

TECHNOLOGY ASSESSMENT AND GUIDANCE FOR PURCHASERS

The National Research & Development Programme now has a comprehensive system of technology assessment in place. The following are the main components of this system.

- The Cochrane Collaboration which is promoting systematic reviews of the treatment of health problems: the first product of this is the pregnancy and childbirth database which all purchasers and providers should have.
- The University of York has been commissioned by the National R&D Programme to produce Effectiveness Bulletins and a number have already been produced in association with Leeds.
- The National R&D Programme has now approved a long list of subjects which need technology assessment and will be commissioning work, although the precise number which will receive resources is not yet clear.

Purchasers are, however, faced with an immense amount of change in the service provided for their population. Change is taking place at an ever faster rate with new drugs, new treatments and new interventions being introduced too quickly for the system of technology assessment to be expected to be able to cope with.

Purchasers will be consulted on major expenditure planned by trusts, for example the purchase of a new MR unit or the development of a new service. Purchasers can also be proactive in the topics covered by the Cochrane Collaboration, the York Effectiveness Bulletins, and the subjects covered by the R&D Technology Assessment Programme. As part of the Oxford Region's responsibility for linking research and purchasing we plan in *Bandolier* to produce much briefer reports to help purchasers cope with what is being called "technology creep".

Technology Creep

As knowledge grows seemingly exponentially, professionals innovate by implementing that knowledge, often using their own criteria for judging the quality of research and the cost-effectiveness of the service changes which seem to be indicated by the research findings. Many of these changes may, by themselves, be quite small - for example, £20,000 capital and £30 per finished consultant episode in revenue costs. However, the Trust that adopts 25 of these in the course of a year will be committing itself to £500,000 of capital expenditure without necessarily exposing it to the purchasers, and may be increasing the cost of care by significant

amounts, again without discussing with purchasers the implications of the actions taken.

In each clinical department the change appears to be too small to discuss with purchasers, and to the diagnostic services the increase in costs may simply be one to be passed on to the clinical departments, who in turn pass on costs to purchasers.

There are different forms of technology creep:-

- New operations, particularly minimally invasive surgery.
- New tests, or new variants of diagnostic tests, which are claimed to give better sensitivity, specificity or cost-effectiveness.
- New drugs, for example drugs which are purported to have a better side-effect profile.

Moving mountains

The Chinese proverb says that the person who wishes to move mountains must begin by moving small rocks. We will be describing interventions and changes in practice that will have relatively small effects on cost, but it is important to bear in mind that 100 changes each costing £5000 equals half a million pounds of purchasing power, and in many services changes costing £5000 are relatively commonplace.

Finding Bullets

The Cochrane Collaboration and the Centre at York will be producing reviews based on the evidence in randomised controlled trials. We will be seeking information for purchasers from two sources:-

- By scanning the literature to spot reviews of new tests, operations or drugs.
- By asking Directors of R&D if they can provide examples from their own Regions.

We would also very much welcome input from purchasers. If any purchaser has either specified a particular test or treatment, or has specified that they do not wish a particular test or treatment to be used in their population, we would be pleased to hear from them and include examples in *Bandolier*.

Our Objectives

Our objectives are to help you as purchasers increase the detail in your specification, indicating what you think pro-

viders should provide or not provide.

There is an interesting third class of intervention where purchasing and R&D overlap, and that consists of those interventions that should only be provided as part of a randomised controlled trial.

GETTING RESEARCH INTO PRACTICE

Oxford is the lead Region for linking R&D with purchasing. Research results in the production of propositions supported by evidence - knowledge. This may initially be in the form of individual trials, and later by trials built into overviews or systematic reviews of evidence. A number of such overviews are available, some from the Cochrane Centre, the King's Fund or the University of York.

The knowledge produced by trials, overviews or technology assessment can be regarded as "bullets" of effectiveness. Just like a bullet, they are of little value by themselves, and need to be loaded, aimed and fired to hit their target.

