

Bandolier

Evidence-based health care

July 1994 Issue 6

PRESSURE SORES

Five reviews & an RCT

Pressure sores are a big problem, with a prevalence of 5 to 9% and more than 70% occurring in patients over 70 years. They are often blamed (falsely) on poor nursing care, but are best seen as a potentially preventable complication of acute immobility illness. Prevention involves a variety of issues, including assessment of risk, appropriateness of care, and the effectiveness of special equipment.

Bandolier became interested in pressure sores after reading an excellent randomised study of a pressure reducing mattress in *Lancet* earlier this year; other studies were sought by searching the literature, with little result. We did find a number of good reviews looking at pressure reducing systems and other facets of pressure sores.

While well written and thorough, they all made the same depressing point - that there are few if any well conducted randomised controlled trials of effectiveness in this area. A survey of 48 products sold for pressure sore prevention revealed that only *two* had been subjected to RCTs to confirm their effectiveness [1].

Bandolier is well aware that few companies making medical equipment (rather than drugs) can produce evidence of effectiveness when asked to do so. Even so, with the financial costs of pressure sore treatment estimated as high as £755 million a year in the UK [2], with concomitant stress on patients, staff, beds and budgets, the professions might have made a greater contribution. This is not just a hospital problem: with more patients being nursed by carers at home, the expertise, techniques and equipment for pressure sore prevention and management need also to be available in the community. The issue needs central co-ordination with a district wide strategy,

Bandolier is on holiday in August, but will return in early September

as suggested by a King's Fund report of 1990.

Right now, neither purchasers nor providers of health care have much to go on, other than standard good practice. That includes guidelines such as turning acutely ill bedridden patients every two hours, a practice developed during the war because that was how long it took the staff to turn all the patients in a ward! There are no effectiveness data for turning two-hourly.

In order, therefore, to try to increase interest in the subject of pressure sores, we report below on one excellent RCT and five relatively recent well written and useful reviews of different areas of this problem.

Epidemiology and current management concepts

This review [1] is from Young & Dobrzanski from Bradford. It covers epidemiology and mechanisms of formation of sores, together with sections on prevention and management.

Cost

Pressure sores are expensive. Estimates of the total cost to the NHS range from £150 million in 1982 to £750 million now [2]. A full thickness sacral sore extends hospital stay by over 25 weeks at a cost of £26,000. This includes all the extra staffing, drugs and dressings as well as hospital overheads. The costs of lost opportunity are even greater - for each sacral pressure sore which is prevented it is possible to undertake 16 total hip replacements. This emphasises the need for prevention.

Incidence & Prevalence

The idea that sores develop only in long-stay geriatric patients is far from the truth. Most pressure sores are to be found in acute hospital wards, though this is hardly well documented. A survey in the '60s showed that the incidence of sores after admission to a geriatric unit was 24%, with the majority occurring in the first two weeks after admission.

In this issue

Pressure sore review.....	p. 1
Health & Deprivation.....	p. 4
Cranberry juice & bacteriuria	p. 4
H pylori & drug prescribing.....	p. 6
Assessment criteria	p. 7

Prevalence rates between 5.3% and 8.8% have been recorded in large studies of hospital and community patients. About 70% occur in those aged over 70 years, though some younger groups such as cerebral palsy and spinal cord lesions also have high prevalence, as do patients with fractured neck of femur. In the latter group, about two-thirds develop pressure sores, especially on the heels.

Mortality

The relative mortality of those with pressure sores has been reported to be five times higher than those without sores. Audit has shown pressure sores to be a primary cause of death in as many as 6% of patients admitted to geriatric wards and a major contributing factor in a further 6%. Pressure sores do not figure highly as a cause of death on death certificates, and so the problem may be seriously underestimated from such sources.

Prevention

The article gives brief descriptions of systems which have been shown to have effectiveness in prevention, but goes into few details.

