Guidelines for drug donations

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Abstract

Drug donations are usually given in response to acute emergencies, but they can also be part of development aid. Donations may be given directly by governments, by non-governmental organisations, as corporate donations (direct or through private voluntary organisations), or as private donations to single health facilities. Although there are legitimate differences between these donations, basic rules should apply to them all. This common core of "good donation practice" is the basis for new guidelines which have recently been issued by the World Health Organisation after consultation with all relevant United Nations agencies, the Red Cross, and other major international agencies active in humanitarian emergency relief. This article summarises the need for such guidelines, the development process, the core principles, and the guidelines themselves and gives practical advice to recipients and donor agencies.

The need for guidelines

International humanitarian relief efforts in natural or other disasters can greatly benefit from donations of appropriate drugs. Unfortunately, there are also many examples of drug donations which cause problems instead of being helpful. For example, after the 1988 earthquake in Armenia, 5000 tons of drugs and medical supplies worth $55m (£36m) were sent, which took 50 people six months to sort out. Only 30% of the drugs were easy to identify and only 42% were relevant for an emergency situation. Most were labelled with only brand names.[1] Eritrea received seven truck loads of expired aspirin tablets that took six months to burn; a container full of unsolicited cardiovascular drugs with two months to expiry; and 30 000 bottles of expired amino acid infusion that could not be disposed of anywhere near a settlement because of the smell.[2] War torn southern Sudan received donations of contact lens solution, appetite stimulants, drugs against hypercholesterolaemia, and expired antibiotics, all labelled in French.[3] In 1992 11 women in Lithuania temporarily lost their eyesight after taking a donated drug. The drug, closantel, was a veterinary anthelmintic but was mistakenly given to treat endometriosis. It had been received without product information and doctors had tried to identify the product by matching its name with those on leaflets of other products.[4] Of all drugs received by the World Health Organisation field office in Zagreb in 1994, 15% were completely unusable and 30% were not needed.[5] By the end of 1995, 340 tons of expired drugs were stored in Mostar. Most of these were donated by European nations, and the mayor has written to the European Union requesting international help to have them destroyed.

The main problems that occur with donations are as follows:

- Donated drugs are often not relevant for the emergency situation, for the disease pattern, or for the level of care available. They are often unknown by local health professionals and patients and may not comply with locally agreed drug policies and standard treatment guidelines; they may even be dangerous, as the case in Lithuania illustrates
- Many donated drugs arrive unsorted and labelled in a language which is not easily understood. Some donated drugs come under trade names which are not registered for use in the recipient country and without

WHO/PAHO

Fig 1 Voluntary worker trying to sort out donated medicines in Mexico, 1991

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BMJ 1997;314:737–40

an international non-proprietary name (generic name) on the label (fig 1)

- The quality of the drugs does not always comply with standards in the donor country. For example, donated drugs may have expired before they reach the patient, or they may be drugs or samples returned to pharmacies by patients or doctors
- The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies. The distribution plan of the donor agencies may conflict with the policies and wishes of national authorities
- Donated drugs may have a high declared value—for example, the market value in the donor country rather than the world market price for the generic equivalent. Import taxes and overheads for storage are usually charged as a percentage of the declared value and may then become unnecessarily high. In some recipient countries the ministry of finance considers a donation removes their obligation to fund the necessary drug budget of the ministry of health, which is then reduced accordingly
- Drugs may be donated in the wrong quantities and some stocks may have to be destroyed. This is wasteful and creates problems of disposal at the receiving end; moreover, stockpiling unused drugs encourages pilfering and black market sales.

There are several underlying reasons for these problems. Probably the most important factor is the common but mistaken belief that in an acute emergency, or for developing countries, any drug is better than none at all. Another important factor is a general lack of communication between donors and recipients, leading to many unnecessary donations. This is unfortunate because in disaster situations and war zones inappropriate drug donations create an extra workload in sorting, storage, and distribution and can easily overstretch the human and transport resources. Often the total handling costs (duties, storage, transport) are higher than the value of the drugs.

Developing guidelines for drug donations

In the early 1980s the first guidelines for drug donations were developed by international humanitarian organisations such as the Christian Medical Commission of the World Council of Churches.[6] In 1990 the WHO Action Programme on Essential Drugs, in close collaboration with the major international emergency aid agencies, issued a first set of WHO guidelines for donors,[7] later refined by the WHO expert committee on the use of essential drugs.[8] In 1994 the WHO office in Zagreb issued specific guidelines for humanitarian assistance to former Yugoslavia.[9]

It soon became clear that one comprehensive set of core principles and guidelines was needed that would be endorsed and used by all major international agencies active in emergency relief. For this reason WHO started a global consultative process to reach consensus with the United Nations High Commissioner for Refugees and Unicef, the Red Cross, and other non-governmental organisations (see acknowledgements). Comments from over 100 humanitarian aid organisations and experts were taken into consideration. The guidelines were issued in May 1996 and have been well received. Many countries have adopted them wholesale and others have adapted them to their specific situation. The guidelines will be reviewed after one year, but it seems that they are already having a significant impact on donation practice.

Box 1—Core principles for drug donations

- Maximum benefit to the recipient
- Respect for the wishes and authority of the recipient
- No double standards in drug quality
- Effective communication between donor and recipient

Box 1 gives the four core principles. The first is that a drug donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited drug donations are to be discouraged. The second principle is that a donation should be given with full respect for the wishes and authority of the recipient, and support existing government health policies and administrative arrangements. The third is that there should be no double standards in quality: if the quality of an item is unacceptable in the donor country it is also unacceptable as a donation. The fourth principle is that there should be effective communication between the donor and the recipient; donations should never be sent unannounced.

