## Clinical trial in general practice?

NIGEL C H STOTT

Why I started

Any doctor worth his or her salt should be asking questions about the fascinating array of problems about which we are consulted every day. The finest aspect of general practice is its colourful diversity, and yet even this has been seen as a disadvantage by those who think that only specialist clinics see enough material of a unified nature to permit research. There are many axes of the generalist work that are highly infections, which form about 60% of the work load of doctors working in primary health care.

So common and mild are many respiratory infections, that often they are not even regarded as diseases; furthermore, there is no clear relation between many of the syndromes and the organism concerned, and host resistance is equally variable. Deleary, socioecomonic, herediatry, family, and atmospheric proposes of the control of the many to begin to provide some of the answers to such as where do control for many

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factors, known and unknown, while testing a particular hypothesis or question.

The question I all use to illustrate the use of the randomised controlled trail is: Do patients with cough and purulent spurum ment antibiotic treatment?\*

When I farst posed this question in 1972 it seemed clear that patients with rough and purulent spurum were not treatment so that the patients with rough and purulent spurum were not treatment antibiotics, some were given possible mixtures, and some were given advice about soothing home remedies. A few were even sent off with a flea-in-the-ear about this being a "non-illness" that should be ignored. The scene was set for a rail to establish whether on not treatment with antibiotics would influence the symptoms or signs of this problem, which some patients clearly regard as an illness and some doctors are prepared to label as a disease. A controlled trial would also provide valuable information about the natural history of the problem.

What I did

Several stages were followed to get the trial underway:
(i) search of literature; (ii) informal survey of local doctors'
opinions; (iii) writing of a protocol; (iv) ethical committee
approval; (v) application for research funds and support;
(vr) discussion with statistical advires; (vii) staff appointments;
(viii) involvement of research practices; (iv) start quality control.
In this article I cannot deal with each aspect fully, but several
points are worth making because they are often overlooked and
cause annoyance or regere.

(i) Al literature search ethics work is vital before a protocol
is ritten because it is and to work on a protect only to find
the stage of the stag

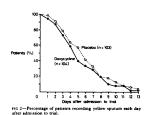
BRITISH MEDICAL JOURNAL VOLUME 285 2 OCTOBER 1982

exercise in allocate potential to the control to the control to identify those who qualified for the trial but were not entered into it: 12 were found. Of these, the doctor forgot in seven, one could not awallow argantee, one had been nausested by doxycycline previously, and three had refused to participate. (Two others started the trial but were non-responders because one changed his mind and the other could not be traced.)

one changed his mind and the other could not be traced.)
Quality control was a time-consuming but essential part of
the study, and I would have failed to find the time for this task
without the assistance of a nurse or health visitor field-worker.
She also played a valuable liaison role between the 22
practitioners and ensured that the capsule dispensers were
always full and a good supply of cards was available in every
practice. Former create cort to include all uniable cares were
regular regular create cort of include all uniable cares were
practiced was probably more important.

The first discovery was that I could not complete the study in one year as my estimates about the frequency of middle respiratory tract infection had been optimistic. This is a very common error in clinical trials and hard to avoid because one is never 100°, sour about the incidence of anything until a full survey is completed. Opinions are notoriously unreliable, and even a pilot study can lead to gross miscalculation.

The most important finding is illustrated in fig 2. Doxycycline



and placebo groups were no different, whether judged by symptoms or duration of illness, purulent sputum, or time off school or work. The figure also illustrates the natural history of middle respiratory tract infection, nearly 30% of patients still having purulent as your days but this resolved symptoms (cough, malaise, fever, headache, etc.). Could the results be biased? Yes, all results can be biased, even those from double-biland randomised controlled trails if the randomisation process fails to provide two identical groups for study. This can happen by chance, and it is another night-mare for the researcher when he or she analyses the results. Fortunately, this study did not suffer from this chance defect but we had to show that the groups were balanced by age, sex, symptoms on entry, duration of illness, severity of illness, severity of illness, compliance with drug taking, occupation, and smoking habits.

