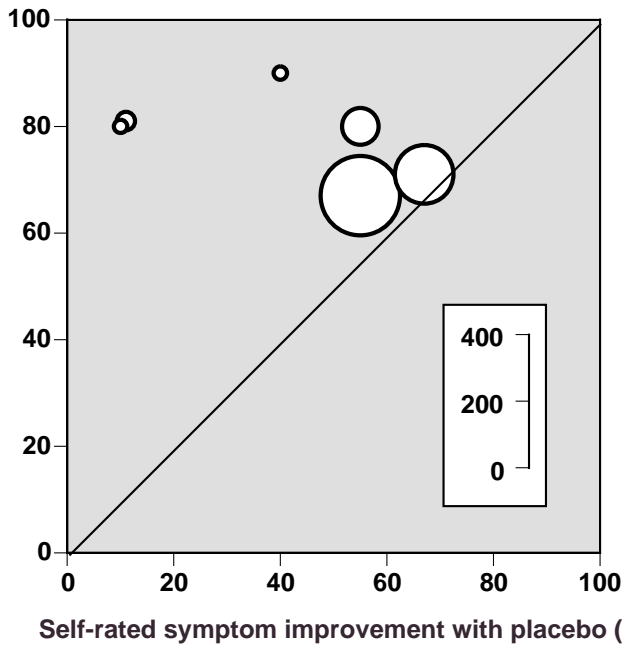
Figure 1: Peak urinary flow

Mean peak urinary flow with Saw-palmetto (mL/min)



## Figure 2: Symptom improvement

### Self-rated symptom improvement with Saw-palmetto (%)



Patient rating of prostate-related symptoms showed significant benefits for Saw palmetto over placebo. In six studies (Figure 2) 242/329 (74%) men had symptom improvement with Saw palmetto compared with 168/330 (51%) with placebo. This means that for every 4.4 men treated with Saw palmetto (95% CI 3.4 to 6.5) one will have symptoms improved who would not have done with placebo.

## The problems

One problem was the short duration of studies, with a mean of nine weeks, and that half the men had symptom improvement with placebo. The largest and longest randomised trial ever done (3,040 men over four years, [3], *Bandolier* 50) clearly demonstrated that with placebo symptom improvement continued over about six months before levelling off or starting to rise. So measuring changes over a few weeks, and with relatively few men (660 for palmetto) means that we cannot be certain of the benefits.

The other problem is that of outcomes. For conventional treatments we look for hard outcomes, like the number of patients needing surgery or being admitted to hospital with acute urinary retention. This is missing from the placebo comparison data for Saw palmetto.

## The answer

This comes from two large high-quality randomised, double-dummy, comparisons of Saw palmetto and finasteride for, respectively, 26 weeks [4] and 48 weeks [5].

The first [4] study had very similar outcomes for Saw palmetto (536 patients) and those treated with finasteride 5 mg (533 patients) (Table). Similar proportions of men had reductions and increases in symptom severity and urine flow. Finasteride produced a larger decrease in mean prostate volume, fewer study withdrawals, urinary retention, and

Table: Comparison between finasteride and Saw palmetto over 26 weeks in 1098 men

Outcome at 26 weeks	Saw palmetto	Finasteride 5 mg
4-point decrease in IPSS (%)	63	67
2-point increase in IPSS (%)	6	7
Increase in max flow by >3 mL/sec (%)	36	39
Mean reduction in prostate volume (%)	7	16
Study withdrawals (%)	16	11
Impotence (%)	1.5	2.8
Urinary retention (%)	1.3	0.6
Needing surgery (n)	3	1

Main results from Carraro et al [4]. IPSS = International Prostate Symptom Score (*Bandolier* 11)