B OBERSON/ICRC

Fig 2 Distribution of standardised kits of essential drugs in former Yugoslavia. All boxes are labelled with a packing list on the outside. Green is the international colour code for emergency medicines

Box 2 summarises the guidelines for drug donations; the full text and explanatory notes are available elsewhere.[10]

Other ways donors can help

New emergency health kit

Immediately after an emergency, or when refugees have no medical care, it is better to send standardised kits of drugs and medical supplies that are specifically designed for this purpose (fig 2). For example, the new emergency health kit,[7 11] which has been widely used since 1990, contains drugs, disposable supplies, and basic equipment needed for general medical care for a population of 10 000 for three months. It is permanently stocked by several major international suppliers and can be available within 48 hours. It is especially relevant in the absence of specific requests.

Donations in cash

After the initial phase of the emergency is over a cash donation to buy drugs locally or regionally is usually much more welcome than further drug donations.

Drug donations as part of development aid

When drug donations are given as humanitarian support to long lasting complex emergencies or as regular development aid there is more time to consider the recipient's specific demands. Drugs should not arrive in an administrative vacuum; drug donations should not create an abnormal situation which may obstruct or delay the building of national capacity to select, procure, distribute, and rationally use drugs. Special care should be taken to ensure that the donated drugs respond to an expressed need, comply with the national drug policy, and meet national treatment guidelines. Administratively, the drugs should be treated as if they were bought. This means that they should be authorised for use in the country through the same registration and quality assurance procedures that are used for government tenders. If cost sharing procedures are operational, donated drugs should not automatically be distributed free of charge.

Box 2—Guidelines for drug donations

Selection of drugs

- All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent from the recipient
- All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO model list of essential drugs, unless the recipient specifically requests otherwise
- The presentation, strength, and formulation of donated drugs should, as much as possible, be similar to those commonly used in the recipient country

Quality assurance and shelf life

- All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient countries. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce should be used
- No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere or been given to health professionals as free samples
- After arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year

Presentation, packing, and labelling

- All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each container should include at least the international non-proprietary (generic) name, batch number, dosage form, strength, name of manufacturer, quantity, storage conditions, and expiry date
- As much as possible donated drugs should be presented in larger quantity units and hospital packs
- All drug donations should be packed in accordance with international shipping regulations and be accompanied by a detailed packing list which specifies the contents of each numbered carton by generic name, dosage form, quantity, batch number, expiry date, volume, weight, and any special storage conditions. The weight per carton should not exceed 50 kg. Drugs should not be mixed with other supplies in the same carton

Information and management

- Recipients should be informed of all drug donations that are being considered, prepared, or delivered
- In the recipient country the declared value of a drug should be based on the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world market price for its generic equivalent
- Costs of international and local transport, warehousing, port clearance, and appropriate storage and handling should be paid by the donor unless agreed otherwise with the recipient in advance

How to implement a policy on drug donations

Actions required from recipients

It is difficult for a recipient to refuse a donation that has already arrived; prevention is therefore better than cure. Recipients should indicate to prospective donors what kind of help they need and how they would like to receive it. To this end recipients should first formulate their own national guidelines for drug donations, on the basis of the WHO guidelines, and present them to their donors.

Recipients should also develop administrative procedures to maximise the potential benefit of drug donations. The following important questions have to be addressed in advance:

- Who is responsible for defining the needs, and who will prioritise them?
- Who coordinates all drug donations?
- Which documents are needed when a donation is planned; who should receive them?
- What are the criteria for accepting/rejecting a donation; who makes the final decision?
- Which procedure is used when donations do not follow the guidelines?
- Who coordinates reception, storage, and distribution of the donated drugs?
- How are donations valued and entered into the budget/expenditure records?
- How will inappropriate donations be disposed of?

The third important action by the recipient is to specify its needs as much as possible, indicating the required quantities and prioritising the items. Information on other donations that are already in the pipeline is

helpful to potential donors. Full openness by the recipient is greatly appreciated by donors and pays off in the long run.

Finally, the value of donated drugs can be considerable, and the gift should be treated with due care. On arrival the drugs should be inspected and their receipt confirmed to the donor agency. They should then be stored and distributed in accordance with normal principles of good pharmacy practice. There must be vigilance to ensure that donated products are not diverted for export, for commercial sale, or into illicit channels.

Action required from donor agencies

Donors should always respect the four core principles for drug donations. Donors should also respect any national guidelines for drug donations and respond to the priority needs indicated by the recipient. Unsolicited donations should be prevented as much as possible. Ask for full information from the recipient about requested and approved donations. Donors should also inform the recipient well in advance and in great detail about which donations are coming, and when. This will help the recipient country to plan for the proper reception of the donations, to inform other donors, and to identify any additional needs.

The guidelines for drug donations were issued by the WHO Action Programme on Essential Drugs as an interagency statement by WHO, Unicef, the Office of the United Nations High Commissioner for Refugees, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Churches' Action for Health of the World Council of Churches, Médecins sans Frontières, and Oxfam. The valuable comments and contributions by all other organisations and individuals are gratefully acknowledged.

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(Accepted 22 November 1996)

Senior house officers in medicine: postal survey of training and work experience

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See editorial by Harris and Ferreira and pp 713, 719

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BMJ 1997;314:740–3

Abstract

Objectives: To describe working conditions for senior house officers in medicine in Scotland and to relate these to the quality of clinical training they receive.
Design: Postal questionnaire survey.
Subjects: All senior house officers in medicine and related specialties in post in Scotland in October 1995 (n = 437); 252 (58%) respondents.
Main outcome measures: Questionnaires covered hours, working patterns, measures of workload, an attitudes to work scale, and experience of education and training.
Results: In the week before the questionnaire, doctors on rotas had worked a mean of 7.4 (95% confidence interval 5.8 to 9.0) hours in excess of their contracts, compared with 3.7 (2.0 to 5.5) hours for those on partial shifts. The most common reason for this was "the needs of the patients or the service." Those on partial shifts reported significantly less continuity of care with patients than those on rotas (Mann-Whitney U test, $z = -4.2$, $P < 0.0001$) or full shifts ($z = -2.08$, $P = 0.03$). Doctors in general medicine reported significantly higher measures of workload (number of acute admissions, number of times called out, and fewest hours' uninterrupted sleep) than those in subspecialties. Consultants' clinical teaching and style of conducting a ward round were significantly related to factors extracted from the attitudes to work scale.
Conclusions: The quality of senior house officers' training is detrimentally affected by a variety of conditions, especially the need for closer support and supervision, the need for greater feedback, and the lack of time that consultants have to dedicate to clinical training. Efforts should be made to improve these conditions and to reinforce a close working relationship between trainee and supervising consultant.

