PRACTICE OBSERVED

Practice Research

Response to paper on "Can the clinical course of acute otitis media be modified by systemic decongestant or antihistamine treatment?"

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We are interested in whether the research papers that we publish in Practice Observed have much influence on anybody. We have, accordingly, asked four general practitioners to write briefly about how they responded to the paper by Professor John Bain on "Can the clinical course of acute otitis media be modified by systemic decongestant or antihistamine treatment?" (3 September 1983, p 654) and whether they have changed their practice in any way because of it. ED, *BMJ.*

Dr Hurwitz's response

"Do not prescribe systemic decongestants or antihistamines for the treatment of acute otitis media in childhood!"

This is the behavioural imperative that leaps from the pages of Professor Bain's report of a randomised control trial in 189 children. The trial compared the efficacy of pseudoephedrine, triprolidine, and placebo in children who were treated, in addition, with antibiotics. These drugs made no difference to the clinical course of the condition and resulted in appreciable side effects in 6% of children aged 3 to 10 years.

My patterned response to a child with acute otitis media has hitherto included a reflex to prescribe such substances. These results should alter my behaviour, my rational self emphatically affirms. Yet I have since caught myself in the act. I take little comfort from the fact that general practitioners apparently prescribe these drugs on 50% of occasions when consulted by a child with this condition and that "No group of drugs has enjoyed such widespread use without demonstration of efficacy. . . ." From whence derives their popularity?

It may be notable that their assumed mode of action lends plausibility to their "value" as therapeutic agents in this condition. Pseudoephedrine stimulates vasoconstriction and decreases production of mucus. Antihistamines block tissue inflammatory mediators and decrease mucosal oedema. It is assumed that both mechanisms facilitate eustachian tube and, therefore, middle ear drainage. Subjectively, these drugs clear the nasal passages at least temporarily. So the "disobedient me" that has occasionally prescribed them since reading the study is the same me that has grown up with these models of drug action, the me of my own subjective experience of taking the drugs, and the me that now rejects their use as unacceptable in view of Professor Bain's unequivocal demonstration that it is merely the side effects that confer pharmacological "advantage."

In a subsequent paper in the series "Papers that have changed my practice" Professor Bain commented that "change is a catalogue of tiny refinements influenced by a variety of people and events."[1] This makes it sound hard, slow, and continuous "self work." The subject of the work may be resistant to change, stubborn, exposed to countervailing influences and may feel in conflict. In addition, such change may involve not just the acquisition of new information but also the shedding of old, more familiar information—a debriefing. How can all these processes be integrated, and how can research in general practice acknowledge the difficulties of change?

I believe that the results of research in general practice should be put into context in print, and that this could be done without loss of rigour. This would provide general practitioners with valuable points of reference, identification, and involvement. It would help us to connect the findings more organically to our current assumptions, policies, and practice. Without the lived context of the study the results may seem to be disembodied truths of "natural science"—difficult to incorporate and causing personal splits in the process of changing practice.

What I would like to have known about this study is:

(1) What were the prescribing habits of the 22 participating general practitioners before the study, and, in view of the range of their differences, how did they react to their patients being prescribed these drugs for *two months* as the trial protocol demanded?

(2) How have the prescribing habits of these general practitioners changed in view of the results?

(3) What were the problems specific to general practice in carrying out this study?

(4) What percentage shift in antihistamine decongestant prescribing for otitis media would pay for the cost, in National Health Service savings, of mounting this study, if the inferences derived from the results were followed by all general practitioners?

It seems to me that the lived experience of general practice research is an integral part of its research findings and should be reflected in reports in the *BMJ*. Its sensitive inclusion could enable us to get a better "feel" for the results of such studies and thereby make for easier incorporation into a lifetime of changing practice.

Dr Acheson's response

There is a constant danger that medical interventions may become stereotyped. For this reason most doctors are aware of the need continually to review previously accepted treatment regimens in relation to new discoveries and better outcome data. For this reason Professor Bain's paper is welcomed. He questioned the effectiveness of decongestant and antihistamine treatment in acute otitis media in children and investigated the effect on outcome of both when compared with a placebo. He found no difference between the various treatment groups and concluded that neither decongestant nor antihistamine treatment affects outcome provided an appropriate antibiotic is prescribed.