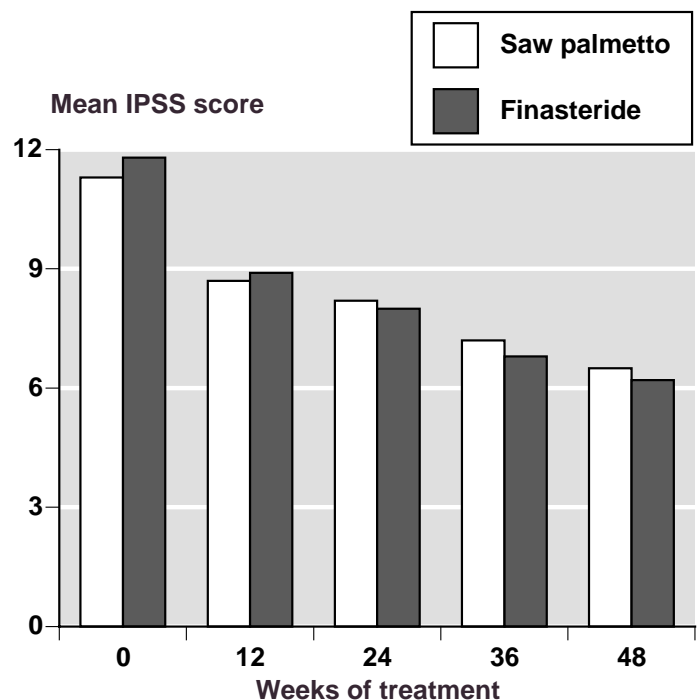
men needing surgery. In this study the mean prostate volume was about 43 mL, and previous research shows finasteride to be effective in men with prostate volumes greater than 40 mL. While this study showed equivalence between Saw palmetto and finasteride, it probably underestimated finasteride efficacy.

The second study [5] examined outcomes over 48 weeks in 543 randomised men. The IPSS symptom score continued to decrease over the 48 weeks in men treated with Saw palmetto and finasteride (Figure 3).

## Comment

There is good evidence that Saw palmetto is effective in men with symptoms of benign prostatic hyperplasia. Finasteride is now considered to be best used in men with larger prostate volumes (*Bandolier* 46) and, consequently, disease that may be considered more severe. We also have excellent efficacy and adverse effect information from a very large randomised trial (*Bandolier* 50, [3]). We don't quite have the same extent of information for Saw palmetto. The evidence on Saw palmetto is sufficient, though, to make it worth considering for men with milder symptoms.

Figure 3: Change in symptom score over 48 weeks in RCT comparison in 543 men



Reference:

- 1 Wilt TJ et al. Saw palmetto extracts for treatment of benign prostatic hyperplasia. A systematic review. JAMA 1998 280: 1604-9.
- 2 Wilt T, Ishani A, Stark G, MacDonald R, Mulrow C, and Lau J. Serenoa repens for benign prostatic hyperplasia (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2000. Oxford: Update Software.
- 3 JD McConnell et al. The effect of finasteride on the risk of acute urinary retention and the need for surgical treatment among men with benign prostatic hyperplasia. New England Journal of Medicine 1999 338: 557-63.
- 4 J-C Carraro et al. Comparison of phytotherapy (Permixon) with finasteride in the treatment of benign prostate hyperplasia: a randomized international study of 1098 patients. The Prostate 1996 29: 231-240.
- 5 J Sökeland, J Albrecht. Kombination aus abal- und urticaextract vs finasterid bei BPH (stad I bis II nach alken. Urologie 1997 36: 327-333.

## HOSPITAL ACQUIRED INFECTION

The burden that hospital-acquired infection places on the NHS has been starkly highlighted by a new report, whose highly readable executive summary is available as a pdf file [1].

### Study

Four thousand patients with a hospital stay of over 30 hours from medical, surgical, orthopaedic, urology, gynaecology, ENT, elderly care and obstetric (Caesarean section) units of a district general hospital were recruited over a 13 month period ending in May 1995. Complete inpatient data was available for 3980 of them with information on daily resource use. Patients who met preset definitions of hospital acquired infection (215 patients), and a sample of those who did not (1234 patients) were followed up post discharge with a questionnaire. The response rate was 71%. Data were excluded from 41 patients who died up to eight weeks after discharge, four of whom had a hospital acquired infection.

### Results

In hospital 7.8% of patients had one or more hospital acquired infections. After discharge, 19% of patients without a previously identified infection reported symptoms or treatment that met the criteria for an infection of urinary tract, chest or surgical wound.

During their stay in hospital, 13% of patients with a hospital acquired infection died, compared with 2% who did not acquire infection in hospital. Adjusted for age, sex, co-morbidity and other factors, the death rate was 7.1 (95%CI 4.3 to 11.7) times higher for infected than for uninfected patients.