In healthcare effectiveness, the gun which does this is the GRiP programme being pioneered in the Oxford Region. The targets vary, and may be public education, professional education and training, information for managers or purchasing specification, including a specification for audit action.

The four GRiP projects underway in the Oxford Region are:-

- Glue Ear in Berkshire
- D&C in women under 40 years in Buckinghamshire
- Stroke in Northamptonshire
- Steroids in preterm delivery in Oxfordshire

In the first year each county will undertake a specific, contracted study with audit. In the second year the other three topics will be introduced using the lessons learned from individual counties in the first year. *Bandolier* will review the GRiP projects, beginning with glue ear this month.

There are different types of bullets available to be fired. Bullets may be "golden" - an example would be the first antibiotic. How good the bullet is depends on how much and of what quality is the evidence for effectiveness - this is not always straightforward. "Silver" and "bronze" bullets will have less solid effectiveness value, but will still need evaluating.

There are questions about how many bullets there are to be fired. The search for bullets is on, and readers of *Bandolier* are invited to send in bullets of their own. A bullet can be about:-

- A treatment (procedure or drug or no treatment).
- A diagnostic test (for detection of disease or monitoring of therapy or disease progression).
- A service (examples could be chiropody, physiotherapy etc.).
- A management issue (organisation of a service, diagnostic, treatment).

A bullet is a proposition supported by evidence:-

- Evidence (RCTs, overviews, technology assessment) of effectiveness (positive bullet) or lack of effectiveness (negative bullet).
- Positive bullets are fired where the use of a treatment or service is low, and negative bullets where the use is high.

For a bullet to be fired, it must:-

- Result in provision of a better health service.
- The improvement must be open to assessment by audit - so that it can be seen that the bullet has hit the target.

GLUE EAR - A STICKY PROBLEM

One of the first GRiP projects involves the question of whether surgical interventions are effective in combating disability from glue ear in children. The GRiP project is to be carried out in Berkshire, and is a response to the Effectiveness Bulletin published by the School of Public Health at Leeds and Centre for Health Economics at York.

What is the problem?

Glue ear is a common cause of hearing impairment in children. It can result in a hearing loss (measured in decibels of hearing loss, dB HL) of 0 to 50 dB HL, with an average of 20 dB HL. This degree of hearing loss can turn normal speech into a whisper. If glue ear is unilateral, there usually isn't a problem, but bilateral glue ear with significant hearing loss is commonly considered to pose developmental problems to children. However, studies have not produced sufficient evidence to demonstrate a causal link between glue ear and significant hearing disability.

Persistent bilateral hearing impairment of 25-30 dB HL is sometimes thought sufficient to justify surgery.

How big is the problem?

Forty-two percent of three year olds may begin an episode of glue ear over the next twelve months. Because these episodes are usually short, the prevalence of children with glue ear is less than this, but in the 2-5 year age range 15-20% of children will have glue ear at any time. The prevalence in children older than this falls to less than 5% by age 7 years.

It is estimated that about 6% of two year olds have bilateral hearing impairment of at least 25 dB HL which persists for at least three months.

The main risk factors are:-

- Younger age
- More common in boys
- Siblings with glue ear
- Higher in Winter and Spring
- Bottle feeding
- Day care attendance
- Parental smoking

What is the natural history of glue ear?

Most episodes are short. About half of affected ears resolve spontaneously after 3 months, 75% by six months, and only 5% of children will have glue ear for a year or more. In the vast majority of cases glue ear will not persist beyond early childhood.

How many children have surgery?

The average rate of surgical treatment for glue ear in England is about 5/1000 children under 15 years, and it is the most common operation in children.

There is great variation between regions and between centres within regions, which reflects a number of different issues, including screening policies, culture, referral practice and surgical decision making, and service supply.

What is the appropriate surgical intervention rate?

No one knows. That is one reason why the GRiP study is being undertaken.

