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Herbal medicinal products

Most herbal medicinal products (HMPs) are marketed as dietary supplements, largely outside the control of the Medicines Control Agency. In Britain, HMPs are more popular than any other complementary therapy¹ and many patients do not tell their doctor about HMP use².

Faced with this situation, GPs should routinely ask their patients about HMP use. Once they know that a patient is using such treatments, there are several options. One could say 'all HMPs are useless, you must stop taking them'. The problem with this approach is that the statement is demonstrably wrong. The efficacy of several HMPs has recently been demonstrated not merely by single RCTs but by systematic reviews of all RCTs available.³ Table 1 provides examples.

Another approach would be to say 'alright, you take this HMP, but this has nothing to do with the treatment I am prescribing'. Wrong again. Most commonly used HMPs have adverse

effects and the potential for herb-drug interactions. Examples are again given in the table below.

It seems to follow that the best way forward for GPs and other healthcare professionals is to catch up with the evidence about HMPs. Reasonably accessible texts specifically written for doctors have now become available.³

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Practice-based social work

Despite the exhortations of successive governments for integration of health and social care, only random changes have taken place in primary care, and this journal has rarely published articles about it. The NHS Plan has now proposed 'a radical redesign of the whole care system' and commends a 'one-stop service'.

The benefits of 'practice-based social work' (increased efficiency, quality and staff satisfaction) have been described in several studies over 30 years.¹ Nowhere have these been translated into systematic area-wide collaboration, and the historical, political, professional, cultural and financial obstacles have been regularly identified.² Nothing has been published about the conditions in which such collaboration can flourish to the benefit of patients, as envisaged in the NHS Plan.

To identify factors which aid collaboration between general practices and social services, I have recently studied six localities with established links. A

Table 1. HMPs supported by evidence from systematic reviews.³

Common name	Effective for	Main adverse affect ^a	Herb-drug interactions
Devil's claw Echinacea	Rheumatic pain Prevention/treatment of common cold	Gastrointestinal problems Allergic reactions	Increased effects of anticoagulants Could decrease effects of immunosuppressants
Feverfew	Prevention of migraine	Mouth ulcers, gastrointestinal problems	Increased effects of anticoagulants
Ginkgo biloba Hawthorn	Dementia, intermittent claudication Congestive heart failure (NYHA II-III)	Nausea Nausea, gastrointestinal problems	Increased effects of anticoagulants Increased effects of antihypertensives, nitrates, cardiac glycosides, central nervous system depressants
Horse chestnut	Chronic venous insufficiency	Allergic reactions, gastrointestinal problems	Increased effects of anticoagulants
Peppermint Saw palmetto	Irritable bowel syndrome Benign prostatic hyperplasia	Gastrointestinal problems Photosensitivity	None known May interact with hormone replacement therapy and oral contraceptives
St John's wort	Mild to moderate depression		Interacts with a long list of prescribed drugs

^aAll rare, mild, and reversible.

Table 2. Characteristics of effective Primary Health Care Team (PHCT) collaboration with social services departments (SSDs).

Characteristic	Typical mechanism
GPs are outward looking and 'open'	At least one GP linking with community organisations
GPs support multi-disciplinary teamwork	Practice manager is facilitator
GPs clear about benefits sought	Exchange of time and resources for ease of access to social care and feedback
SSD has strategy to work at level of primary care	Organisational design made compatible
SSD practitioners have collaborative ideology	Sacrifice of the identity and support of own team to join multi-disciplinary team
SSD staff dedicated to the practice	Co-located or linked care managers dealing with all patients from practice
SSD investment in 'prevention and support'	Devolution of budget and staff management
PHCT teamwork is optimised	PHCT staff willing and permitted to undertake social care assessment and care planning

range of interviews was undertaken, the extent of progress towards integration identified, and a sample of social services case records analysed. Also, in view of reported limitations of teamwork in primary care³ and the importance of teamwork involving social services,⁴ local arrangements were analysed.

Patients received social care services smoothly and quickly. All six practices had developed their teamwork to a level far in excess of the norm for primary health care teams. Interviewees consistently believed that integration had improved not only inter-professional understanding and respect, but also the efficiency and quality of service to patients. All practices had progressed significantly through key stages of integration: gaining knowledge of their partners; improving communications; establishing a system of collaboration; using common tools; and creating a common culture of care. Characteristics which seemed most associated with this progress are shown in Table 2.