Figure 1: Effect of hospital acquired infection on length of stay

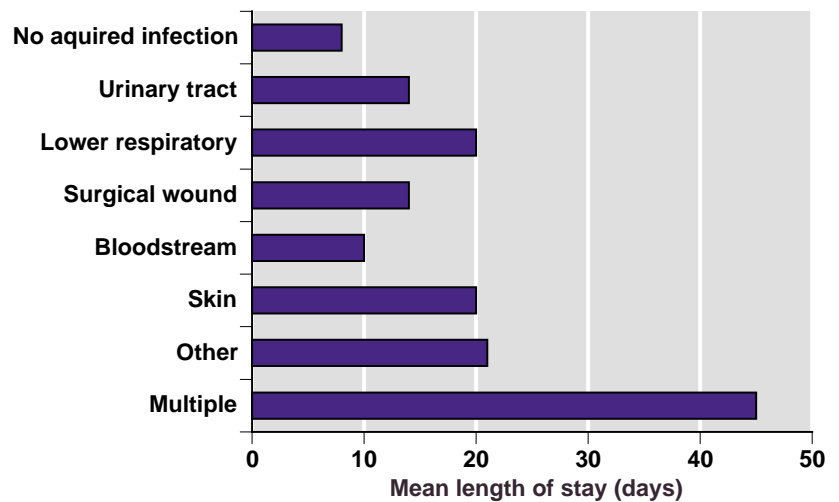
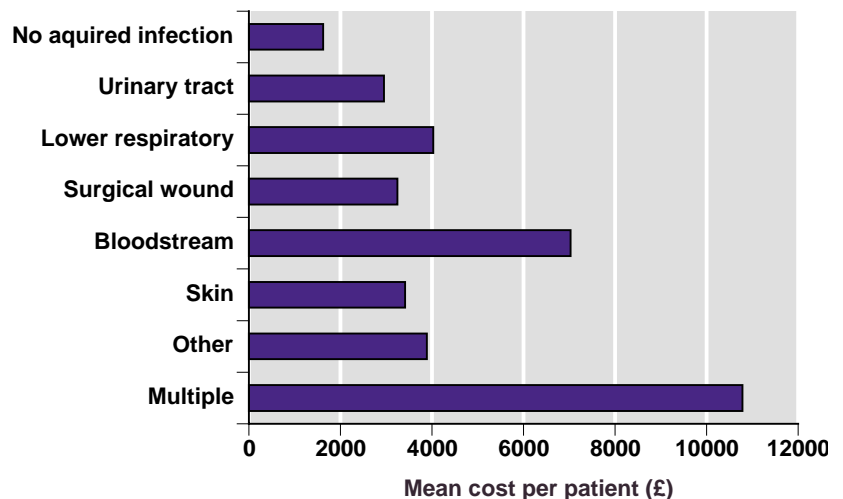


Figure 2: Effect of hospital acquired infection on cost of treatment



### Costs and consequences of hospital acquired infection

	No HAI	HAI	HAI effect
Mean costs (£)	1628	4782	3154
Mean stay (days)	8	22	14
Deaths (%)	2	13	11
Mean admission to work (days)	23	29	6

The mean length of stay was eight days for uninfected patients. It was considerably longer for those with infections of any type (Figure 1). The mean cost of treatment was £1628 for uninfected patients. It was considerably greater for those with infections of any type (Figure 2).

## Comment

Overall, hospital acquired infection resulted in an extra 14 days in hospital, a 10% chance of dying, an extra £3154 spent on healthcare and six extra days off work (Table). The study concluded that the economic burden of hospital acquired infection was about £1 billion a year for the NHS in England and affects 1 in 10 patients. The total number of bed days consumed by hospital acquired infection was estimated at about 3.6 million a year, or equivalent to about 27 400-bed hospitals working at 90% capacity.

By any standards, this is stunning stuff from a detailed, large, and well conducted study. Even more stunning is the estimate that hospital acquired infection may kill about 5000 people a year in the UK. *Bandolier* 67 carried information about how simple handwashing protocols reduced hospital acquired infection by about half. Searching for other literature about mechanisms of preventing the problem did not provide anything of note, but perhaps we looked in the wrong place. *Bandolier* and *ImpAct* would like to hear from organisations that have tackled this successfully.

Reference:

- 1 R Plowman et al. The socio-economic burden of hospital acquired infection. Executive summary at [www.doh.gov.uk/haicosts.htm](http://www.doh.gov.uk/haicosts.htm)

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## PREVENTING MEDICAL ERRORS

*Bandolier* 28 reported on a study from Boston showing that about 2000 adverse drug events per hospital occur each year. An ADE was defined as an injury resulting from medical intervention relating to a drug. The importance of preventable errors has been brought home by surveys showing that they impose major burdens on health services, and may injure or even kill thousands of patients a year. It is probably a much bigger problem than hospital acquired infection, and a serious and thoughtful paper [1] quotes one estimate of 180,000 people dying every year in the USA at least in part due to iatrogenic injury. These episodes are also expensive. The estimated cost is \$4,000 per event in the USA.

### Systems causes of error

The question left begging is how to prevent what has been called serious medical error. This is not a pejorative phrase. It is not intended to blame individuals, but rather a complaint that healthcare professionals are too often expected to do too much with too few tools. Most errors result from failure to use basic human factors in the design of tasks and systems. Excessive reliance on memory, lack of standardisation, inadequate information availability and poor work schedules create situations in which individuals are more likely to make mistakes.

Method of detection	Errors (%)
Voluntary self-reporting	0.20
Patient review	0.70
Computer screening	3.80
Chart review	6.50
Chart review + computer	10.00

One of the biggest problems is in measuring errors. Leape makes the point that the rates of medical errors reported vary by a factor of at least 50-fold (Table). Voluntary self-reporting gives low rates, while the use of chart reviews and computer screening provides much higher rates. The paper examines a variety of different factors that contribute to medical error:

*Process design failures* result from the failure to analyse the purposes of a system and how they can best be achieved, relying on the ways things were, perhaps. This is a big effect, may be the cause of about half of all errors. An example may be over-reliance on memory rather than having computerised systems to help.

*Task design failures* result from failure to incorporate human factors. Checklists, protocols and computerised decision aids (again) can help reduce this. Standardise and simplify might be the simple message here. An example might be to standardise postoperative analgesia protocols in an institution, locking into a system the impossibility of choosing wrong drugs or dosages and making everyone familiar with one system.

*Equipment design failures* arise from the bewildering number of different machines used in a hospital with so few people fully knowing how to use them. Should it be possible, for instance, to connect an epidural catheter to a syringe with a drug prepared only for intravenous use?

*Organisational and environmental failures* come from overall cultures in organisations, such as how it deals with issues of quality, training, and team building. Put simply, this comes down to a simple question: does the organisation care? If it doesn't, then why should its workers?

### The big picture

If this sounds boring process gobbledegook, then it shouldn't. This is a thoughtful exposition of the problem from an author who has spent time thinking about it, in the Harvard Health Policy and Management Department. Healthcare systems are big, they are complex, they are often impersonal, and are difficult to change. Change comes not from one big idea, so beloved by governments and politicians, but by doing the right things better and continuing to do so. For anyone starting down that long road, this paper gives a good place to get the big picture before getting overwhelmed by the underbrush of detail.

Reference:

- 1 LL Leape. A systems analysis approach to medical error. *Journal of Evaluation in Clinical Practice*. 1997 3: 213-222.

# COMPUTER SYSTEMS PREVENT ERRORS

**Table 1: Healthcare professional performance in studies of CDSS**

Study area	Studies showing benefit/total
Drug dosing systems	9/15
Diagnostic aids	1/5
Preventive care systems	14/19
Other medical care	19/26
All CDSS studies	43/65

What is the evidence that giving healthcare professionals better tools makes them perform the complicated tasks they do better? A systematic review [1] of computer based clinical decision support systems (CDSS) shows two things. It demonstrates that there are many studies in a wide variety of different clinical areas. It shows that they work.

## Search

Studies using CDSS in a clinical setting by a healthcare practitioner and assessing the effects in a prospective setting with a concurrent control were sought. Five databases, reference lists and conference proceedings were searched.