Does surgery help?

Surgery for glue ear usually means surgical removal of the contents of the middle ear (myringotomy), insertion of grommets, adenoidectomy and tonsillectomy, and usually combinations of some of these.

There have been 19 published RCTs which examine the effectiveness of surgical intervention for glue ear. Those which examined hearing level as an outcome compared with no-treatment control group indicate that both grommets and adenoidectomy reduce the mean hearing impairment in children with glue ear.

However, the gains are neither large nor long-lasting. The mean reduction in hearing loss was 12 dB HL at 6 months and 6 dB HL at 12 months, though there was a very large variation, from no benefit to complete restoration of hearing.

Does surgery have problems?

Grommet insertion is not without complications, including risks associated with anaesthesia. There may be a greater risk of chronic perforation, and infection is common, with between 20 and 35% of children likely to experience discharge, and this is persistent in 5%.

When is treatment appropriate?

The big question. If children with glue ear and a hearing loss of 25dB HL or more are not treated immediately, but monitored over a period of time (*watchful waiting*) to establish that the condition is persistent, fewer will be treated because of the natural spontaneous resolution.

There is already some delay because of waiting lists, and to ensure that an inappropriate amount of time does not occur before surgery in those where the condition is persistent, a *provisional waiting list* system should be used. Children should be put on the provisional waiting list after initial audiological assessment indicates potential need for surgery and should remain on this list during the period of watchful waiting.

Retesting before surgery will also ensure that *dry taps* (i.e. no glue in ear at surgery) occur much less frequently, and that children are not subject to the hazards of anaesthesia and surgery for no reason.

THE GRiP INITIATIVE

The programme agreed with Berkshire HA is the following:-

Audit current practice to establish baseline.

- Establish provisional waiting list and watchful waiting.
- Establish audiology assessments at presentation, during watchful waiting, before and after surgery.
- Monitor audiological benefits and dry tap rate.
- Audit new practice to establish change and benefit.
- Indicate ways system can be improved.

GRiP for glue ear - the future

If the study in Berkshire demonstrates that this system of dealing with glue ear provides a sensible way of delivering healthcare to the patients who need it, it will form the basis of purchaser-provider contracts for the following year for Oxfordshire, Buckinghamshire and Northamptonshire. Other regions may then also use the Berkshire GRiP initiative as the basis for their purchase of services.