Introduction

The "new deal," formulated as an initiative to reduce junior doctors' hours, has necessitated changes in working patterns for senior house officers, with the introduction of full and partial shifts.[1] At the same time there are indications that senior house officers in medicine in Scotland are becoming increasingly dissatisfied with their training experience.

A working group on doctors in basic medical training, with representatives from the Royal College of Physicians of Edinburgh, the Royal College of Physicians and Surgeons of Glasgow, and the Scottish Postgraduate Council for Medical and Dental Education, initiated a survey of doctors in training in medicine and engaged an independent agency to carry it out. The aim was to determine current working conditions and educational experience and how these influence the quality of clinical training. The full report,

which covers careers, clinical experience, educational structures, and the specific needs of women doctors in medicine, will appear as a joint publication from these institutions.[2] This paper indicates some principal findings.

Methods

The working group constructed a questionnaire that contained questions on type of post, hours, workload, training experience, and careers; an existing attitudes to work questionnaire which has been used elsewhere for junior doctors[3]; and a section for comments in response to three open questions. It was piloted among junior staff, and the final version was sent to all 437 medical senior house officers in post in Scotland in October 1995 with a covering letter and a stamped addressed envelope for return of the questionnaire. The questionnaires were anonymous, and respondents were asked to return them within three weeks. Two reminders were sent out, resulting in a total response of 252 (58%). Statistical analyses used SPSS for Windows (version 6.0).

Results

Of the respondents, 43% (108) were working in a teaching hospital with a university department of general medicine; 40% (101) were in district general hospitals; and 17% (43) were in teaching hospitals without university departments. There were more men (55%) than women (45%), but this sex ratio does not differ significantly from that in the latest available census data (1994) for senior house officers in hospital medicine (57:43). The median age of the survey population was 26 (range 23 to 43) years.

At the time of the survey, 44% (111) of the respondents were working in general medicine; 18% (45) in geriatric medicine; 7% (18) in cardiology; 6% (15) in infectious diseases; 5% (13) each in renal medicine and gastroenterology; 4% (10) each in dermatology and neurology, and the remaining 7%% (18) in a variety of subspecialties, each less than 3%. Again, this pattern does not differ appreciably from the latest published figures for senior house officers in medicine in Scotland. In these respects, the sample can be viewed as representative of the total population.

Contracted hours and patterns of working

Table 1 shows the hours which the respondents were contracted to work and respondents' actual working pattern. For assessment of hours worked in practice, subjects were also asked to report how long they had actually been on their feet working during the previous week. The responses ranged from 0 to 100 hours (mean 56.9 (54.8 to 59.1) hours).

Working in excess of contracted hours

Senior house officers were asked about hours worked in excess of their contract: 48% (121) had worked at least some excess hours in the preceding week. There were differences among the different working patterns, with those on rotas working the greatest number of excess hours (mean 7.4 (5.8 to 9.0) *v* 3.7 (2.0 to 5.5) for those on partial shifts).

Table 1 Working pattern and contracted hours of senior house officers in medicine in Scotland, 1995. Values are numbers (percentages)

No of hours	Full shift (n=13)	Partial shift (n=35)	Rota (n=180)	Mixed shift and rota (n=18)	Other (n=3)	Total (n=249)
<56	1 (8)	2 (6)	5 (3)	1 (6)		9 (4)
56-63	2 (15)	8 (23)	20 (11)	2 (11)	1 (33)	33 (13)
64-71	4 (31)	22 (63)	59 (33)	9 (50)	1 (33)	95 (38)
72-84	6 (46)	3 (9)	93 (52)	6 (33)		108 (43)
⩾84			2 (1)			2 (<1)
Other			1 (<1)		1 (33)	2 (<1)

Table 2 Reasons for senior house officers working in excess of contracted hours. Values are numbers (percentages)

Reason	Degree to which reason applies			
	Never	To some extent	Quite a bit	Strongly
Need for good reference from consultant	76 (39)	70 (36)	33 (17)	17 (9)
Greater opportunity to learn	32 (16)	109 (55)	41 (21)	16 (8)
Needs of patients or service	8 (4)	25 (13)	70 (35)	95 (48)
Personal job satisfaction	38 (19)	66 (34)	64 (32)	29 (15)
Covering for absent colleague	19 (10)	96 (49)	44 (22)	37 (19)

Table 3 Measures of workload (mean numbers during most recent night on call) and of agreement with item on attitudes to work questionnaire for senior house officers

	General medicine	Geriatric medicine	All other specialties	*F* ratio	P value
Workload:					
Called to a clinical area	5	2	3	13.02	<0.0001
Called to the telephone	5	2	3	7.57	0.0007
Admissions	11.4	1.6	7.7	26.4	<0.0001
Uninterrupted sleep (hours)	2.7	5.3	3.9	24.49	<0.0001
Attitude to work:					
"I am very satisfied with my choice of medicine as a career"	2.0	2.2	2.4	3.22	0.04

Those regularly working excess hours were asked to identify to what extent several possible reasons applied to them; table 2 shows the results. The most strongly endorsed reason was "the needs of the patients or service," which 83% (209) reported as applying quite a bit or strongly. Across specialties, those working in general medicine and geriatric medicine most often cited the need to cover for an absent colleague (49% (45/92) of those in general medicine and 46% (13/28) in geriatric medicine compared with 31% (23/75) of those in the other specialties; $F=3.97$, $P=0.02$).