Management

A whole range of treatments including airwave and polystyrene bead systems is reviewed, each briefly. The depressing repetition that none of the treatments has evidence of effectiveness is topped off by a description of the use of chlorinated solutions. "Despite widespread use for over 70 years on all types of dirty wounds, it is not clear if these solutions actually work.....It is important to appreciate that chlorinated solutions kill healthy cells. If ulcer improvement occurs it may be despite their use rather than because of it."

Pressure ulcers and the elderly

447 papers (1980-1990) were found via MEDLINE [3]. Forty four made it into the review, which was focused on the elderly.

There are good sections on prevention strategies and treatment and management, though again the main theme is the lack of good clinical studies of effectiveness. This review is useful mainly for the references, and the tantalising hints from some of the reports that the right strategy can crack the problem. These include a Swiss report that a combination of soft bedding support and regular turning could reduce the incidence of pressure sores to near zero and the effects of intensive educational programmes.

Nutrition and pressure sores

Another American nurse, Rosalind Breslow, has researched the literature from 1943 to 1989 concerning nutritional status and dietary intake of patients with pressure sores [4]. Few of the studies she reviewed were blind, none randomised, many were retrospective evaluations from notes, and most studied small numbers of patients. The review has a limited number of references (20) and has three main and well recognised conclusions.

Proteins

There is a strong association between protein-calorie malnutrition and pressure sores. Low serum total proteins, albumin and haemoglobin as well as low lymphocyte counts have been shown to be associated with higher rates of pressure sore formation in a number of studies. In one survey of 634 hospital patients, for each 10 g/L reduction in serum albumin there was a three-fold increase in the chance of having a pressure sore.

A number of studies indicated that increased nutrition intake of protein and calories improved the healing rate of pressure sores.

Ascorbic acid

Ascorbic acid is necessary for the formation of hydroxyproline from proline; hydroxyproline is an essential constituent of collagen. In a prospective double-blind study of ascorbic acid (1 gram per day) in 20 patients, the 10 who received placebo had reduction in pressure sore area of 43% over one month. The ten who received ascorbic acid had much higher tissue levels, and had a reduction in pressure sore area of 84% ($p < 0.005$).

Zinc

While serum zinc is apparently lower in patients with pressure sores, dietary supplementation with zinc has not been shown to be effective in aiding healing in any study.

Review of pressure reduction device studies

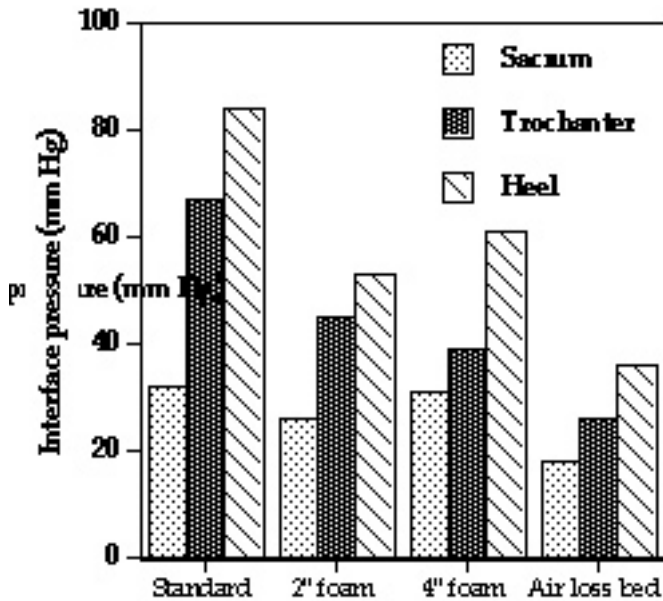
A third American nurse, Judith Hedrick-Thompson, has reviewed five studies on devices which reduce pressure [5] and should therefore aid in prevention of pressure sores. Capillary blood flow pressure ranges between 22 and 32 mm Hg; when external pressure is above this, blood flow is obstructed and circulation reduced, setting the stage for pressure sores. Pressure reduction devices should spread the pressure between the patient and the bed and avoid pressures above 35 mm Hg, especially at sacrum, trochanters and heels.