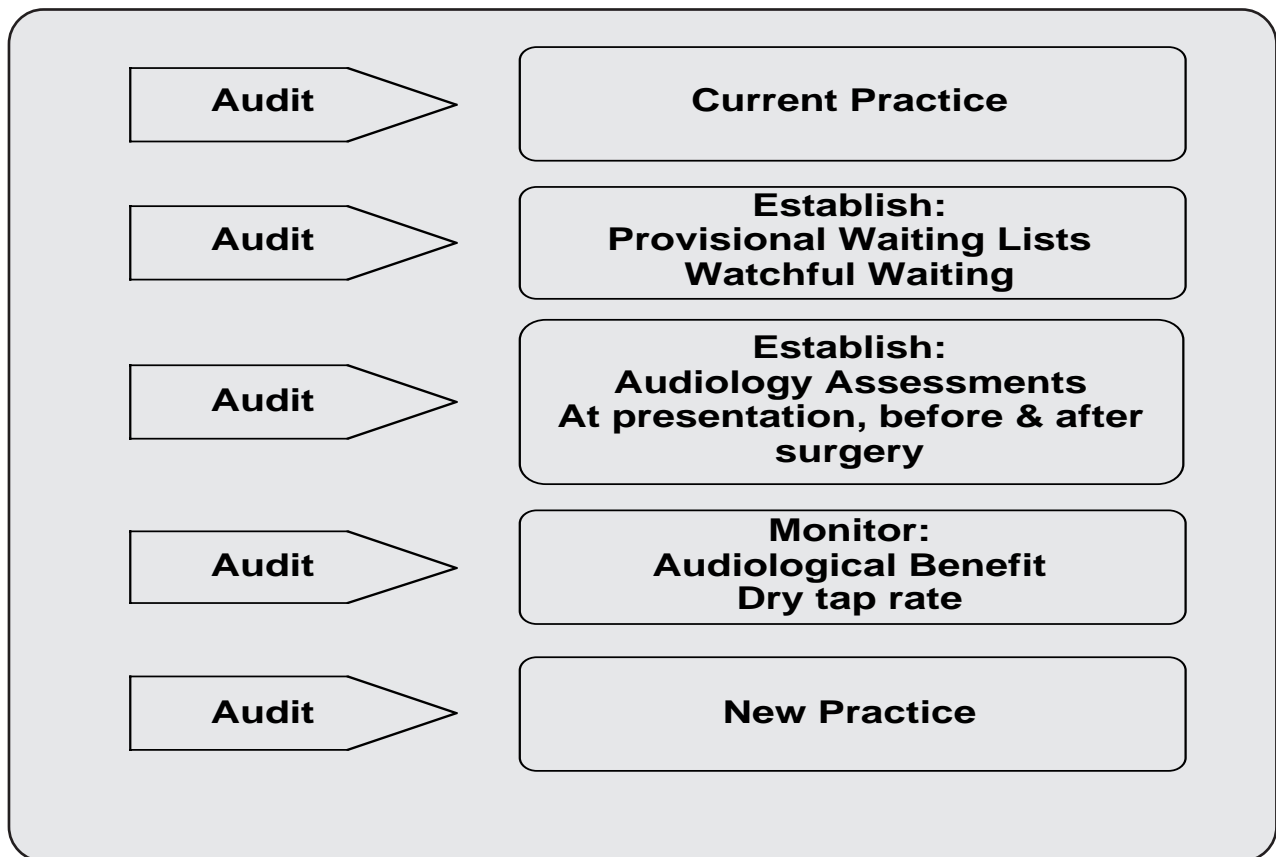
The whole story?

Well, most of it anyway. However, glue ear seems to pop up in the most curious places - including the correspondence columns of The Times (December 28 1993).

Vice Admiral Sir Louis Le Bailly suffered from several episodes of glue ear following a war injury. Grommets helped on several occasions, but the third time glue ear occurred a Harley Street ENT consultant recommended a drug which did the trick. The Vice Admiral was told that this drug should be used in children to replace grommet operations, but that it was not available on prescription and that the manufacturer (Rhone-Poulenc Rorer) was supplying the drug free to several thousand children.

The Vice Admiral wrote to the then minister (Kenneth Clarke), using his style and title, reiterating the advice he had and commending the treatment for inclusion on the approved list. He says.....

"The answer I received was that if I was still under 18 and had had a tracheotomy the drug would be supplied".



This poses the question whether the drug (Mucodyne; carbocysteine), which does have the indication for children with glue ear, is effective.

Bandolier has found four papers on s-carboxymethylcysteine in glue ear (references below). None is particularly recent, nor did any have particularly large numbers, though three were randomised controlled trials. Statistical analysis was not profound.

Two studies showed improvement over about one month in children with bilateral glue ear, with improvements of the order of 10 dB HL occurring in more treated patients than in controls. A further study over three months (but with a high drop-out rate) showed no improvement in treatment over control.

The fourth study examined the use of s-carboxymethylcysteine in children undergoing myringotomy, with a one-month follow-up. Hearing improvement for treated children was 20 dB HL better than placebo on average.

References:

- Taylor & Dareshani, Br J Clin Pract 1975 29: 177-9
- McGuinness, Br J Clin Pract 1977 31: 105-6.
- Ramsden et al, J Laryngol and Otol 1977 9: 847-51.
- Khan et al, J Laryngol and Otol 1981 95: 995-1001.