When subjects were asked for open comments on what might deter them from a career in medicine, long hours of work emerged as the most important factor in putting them off. Their comments showed concern that this will not diminish with increased promotion—for example, "My consultants are at present working until 9 pm most nights, therefore not an attractive prospect."

On call work

Subjects were asked to record several measures of workload during their most recent night on call. Table 3 shows that these differed among the specialties. Those in general medicine reported the highest numbers of calls both to a clinical area and to the telephone; highest number of admissions; and fewest hours' uninterrupted sleep. They were also least satisfied with their choice of medicine as a career.

Table 4 Continuity of care of inpatients reported by senior house officers. Values are numbers (percentages)

Working pattern	Full shift (n=13)	Partial shift (n=35)	Rota (n=182)	Mixed (n=18)	Other (n=2)
No continuity		4 (11)	7 (4)	1 (5)	
Only a few cases seen right through	3 (23)	15 (43)	27 (15)	4 (23)	1 (50)
Most cases seen right through	8 (61)	14 (40)	109 (60)	12 (67)	1 (50)
All cases seen right through	2 (15)	2 (6)	39 (21)	1 (5)	

Table 5 Working pattern preferred by senior house officers. Values are numbers (percentages)

Working pattern	Best for own health and personal life	Best for patient care	Best for education and training
Rota with day off after 24 hours on call	154 (61)	106 (43)	150 (60)
Rota	24 (10)	78 (31)	46 (18)
Partial shift	23 (9)	38 (15)	34 (14)
Shift system	50 (20)	27 (11)	20 (8)

When all the measures of workload were examined, the number of acute admissions seemed to be a key factor. Data from the attitudes to work questionnaire for all subjects showed that the number of acute admissions was significantly negatively correlated with scores on the item "I am very satisfied with my choice of medicine as a career" ($r = -0.13$, $P = 0.03$) and positively correlated with the item "I am worried about my career in this specialty" ($r = 0.17$, $P = 0.007$).

Continuity of care

Senior house officers were asked about their perception of continuity of care with inpatients. The majority of those on full shifts, rotas, or mixed shifts reported high continuity, with most cases being seen right through. However, those on partial shifts, of whom only 46% (16/35) said that most or all cases were seen right through, differed significantly from those on rotas (Mann-Whitney U test, $z = -4.2$, $P = 0.000$) and those on full shifts ($z = -2.08$, $P = 0.03$) (table 4). Comments about this included: "There is now a lack of a 'team' with partial shift systems, as well as loss of continuity. This has reduced job satisfaction to a minimum."

Working patterns and continuity of learning

Since the type of working pattern affected perceived continuity of care for patients, we thought this might affect the learning experience. This hypothesis was tested by looking at the item on the attitudes to work questionnaire that relates to learning: "I am developing new skills." Doctors on partial shifts agreed significantly less strongly with this item than those on rotas ($z = -1.8$, $P = 0.05$).

Preferred working patterns

The doctors were asked to choose which working pattern they thought was best from three points of view: their health and personal life, patient care, and education and training.

On all three counts, most preferred some kind of rota (table 5). The data were subsequently analysed by the type of working pattern that the senior house officer was on at the time of the survey, to see if those on partial shifts (14%) differed from the rest in these preferences. They gave the same order of preference: most preferred a rota, though the response was less emphatic.

Clinical teaching

Senior staff have different styles of teaching which may be more or less effective in training senior house officers. Among our subjects, 1% (2) reported that consultants conducted a separate teaching round; 59% (147) of consultants spontaneously discussed cases on a working round; 33% (82) only responded to questions on a working round; and 7% (18) did not discuss cases.

A simple scale was used to measure the amount of feedback that senior house officers considered they received from their current consultant on their inpatient work (table 6). Although most felt that the feedback they received was helpful, they also said that it was not enough. More than a quarter reported that feedback was both inadequate and unhelpful.

Influences on feelings of competence, coping, and relationships with senior staff

To examine the factors that affect senior house officers' perception of competency, the attitudes to work inventory was subjected to a factor analysis by varimax rotation. Seven factors emerged, and the first three accounted for 38% of the variance. Factor 1 was the feeling of effective learning and competency, with high loadings for such items as "I am useful most of the time," "I am developing new skills," and "I use my skills to the full." Factor 2 was the perception of not coping: "The responsibilities of my job are overwhelming," "I regularly feel I am working beyond my capabilities," and "I am under great pressure at work," and factor 3 represented relationships with senior staff: "Senior doctors let me know how well I am doing," "I can discuss work problems with senior staff," and "I can discuss personal problems with senior staff." Subjects were then assigned the factor scores, and the results were correlated with hypothesised influences (Spearman rank correlations). There were no significant sex differences in the factor scores.

Feedback from consultants—The reported feedback on inpatient work was significantly related to all three factors. The better the perceived feedback, the more competent the senior house officers felt themselves to be (factor 1, $r = 0.25$, $P < 0.0001$), the less overwhelmed they were by responsibility (factor 2, $r = -0.15$, $P = 0.01$), and, understandably, the better their relationship with senior staff (factor 3, $r = 0.45$, $P < 0.0001$).

Ward round style—The analysis was taken one step further with ward round style, to see if this concrete measure of teaching influenced the attitudes to work in the senior house officers. Using the hierarchical scale on the style of teaching, this was correlated with the same three factors, with similar results: the less detailed the ward round, the less competent the senior house officer felt (factor 1, $r = -0.26$, $P = 0.000$), the more overwhelmed by the pressure (factor 2, $r = 0.16$, $P = 0.013$), and the worse the relationship with the senior member of staff (factor 3, $r = -0.2$, $P = 0.002$).