As part of a recent research project (unpublished results), 114 randomly selected general practitioners, 85 general practice trainers, and 10 ear, nose, and throat consultants were asked what treatment they would prescribe for a patient with acute otitis media (table). None mentioned an antihistamine, though I am aware that many general practitioners do prescribe antihistamines in this condition, and about a third mentioned a decongestant. Penicillin V was the preferred antibiotic.

It is my practice to prescribe an antibiotic, usually penicillin V, for those over 5 years of age and amoxycillin for those under 5, together with an analgesic for the first 48 hours if pain is a prominent symptom. In my view the rationale for the use of decongestants and antihistamines, singly or in combination, has never been firmly based and I never use either. Bain's well designed study has proved the point.

Drug treatment in acute otitis media

Drug category	Percentage of general practitioner trainers (n = 85)	Percentage of random group of general practitioners (n = 114)	Percentage of ear, nose, and throat consultants (n = 10)
(a) Antibiotic	98·8	96·5	100
(b) Analgesic	57·6	63·2	70
(c) Decongestant	30·6	37·7	50
(a) only	30·0	23·0	
(a) + (b)	37·0	35·0	
(a) + (b) + (c)	18·0	24·0	Not available
(a) + (c)	11·0	12·0	
(b) only	1·0	1·0	
Preferred antibiotic*:			
Penicillin V	70·6	50·0	60
Ampicillin	20·0	23·5	—
Erythromycin	15·3	21·9	10
Amoxycillin	14·1	13·2	10

*When stated, more than one may be mentioned.

Dr Steel's response

I very much enjoyed Professor Bain's paper. The evidence, presented clearly, supports the view that pseudoephedrine and triprolidine do not alter the clinical course of acute otitis media. It was especially interesting to have the side effects of treatment with these drugs highlighted, together with their effects on compliance with treatment.

In the study 21% of children had a recurrent attack of otitis media. This sounds high and may be related to the Aberdeen climate. It would, however, have been helpful to know what dose of antibiotic was prescribed—was amoxycillin 50 mg/kg body weight for 10 days used? Did the antibiotic affect the recurrence rate in the study even if pseudoephedrine or triprolidine did not, or, alternatively, were those cases with a red drum more or less likely to have a recurrent attack within two months?

Professor Bain discusses whether the items in his table IV (earache, wakened by earache, cough, wakened by cough, runny nose, trial medicine) provide a valid test of outcome, and defends them on the grounds that they are in common use in general practice. For the purposes of this study I agree with his conclusion.

I was asked would this paper alter the management of acute otitis media in general practice? If one used decongestants before reading this paper then clearly one should at least look carefully before continuing to do so, and many general practitioners would stop. But, would the child be any better off? Unfortunately, Professor Bain did not include a hearing test in table IV, so the answer is not known.

Preschool children—Half of all children with serous otitis media will have a history of recurrent otitis media and half will have a history of recurrent upper and lower respiratory tract infections.

Schoolchildren—It is thought that 5% of children between 5 and 7 years have a conductive hearing loss sufficient to impair their education.

The *only* action that is known to have a beneficial effect on hearing is the insertion of grommets with or without myringotomy and adenoidectomy. The hearing is improved. The pathological changes in the mucosa of the middle ear and eustachian tube are returned to normal. Eustachian tube function may also be improved but the serous cases may not do so until 9 or 10 years of age. In this instance grommets may well have to be re-inserted many times.

It would be helpful if ear, nose, and throat surgeons could: (*a*) decide on criteria for operation; (*b*) assess whether if acted on it reduced the number of children with hearing loss sufficient to impair education; (*c*) discuss with general practitioners how they can identify the correct children for referral to meet requirements for operation.

Professor Bain produced another interesting paper previously where he showed that the referral pattern of children with catarrhal otitis media to ear, nose, and throat surgeons bore a greater relation to the pressure from the child's parents than the clinical state of the child. Clear guidance from surgeons could surely help here to the children's benefit.

Dr Carney's response

Bravo! This is the sort of article I have been asking for.[1,2] A report of research by a general practitioner (albeit a professor) investigating the outcome of a disease seen only in general practice. Acute otitis media is one of the most common diseases seen in general practice,[3] yet its treatment has not been adequately researched.

It may lack the glory of such papers as "Initial experience with indium 111 autologous leucocyte imaging in patients with acute pancreatitis," but acute pancreatitis has an incidence of 0·2 per 1000 patients, whereas that of acute otitis media is 66 per 1000 and is the bread and butter of general practice.

The audit group to which I belong had discussed this paper at length before I was asked to write this article. Though Bain claimed that 49% of prescriptions for acute otitis media included a decongestant or antihistamine, few of us prescribed them, nor did Fry or Hodgkin mention them.[4,5] After discussion, this paper reinforced our clinical impression with scientific evidence not to prescribe them in the future.

I felt that there had been a change in my own prescribing habits because of this paper. A review of the cases that I saw during November 1981, however, showed that I saw nine cases of acute otitis media, I prescribed antibiotics in eight cases and an antihistamine and antibiotic in one case, while a review of the last four weeks showed only four cases of acute otitis media, all of whom were prescribed amoxycillin and one Actifed. My thought process may have changed: the facts had not.

It is a paper that could be criticised for its lack of criteria of the diagnosis of acute otitis media: were all 22 general practitioners treating the same disease? Perhaps one general practitioner gave antibiotics to a child with coryza and bilateral pink drums, while another insisted on a 24 hour history of earache, a unilateral red drum, and the presence of fluid in the middle ear before prescribing antibiotics.

Secondly, if 73% of cases received amoxycillin or ampicillin would it not have been possible to agree to use only one antibiotic and eliminate one of the variables?

Thirdly, there may be those general practitioners who comment that Professor Bain chose the wrong decongestant or antihistamine. I not only hope there are, but that they will now set up their own research projects and publish the results, so that when this subject is next discussed by audit groups there is not one but three or four papers to use as resource.

My congratulations to the *BMJ* for publishing the papers on practice research and this paper in particular. They are fulfilling their obligation to provide resource research for general practitioners.

Unfortunately, the results of a strawpoll of five other audit groups in Northumbria and a larger number of individual general practitioners found that no other audit group that I knew of had discussed the paper and only two general practitioners recognised the reference.

General practitioners have an obligation to continue their education. Papers like this must be read individually and by groups. Continuing education is not something that has to be provided by course organisers and clinical tutors but something that we all have to be personally responsible for by reading the latest research, from and about general practice.

My apologies to J R Anderson *et al*, authors of the indium 111 paper, for choosing their paper, a purely random choice. My thanks to Miss V Male and Mrs G Richardson for analysing the two periods of four weeks for the data in this paper.

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Research in General Practice

Attaining the Impossible

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I have been accused by the assistant editor of this journal of stating that "the most interesting things in general practice cannot be researched." As a young boy I remember my father, who was a self made businessman, saying "The very difficult we can do at once, the impossible takes a little time." It was perhaps this that I had in mind when I described some of the problems in general practice as impossible to study by research. The scientific analysis of the general practitioner's work is a relatively new development, and much of the methodology is primitive. Given time the impossible may yet be achieved. To examine the proposition however it may be helpful to consider a case history.

Mr W, aged 60, who suffered from ischaemic heart disease was dying of carcinoma of the lung. Mrs W, aged 58, had survived a severe hemiplegia and was just able to cope with the housework but could not go out alone. Their daughter C, aged 35, lived in the same block of flats with her husband and three children but had never got on with her parents. The eldest son B lived 200 miles away with his wife and family. The W family had been my patients for 15 years. Among my few achievements were weaning Mrs W off Durophet, to which she had become addicted 12 years ago, and satisfactorily treating Mr W's anxiety impotence 10 years before. I had also looked after C during her pregnancies and subsequently cared for the children.

In response to Mr W's wishes he was told the nature of his illness and the prognosis and he asked to have terminal care at home. Daughter C and her children agreed reluctantly to provide support for Mrs W, while son B complained from afar that his father should have only the best care in hospital. In due course Mr W died at home.