Mucodyne in glue ear

- 1 Evidence for effectiveness insufficient: research/ re view needed.
- 2 Allow to be used on a population if part of a RCT.

LARGE VOLUME PLASTIC SPACERS IN ASTHMA

The symptoms of many asthmatic patients are poorly controlled. A recent study from Southampton demonstrated that 51% of patients were waking at night with wheeze, 49% were wheezy at least once a week, 31% had missed school or work in the previous year and 23% were avoiding certain physical activities between attacks.

Ways in which this situation could be improved have been outlined in a paper in the BMJ by Duncan Keeley, an Oxfordshire GP. One of the points he makes is that drugs may not be reaching their site of action in the airways effectively.

Pressurised aerosol inhalers are the mainstay of inhaled treatment for asthma. For a decade there has been the option to prescribe large volume plastic spacers to improve the effectiveness of metered dose inhalers, but their use is still limited.

The main advantage of the spacers is that they increase the proportion of the dose delivered to the airways (where the drugs produce the desired effect), while reducing the proportion absorbed into the body (which is usually the cause of unwanted effects). Metered dose inhalers with large volume spacers deposit at least 30% *more* drug in the lung but deposit 60% *less* drug in the patient, because of reduced oropharyngeal deposition (Table).

Specific benefits from the use of large volume spacers include:-

Pattern of drug deposition with different inhalers - values are percentage of total drug dose

Site of deposition	Dry powder inhaler	Metered dose inhaler	MDI with large volume spacer
Lung	10-15	10-15	20
Oropharynx	80	80	15
Device	5	5	65
Patient	95	95	35

- More effective treatment with fewer side-effects because of better deposition pattern.
- Problems of poor inhaler technique largely overcome.
- Easily used by children and the elderly (except those with weak or arthritic hands).
- As effective as a nebuliser in treatment of acute attacks but light, cheap, maintenance free, portable and prescribable.
- Useful for treatment of first attacks of wheezing in patients who have not used inhalers before.
- Useful for administration of bronchodilator when testing reversibility in the surgery to establish the diagnosis of asthma.
- Reduced prescribing costs by basing treatment on the much cheaper metered dose inhalers.

As well as the issue of effectiveness, there is also the issue of cost. In England alone in 1991, the costs for salbutamol was £66 million and for beclomethasone £98 million. Both these drugs are now off patent and considerable savings to NHS drug budgets are possible if GPs prescribe these drugs generically. If savings are to be achieved, a number of issues have to be addressed:-

- GPs need to be confident that generically prescribed salbutamol and beclomethasone inhalers will conform to the colour code *blue* for *bronchodilator* and *brown* for *steroid* inhalers, and will have inhaler mouthpieces of standard shape to fit the Volumatic spacer devices. Moves towards conformity are in progress through voluntary agreements by the generic manufacturers. *Explicit purchasing policies to this effect by regional and district HAs should be considered.*
- HAs will need to publicise to GPs the basis on which they can be confident in the colour coding and mouth-piece shape of generic metered dose inhalers.
- The continued availability of metered dose inhalers must be assured. They presently use CFC propellants, and adequate stockpiles of CFCs for this purpose must be assured until alternative ozone friendly propellants become available.

- GPs need information to appreciate the numerous clinical and cost advantages in relying on metered dose inhalers as opposed to the much more expensive dry powder devices.

References:

Keeley BMJ 1992 305: 598-99
 Keeley BMJ 1993 307: 1261-63
 Jones et al BMJ 1992 304: 361-4
 Newman et al Thorax 1984 39: 935-41

Questions to be Answered

- Q: What need is met by this device?
 A: Significant improvement in treatment of asthmatics, with more effective drug action and reduced side effects, all at reduced cost with generic drugs.
- Q: What happens at present?
 A: Non-generic drugs predominate. About 30% of total costs are accounted for by dry-powder devices.
- Q: Is quality improved?
 A: Use of large volume spacers with metered dose inhalers should improve effectiveness of the drugs.
- Q: Are large volume spacers prescribable?
 A: Yes.
- Q: Can cost savings be made?
 A: Generic drugs cost less. Change to metered dose inhalers with large volume spacers from dry powder devices would have major cost saving implications.
- Q: What is the likely saving cost per million population?
 A: As much as £0.5 million per annum per million of population based on a 50% conversion of dry powder to metered dose inhalers and a switch to generic prescribing.