Table 6 Feedback to senior house officers on inpatient work

Feedback	No (%)
Non-existent	40 (16)
Scanty and not helpful	27 (11)
Scanty but helpful	94 (38)
Generally adequate and helpful	83 (33)
Extensive and very helpful	5 (2)

Discussion

Response rate

The response rate in this survey (58%), although limited, seems to be representative of senior house officers in terms of sex, specialty, and working pattern. We encountered some difficulties in distributing the questionnaires: one hospital returned the questionnaires because the envelopes did not have ward numbers, even though they had names and departments; others returned the envelopes, denying that the senior house officer was there (although we later found them at the same location); and some doctors reported that they did not receive questionnaires addressed to them. This reveals something about the status of senior house officers (and the distribution of their mail).

Key messages

- Many senior house officers continue to work long hours in excess of their contracts
- Senior house officers see partial shifts as detrimental to their own health, patient care, and clinical training
- Acute general medicine has a higher intensity of work than the allied specialties
- The quality of consultant feedback has an important influence on perception of learning, ability to cope, and relationships between junior and senior staff

Working patterns

There are two main concerns with the "new deal." Firstly, despite the introduction of new contracts, many senior house officers in medicine in Scotland were still working in excess of contracted hours. Secondly, though only 14% of the sample were working partial shifts, the evidence and opinion were that partial shifts are detrimental to patient care, training, health, and personal life.

The difficulties in devising a successful reduction in junior doctors' hours are apparent. Despite the advocacy of the Junior Doctors Committee of the BMA in *Shifting Work Practices*,[4] the partial shift has not been widely implemented in Scotland. We know that in some hospitals it has been tried and rejected by mutual agreement. Neither the high intensity of work and long hours experienced on the rotas nor the lack of continuity with patients and staff reported by those on partial shifts is conducive to high quality training. It is unlikely that a standard solution will work in all medical settings. A flexible approach to working patterns is needed, but the need to solve the problem is urgent.

Special difficulties in acute general medicine

The data highlighted the particular problem of acute general medicine, where workload on a range of measures was shown to be significantly higher than in the medical subspecialties and satisfaction was lowest. In all medical specialties, the principal difficulties in the nature of training were identified by the senior house officers as being the need for closer support and supervision; the need for greater feedback; and the lack of time that consultants have to dedicate to clinical training.

Senior house officers are aware of the increasing pressure on senior staff in terms of clinical workload and administration, but the data revealed the overwhelming importance of effective, constructive feedback for doctors in training. It was shown to have a major influence on the senior house officers' perceived competence and ability to cope on the wards. While many consultants may give such feedback regularly and spontaneously, the data show that most senior house officers consider that they receive inadequate feedback. Similarly, the more specific the teaching associated with a ward round in hospital, the more effective the learning is perceived to be, and the better able the doctor is to cope with clinical duties. This finding highlights the importance of focused teaching in the clinical setting and supports the need for a closer working relationship between the senior house officer and supervising consultant.

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Funding: Scottish Council for Postgraduate Medical and Dental Education .

Conflict of interest: None.

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(Accepted 31 December 1996)

My biggest financial coup

When I qualified in 1959 I paid a subscription to the Medical Defence Union. It was £2 and with my receipt came a dire warning against the dangers of forgetting to renew punctually. Life membership was offered for £50—actually £48 as I had already paid £2. Terrified that I might not be covered due to renewing my subscription a week late one year, I sent off a cheque for the then enormous sum of £48 and became a life member. Shortly afterwards life membership was abolished but as the subscription has risen from £2 to its present astronomical figure—as a general practitioner I would now have to pay £1740—I have been somewhat complacent and never failed to remind the secretary of the MDU, who had been a fellow student, of my life status when we met. I often wonder how many other life members exist, because I have never met one.

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Primary care—opportunities and threats

Developing prescribing in primary care

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This is the fifth in a series of articles discussing the imminent reforms in primary care

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BMJ 1997;314:744–7

Summary

The latest white papers on the NHS focus on stimulating innovation in the delivery of primary care and removing barriers to further development. Some of this innovation relates directly to prescribing in primary care, and in this article the authors speculate on what might happen if the prescribing initiatives referred to in the white papers were extended and disseminated more widely. The initiatives which might have the biggest impact are those encouraging closer collaboration between general practitioners and community pharmacists and those aiding extension of the current nurse prescribing scheme in primary care. Both offer considerable opportunities to improve primary care, but both bear some potential risks.

The recent white papers on primary care[1 2] propose the extension of two specific pilot schemes in prescribing—the nurse prescribing scheme and the computerised decision support scheme called PRODIGY (Prescribing RatiOnally with Decision-support in General-practice studY).[3 4] However, several other declarations in these documents could have much more profound implications for prescribing in primary care. For example, *Primary Care: Delivering the Future* states that "the government intends to set up a professional working party, to undertake a review over a 12 month period of the prescribing and supply of medicines." [1] This review will look into the circumstances in which "health professionals could undertake new roles with regard to the prescribing or supply of medicines." This might refer simply to facilitating the development of schemes for repeat dispensing, such as those already underway in Scotland.[5] A recent consultation letter from the Medicines Control Agency has, however, raised the possibility that chiropodists, independently of doctors, might supply a wider range of medicines, including some systemic antibiotics. Extended to other professionals, such as optometrists, this could lead to fundamental erosions of the principles of the Medicines Act, which designated doctors and dentists (and veterinarians) as "appropriate practitioners" with authority to prescribe prescription only medicines.[6]

General practitioners and pharmacists

Current contractual arrangements between health authorities and primary care providers, which the government sees as barriers to innovation, are the focus of much of the legislation proposed in these white papers. The contractual arrangements with the largest impact on prescribing are those held with community pharmacists. At present, any pharmacy which holds an NHS contract and meets basic regulatory requirements can provide general pharmaceutical services. Health authorities cannot choose which pharmacists it wishes to provide any additional services or direct who should receive those services; the proposed legislation could give health authorities more control and choice.