All five studies reviewed looked at healthy volunteers and measured interface pressures with a variety of devices. The products were those found in the United States, and the results are not entirely applicable in the UK, but the figure below aggregates data from the review to give an idea of the results found with different types of products.

Over a number of studies, each of which used up to 15 volunteers, standard hospital beds produced average interface pressures at the sacrum of 32 mm Hg, with much higher interface pressures at trochanters and heels. Foam (either 2 or 4 inches thick) did reduce the pressures somewhat, but not significantly below 32 mm Hg at any site. Only the air loss beds and mattresses produced interface pressures significantly below the critical level at sacrum (18 mm Hg) and trochanter (26 mm Hg). Several devices were intermediate between foam and air loss beds.

low pressure supports.

Aggregate interface pressures



This is relatively simple science, easily performed in non-invasive ways with volunteer subjects and which can provide good indicative information that devices intended for pressure sore prevention are likely to be effective. With a very large number of such devices available, this area is crying out for a "Which?" type of survey even before randomised controlled trials for effectiveness are begun.

Overview of RCTs of alternating pressure supports

This review [6] by Mary Bliss and Janice Thomas from London is one of a series which appeared last year. The first part [7] highlighted the importance of referring to clinical randomised controlled trials when making purchasing decisions regarding pressure-relieving mattresses, and should be a well thumbed reprint on the desks of people making purchasing decisions.

Bliss & Thomas [6] examined five randomised controlled trials of the benefits of different types of alternating pressure mattresses. They came up with four key points:-

- Large-cell alternating pressure mattresses are more effective than small-cell mattresses in preventing pressure sores.
- Mattresses must be sufficiently robust not to break down in use.
- Clinical trials are often faulty and therefore need to be read carefully.
- Control regimens must be fully described.

This review is useful, not because it gives any indication of what to purchase in what circumstance, but Bliss & Thomas do point out clearly the faults in the studies (including one of their own) which makes it easier to design studies which are useful for purchasers.

A third article in the series deals with trials concerned with

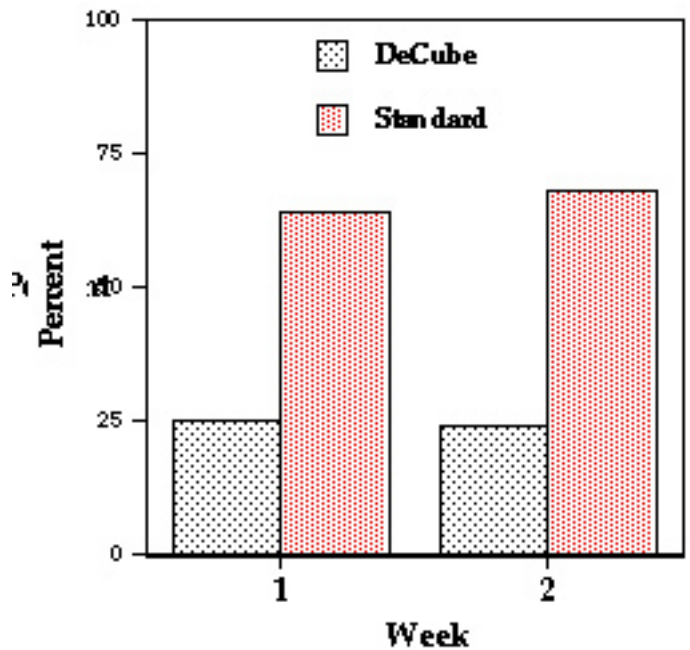
RCT of pressure decreasing mattresses

This RCT compared the Comfortex DeCube mattress with a standard hospital mattress used in The Netherlands [8]. The DeCube mattress uses a special surface covering; small cubes of the mattress under bony protuberances of the patient can be removed to reduce pressure locally.

The study was carried out in 44 patients with femoral-neck fractures (mean age 85 years) who have a high risk of developing pressure sores. Patients were randomised to one type of mattress; the study was not blind.

Patients were examined one and two weeks after surgery, and the presence and grade of sores on the sacrum, trochanters, shoulders, heels and elsewhere were noted independently by two physicians.