Advice to Purchasers

- 1 Will increase quality and effectiveness.
- 2 Will reduce costs.
- 3 Research/ review would be helpful.
- 4 Include in specification with target for conversion with audit. RCTs also helpful in promotion.

ESOPHAGEAL pH MONITORING MADE EASY

As many as 44% of adult Americans complain of heartburn at least once a month and 13% take indigestion tablets at least twice a week, according to a poll in the USA. Most never consult a doctor, but almost all probably suffer some degree of gastro-oesophageal reflux disease (GORD).

GORD is generally not difficult to diagnose, and simple advice on weight loss, smoking, alcohol, diet and posture takes care of most sufferers. A small proportion, but significant number, have atypical symptoms of angina-like chest pain, globus, hoarseness or atypical asthma. The diagnosis of GORD is aided in these patients by using 24-hour ambulatory oesophageal pH monitoring.

Equipment is now becoming available that makes this possible on an outpatient or GP basis. Though not cheap at about £4000 with £30 consumables each test, the equipment and associated computer programs are simple to use, and costs per patient test are less than traditional methods of diagnosis as well as having better diagnostic specificity. An antimony 2.3 mm catheter is calibrated, followed by nasogastric insertion as far as the stomach - detected by a sharp drop in pH. It is then pulled back to be some 5 cm above the lower oesophageal sphincter.

The small data logger records the oesophageal pH at several positions over 24 hours. An event button is pressed by the patient when symptoms occur, and a diary is kept of eating and activities. By hooking up the data logger to a computer a virtually instantaneous picture of oesophageal relating symptoms to oesophageal pH is obtained.

A number of studies confirm that 24-hour oesophageal pH monitoring is the best diagnostic tool available. Hospital research is continuing, but there is a dearth of RCTs, and no studies in the GP setting to indicate whether this approach can deliver benefits in care or cost.

References:

Owen et al, Hospital Update, January 1993.

Caestecker & Heading, Editorial, European Journal of Gastroenterology & Hepatology, 1991, 3: 285-287.

Hewson et al, American Journal of Medicine, 1991, 90, 576-583.

Questions to be Answered

Q: What need is met by this test?

A: Differential diagnosis of chest pain.

Q: What happens at present?

A: A proportion of people with chest pain have cardiac disease excluded but have no specific cause identified. Reflux of gastric acid is a cause of such pain. Present tests for this cause are of low sensitivity.

Q: Is quality improved?

A: Sensitivity is increased.

Q: What is the capital cost?

A: About £4000.

Q: What is the revenue cost?

A: About £30 per case.

Q: What is the likely cost per million population?

A: No general estimate because of different clinical policies.

Q: Will this increase or decrease the total cost of secondary care?

A: Diagnosis will be reached more quickly. This will reduce costs in those cases. None of the papers gives adequate cost analysis.

Q: What is the effect on the total cost (primary + secondary)?

A: Will have little effect on primary care costs.

Advice to Purchasers

- 1 Will increase quality or effectiveness
- 2 Cost neutral if other tests done less often
- 3 Worth considering including in specification if no increase in investigating non-cardiac chest pain

SCREENING FOR ALLERGY

- KEEPING IT SIMPLE.

IgE-mediated allergy is common - as many as 40% of adults in the UK are immunologically atopic (i.e. with raised serum IgE). About half of these go on to experience clinical atopy - with symptoms that often take them to their doctor. The exact ways in which the clinical syndromes are precipitated are not clear, but whatever the reason, patients are becoming more interested in allergy, with considerable press and advertising. Try counting how many pictures of house dust mites you can see in the average quality daily!

So what does the GP do when confronted with patient with symptoms that could be allergy? How is the decision made whether to seek advice from an allergy clinic?

In a paper published in 1980, Dr Terry Merrett demonstrated that some cheap diagnostic tests and a good history could help make an effective decision. Three pieces of information are needed:-

- Serum total IgE.
- Patient questionnaire.
- Specific tests for pollen, dust mite and cat epithelium (the three most common inhaled allergens).

The paper describes how 95% of patients with IgE antibodies to specific allergens are positive to cat, mite or pollen, as well as other specific allergens. Used in conjunction with either a raised total IgE or a positive symptom score by questionnaire, 265 of 275 patients were correctly identified (96.3% of patients with IgE-mediated disease).

In a control group, only 65 of 150 had two positive scores, and none was positive for pollen, cat or mite. It is possible, then, to screen those patients with specific allergies with high sensitivity, leading to more effective diagnosis, referral and treatment.

This is a good read, with ideas that have stood the test of time. It contains the full patient questionnaire, and computer programmes have been written to generate expert systems reports from the questionnaire.

References:

Merrett et al, *Allergy*, 1980 35: 491-501.

Pantin et al, *Clin Allergy* 1978 8: 227-233.

Questions to be Answered

- Q: What need is met by this test?
A: Rapid diagnosis of 95% of patients with inhaled allergies.
- Q: What happens at present?
A: Not clear - many patients may not be tested, while others may be tested for sensitivity to many different allergens.
- Q: Is quality improved?
A: Sensitivity is increased.
- Q: What is the capital cost?
A: Nil for clinicians. Allergy testing is available at least at regional level. Computer software for questionnaire is not available.
- Q: What is the revenue cost?
A: About £15 per case, much less than multiple allergen testing.
- Q: What is the likely cost per million population?
A: No general estimate because of different clinical policies.
- Q: Will this increase or decrease the total cost of secondary care?
A: Diagnosis will be reached faster. This will reduce costs in those cases. None of the papers gives adequate costs analysis.
- Q: What is the effect on the total cost (primary + secondary)?
A: Will have little effect on primary care costs.

Advice to Purchasers

- 1 Will increase quality or effectiveness
- 2 Cost neutral if other tests done less often
- 3 Research / review needed for clarification

COCAINE ABUSE

Good information in the field of drug abuse is rare, and it is a delight to be able to recommend a cracking good read on the subject of cocaine abuse.

Elizabeth Warner, of the University of Florida at Tampa, has sourced 144 articles on cocaine using a MEDLINE search of years 1986-1992 and through a manual search of bibliographies of all identified articles. They were case reports, review articles or small series, and no controlled studies of the subject were available.

The overview looks at qualitative descriptions of reported complications, as no quantitative methods have been used. Despite these apparent drawbacks she has written a gripping and informative paper that brings anyone not knowledgeable on the subject right up-to-date with the clinical story, and with methods of screening for cocaine abuse, the incidence of use of cocaine and the chemistry of the major forms of the drug.

In the 18-34 year-old age group in the USA, 7% use cocaine at least monthly, and nearly 1% use the drug more than once a week. Crack cocaine (a free-base form made by heating cocaine with baking soda) is associated with high levels of crime (50% or more where its use is endemic). Europe has seen exponential growth of cocaine use in the last few years, and the problems here begin to parallel those in America.

Medical complications of cocaine use are many and varied - cardiac, gastrointestinal, head and neck, neurological, pulmonary, psychiatric, renal and obstetric, as well as involvement with sudden death through suicide and homicide. This paper brings all this together. There is a small section on treatment of cocaine addiction, without much in the way of hope.

Reference:

Warner, *Annals of Internal Medicine*, 1993, 119: 226-235.