Another important aim of the white papers is to break down barriers, encouraging more interprofessional cooperation to provide services and greater mixing of skills. The interrelationship of pharmacists and general practitioners receives particular attention, and 17 pilot projects funded by the Department of Health in 1995-6 (box 1) are mentioned (Department of Health, personal communication).

Box 1—Models of pharmaceutical input to primary care prescribing

- Review of repeat prescriptions:
  - General practice based
  - Pharmacy based
  - In residential and nursing homes
- Total medication review ("brown bag" review):
  - General practice based
  - Pharmacy based
  - Domiciliary visits
- Analysis of PACT data
- Development, monitoring, and updating of practice formularies
- Development of prescribing policies (for example, for antibiotics)
- Prescribing audit by disease or condition

Evaluated schemes

The Department of Health is supporting other initiatives to promote closer working of pharmacists and general practitioners.[7] In relation to prescribing, these developments comprise six broad types (box 2). In Derbyshire, for example, community pharmacists were paired with general practitioners to review individual notes of 722 patients to identify any problems related to prescribing for these patients.[8] Problems were identified with 2960 (48%) of 6131 medicines reviewed. Inspired by American studies, Bexley and Greenwich Health Authority undertook a "brown bag" medication review.[9] Inspired by American studies in which patients were given a brown grocery bag for bringing in their medication, patients were invited to bring all their medicines, whether prescribed or not, to a community pharmacist. The pharmacist discussed the medicines with the patient, identified any problems, and made recommendations to the general practitioner. Similar schemes have been run in Hull and Devon.[9] In Staffordshire and Shropshire, hospital trained clinical pharmacists conducted prescribing audits, in conjunction with general practitioners and a clinical pharmacologist, in three fundholding practices.[10] In another scheme specially trained pharmacists have been delivering targeted prescribing messages to general practitioners.[11]

Published evaluations of these types of project have been mostly simple comparisons of current prescribing data with historic data and qualitative feedback from various participants. A favourable impact on the goals they set themselves is usually reported. Most of these studies have reported improvements in the chosen outcomes, but information on the schemes' cost effectiveness is limited. It is difficult to see how schemes based in general practice rather than in pharmacies could expand nationwide because of the legal requirement for community pharmacists to be present when medicines are dispensed. Additional funding would be required to provide locum cover for the pharmacy, or the new work would have to be done by peripatetic freelance pharmacists.

Another blueprint for coworking between general practitioners and pharmacists has been developed in fundholding practices that have employed pharmacists to help them control their prescribing budgets by providing more information on drugs and developing prescribing policies. Once in post, many of these pharmacists have seized the chance to deploy other skills. Freed from the usual constraints of having to supervise dispensing, some have developed schemes to educate patients and improve compliance and have set up clinics for anticoagulation and pain control, along with other initiatives to enhance patient care more generally.[12 13] This model is unlikely to be acceptable to the pharmacy profession as a whole, however, because its effect on the existing pharmacy network is unknown and it probably could not be resourced across the country within the current establishment of pharmacists.

ALASTAIR TAYLOR/THE INKSHED

Box 2—Pilot projects of closer working between community pharmacists and general practitioners on prescribing issues

- Birmingham Family Health Services Authority: Community pharmacist support for family health services authority prescribing team
- Derbyshire Family Health Services Authority: Repeat prescribing review
- Devon Family Health Services Authority: Repeat prescribing review ("brown bag" programme)
- East Sussex Family Health Services Authority: Repeat prescribing review (intervention study)
- Hertfordshire Family Health Services Authority: Prescribing advice in support of pharmaceutical adviser (comparison study)
- Kensington, Chelsea and Westminster Health Agency: Formulary development
- Isle of Wight Commission: Repeat prescribing review (intervention study)
- Lancashire Family Health Services Authority: Pharmacist led prescribing seminars
- Leeds Family Health Services Authority: Practice based advice (facilitated)
- Leicestershire Family Health Services Authority: Repeat prescribing review
- Northamptonshire Family Health Services Authority: Community pharmacist led prescribing audits
- North West Anglia Health Commission: Repeat prescribing review (elderly domiciliary)
- Rotherham Family Health Services Authority: Prescribing advice at the interface between primary and secondary care
- Sefton Family Health Services Authority: Repeat prescribing review (residential and nursing homes)
- Southampton and South West Hampshire Health Commission: Repeat prescription review (over 75s)
- St Helens and Knowsley Family Health Services Authority: Pharmacist led prescribing seminars
- Wirral Family Health Services Authority: Practice based pharmacist

Seamless prescribing

Closer working of pharmacists and general practitioners is widely hailed as a good thing. Pharmacists are certainly keen on it because their traditional roles in preparing and dispensing medicines are being eroded by the universal use of manufactured pharmaceuticals in standard packs complete with patient information leaflets.[14] In particular, they welcome roles which exploit their extensive knowledge of pharmaceuticals. The success of clinical pharmacy in hospital, in which pharmacists have been involved in discussions with doctors about prescribing decisions at the bedside, has prompted a belief that a similar close involvement in prescribing decisions in primary care would be desirable.[15] Formularies and prescribing policies provide the opportunity, and the possibility of cost containment in fundholding or prescribing incentive schemes provides the motivation for extending the pharmacist's role in primary care.