Patients with sores of grade 2 or more



The distribution of maximum pressure sore gradings differed significantly at one and two weeks ($p < 0.01$). Of patients nursed on the DeCube mattress, 25% had clinically relevant sores (grade 2 or more) at one week and 24% at two weeks. Figures for the standard mattress were 64% and 68% respectively.

The occurrence of pressure scores with high grades was much more frequent in patients nursed on the standard mattress than in those nursed on the DeCube mattress.

This was a well conducted study which showed clearly the benefits in pressure sore reduction accruing from the use of one product. It is an example of the type of information needed by purchasers and providers of health care.

The future

A number of district health authorities are now tackling pressure sores in a co-ordinated manner using local guidelines. It is, however, undeniable that guidelines are likely to be based on inadequate information due to the lack of RCTs.

In the absence of adequate effectiveness information, purchasing the cheapest product would seem to make sense. Manufacturers should urgently seek to conduct studies of effectiveness for their products.

References:

- 1: JB Young ,S Dobrzanski. *Pressure sores: epidemiological and current management concepts. Drugs & Aging* 1992 2: 42-57.
- 2: P West, J Priestley. *Money under the mattress. Health Service Journal* 1994, 14 April, 20-22.
- 3: M Krainski. *Pressure Ulcers and the Elderly: A Review of the Literature, 1980-1990. Ostomy/Wound Management* 1992 38: 22-37.
- 4: R Breslow. *Nutritional Status and Dietary Intake of Patients with Pressure Ulcers: Review of the Research Literature 1943 to 1989. Decubitus* 1991 4: 16-21.
- 5: JK Hedrick-Thompson. *A review of Pressure Reduction Device Studies. Journal of Vascular Nursing* 1992 X: 3-5.
- 6: MR Bliss, JM Thomas. *An investigative approach: An overview of randomised controlled trials of alternating pressure supports. Professional Nurse* 1993 8: 437-44.
- 7: MR Bliss, JM Thomas. *Clinical trials with budgetary implications: establishing randomised trials of pressure-relieving equipment. Professional Nurse* 1993 8: 292-6.
- 8: A Hofman, RH Geelkerken, J Wille, JJ Hamming, J Hermans, PJ Breslau. *Pressure sores and pressure-decreasing mattresses: controlled clinical trial. Lancet* 1994 343: 568-71.

- uptake (e.g. screening programmes)
- providing information not available previously (e.g. diet)
- direct national or local policy to protect health (e.g. seatbelt legislation)

Of these the most effective were prevention measures (e.g. screening) and protection measures (e.g. seatbelts).

There is a strong case for demanding proper evaluation of any health promotion endeavours. This review will tell you where to start.

Reference:

Bunton R, Burrows R, Gillen K, Muncer S. *Interventions to promote health in economically deprived areas: a critical review of the literature - 1994. Report to Northern RHA* 1994.

Bandolier's attention was caught by a neat matrix (Feinstein, 1993).

		Inequality	
source		Life Span	H e a l t h
Care			
Explanation		Access & Use	
Access to buy resources (Materialist)	housing, overcrowding, sanitation, occupational hazards, environmental hazards		ability to health drugs
Psychological Genetic Cultural	diet, smoking exercise, leisure, risk	medical information, "playing the system	
(Behavioural)	taking, drug & alcohol use	compliance	

HEALTH & DEPRIVATION

Does Health Promotion Work?

The DoH committee looking at health and deprivation has a tough task. The unpalatable truth across the developed world is that people with lower socio-economic status face higher mortality rates. Social class V had twice the mortality rate of social class I in 1971; these findings of the Black report (1988) have been confirmed by other methods. The cause is less clear than the effect. Is health promotion a good buy for commissioners who want to rectify the imbalance?