### SIDE EFFECTS OF TREATMENT

All treatments have some possible side effects, and a drug that causes rashes or nausea or diarrhoea is much less likely to

be taken by patients than one that has no side effects. In a trial this can be a cause of failure and can lead to drop-outs from half of the study unless all patients are warned about possible transient or minor symptoms. In this study equal numbers of patients on placebo and doxycycline felt nausseted, and so it is likely that this was an effect of the infection or expectations which were set by the clinicians. None of the subjects, however, actually stopped taking the drug for this reason.

(1) Always allow 50% additional time on your estimate for project duration.
(2) Plan for adequate fieldwork or clinical assistance, or both, even if you think that your present staff can carry the additional

Lists in you tunix unit your present staff can carry the additional load.

(3) Take advice from as many sources as possible before starting the project. This helps to avoid mistakes and mis-calculations, but it is time-consuming.

(4) The randomised controlled trial is a very powerful research tool that yields useful results, but it is also very demanding of time and resources. Sometimes small differences between two groups cannot be shown until very large numbers of cases are recruited into the trial. A statistician must guide you or you will be tempted to take short-cuts that you will regret sub-sequently.

The conclusions I was able to draw

Six years after the project on middle respiratory tract infection was published Inf and myself identifying two sets of conclusions. The first is a constant: that otherwise healthy adults who present to their doctors with cough and purulent sputum of up to seven days' duration and whose chests show no abnormal signs on aucutation—that is, middle respiratory tract infections—unautation—that is, middle respiratory infections and in adults given early treatment for colds and influenza-like inlines.\*1 This study' also provided useful information about the natural history of middle respiratory tract infection by confirming that it is usual for symptoms to persist for a word of the study also provided useful information about the natural history of middle respiratory tract infection by confirming that it is usual for symptoms to persist for a word of the study have been used by doctors and researchers since publication: it has been disappointing to find that many clinicians continue to presenble antibiotics for middle respiratory of this strategy. It has also been misquoted in defence of not giving antibiotics to patients with chronic bronchitis with acute exacertation. I can only conclude that some clinicians seek too justify their clinical behaviour by misuse of references. Perhaps if more clinicians conducted that some clinicians such too justify their clinical behaviour by misuse of references. Perhaps if more clinicians conducted that some clinicians such too justify their clinical behaviour by misuse of references. Perhaps if more clinicians sonducted clinical trials themselves they would learn how cautiously one has to interpret original work about the some clinical residence of the processors.

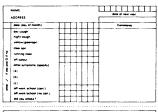
Evidence for the limited efficacy of antibiotics in many respiratory tract infections is now well documented, but there is a paucity of controlled clinical research into the relative efficacy of substances that are supposed to provide symptomatic relief. Analgesics, decongestants, cough suppressants, expectorants, and soothing vapours are all used, but do they have

trends.

(ii) Consultations with local doctors and researchers for opinions can be helpful for both practical and political reasons. I found that the doctors were divided into those who treated cough and purulent sputum with antibiotics and those who did not. They were also helpful in clarifying unitable diagnostic criteria and exclusions from the study. For example: Included: All patients from three group practices aged over 14 years who had cough and purulent sputum for up to seven days.

14 years who had cough and purulent spurum for up to several days.

Eschuled: Those with abnormal clinical signs in the chest on auscultation. Those with persistent spurum expectoration in winter months. Those with other chronic disease (diabetes, emphysema, etc.) Those sensitive to tetracycline. Those pregnant (or possibly pregnant) are strictly as the cough the cough the persistent spurum of the proposition with cough The aim was to study a healthy adult population with cough the cough the



doctor-	
Occupation	
number cigarettes/day or our tobacco/week .	
clinically lebrile YES/NO	
pulse rate	
general chrical impression WELL/ ± /TOXIC./LL	
Medicine bottle number	
number lables returned :	

FIG 1-Card for doctor and patient to record symptoms on

BRITISH MEDICAL JOURNAL VOLUME 285 2 OCTOBER 1982

the future. I had decided to try to answer two basic questions:

(a) Does ambibiotic treatment modify the clinical course of middle respiratory infection in otherwise healthy adults who have been unwell for up to a week? (b) Does such treatment influence the incidence of subsequent infections and for the doctor to record clinical symptoms and signs and a card for the patient to self-record symptoms while taking treatment or placebo on a day-to-day basis (fig. 1). The doctors had to agree to review the patients at the end of week I and stop treatment if both doctor and patient were satisfied with the outcome, and if sputum was clear. Question (b) refers to the incidence of infections brought to the doctor and inplies a need for either patients at electrociting for a further six months (which is approached to the control of the control

Every area has local research committees that supply small grants, but consultation with local academics will always help in the search for anappropriate fund-raising body if the researcher is no dout.

It is not to be a search of the property of the control of

a pharmacological action or do they simply pander to mankind's tendency to seek magical cures for illness? A host of studies is waiting to be done in respiratory infections alone, but each one provide a definition anower. In the meantime the Department of Health is becoming more hard-line in its attitude to paying for symptomatic treatment, so if you have a favourite mixture you had better evaluate it quickly!

If you do not like respiratory infections just try to examine the evidence for other favourite treatments. How is your management of in mucle sprains, low back-ache, tension symptoms, dysuria, tennis elbow, etc? General practice is still await careful evaluation in the community. Most treatments will swing with fashion and advertising until a solid evaluation in the form of a clinical trial casts fresh light on the problem. Do not forget, however, that treatment other than drugs is also amenable to this approach and we need more assessments of non-drug treatments in general practice. We also need to keep a wactfull eye on those non-medical treatments that are being promoted and applied by healers on the fringes of

BRITISH MEDICAL JOURNAL VOLUME 285 2 OCTOBER 1982

medicine because some are harmful and others may merit our serious attention.

Keferences
Genden PS, Stanfield JP, Wright AE, Court SDM, Green CA. Viruses, bacteris, and respiratory disease in children. Br Med J 1900; 1077-81.
Hower JGR, Richardson IM, Gill G, Dumo D. Respiratory illness and the standards of the control o

Gerfein M, Lorell SS, Dugtate ne. 1 more respiratory litera in children is controlled trial. Med J Aust 19/14/2: 1040-7. Clark GA, Double-bland trial of early dimethylchlor-flower-golden is minor respiratory illness in general proctice. Laseet 1970/a;1090-1102.
Tyler B, Abbott GD, Kerr MMCK, Fergusson DM. Amonycillia and co-trimoxazole in presumed viral respiratory infections of childhood: Short NCH. Management and outcome of winter upper respiratory tract infections in children aged 0-9 years. Br Med J 1979;120-31.
Leventh CT. Anapacture: in place in uniteres medical science. Welling-borough: Thorston, 1982.

# Organising a Practice

## Communication in the practice

K W MILLER

Two changes in the pattern of British general practice over the past two decades have increased the need for good communications in practices: more and more doctors practise in partnerships and the number of employed and attached staff has grown. This is well illustrated in our semirural practice near Bristol. When I joined my late senior partner more than 25 years ago there were just the two of us and a part-time screenay. Her job and entering requests for visits in the appropriate book. Between calls she kept up to date with the latest issues of Vogue, Country Life, and The Taller before they came to rest in the waiting room. Charming and decorative, she has long since retired to raise a family, and life has become more complex. Today there are six partners, two trainness, a practice manager, and no fewer than 25 other non-domestic staff working in the practice, which now is run from a converted private house in the original village for Bristol communets has grown. Many of these people are partitine, of course, which increases the communication problem, and the treatment-room nurses at the health centre are shared with another practice. When we moved into the health centre the county medical officer of health bet me that the practice would split in two within five years. I that it is a measure of our success in maintaining good communications that 10 years later we are still a closely

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knit practice and fully expect to remain so. No partner has ever left, and secretaries and nurses seem to do so only if their husbands move or they become pregnant, and even then they usually returns soon after. One receptionist joined us 2° years ago to help out for a few weeks and has been with us ever since. Gegree of stability and staff postlys. All will be different, but all would probably agree that good communications are high on the list of factors that have led to their success. How then is close lision between six individualists of quite different personalities achieved, so that in the end coherent policies emerge, decisions are taken, everyone feels involved, and splits do not form within the group? Partners usually communicate informally during their day-to-day contact (all right if there are only two or three and all work from the same building) and more formally by practice meetings.