Community pharmacists should be able to ensure more cost effective and rational prescribing. Their intense and exclusive focus on the use of medicines puts them in a better position than doctors to advise patients on their drugs, but such advice must be informed by a clear understanding of the doctor's therapeutic intent. This is best achieved when both professionals are working together closely. This sort of thinking underpins the notion of seamless care; given that the traditional right of the patient to choose a community pharmacist is to be retained, though, seams may remain.[16]

Dangers of closer working

There are drawbacks, however, in doctors and pharmacists working more closely together. There is a danger that doctors and pharmacists, having been brought together to contain the costs of prescribing, will begin to compete and collude with each other to

achieve the most impressive savings possible. There might come a point at which patient care suffered, but if the two professions were engrossed in a continuing exercise to contain costs, egged on by the health authority, this point could be passed without any party noticing. The two professions are currently kept separate; this limits the capacity of either to exploit patients or the system. The two professions also maintain a distance, in part to avoid being seen as having too cosy a relationship, which might raise suspicions of possible fraud. Any new contract, however, would include safeguards to limit these risks, and developments in information technology may provide new checking mechanisms.

Other less specific drawbacks could arise from extending the primary healthcare team so much that patient care disintegrates. This concern was aired[17] particularly in response to Geoffrey Marsh's controversial book,[18] which promoted the idea of a large and comprehensive primary healthcare team in which all aspects of care are provided by a variety of allied professionals but in which the role of personal doctoring is, allegedly, in danger of being squeezed out. In this scenario the patient is exposed to what Balint described as the "collusion of anonymity" in which several professionals provide care without anyone having a clear overview or taking responsibility for overall management.[19]

Nurse prescribers

The other large professional group to be affected by the prescribing proposals in the white papers are nurses. The nurse prescribing scheme, begun in 1994,[3] is to be extended. This extension will start in seven NHS trusts in each of the regions not yet running a scheme, and the scheme should be implemented nationally from 1 April 1998. The scheme enables specific groups of nurses (mainly health visitors and district nurses) to prescribe from a nurse formulary. Each prescribing event follows a group protocol which includes arrangements for initial assessment and review, and a patient specific protocol for adjusting the timing and dosage of medicines. The nurse prescribing scheme has been evaluated formally and the findings have been published in executive summary form.[3] The government has said that the scheme is going well so far. Indeed, the Department of Health's decision to extend the scheme implies that nurse prescribing has no fundamental flaws and poses no danger to patients, even if it needs further refinement. Although the scheme is apparently cost neutral, there were wide variations in effects on costs at the pilot sites and it is probably this which has held up full implementation.

Limits to the scheme

The present scheme remains limited. Only some nurses can prescribe. Practice nurses, the group with probably the greatest desire to prescribe, are often excluded because many lack the requisite qualifications. The range of prescribable medicines is severely restricted, excluding all but a few drugs available only on prescription. Meanwhile more and more medicines are being deregulated to P (pharmacy) status, which makes them available over the counter, and this limits further the value of nurse prescribing. Nonetheless, other developments proposed in the white papers—particularly those for practice based contracts[20] and the proposed working party's review of arrangements for the prescribing and supply of medicines[1] may lead to further development of the nurse as a prescriber.

Nurses have no specific basic training in either diagnosis or therapeutics. While the nurse prescribing scheme ensures a combination of postqualification training and operating within strict protocols, the complexity of managing patients with multiple problems and multiple treatments may limit nurses' effectiveness as prescribers. Extending nurse prescribing across a larger range of medicines therefore remains controversial. The prescribing role also exposes nurses to the marketing prowess of the pharmaceutical industry, which is already sponsoring many nurse training courses in subjects such as asthma care.

Health authorities have made considerable efforts, backed by government initiatives, to win general practitioners over to the notion of cost containment in prescribing. The task might prove even harder with relatively inexperienced nurse prescribers and this, probably more than any other concern, is probably holding up the full development of nurse prescribing. One solution to the perceived deficiencies of nurses as prescribers is for them to work jointly with pharmacists. Ealing, Hammersmith, and Hounslow Health Authority developed a scheme in which prescribing problems identified by nurses reviewing patients' medicines (following protocols) during home visits were referred to the community pharmacists (E Hartley, personal communication). Pharmacists and nurses could also work together to follow up patients after discharge from hospital or at other times when patients' treatments are having to be changed rapidly.

Conclusion

All primary care providers in Britain will soon have to decide whether to take up the opportunities being offered to enter into new contractual arrangements and offer extended services—or to stick with the current contracts, while others around them change to an unpredictable degree. The costs and benefits of both decisions are inordinately difficult to predict, particularly in an unstable political climate and without knowledge of how many others will opt into new arrangements. The success of any new arrangement in protecting the strengths of the current system while making the most of the new flexibility will depend crucially on primary care providers and on the quality of their interprofessional liaison.

The main dangers are that commercial exploitation, in various guises, might conspire with barely submerged interprofessional rivalries to result in fatal damage to the NHS system of primary care. Despite its defects, that system is admired widely for providing universal and comprehensive access to state funded care at lower costs than in most other countries.

Traditional primary care providers must decide now whether to opt in or stay out and, in either case, to prepare to respond to any competition from non-traditional providers. The principal benefit of the

white papers may yet prove to be the stimulus they provide to interprofessional dialogue and collaboration, leading to better primary care for patients.

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Personal paper: Writing prescriptions is easy

Marshall Marinker

> To write prescriptions is easy, but to come to an understanding of people is hard.
>
> Franz Kafka, *A Country Doctor*

Only about 50% of patients with chronic diseases take their medicines in therapeutically effective doses.[1] Although the cost of non-compliance in illness and premature death is staggering, the issue has been neglected in the debates on healthcare resources and rationing. This week a working party of the Royal Pharmaceutical Society of Great Britain publishes its report on medicine taking.[2] It was set up to consider the scale and consequences of non-compliance and to make recommendations. Many of our group, which was made up of doctors, pharmacists, nurses, and social scientists, admitted early on that we rarely took medicines as prescribed. Some confessed to abandoning courses of antibiotics after the first day or two. After we reviewed published work it became apparent that non-compliance might be no more deviant behaviour than compliance, and that this often had serious consequences.