This exploratory study identifies ideas and issues for further consideration, and confirms the likely barriers to progress elsewhere (for example will social services departments devolve power? can unfavourable GP attitudes change?) Outside the atypical practices in this study, the current picture in the southwest is that the NHS Plan is unlikely to achieve the desired improvements for patients unless change is facilitated. Without evidence from research of financial or clinical gain, sceptics on both sides may not take the first steps.

This is a challenge for Primary Care Trusts, and highlights the need for more discussion in this journal.

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Cataract a pre-referral protocol

Patients diagnosed with cataracts by optometrists constitute an increasing proportion of GP referrals to ophthalmologists.¹ At the outpatient clinic the main issue addressed is the resultant functional visual disability — i.e. whether daily essential activities are compromised.

Apart from therapeutic indications, cataract surgery is indicated only if vision becomes inadequate for the patient's needs, or if the patient is unable to see well enough to work safely or drive.² The degree of visual impairment required therefore varies with lifestyle, occupation and hobbies.

Vision is often insufficiently compromised to warrant surgery. The patient may then be reviewed periodically until vision deteriorates sufficiently, or discharged, to be re-referred when surgery becomes necessary — the guideline being the patient's own perception of the visual handicap.

Many GPs tend to refer anything ophthalmic, reluctant to make clinical decisions, given lack of training and

unavailability of specialist examining equipment. However, if the optometrist has already conducted an ophthalmic examination and no other pathology has been noted, then it seems appropriate for the GP to exercise clinical judgement regarding further referral. For visually insignificant cataract, this would allay patient anxiety and obviate the long waiting period for an unnecessary ophthalmic consultation.

Visual acuity measured under ideal lighting with high contrast letters may not reflect visual disability caused by cataract, which may involve difficulties with glare or contrast sensitivity. Comprehensive questionnaires have therefore been formulated to assess functional visual disability.³⁻⁵

A simple protocol that assesses visual function in terms of overall disability, distance and near vision, hand-eye coordination, navigation and driving, and wearing corrective spectacles is as follows:

1. Do you have problems with vision?
2. Can you see the television, bus numbers and recognise people in the street?
3. Can you perform your usual near work (reading and writing) easily?
4. Can you see well enough to manage in the kitchen?
5. Do you have trouble seeing stairs and curbs that make it difficult for you to move about safely?
6. Do you drive? Do you find difficulty with headlights of oncoming cars? (The DVLA mandates the ability to read a registration mark from 20.5 metres for a Group 1 license, slightly below 6/9. Surgery is warranted for 6/12 vision or worse. Glare may warrant surgery, irrespective of acuity).

Though opticians diagnose ocular pathology with more accuracy, GPs

maintain higher quality of referral, since optometrists tend to refer all patients, irrespective of visual disability, perhaps because of an obligation to report any ocular abnormality.⁶ The exercise of clinical judgement by the GP is therefore invaluable.

This protocol targeted at minimising inappropriate referral offers the benefits of reducing congestion in eye clinics, shortening waiting periods, and expediting the treatment of sight-threatening disease.

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Current issues in fitness for work certification

The paper by Philip Sawney¹ started out very promisingly but failed to be clear on two major aspects of this subject. First, that it is very hard to get a patient back to work who has no desire or motivation to do so. Secondly, rehabilitation opportunities and encouragement is grossly lacking and there is no communication from relevant agencies to GPs. (Sadly this

also includes NHS hospitals occupational health services).

Instead the author unfairly blames GPs for lack of skills and knowledge.

I would say only up to 2 in 10 incapacity benefit reports that I do (admittedly in an inner-city area) are for people whose best interest is *really* served by not working. A large proportion of the others desperately need to get back into working life but are unable to see this as a realistic or attractive option, and also receive minimal practical help or useful encouragement from employment of benefit services. This is particularly a problem for people with mild to moderate mental illness — often exacerbated by both the poverty resultant from a dependence on benefit plus the well known mental health consequences of lack of employment.

I was shocked at the figure of 10% of the work-age population 'unfit for work'. What a waste it is of lives and public money that more is not offered to help and encourage these people back into gainful employment.

In the meantime it remains very hard to refuse a Med 3 to an angry patient who is bigger than me, and between myself and the door! What a shame that the benefit agency medical service seems to take no notice of our RM7 requests. There is far too much nihilism from the state regarding long-term sick leave. This is not the fault of the GPs and we should not be put in the position of policing the benefit system.

With lack of support services to help people back to work, our hands are tied.

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Is quinsy often managed in the community?

I was interested in the assertion by Little *et al*¹ that few patients with quinsy are managed in the community. In

my practice there have been 19 cases of quinsy recorded in 16 people in the past ten years. This gives an annual incidence of approximately one in 2300; this is lower than the figure quoted by Little. However, these cases resulted in only two hospital admissions. Only two of the cases were prescribed penicillin prior to the diagnosis being made. The majority of cases were first presented with the quinsy present and were then prescribed penicillin. Six patients had one follow-up visit after their initial diagnosis and one patient returned twice. Although GPs in this practice may be underdiagnosing quinsy, it is unlikely that any of the undiagnosed cases were admitted.

If these results are representative, it does not necessarily negate the findings in this paper. However, it is possible that low prescribers admit cases of quinsy to hospital on presentation without penicillin treatment first; high prescribers may treat cases of quinsy, possibly inadvertently, and cure them in the community. This is another possible explanation for Little's findings.

One of the most difficult GP skills is having flexibility to accommodate every clinical situation. Research on populations only tells us whether the population, not the individual, will benefit from the tested intervention. If only it were possible to identify the small number of patients with a sore throat who will develop a quinsy, because the benefit of penicillin in this group is likely to be large.

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Evaluating prescribing interventions

Walker and Mathers¹ should be congratulated in trying to tackle the tricky area of the prescribing budget. However, their analysis of the costs involved in their cost reducing intervention leaves much to be desired. We

are told, in some detail of the intervention; targeted at 36 general practitioners, that a pharmaceutical advisor worked for one day a week for one year and '...six fortnightly postgraduate educational allowance accredited meetings were held between February and May 1998...', but we have no idea of the direct and indirect cost incurred in executing the intervention. In light of the fact that the saving was £22 000 (when compared with the control group) it is hard to decide if the intervention was worth it.

This is not the first example of inadequate attention being paid to assessing the cost effectiveness of an intervention. An article in *Bandolier* summarising Mason *et al* clearly illustrates that, '...the cost of a health intervention is the sum of the cost or saving of the intervention itself, plus the cost of implementing the new policy. Both costs have to be taken into account in calculating cost effectiveness.'² Briggs points out that to know if an intervention is cost effective, decision makers need to know not only about the costs of the intervention but also if resources were shifted to fund the intervention. Furthermore, a health economist needs to be involved in the study design from the outset so as to avoid the common pitfall of having a study which is insufficiently powered to determine cost effectiveness.³ It is thus unclear if Walker and Mathers' intervention is going to save the NHS money or merely spend it differently.

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Community-based hospital-style treatment

It is refreshing to encounter discussion in a primary care journal around the subject of community-based hospital-

style treatment.¹ There exists a middle ground between traditional primary care and hospital care that is being explored in many parts of the world.^{2,3} In some cases these are hospital outreach services with limited GP involvement but there are opportunities for primary care physicians to retain ownership of their patients during 'admissions' to these 'hospitals without walls' and to become part of the multidisciplinary team.

However, it is disappointing that the highlighted scheme restricted itself to elderly clients as part of an admission avoidance scheme. Although common physical complications of hospital admission are reduced in the elderly through admission to ambulatory services⁴ it need not be age limited. Adverse events during a hospital episode affect all age groups and account for significant morbidity and mortality.⁵ Complete substitution of hospital care, post-acute care, and management of chronic and complex disease is possible via ambulatory services and has the potential to reduce the number of physical adverse events, such as the exposure to nosocomial infection and falls. It may also, as Wilson, Wynn and Parker suggest, contribute to the psychosocial well being of a large proportion of patients and their carers.

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Exercise training and heart failure

We would like to congratulate Lloyd-Williams and colleagues on their useful and well-researched systematic review of the evidence for using exercise therapy in chronic heart failure (CHF)¹. We wholeheartedly agree with their conclusions that trials to date have not included patients representative of the vast majority of CHF sufferers.

As the authors remind us, the majority of patients with CHF are over the age of 65, and many have significant comorbid disease². Although mortality has been a key outcome indicator for heart failure therapies to date, it may not be an appropriate primary outcome measure for trials of heart failure therapy in older, frail people³. If the intention (as it should be) is to add life to years, rather than years to life, functional capability and quality of life should be the two key outcomes to study. An improvement in mortality would be a welcome bonus, but its absence would not invalidate exercise as a therapy.

The other point to be emphasised is that not only have most trials so far enrolled an atypical patient population, they have mostly used relatively high intensity exercise, often based around expensive equipment, such as exercise cycles and weights machines. If an exercise programme is to be deliverable to the majority of patients with heart failure, it must be tailored to allow frail patients with comorbid disease such as arthritis to participate, and should preferably be deliverable without major infrastructural modifications. It should also, as the authors point out, be sustainable, encouraging those who participate to continue exercise long term. Failure to do so will lead to rapid loss of benefits.⁴

Exercise therapy for CHF has, up until now, been a therapy tested and shown to work in the laboratory. What we need to do now is demonstrate that it can work in the clinic and in the community.

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What is the role of urine dipstick testing in the management of UTI?

Urinary tract infections (UTI) are among the most common infections seen in both hospitals and general practice. The clinical diagnosis of UTI is imprecise. Urine samples constitute a major proportion of the laboratory workload and most prove to be uninfected. There is therefore a need to obtain a faster and more cost-effective method of diagnosis.

Urine dipsticks have been recommended as a useful tool for excluding the diagnosis of UTI based on their high negative predictive values (NPV). Flanagan *et al* and Hiscoke *et al* proposed that urine samples that are visually clear and negative by dipstick testing for blood, protein, nitrites, and leucocytes could be discarded as 'uninfected', based on negative predictive values of 92% and 98% respectively.^{1,2}

The NPV defines the proportion of those individuals with a negative dipstick result who do not have an infection. It is dependent on the prevalence of a disease. The prevalence of culture-proven UTI in the studies of Flanagan *et al* and Hiscoke *et al* were 33% and 20%, respectively. Therefore, a high NPV is not unexpected since the majority of those screened will by definition be disease-free.

From the perspective of the patient

and the attending physician it is also important to consider the false-negative rate; i.e. the likelihood of incorrectly assessing the patient's sample of urine as free of infection. Unfortunately, there is little consistency in the assessment of dipsticks in published studies and we can find only six studies where it is possible to establish the NPV and compare this with the false-negative rate.

Zaman,³ Boreland,⁴ Lejeune⁵ and Lachs⁶ *et al* evaluated the performance of dipstick urinalysis as a screening test for urinary tract infection. These trials showed negative predictive values ranging from 94% to 97%, but false-negative rates were high, ranging from 11% to 22%. Hiscoke¹ and Flanagan² *et al* decreased the false-negative rate by increasing the number of biochemical tests evaluated for each urine sample. Urine was considered to be potentially infected when any one of the following was positive: visual turbidity, leucocyte esterase, nitrite, blood and protein. This produced sensitivities of 97% and a false-negative rate of only 3% (Data available from correspondents). Unfortunately, employing this approach reduced the specificities to 49% and 24% (false-positive rates of 51% and 76%, respectively), thus substantially increasing the possibility of incorrect diagnosis of UTI and unnecessary treatment. This has been considered acceptable in some populations at high risk of UTI, such as renal transplant patients.⁷ It should be noted, however, that the reliability of dipsticks as a diagnostic tool has been found to be considerably lower in daily practice than under optimal and standardised research conditions.⁸

The role of urine dipstick as a tool to reduce laboratory workload has also been studied. Bowler *et al* assessed the impact of guidelines on the diagnosis of UTI in a local surgery.⁹ The guidelines were based on the use of leucocyte esterase and nitrite dipstick tests and their implementation resulted in a 53% fall in urinary samples submitted to the laboratory. However, this study did not offer a statistical evaluation of the validity of this approach; Lachs *et al*,⁶ using the same parameters, obtained a false-negative rate of 17%. The additional costs of repeat visits and hospitalisation as a result of

missing this significant proportion of true infections indicates that this approach may be neither clinically acceptable nor cost-effective. Conversely, we cannot account for the costs of delayed diagnosis, when the clinician has elected not to treat patients with a positive dipstick test but to await the results of laboratory tests.

Bowler *et al* suggested that the use of dipsticks as a screening test in this way could offer financial savings to the health service, but offered no further analysis. Savings may not be as large as anticipated, as the cost of processing culture-negative urine samples is minimal and many other associated costs (e.g. specimen delivery services and incubator rooms) are fixed. For our own laboratory, processing 300 urine specimens daily, a 53% reduction in the workload for the urine bench would save £59 per day in labour and material costs. Our local health service includes 130 general practices and 70 hospital wards and clinics. The cost of testing the 300 urine samples by dipsticks would be £310 daily. This would rise to an expense of £354 daily assuming each practice, ward and clinic used an automated reading machine (at £580 per unit each with a 10-year life-span). Rumley recommended the use of an automated reader to remove the subjectivity inherent in the visual reading of results, noting a difference between the visually-read and the machine-read result in approximately 40% of urine samples tested¹⁰. Both these costs are higher than the current estimated labour and material cost of £263 per day for processing all urine samples in our laboratory.

Wide disparities have been reported in sensitivity and specificity of dipstick testing according to the population studied and the prevalence of UTI. Lachs *et al* found the sensitivity of dipsticks to be too low to justify their use as a screening test in patient groups with a low pre-test probability of UTI or those without classic symptoms of UTI⁶. Non-pregnant women with classic symptoms of UTI have a high pre-test probability of infection, but Fenwick¹¹ *et al* have also queried the cost-effectiveness of dipsticks in the management of this group. They found empiric treatment with or without labo-

ratory culture to be more cost-effective than dipsticks alone in the management of UTI in non-pregnant women¹¹. A comprehensive evaluation of the cost-effectiveness of the management of UTI by dipstick testing is urgently required.

Based on the data currently available, we do not recommend the use of dipsticks in the management of UTI. Non-pregnant women with simple cystitis in general practice may be treated for UTI empirically without laboratory testing. A specimen should be sent for culture in all other cases, in which the need for antibiotic therapy must be assessed individually.

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Precisely wrong rather than vaguely right

Kay's analysis of the lessons for evidence-based policy making learned from the abolition of GP fundholding¹ is important, as it illuminates how health care analysts and policy makers continue to be precisely wrong rather than being vaguely right. Overlooking the fact that research has little direct influence on health service policy,² health economists continue to develop technical solutions that are inaccessible and find little impact at grass-roots level,³ and rational priority-setting frameworks remain elusive.⁴ Kay's prescription for policy making is for a more detailed analysis of the significant motors of change in the system under study; an accumulation of reliable data on the effectiveness and cost-effectiveness of new initiatives and those already in place — just a little more academic effort and the system will inevitably succumb to the principles of modern science.

This approach sits within the rational model of analysis. It is a confident assertion that decisions can be made by an explicit statement of values and objectives, and comparison of the costs and consequences of well-defined alternative courses of action. Kay's health care system is linear (there is a simple and proportional relationship between inputs [cause] and outputs [effect] for any part of the system), reductionist (a system can be understood by breaking it down and understanding its component parts; the behaviour of the system can be inferred from the sum of its parts) and deterministic (a knowledge of the component parts will predict the future).

Unfortunately, the world of health care is non-linear, emergent, and highly unpredictable. Changes in one part

of the system can have unpredictable and quite unintentional changes in all the other parts. Health care analysts may find it more profitable to develop analytical frameworks that reflect the realities of the health care environment they seek to study, rather than attempting to compress them into their disciplinary frameworks.

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A short sharp commentary directed at complex problems

Pity the poor quantitative researchers¹ who, five years after starting their research with 1275 patients and 82 practices, publish their disappointing results. Pity them more if they have a derogatory commentary published with their paper. Pity the commentator's disposition?

We learn by asking questions. Asking and answering good research questions is difficult. We are wiser at the end of the research than at the beginning. The conclusion of all research is sure, more research and researchers are needed.

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