Northern RHA commissioned a review of the effectiveness and cost-effectiveness of health promotion in deprived areas. The review shows the dearth of evaluations of health promotion. Most of the published work is from North America and may not transfer easily across culture. Four relatively successful types of health promotion emerged:

- interventions that work with community support & participation
- offering a service previously unavailable or with low

DRUG WATCH

Cranberry juice reduces bacteriuria and pyuria

For many decades cranberry juice has been thought to reduce bacterial infections of the bladder. Studies in recent years have shown that cranberry juice inhibits adherence of E. coli cells to cells lining the bladder. Two different constituents have been implicated, one being fructose and the other a large polymeric compound of unknown structure. Fructose is present in all fruits, but the large polymeric compound is found only in cranberry and blueberry juices, and not those of grapefruit, orange, guava, mango and pineapple.

How big is the problem?

Bacteriuria is common among elderly women both in and out of institutions. While it is often asymptomatic, and does not require treatment, a large proportion of women over 65 years will experience at least one urinary tract infection each year. Recurrent urinary tract infection is common in patients who are incontinent: 73% of catheterised patients may receive treatment for bacteriuria, as well as 40% of patients managed by incontinence pads [1]. Young women with symptomatic cystitis also represent a large group.

How to organise a study

The well-conducted randomised, double-blind, placebo controlled trial performed in Boston and published in JAMA [2] is a superb example of how studies should be conducted.

The authors studied 153 elderly women (mean age 79 years) in whom bacteriuria with pyuria was likely to have a high incidence (above 30%). The women were both inside (44) and outside (109) long-term care institutions, and were asked to consume 300 mL of a cranberry juice cocktail every day for six months. Urine samples were collected each month, and the main outcome measure was the presence of bacteriuria (defined as more than 100,000 organisms per mL) with pyuria.

The study went to great lengths to ensure that there was true double blinding - a cranberry juice manufacturer made a placebo beverage containing no juice, but flavoured and coloured to simulate the appearance and taste of commercially available cranberry juice cocktail. To prevent the possibility that subjects in the institutional setting who were randomised to placebo might inadvertently drink standard cranberry juice elsewhere in the institution, all such beverages were converted to placebo throughout the institution for the duration of the study.

Patients were interviewed by a research nurse each month to help ensure compliance and to collect used bottle caps. The nurses also ensured that the urine samples were collected regularly and taken immediately to the bacteriology laboratory.

The results

A total of 818 urine specimens were collected from the study subjects after baseline. About one third produced growths above 100,000 organisms per mL, one third no bacterial growth and one third intermediate growths. *E. coli* was the most prevalent organism (43%), with *Klebsiella* the second most common (7%). About 45% of all urines had microscopic or chemical evidence of the presence of white cells, and symptoms relating to the urinary tract were noted on 22% of interviews. Consumption of study beverages exceeded 80% of assigned quantities.

Bacteriuria was noted in 28% of urines in the placebo group and in 15% of the cranberry group. The difference was not apparent in the first month, but appeared between months one and two and remained fairly stable thereafter.

The study demonstrated that the odds ratio of bacteriuria with

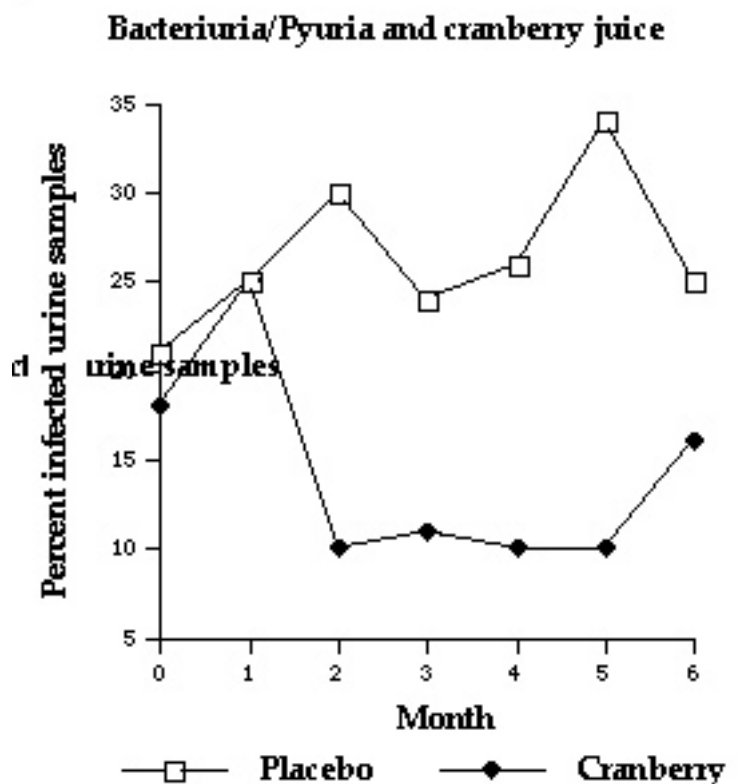
pyuria in the cranberry group compared with placebo was 0.42 (95% confidence interval 0.23 to 0.76, $p = 0.004$).