Mr W will appear in the mortality statistics as dying from carcinoma of the lung with ischaemic heart disease as an associated condition. In the general practitioner's statistics he will appear as a large number of doctor initiated home visits and will also appear repeatedly in the district nurse's returns. He will not appear at all in the hospital statistics in the year of his death. The Prescription Pricing Bureau will record that I cost the National Health Service a good deal of money in prescriptions for diamorphine, chlorpromazine, and diazepam over that period. No record will appear of the saving of several thousand pounds to the district hospital which did not have to provide terminal care.

Quality and outcome

So much for the data which could contribute information that would help to construct a profile of care provided in the district, if such data were ever correlated. They convey little information, however, about the quality, outcome, or patient satisfaction with the care provided, and yet for individual patients, their relatives, and the doctors and nurses giving primary care, these are important issues.

From the patient's view we need to know how satisfied he was in terms of pain relief, reduction of anxiety and depression, and the many other symptoms experienced by the dying patient. We need to know the quality of the nursing care and other supporting services. We need to know the outcome of this experience of caring for Mr W in his terminal illness and on Mrs W, the son, daughter, and grandchildren.

Measuring patient satisfaction in circumstances much less threatening than terminal care are notoriously difficult. Locker and Dunt, in a review of 55 publications on the measurement of patient satisfaction, concluded: "There is a sound rationale for making medical services responsive to consumer opinion. Studies of dissatisfaction with services are, however, at an early stage of development and, as we have indicated, further research is needed to identify an appropriate method of measuring satisfaction."[1] Cartwright, showing great sensitivity which led to a response rate of 82% from recently bereaved relatives to agree to an interview, illustrated how much more difficult it is to obtain information about the quality of terminal care.[2] The patient's final assessment can of course never be known.

From the viewpoint of the doctor many questions remain unanswered about the importance of continuity of care or the doctor-patient relationship on the place and quality of the terminal care provided. In a recent review designed to identify papers relevant to continuity of care in general practice, M Roland (personal communication) found that only a fifth of the 39 papers reviewed attempted to measure objectively the effects of continuity of care, and these were related to such measures as consultation rates and compliance with treatment. The doctor-patient relationship, in contrast, has been explored in great detail, by Balint[3] and by Browne and Freeling,[4] and this research has made an important contribution to understanding the importance of communications in primary care and the interactions that may or may not be therapeutic in the relationships between patients and doctors. Attempts to reduce this relationship to quantitative measurements that relate to the outcome of care have, however, been less successful.[5]

Questions likely to be raised by those who provide hospital services by this description of Mr W's terminal care will be different from the foregoing but none the less related. Why, they may ask, was Mr W cared for at home when so many other patients with similar diseases and problems are referred to hospital? The wide variety of referral rates of patients from general practice to hospital has been known for at least 20 years. The most extreme rates for outpatient referrals were described by Scott and Gilmore in Edinburgh (0·6-25·8 per 100 patients on the doctor's list a year).[6] Repeated attempts to explain these differences by the educational characteristics of the doctors or their practice organisation have failed. Cummins *et al*, following a detailed study of this problem, invented the term "referral threshold" which they thought could be applied to individual general practitioners.[7] It seems likely that this threshold represents an amalgam of a doctor's ability to tolerate uncertainty, establish sound relationships, evoke satisfaction in his patients, and all those other things which we have seen are so difficult to measure.

General practitioners are notorious for generalising from a sample of one. The case of Mr W is used not for this purpose but to illustrate some of the complex issues that are important in making decisions in general practice and in measuring the outcome of the care provided. That general practice research has made little progress in solving these problems may be due to two factors. Firstly, there has been a great need for descriptive research aimed at defining the doctor's role and understanding the natural history of illness seen in primary care, and a great need to develop the way primary care services are delivered and to monitor the effect of the changes carried out. This less difficult work has kept the relatively small numbers of general practitioners who are interested in research fully occupied. Secondly, few general practitioners have the knowledge or skills to develop research into areas concerned with patient satisfaction and human behaviour, and attempts to develop a multidisciplinary approach to general practice research have not always been successful. This is not surprising because both disciplines, medical sociology and general practice, have been establishing themselves in the past two decades. I hope that greater participation of medical sociologists in undergraduate medical education and better resourced departments of general practice will encourage a more productive partnership in research between these disciplines in the future. Attaining the impossible may take a little time.

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