Patients frequently fail to adhere to their antihypertensive drug regimens, for example, which profoundly undermines the attempts to prevent strokes and reduce the risk of coronary heart disease.[3] One study suggested that failure to take immunosuppressive drugs was the commonest cause of kidney transplant failure.[4]

Although efforts have been made to improve patients' compliance, there is little evidence of sustained success.[5] There seem to be two reasons for this. Firstly, resistance to taking medicine seems to be quite profound and pervades different cultures and categories of disease. It is instinctual and complex. Secondly, there is something morally and psychologically flawed in the very concept of compliance.

Compliance may be described as follows. The patient presents with a medical problem for which there is a potentially helpful treatment. What the doctor brings to the consultation—scientific evidence and technical skill—is classed as the solution. What the patient brings—"health beliefs" based on experience, culture, personality, family tradition, and so on—is seen by the doctor as the impediment to the solution. The doctor's task is to overcome the impediment.

A more robust model is needed

It was only when the working party met representatives of patients' organisations, many of whom were themselves patients, that a different and more robust model of the relationships between doctors and patients was suggested. This can be described as follows. The clinical encounter is concerned with two sets of contrasted but equally cogent health beliefs—those of the patient and those of the doctor. The patient's task is to tell the doctor his or her health beliefs and the doctor's task is to enable this to happen. The doctor must also convey his or her (professionally informed) health beliefs to the patient. The intention is to form a therapeutic alliance—to help the patient

Many patients do not take their medicines as prescribed, costing the health service a considerable amount in illness and premature death. Professor Marshall Marinker reports from a working group that believes compliance is an out of date concept

BMJ 1997;314;747-8

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make as informed a choice as possible about the diagnosis and treatment. Although this alliance is reciprocal, the most important determinations are made by the patient.

We called this model "concordance." It recognises that just as all prescribing is an experiment carried out by the doctor so all medicine taking is an experiment carried out by the patient.[6] But concordance does not imply any abandonment of the evidence from science. Rather, we wanted to convey mutual respect for the differing perspectives of both doctor and patient without predicating that the differences between them should be resolved on the grounds of "superior" medical evidence.

Compliance is out of date

There is a historical perspective to this. Compliance may have been appropriate within a welfare state rooted in the values and thinking of society in the 1930s, when services were driven by benign paternalism and the practice of medicine was based on patients trusting their doctors. In the l990s these values and assumptions are changing. The media, consumer groups, policy makers, and patients challenge them and look for relationships between doctors and patients that are based more on openness and respect.

These earlier values are not rejected but overlaid with more modern concerns for transparency of information and accountability. The price of compliance was dependency—it belongs to an older world. The price of concordance will be greater responsibility—in the doctor's case for the quality of the evidence, diagnosis, treatment, and explanation; in the patient's case for the consequences of his or her choices.

The achievement of concordance will require a major effort in research, professional re-training, and public awareness. It will also require the scarcest of commodities—more time in the consultation. The likely cost is high. But not as high as continuing to pay the exorbitant, though largely hidden, price of failing to make optimum use of powerful and potentially effective treatments.

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(Accepted 13 February 1997)

WORDS TO THE WISE

Poison arrows

In 1542 the Spanish explorer Francisco de Orellana, ensconced aboard a tiny two masted ship, drifted down river for 4000 kilometres through the steaming South American jungle. On his return to Spain, he told (among other things) of the poisoned arrow with which the natives had killed one of his companions. The arrow poison, curare, became part of the practice of anaesthesia exactly 400 years later.

We'll return to Orellana at the end of this piece, but move for now to ancient Greece, where arrow poison was well known. The Greek word for a bow was *toxon*. Arrow poison was *toxicon pharmacon: toxicon*, an arrow, and *pharmacon*, poison. The Romans derived the Latin word for poison by shortening *toxicon pharmacon* to *toxicum*. They had got the wrong end of the pointed stick, so to speak, and our English word *toxin* perpetuates their confusion. The original meaning of *toxon* is with us still, though, in *toxophily* (archery), *toxocara* (a nematode with a bow shaped head), and *toxoplasma* (a bow shaped organism).

The Greek usage of *pharmacon* is perhaps a little surprising, since it is the origin of our word *pharmacy*, but it reflects the transition between poison and potion that can be made by many drugs, including curare. That linkage appears again in the derivation of the word *venom:* the Latin *venenum* may actually have been a love potion, taking its name from the goddess Venus. And, indeed, *poison* and *potion* share a common root in Latin *potare*, to drink. There is probably a connection, too, with Irish *poteen*, a substance that hovers on the dangerous borderland between potions and poisons.

Drugs, then, were as likely to kill as cure, and antidotes were always welcome. Kings of ancient Persia, who were often targets for wilful poisoning, liked to keep a calculus from the intestinal tract of the Persian mountain goat at the bottom of their wine cups. Its porous structure may actually have absorbed some poisons, and it was credited with magical protective powers. It was called *padzahr*, "against poison," in Persian, and the derived word *bezoar* is still used to designate large, unpleasant gastrointestinal concretions.

The Scythians were distant nomadic relatives of the Persians, and they occupied the southern Ukrainian plains during the fifth and fourth centuries BC. The landscape is still dotted with their burial mounds, and a fifth of the female burials are found to be accompanied by bows, arrows, and armour: female warriors, buried with honour. The existence of such women was rather disturbing for the patriarchal society of ancient Greece, and Greek storytellers (presumably male) spun tales of how these wild women burnt off their right breasts, the better to pull back a bowstring. They used a word that is still in the medical lexicon today, indicating an absence of breasts: *amazia*. They called the warrior women *Amazons*.

And 2000 years later in South America, Francisco de Orellana found himself dodging poisoned arrows that were being fired by women. The experience provided him with a name for the river he was following: the Amazon.

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We welcome filler articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake,* or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk.