management firms will accumulate the knowledge of how best to manage patients with chronic diseases while primary care physicians may increasingly lose these skills.

Conclusion

Disease management programmes show promise in improving the care of patients with chronic illnesses. But commercial disease management may have damaging, unintended consequences for healthcare systems. Healthcare institutions should initiate in-house disease management programmes that assist primary care physicians in doing a better job rather than outsourcing growing portions of health care to specialised commercial outfits.

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1 Bodenheimer T, Sullivan K. How large employers are shaping the health care marketplace. *N Engl J Med* 1998;338:1003-7, 1084-7.
2 Blendon RJ, Brodie M, Benson JM, Altman DE, Levitt L, Hoff T, et al. Understanding the managed care backlash. *Health Aff (Millwood)* 1998;17:80-94.
3 Hunter DJ, Fairfield G. Disease management. *BMJ* 1997;315:50-3.
4 Bodenheimer T. Disease management—promises and pitfalls. *N Engl J Med* 1999;340:1202-5.
5 Burns H. Disease management and the drug industry: carve out or carve up? *Lancet* 1996;347:1021-3.
6 National Health Information. *1999 disease management directory and guidebook*. Atlanta, GA: National Health Information, 1999.
7 Schulman KA, Rubenstein E, Abernethy DR, Seils DM, Sulmasy DP. The effect of pharmaceutical benefits managers: is it being evaluated? *Ann Intern Med* 1996;124:906-13.
8 Rice TT. The king of cancer. *Hosp Health Netw* 1997;71:34-8.
9 Rubin RJ, Dietrich KA, Hawk AD. Clinical and economic impact of implementing a comprehensive diabetes management program in managed care. *J Clin Endocrinol Metab* 1998;83:2635-42.
10 Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisclipinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med* 1995;333:1190-5.
11 West JA, Miller NH, Parker KM, Senneca D, Ghandour G, Clark M, et al. A comprehensive management system for heart failure improves clinical outcomes and reduces medical resource utilization. *Am J Cardiol* 1997;79:58-63.
12 DeBusk RF, Miller NH, Superko R, Dennis CA, Thomas RJ, Lew HT, et al. A case-management system for coronary risk factor modification after acute myocardial infarction. *Ann Intern Med* 1994;120:721-9.
13 Robinson JC. HMO market penetration and hospital cost inflation in California. *JAMA* 1991;266:2719-23.
14 Anderson GF, Zhang N, Worzala C. Hospital expenditures and utilization: the impact of HMOs. *Am J Managed Care* 1999;5:853-64.
15 Freudenheim M. Employees facing steep increases in health costs. *New York Times* 1998 November 27;sect A:1.
16 Ginzberg E, Ostow M. Managed care—a look back and a look ahead. *N Engl J Med* 1997;336:1018-20.
17 Iezzoni LI. Paying more fairly for Medicare capitated care. *N Engl J Med* 1998;339:1933-7.
18 Neuman P, Langwell KM. Medicare's choice explosion? Implications for beneficiaries. *Health Aff (Millwood)* 1999;18:150-60.
19 Anders G. *Health against wealth: HMOs and the breakdown of medical trust*. Boston: Houghton Mifflin, 1996.
20 Families USA Foundation. *Premium pay II: corporate compensation in America's HMOs*. Washington, DC: Families USA Foundation, 1998.

Commercial partnerships in chronic disease management: proceeding with caution

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The spirit of "new Labour" strongly supports efforts to align commercial and NHS interests. The use of private funding for capital projects, such as building hospitals, is now well established, although this practice is not without controversy.[1] We discuss a different form of private finance initiative—the development of packages for disease management in collaboration with commercial companies. We describe our preliminary experiences from a health authority perspective.

The Clinical Effectiveness Review Group was established in 1995 at Barnet Health Authority to address the implementation of evidence based practice at health authority level. The Director of Public Health (SF) noted that he occasionally received offers from independent organisations of "free" packages of services, directed ultimately at general practices, hospital departments, or community pharmacies. These organisations were pharmaceutical companies, producers of medical equipment, or their agents, which, despite a clear conflict of interests were perceived as offering a potentially important contribution to the health of the population (box 1). Somewhat confusingly, these offers were often presented as "managed care" packages, a term that generally implies a different approach aimed at centralised control and cost containment.[2]

We defined commercial packages for disease management as materials or support supplied by a third party in addition to, and capable of being integrated with, services routinely provided in public sector health care. This definition encompasses the provision of educational leaflets, help with training staff, audit, decision support systems, investigations (such as echocardiography), or a specialist clinical service along with a pharmaceutical product.