## Results

Sixty-eight studies were found (Table 1). Of 15 studies of drug dosing systems, 60% found benefit. Of 19 studies on preventive care systems, 74% found benefit. Of 26 studies in other clinical areas, 73% found benefit. Only one of five diagnostic decision support systems found benefit; that used a system to identify postoperative patients at risk of respiratory complications for physiotherapy.

## Comment

The systematic review is a terrific bit of work. But the question still hanging is whether computer systems can contribute significantly to reduce adverse drug events in hospitals. Two US examples show exactly what can be achieved [2,3].

### Boston

In the Brigham and Women's Hospital, which is a 726-bed tertiary referral centre, the use of a physician computer order-entry (POE) system was evaluated, in which doctors wrote all drug orders online. The study had a baseline period during which an audit of medication errors was examined, followed by implementation of the POE system and re-audit. Incidents were identified by three mechanisms: nurses and pharmacists reported incidents, an in-

vestigator visited wards twice daily to solicit information, and patient charts were examined daily by an investigator.

The main outcome was the number of nonintercepted serious medication errors. These were either an error preventable by systems currently in use, or had the potential for harm but did not result in injury.

### Results

Use of the POE system prevented more than half of the serious medication errors. There were just under 11 of these per 1000 patient days at baseline, and under 5 per 1000 patient days during use of the POE system. Potential errors which had not been intercepted fell most, by 84%. Preventable errors fell by 17%.

The authors concluded that their system could be extended to different drug types, like sedatives, which actually rose, which had not been included in their original system, and by extending the system in other ways. They also show that the cost of running a POE system for their large, complicated, hospital, would be of the same order as money saved directly. When other costs, like extra work caused by serious drug errors, or malpractice litigation, were included, it could save \$5-10 million a year. The system could both save money and improve quality of care.

### Phoenix

The Good Samaritan Regional Medical Centre in Phoenix is a 650-bed referral centre. It has an integrated hospital information system. A multidisciplinary team of professionals met

**Table 2: Adverse drug event alerts**

Event	Number	per 1000 admissions	Percent
Nonobstetric admissions	9306		
ADE alerts	1116	120	100
Evaluator needed to alert physician	794	85	71
True potential adverse drug events	596	64	53
Physicians unaware of potential for harm	265	28	24
Changes in treatment	265	28	24

and identified 37 drug or class-specific areas where adverse drug events might be expected. The system was modified so that if circumstances arose where an adverse drug event might occur (digoxin toxicity was one example), then a pharmacist or radiologist was alerted. If necessary, the physician attending the patient was contacted.

## Results

Over six months there were 9306 non-obstetric admissions. There were 1116 alerts (Table 2). Physicians needed to be contacted 794 times, and 596 times the event had not been recognised. The average time taken for each contact was 15 minutes.

The rates of clinically unrecognised events varied for different clinical circumstances. For instance, more than half of the potential problems for renal toxicity with the use of radiocontrast media had been previously recognised, but it was felt that potential benefit outweighed potential harm.

Using some literature data on costs, the authors calculated that the potential saving to their 650-bed hospital was some \$3 million a year, and could be more if the system were extended to other areas.

## Comment

These are two different types of interventions. One depends on putting systems in place to stop mistakes happening. The other depends on real-time interventions to stop mistakes when they happen. Both had a major effect in stopping medication errors in large, complex institutions. Both would improve patient care. Both would reduce costs.

Concentrating on stopping bad things happening is what quality control is all about. These are two excellent examples of how to do it. Moreover, all three papers have extensive referencing of a wealth of literature in this area, and are worth reading for that alone.

Reference:

- 1 DL Hunt, RB Haynes, SE Hanna, K Smith. Effects of computer-based clinical decision support systems on physician performance and patient outcomes. *JAMA* 1998 280: 1339-1346.
- 2 DW Bates et al. Effect of computerized physician order entry and a team intervention on prevention of serious medical errors. *JAMA* 1998 280: 1311-1316.
- 3 RA Raschke et al. A computer alert system to prevent injury from adverse drug events. Development and evaluation in a community teaching hospital. *JAMA* 1998 280: 1317-1320.

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## WHAT HAPPENS AFTER PROSTATE CANCER SURGERY?