Antibiotic use for treatment of urinary tract infection occurred on 16 occasions in the placebo group compared with eight in the cranberry group; this is a rate of 3.2 per 100 patient months compared with 1.7 per 100 patient months in the cranberry group.

Prevention or cure?

Cranberry juice could have been working by curing existing infections, by preventing new infections, or by a combination of these mechanisms.

The average one-month probability of change from infection to non-infection was 0.54 in the cranberry group, compared with 0.28 with placebo. The average one-month probability



of changing from non-infection to infection was 0.09 in the cranberry group and 0.12 with placebo. The implication here is that cranberry juice actually cures existing infection. Indeed, the odds ratio for monthly intervals beginning with a bacteriuric-pyuric infection ending with a bacteriuric-pyuric infection was only 0.27 in the cranberry group compared with placebo, indicating that cranberry drinkers were only a quarter as likely as placebo to continue to have bacteriuric-pyuric urine samples.

Biochemical results

Thirteen samples of cranberry juice and 15 of placebo were tested blindly for their effect on bacterial adhesiveness. All cranberry juice samples inhibited *E. coli* adhesion; none of the placebo samples did this.

Is cranberry juice effective?

The answer seems to be a very definite yes! It would appear that cranberry juice reaches parts that other juices can't reach, and that the components of the juice which affect bacterial adhesion to cells lining the urothelial tract are effective in vivo as well as in vitro. Only cranberry and blueberry juice seem to contain the large molecular weight component.

What are the implications of this?

The effect of cranberry juice was more pronounced in converting urine samples out of a state of bacteria with pyuria as compared with preventing the conversion of non-infected urine samples to infection. This does not imply that a regimen of cranberry juice should displace antibiotics as the therapy of choice when treatment is needed, but it could be a useful adjunct to treatment in high risk groups.

It is certain, though, that drinking cranberry juice does no harm. Addition of cranberry juice to dietary regimens in circumstances where urinary tract infections have a high incidence would be sensible, and would probably reduce both the incidence of infection and the need for antibiotic treatments.

More studies needed

There are a whole series of further studies needed. They could include RCTs in younger women with symptomatic cystitis and other groups with persistent urinary tract infections. Does cranberry juice plus antibiotics give some benefit over either alone?

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- 1: MET McMurdo, PG Davey, M-A Elder, RM Miller, DC Old, M Malek. A cost-effectiveness study of the management of intractable urinary incontinence by urinary catheterisation or incontinence pads. *Journal of Epidemiology and Community Health*. 1992 46: 222-6.
- 2: J Avorn, M Monane, JH Gurwitz, RJ Glynn, I Choodnovskiy, LA Lipitz. Reduction of bacteriuria and Pyuria After Ingestion of Cranberry Juice. *Journal of the American Medical Association* 1994 271: 751-4.

Questions to be answered

Q: What need is met by this treatment?

A: Reduction in bacteriuria/pyuria in patients in which the condition is prevalent. Reduction in the prescription of antibiotics for the condition.

Q: What happens at present?

A: No dietary additives are used for this.

Q: Is quality improved?

A: Likely, through reduction in symptoms of urinary tract infection.

Q: What is the cost?

A: Negligible.

Q: Can savings be made?

A: Not of any significance.

Q: Can Ribena be substituted for cranberry juice?

A: No. Only cranberry and blueberry juices contain the "active" ingredients.

Q: Is more information needed?

A: Yes, further RCTs in a variety of conditions where urinary tract infection is present.

H.PYLORI - THE BANDWAGON STARTS TO ROLL

In *Bandolier* 2 we carried a major feature on helicobacter pylori, a microbacterial infection which is closely related both to duodenal ulcer and to gastric cancer. Each month new articles are published and the management of recurrent upper abdominal pain becomes more complex.

Upper abdominal pain is big business. For each million of the population, about £3 million per annum is spent on upper abdominal pain medication, mostly medication to control acid production, with omeprazole being one of the fastest increasing drugs in the UK at present. In one region where there was concern about ranitidine costs it came as a surprise to note that expenditure on ranitidine had hardly changed during 1993/94, whereas expenditure on omeprazole had increased by 80 percent. In addition to the £3 million per million population spent on medication, a considerable amount of money, perhaps between £0.5 million to £1 million, is spent on investigation with endoscopy referral rates increasing steadily. Two new twists to the H.pylori saga have developed in the last few months.

Diagnosing H.pylori infection

Manufacturers have been busy developing machines to diagnose H.pylori infection. One edition of *Medical Laboratory World* carried two features on instruments for measuring salivary antibodies against H.pylori and some clinical teams may well start this test. But it is not clear how knowledge of the presence or absence of salivary antibodies aids either diagnosis or treatment. There appears to be no need to include this in specifications for 1995/96.

The March edition of *Medical Laboratory World* carried a feature on a much larger piece of machinery (as big as a room) which can measure the concentration of urea in the breath. This not only indicates the presence or absence of H.pylori infection but also gives some indication of the activity of infection. It does not, however, appear to make a useful contribution to the management of upper abdominal pain, and urea breath testing should also be excluded from any specification for GI medicine or surgery being written for 1995/6.

Recurring prescribing

A very important article from the Department of Gastroenterology at Northwick Park Hospital [1] showed just how high the prevalence of acid suppressing treatment is in the population. In a survey of 60,148 patients in seven practices they found that 0.82 percent of the population (492

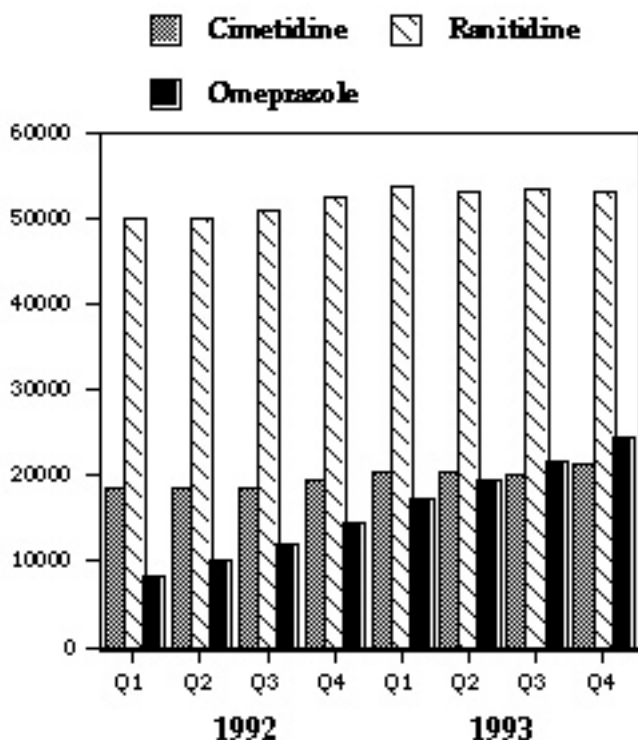
patients) was taking long-term treatment; three quarters had been taking continuous treatment for more than five years at the time of the survey.

However, "a substantial number of patients are taking these drugs long-term without a diagnosis having been reached"; 19 percent were being treated for abdominal pain with no diagnosis or with only the diagnosis of gastritis based on endoscopic examination. In addition, 37 out of the 492 patients were also taking either prescribed non-steroidal anti-inflammatory drugs or regular aspirin or ibuprofen.

Guidelines have been implemented after analysis of these results and the impact of these guidelines on prescribing practice will be monitored. This important study supported by the North West Thames Regional Audit Fund, emphasises the need to get research into practice and reach agreement about the implications of research findings for informed patient choice, effective prescribing, and the purchasing of gastroenterology services which give good value for money.

Substantial increases in prescribing of acid-suppressing drugs, especially omeprazole, have been noted in the last several years, and data for the Oxford Region in 1992 and 1993 are shown in the Figure. If omeprazole is increasing, why aren't the others falling? Despite FHSA pressure to switch from ranitidine to cimetidine there is no evidence that this had any effect by the last quarter of 1994

Prescriptions in the Oxford Region



1: SD Ryder, S O'Reilly, RJ Miller, J Ross, MR Jayyna, AJ Levi. Long term acid suppressing treatment in general practice. *British Medical Journal* 1994 308: 827-30.

ASSESSMENT CRITERIA

Purchasers of healthcare are faced increasingly with decisions on which interventions are effective and should be purchased, and which are not effective and should not be purchased. Judging the strength of the evidence becomes an important part of the decision making process.

Type & Strength of Evidence

Critical appraisal teaches us to assess reports of a new or an established intervention. Much of the time we are involved in a wider process. How does that intervention fit in the management of that problem? Guidelines often involve multiple 'steps', and for each step there may be several possible interventions. One way of judging the overall evidence for each step is proposed below. I is the best, V is the worst.

- I Strong evidence from at least one published systematic review of multiple well-designed randomised controlled trials.
- II Strong evidence from at least one published properly designed randomised controlled trial of appropriate size and in an appropriate clinical setting.
- III Evidence from published well designed trials without randomisation, single group pre-post, cohort, time series or matched case-controlled studies.
- IV Evidence from well-designed nonexperimental studies from more than one centre or research group.
- V Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert consensus committees.

Readers of *Bandolier* involved in purchasing may have developed their own quality scores for evidence-based healthcare. *Bandolier* would be interested in publishing assessment criteria that purchasers of healthcare have found to be effective in practice.

CAFFEINE

Caffeine is the most widely used psychoactive substance, taken primarily for its stimulant effect on the nervous system. Dependence can occur and there is a definite withdrawal syndrome. An easy-read review in *The Pharmaceutical Journal* is a useful reminder about this near ubiquitous drug.

S Wills. Drug and substance misuse (9) CAFFEINE. *The Pharmaceutical Journal* 1994 252: 822-4.

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Index

Acid suppressing prescribing	July 94
Allergy Screening	Feb 94
Antioxidants for chronic pancreatitis	Jun 94
Baths and the elderly	May 94
Battles of the 90's	Mar 94
Benzodiazepine reduction by GPs	May 94
Cholesterol screening	Jun 94
Cocaine abuse.....	Feb 94
Cranberry juice & bacteriuria	July 94
D&C appropriateness	May 94
Deprivation & Health	July 94
Dermatomyositis	Apr 94
Drug screening in the USA.....	Jun 94
Glue ear	Feb 94
GRIp	Feb 94
Hospital-led prescribing	May 94
H. pylori and gastric cancer	Mar 94
H. pylori and ulcers.....	Mar 94
H. pylori testing.....	Mar 94
Large spacers in asthma	Feb 94
Minimal access surgery	Apr 94
Near patient testing.....	Apr 94
Oesophageal pH monitoring	Feb 94
Osteoarthritis of the knee	May 94
Osteoporosis	Apr 94
Pressure Sores	July 94
Prostate cancer review	Apr 94
PSA and bone scans.....	Apr 94
Steroids in preterm delivery	Mar 94
Stroke rehabilitation	Apr 94
Subfertility review	May 94
Technology assessment.....	Feb 94
Testing a screening test	Jun 94
Testing tests	Apr 94
Thyroxine replacement.....	May 94

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