Practice meetings

There seems to be surprisingly little consensus among practices as to the form practice meetings should take and how often they should be held. We because the state of the state of

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except on special occasions, such as deciding on a new partner. Lunch-time meetings cannot ramble on indefinitely as some partners will have afternoon clinics to attend, the doctors are feeling reasonably fresh, and the duty doctor is less likely to be

except on special occasions, such as declang on a new partner. Lunch-time meetings trainer namble on indefinitely as some the control of the control of

we are working harder than our partners, and it can be very salutary to see the figures in black and while. It is a iso useful in deciding on the nead to employ locums, part-time assistants, or not partners.

The partners is usually returnagement of not-call duties. Since we do not have a computer we find that the easiest way to work out an on-duty roster is for each partner to have the same night on each week, while weekends are worked out in advance for the year. They are then swapped around when partners are away on boliday, sick leave, or just want a particular weekend free. The bargaining that goes on would not put a perfect of the partners are away on boliday, sick leave, or just want a particular weekend free. The bargaining that goes on would not put a perfect of the many partners are away on boliday, sick leave, or just want a particular weekend free. The bargaining that goes on would not put a perfect of the mild and the partners are as chance to air his views and decisions may be arrived at by consensus. On rare occasions more ensuitive mattern need discussion—a partner feed in the partners are a shance to air his views and decisions may be arrived at by consensus. On rare occasions more ensuitive mattern need discussion—a partner feed may be a standard of the present of the partners are a shance to air his views and decisions may be arrived at by consensus. On rare occasions more ensuitive mattern need discussion—a partner feed to the partners are also as the partners has he a row with a patient and wants to remove the patient from his list. On these occasions plain speaking supported by underlying mutual respect will bring disagreements into the open before feeds or cliques develop, which can ruin a successful partners of the partn

ment of Health can produce detailed computer print-outs of prescriptions written by individual partners and trainees.

The "gossip point"

Should health visitors, nurses, secretaries, and other staff attend these meetings? Except occasionally for the clinical meetings, we think not. The meetings would be too cumbersome and time-consuming, and much of the discussion is of interest only to the partners. Nevertheless, good communications with the rest of the practice team are important; indeed, the larger the practice team the more important they become The properties of the pr

LIMITS OF MEDICAL ANY Whoever penetrates sufficiently far in the knowledge of physic will unfortunately find medicine does not possess that consuperare power over disease that younger practitioners are prone to attribute to it, or as it might be wished: and, moreover, if his practice and attention be sufficient: . . he will clearly discern the acrual limits by which the power of the medical art is bounded, despising the value attention to the ignorator of these reperienced to present the property of the property of the present of the presen

BRITISH MEDICAL JOURNAL VOLUME 285 2 OCTOBER 1982

The final list

In the shortlisting and interviewing that I have been concerned in the sex of the applicants was not discussed at any stage, but positive and negative racial feelings were aired openly and discussed, preduction such earlier and reiested, and in the end rational non-racial decisions taken. This can be difficult. Does command of English is spore because of having been in Britain only for a short time? I think not, when there are so many excellent candidates presenting themselves for interview without such a problem. The final agreement on the shortlisting rested with the clinical tutor and his consultant colleagues. It was their job to reduce my final list of 15 to 12 and to add other applicants whom I might have overlooked. The result was two groups of six doctors who were invited to attend for interview one afternoon. Four days before the event four had withdraw and were replaced in part by local applicants not originally shortlisted.