Prostate cancer is the commonest cancer in men, and in the majority the cancer will be clinically localised at diagnosis. There are various treatment options, including radical prostatectomy, radiotherapy, and watchful waiting. To make informed choice, one of the most important pieces of information is what happens after each of these choices. A new US study gives good information about urinary and sexual function in a large population-based cohort of men [1].

## Study

The prostate cancer outcomes study was conducted in five major centres in the US. Men diagnosed with primary prostate cancer in the 13 months up to November 1995 were eligible cases. There were over 11,000 eligible cases, and 5700 were randomly sampled. For the analysis of surgery, 1291 men aged 39 to 79 with histologically confirmed, clinically localised prostate cancer undergoing radical prostatectomy as primary treatment were selected because they had survey data and medical records available.

They were surveyed by postal questionnaire at six, 12 and 24 months to collect detailed information on urinary and sexual function. The response was high. The men who had answered both a 6 or 12 month questionnaire, plus a 24 month questionnaire, comprised 81% of the total sent.

## Results

About half the men were younger than 65 years at diagnosis. The Gleason score (how advanced the tumour was) was

6 or above in about 70%. Arthritis and hypertension each affected about a third of the men, and diabetes and depression a further 10% each.

Information on urinary problems included results on urinary control and leakage, frequency of incontinence, use of incontinence pads and frequent need to urinate. Perhaps the best summary was whether the men considered the totality of these items to constitute no problem, a small problem, or a moderate to big problem. Figure 1 shows these results over 24 months. Clearly the proportion of men who considered urinary incontinence to be a problem surged in the 6-12 month period after surgery, and then settled somewhat. This was not just that they were getting used to having a problem, as the same pattern was seen in control of urination, frequency of incontinence and need for incontinence pads.

Information on sexual function included the level of interest in and frequency of sexual activity, and whether erections were firm enough for sexual intercourse and problems in keeping an erection. Again there was a summary of whether problems with sexual function were none, small, or moderate to big. Figure 2 shows the results over 24 months. The proportion of men with no problem dipped dramatically after surgery and remained low thereafter. It is a moderate to big problem for 61% of men six months after surgery, and remained a big problem for 42% at 24 months. The problem was in getting and maintaining erections firm enough for sexual activity.

For both urinary and sexual function men aged 75 to 79 years had worse outcomes, and outcomes for white men were worse than those for black men.

## Comment

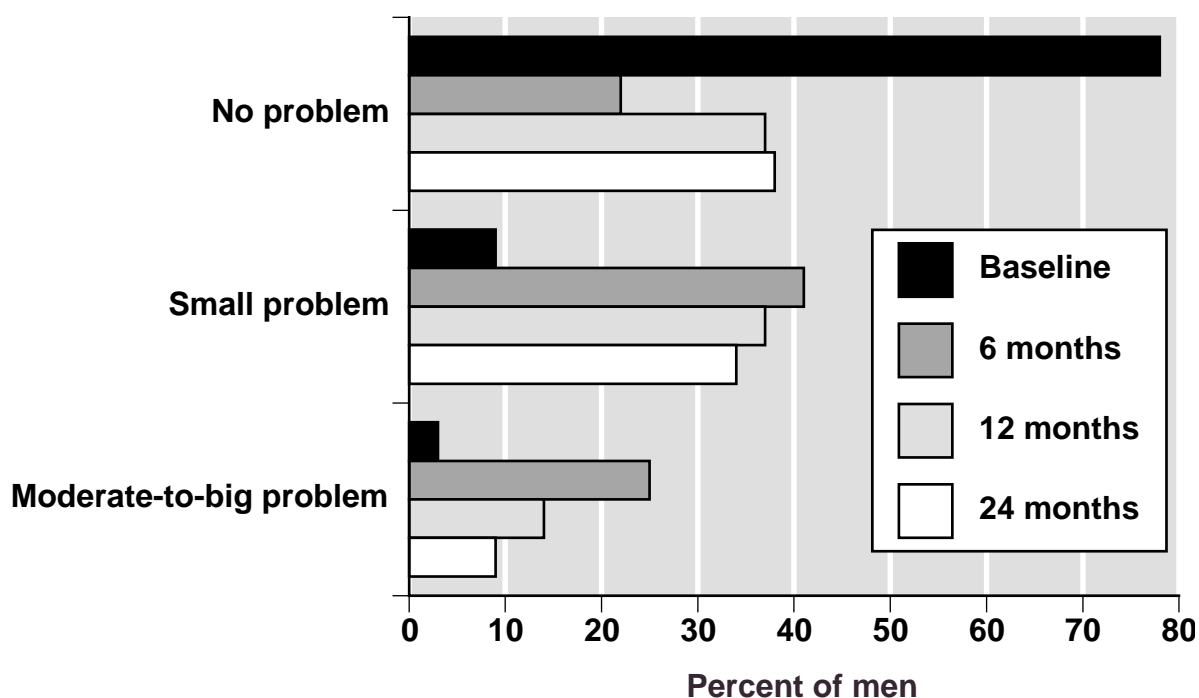
Eighteen months after surgery 72% of the men said they would make the same treatment choice and only 7% said they would not choose radical prostatectomy again. Choice is a funny sort of word in this context. Most men would not choose to have prostate cancer, but if it does strike, a man