The interviewing committee consisted of six consultants and myself, and each candidate had about 20 minutes of our time. They had to sell themselves as reasonable, competent, hardworking, thinking doctors. The extroverts tended to do better with some of the committee and the quieter ones with others. Some candidates did not seem to correspond with their curricular to the constant of the constant

# Overcoming Isolation

### Keeping up to date in Gateshead

COLIN M LEON, JR YOUNG

The postgraduate centre is a "temporary" wooden structure in the grounds of the Queen Elizabeth Hospital, Garethead, It is situated rather too near to the main road and bus route for comfort or security and rather too far from the two other hospitals in Garethead to allow their junior hospital doctors easy access. It has served its purpose well over the last 13 years, however, and there will be some nostalgic reperts when it is superseded by a large, modern teaching centre in the near future. The organisation and administration of the centre is provided by the secretary/librarian and the clinical tutor (in that order), and the programme is produced by the clinical tutor and the general practitioner course organiser. The incumbents of the posts have changed over the years but the philosophy of the centre has continued relatively unchanged.

We see our postgraduate centre as the most important locus for the continuing medical education of the general practitioners and community and hospital doctors. Its work is not meant to compete with or to replace the organised postgraduate training leading to higher examinations that is organised by the academic departments of the university. The emphasis is on inter-continuing process in all specialities, including community and family practice. The Queen Elizabeth Hospital, being only five

The Postgraduate Medical Centre, Gateshead NE9 83X COLIN M LEON, MB, FRCGF, general practitioner and course organiser J R YOUNG, MB, FRCR, clinical tutor

miles from the university hospitals, is also conveniently situated for benefting from and contributing to the organized courses. We see our centre as a place for socialising and for breaking down artificial barriers between hospital and general practice. We believe that we have developed a better understanding with the other health workers by addressing some of our problems in accurate the second s

The programme our clinical and GP tutors together devise the programme, and we would like to claim that programmes are based on clear educational objectives, preferably phrased in behavioural terms. Honesty must prevail, however. Programmes are based on several well established criteria. A newly appointed consultant, and more recently a newly appointed principal in general practice, is always invited to give an "inaugural lecture." This is a bit like a parliamentary maden speech, but it at least allows a new consultant the opportunity to declare his interests and entered the control of the control o

BRITISH MEDICAL IOURNAL VOLUME 285 2 OCTOBER 1982

# Shortlisting Trainees

## Thoughtful applications wanted in Birmingham

K G DICKINSON

For some time I have been a member of various committees that select trainers for general practice. Recently I have been more involved, and the potential power is worrying. I was asked to involved, and the potential power is worrying. I was asked to district general hoopital for the two-year hospital period of the vocational training scheme. The hoopital has a fine reputation and an excellent postgraduate centre with a very efficient secretary and a clinical tutor who is keenly interested in training. In the past the shortlisting was done mainly by the clinical tutor, but, he argued, as the aim is to produce well-trained general practitioners it was only reasonable that a seasonad general practitioners it was only reasonable that a seasonad exact produce of a popular that has been advertised locally and in the BMJ.

The number of applicant has steadily risen over the years as entry into general practice has become more popular and our scheme has established itself as well thought out and practical. Potential candidates were invited in the advertisement to apply for either of two slightly different rotations (one did not include the state of the

What we do not want.

The initial sorting was easy. Applications that were illegible or had a badly photocopied curriculum vine were rejected—show 20. Applications that had been put together in haste, with little thought, were also easily dismissed—about 10. Applications that consisted of just a curriculum vitea and a very brief letter were also removed. One does expect a candidate to show some

interest in the position and outline in a little detail why he would like to work in our hospital, even if it is not true.

The work in our hospital, even if it is not true.

The work is the hard work staredt. There were probably 30 good properties to be a properties of the properties of the properties. I had to read each letter of application with care. It does not help, therefore, if it is overlong. I do not need to have the philosophy of general practice spelt out in great detail to understand that an applicant is kennet on much detail in fact is boring. What is of course even more critical is the presentation of the curriculum viate. It must be haid out well and clearly typed. It must be up to date and not have insertious added on. Again, it should not be date and the properties of the pro

know. Similarly, a standard elective done while a fifth-year student is of little interest, but it the doctor had spent extra time in New Guinea because of a crisis in the hospital he should mention it.

The control of the control

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lecture by the respected specialist from the teaching hospital, who arrives and impresses us with his account of the recent advances in his specially. We have case presentation by GP<sub>1</sub>, singly or jointly with a consultant. We encourage topic presental control of the recent advances in his specially. We have case presentation by GP<sub>2</sub>, singly or jointly with a consultant. We encourage topic presental control of the property of the presental practice of the decision groups, and each term one 'slot' is reserved for a presentation by one of the general practice vocational trainers in the town. This innovation has been a series of "plant man is 'quides to various aspects of advanced technology—for example, M-mode cehocatlography (Voldata! May 1982). General practitioners are intentional processes of the presentation of the prese

BRITISH MEDICAL IOURNAL VOLUME 285 2 OCTOBER 1982

BRITISH MEDICAL JOURNAL VOLUME 285 2 COTORES 1982 their own continuing education and there are advantages in basing some of these educational facilities in the practice premises. The timing of the session can be decided by the group, and many of the group extrivites would be impossible in the constraints of the 1/3 lunchtime session. There are obvious benefits to be found when general practitioners willingly exposential to the found when general practitioners willingly expose the session of the session of the session. There are obvious brown to the session of the sessio

The problems—the future

The difficulties created by the inadequate building should be solved when the new teaching centre on the Queen Elizabeth Hospital site is commissioned in 1985. The solution to other problems is not so obvious. Despite our policy of encouraging participation by all doctors in the district and our attempts at making the centre an enjoyable place to visit, we still cannot reach more than a small proportion of doctors, particularly family doctors. We tend to see the same loyal, similiar faces week after week. Greater centralisation of acute medicine and surgery in the near future should help, particularly in regard to anyeary in the near future should help, particularly in regard to the depths of the hospital rather than from general practice and thus may not have the necessary training that the job demands, even though he or she may have particular experience in a specialty. In the next few years, for instance, there will be a greater demand for more up-to-date and accurate advice to junior doctors because of the changes in staffing structure. We feel that the clinical tutor may gain from having more detailed in-course training than is now available through the regional meetings of clinical tutors. The general practice course organiser has already received some instruction in educational methods. The clinical tutors, like many other doctors in similar positions, is regarded as being comiscient.

### Training for General Practice

Training for General Practice

Whether we like it or not it ji now impossible to enter general practice as a principal without three year' postregastration experience in approved posts—approved, that is, by the Joint Comminee on produced a booklet, Training for General Practice, in the hope that it will provide an authoritative guide to vocational training. It is aim but ambitious, stemping to cover everything from the organisation and aims of training to the philosophy of general practice. It reads like a policy document: this is training as the JCPTGP would like the policy document: this is training as the JCPTGP would like training schemes that meet the idealised criteria we read here. How many schemes have obstactive as part of the hospital rotation, for instance? How easy is it for the sapring GP to gain obsterric or other experience if he is one of the many who are unable or unwilling to join a formal training scheme? Hospital consultants who are symptotic to the needs of traines and GP rainings who regularly one of the continual content of the cont

The ICPTGP achnowledges that a vocational training rehense and no more than provide the trainer with learning opportunities, and it is up to him whether he taket them or not. Note the leas it believes that a compulsory period of postgraduate training will produce better GPs than did the less structured approach of the past. Whether you share this view or not, if you are thinking of entering general practice it is sworth flipping through this booklet on terring general practice it is sworth flipping through this booklet of or those who have not had formal training, and the complexities of the certification system are unwelled. The list of useful addresses it exhaustive, and the suggested reading list is exhausting. Doctors who have already started their training might find it interesting to compare their experience of reality with the worthy theorising of thould read this booklet. But have a sait cellar handy—servin ILELIY, general practitioner, Bromyard, Herefordshire.

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Training for General Practice; £1; available from regional advisers or from the Joint Committee on Postgraduate Training for General Practice, 14 Princes Gate, London SW7 1PU.

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