wants to know what is the best treatment option for him. This gives real-world outcomes from a large group of men, from several centres, at different ages, and over two years following surgery. It warns of major problems immediately afterwards, but that some of these problems wane with time.

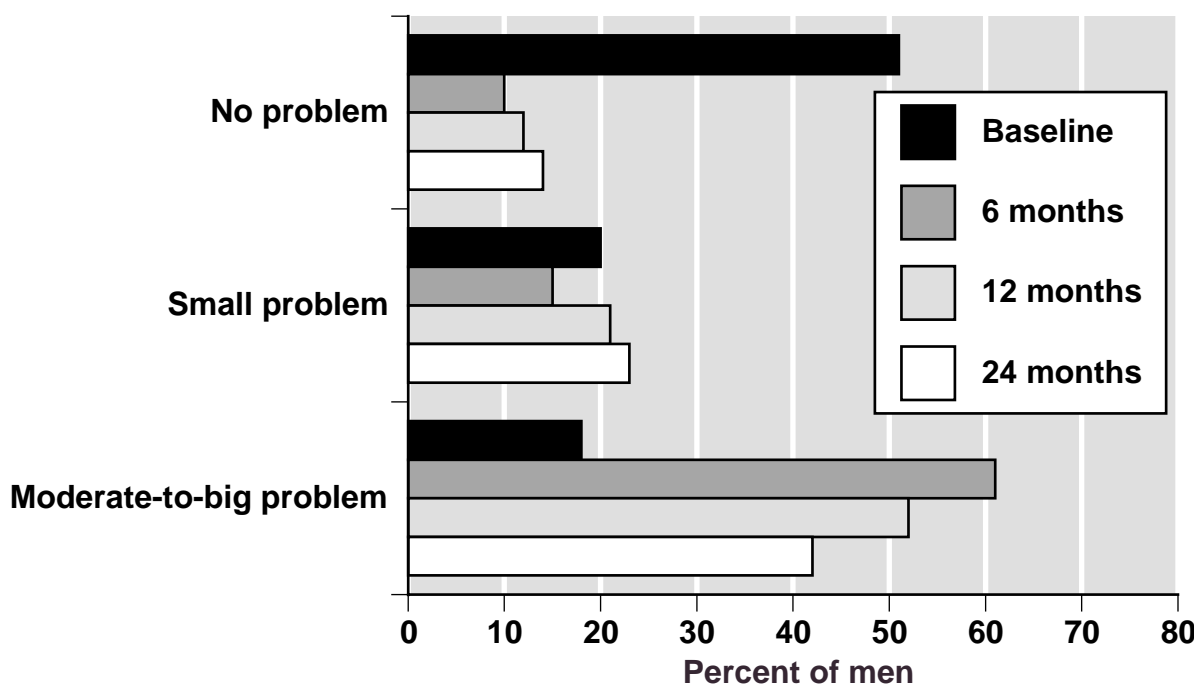
Reference:

- 1 JL Stanford et al. Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer. The prostate cancer outcomes study. JAMA 2000 283: 354-360.

**Figure 1: Effect of prostate cancer surgery on problems men had with urinary incontinence**



**Figure 2: Effect of prostate cancer surgery on problems men had with sexual function**



## INFLUENZA VACCINATION

The end of the influenza season seems timely for the publication of an authoritative review of effectiveness of vaccines, ion-channel inhibitor antivirals and neuraminidase inhibitor antivirals [1], and to begin to plan for next Winter using some evidence. The review concatenates several Cochrane reviews, adds an economic evaluation and a definitive discussion of the problems of trial assessment in influenza. It concentrated on healthy adults aged 14 to 60 years, specifically avoiding vaccination in the elderly for which there is only one RCT (*Bandolier* 11). A review of influenza vaccines in the elderly was published some years ago [2].

### Search and Results

The search was typically thorough. The major outcome from the economic evaluation was that in healthy adults inactivated vaccines appear to be the best buy, if needed.

There were 14 comparisons evaluating inactivated influenza vaccines against placebo or non influenza vaccine in healthy adults. The outcome was clinically defined influenza cases. With influenza vaccine 1034/5953 people (17%) developed influenza, compared with 791/2798 people (28%) given control. Studies covered a range of influenza infection rates, and five individually showed vaccine statistically better than control. The mean reduction in influenza cases was by 29% (95% confidence interval 12 to 42%). It was somewhat higher when vaccines matched the circulating strain. The number needed to treat was 9.2 (7.8 to 11.1). This means that for every nine people given influenza vaccine, one avoided having influenza who would have had it if they had not been vaccinated.

### Adverse effects

Local effects were reported by 69% of people given influenza vaccine. Some parenteral adverse effects were experienced by 30% of people given influenza vaccine, but no individual symptom was significantly commoner than control. Many could be attributed to influenza-like illnesses.

### Comment

*Bandolier* will be more forceful with older relatives next winter. A 1 in 9 chance of avoiding influenza, with its possibly disastrous effects, is worth it if the downside is some local discomfort. Many older relatives complain about minor 'flu-like illness after vaccination. We can tell them that it is not the vaccine. In older people from one trial the NNT was 23. For those who have to deliver healthcare to the elderly, this is essential reading. *ImpAct* would like to hear from groups showing how to deliver high vaccination rates.

#### Reference:

- 1 V Demicheli, T Jefferson, D Rivetti, J Deeks. Prevention and treatment of influenza in health adults. *Vaccine* 2000 18: 957-1030.
- 2 PA Gross et al. The efficacy of influenza vaccines in elderly people: a meta-analysis and review of the literature. *Annals of Internal Medicine* 1995 123: 518-527.

## GREAT WEB SITES FOR STUDENTS OF THINGS MEDICAL

*Bandolier* is starting to collect together Internet sites which provide useful information for medical students, nurses and PAMs, as well as those of us who have completed our training but want a refresher. Sites are being collected by Owen Moore, a third year student at Queen's, Belfast. If you know of good sites, send them to him to collate at: [m9702342@qub.ac.uk](mailto:m9702342@qub.ac.uk). The first offering follows.

[www.rad.washington.edu/anatomy/index.html](http://www.rad.washington.edu/anatomy/index.html)

Excellent pictures and teaching resources, plus a lot on musculoskeletal stuff.

[medicus.marshall.edu/medicus.htm](http://medicus.marshall.edu/medicus.htm)

Smashing - you can take a history, examine and request different tests. There are 20 patients to play with.

[www.s2smed.com](http://www.s2smed.com)

This is a website dedicated to medical and premedical students. The links to step 1 look very useful. Though the whole site is completely US, it looks worth a browse.

[medicalstudent.com](http://medicalstudent.com)

Found this from a place called the virtual hospital at [www.vh.org](http://www.vh.org) from a link for practitioners. It has enough links to online textbooks to make you cry. At the moment I've only looked at the electronic orthopaedic textbook which looks good despite having nothing about arthritis. But there is also a list of internet directories and search engines and some clinical stuff. You'll be happy to see a link to the Cochrane Collaboration under EBM.

[www.medstudents.net](http://www.medstudents.net)

Seems quite complete with mix of medicine, book searches and financial/lifestyle news, though more social and commercial than most sites.

[www.secondvision.com/msc/index.htm](http://www.secondvision.com/msc/index.htm)

This looks to have a lot of good info, but again is mainly North American and most of the clinical stuff is through direct links from s2smed.

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ISSN 1353-9906