Summary points

Commercial companies, especially the manufacturers of drugs and medicines, increasingly seek to work in collaboration with NHS service providers to manage particular diseases or problems

With such relations there are risks, but also potential benefits, and it may be more realistic to require all parties to be explicit about their potential conflicts of interest than to impose a blanket ban on negotiations

One London health authority developed and used a set of standards for collaborating with the commercial sector in "managed care" initiatives

The draft proposals could be used with a view to developing definitive guidance for health authorities, primary care groups, and trusts when considering such collaborative relations

Written offers of such packages were uncommon at health authority level, but several health authority staff recalled letters, telephone calls, or personal visits from company representatives asking whether there might be interest in further talks. These offers were routinely rejected and were not formally noted or recorded. We suspected, but could not confirm, that similar offers were made commonly to individual general practices. A similar situation had arisen a few years previously when the manufacturers of computer systems for general practitioners offered free packages of information technology in exchange for clinical information; heated debate about the ethical implications occurred, but no clear official guidance was produced.[3]

We recognised that the unregulated spread of commercial packages for disease management was likely to lead quickly to undesirable and perhaps unethical relations between the pharmaceutical industry and the public sector. Major concerns, including some already raised by the NHS Executive,[4] included: legality—the development of "favoured" relations for purchasing from a single company may contravene UK or EU law; confidentiality—disclosure of NHS data to a third party is expressly prohibited except in special circumstances; ethical issues, including those concerning clinical care (for example, if the use of a more effective drug were prohibited by a commercial agreement) and consent (for example, if patient data, even if anonymised, were used for commercially oriented research); ownership of data—who has the "rights" to aggregated patient data held by a third party?; clinical emphasis—for example, a potential distortion of the "holistic" approach to patient care, with an undue focus on drugs or some other product based treatment; and cost escalation—drugs or other product based costs, even if "evidence based," may divert limited funds from other priority areas.

In an ideal world all commercially motivated offers of help would be rejected. In practice, however, the interests of the private and public sectors may coincide or cooperation may help both sides (box 2).

Box 1: Examples of "disease management packages" offered by commercial companies to a London health authority 1997-9

- Asthma care service for primary care offered by a drug company, to comprise:
  - On-site training for practice nurses
  - Identification of patients overdue for review
  - Recall of these patients for review of their care plan in a clinic run jointly by a specialist nurse employed by the company and the practice nurse
  - A written contract guaranteeing no compulsory switch to the company's own products
- Integrated epilepsy service for primary and secondary care offered by a drug company, to comprise:
  - Initial overview of district strategy for epilepsy
  - Audit of unmet need in both primary and secondary care, with particular focus on identifying patients whose drugs have not been reviewed for some time
  - Individual recall where appropriate to review drugs in either primary or secondary care
  - Introduction of "shared care" programme if desired, in collaboration with local consultants and general practitioners
- Secondary prevention programme for coronary heart disease in primary care offered by an independent company representing a drug company, to comprise:
  - Audit of computer and manual records to identify patients in need of secondary prevention
  - Invitation of patients to health check clinics run by the company nurse and practice nurse
  - Use of algorithms including lipid measurement to identify treatable risk factors for occlusive vascular disease, in particular hyperlipidaemia
  - Treatment of these patients, with lifestyle advice and a statin if required, with regular monitoring
  - Presentation of results of audit to practices

Methods

Developing quality standards for commercial partnerships

Mindful of both the risks and the potential benefits of commercial partnerships, we set out to develop a benchmark for the scientific and ethical standards that staff in our own health authority could apply to any such offers. We knew that other health authorities had developed criteria for collaborative working with commercial organisations, offering support both for meetings and in areas such as guideline development, but we were unaware of any published document that addressed the whole range of activities encompassed by packages for disease management.

The UK NHS Executive had earlier cautiously welcomed potential private-public sector alliances but had stated that "purchasers and NHS authorities must not make commitments to purchase drugs which exclusively link prescribing to a particular company's products."[4] In the absence of more detailed official guidance we made a draft checklist of quality standards against which we could assess the legitimacy and usefulness of offers (box 3) and some draft recommendations for implementing those that satisfied our criteria (box 4).

The draft quality standards and recommendations, initially drawn up by TG and AH, were discussed and refined at two meetings of the Clinical Effectiveness Review Group and were subsequently approved in draft form by the executive board. We then applied them in a pilot project—the unsolicited offer of a "secondary prevention package" for coronary heart disease by a third party company representing the manufacturer of a lipid lowering drug (third example in box 1).

Box 2: Examples of coincidental interests or cooperation between private and public sectors

- Health authorities, trusts, and primary care groups are under heavy pressure to provide limitless or, at least, unrationed, care from limited resources
- The freedom of pharmaceutical companies to make offers of packages for disease management is unlikely to be curtailed in the present political climate (if such offers are routinely rejected by overseeing authorities, they are likely to be made to individual practices and hospital departments, and the opportunity to enforce standards will be lost)
- In areas of health care involving the organisation or administration of care or the training and appraisal of staff, the commercial sector may well have important lessons for the NHS
- There is, at least in theory, a potential for offering reciprocal training for employees of pharmaceutical companies (for example, in evidence based practice) with a view to more informed dialogue across the wide cultural divide that now separates the public and commercial sectors
- Increases in drug costs are probably inevitable, and agreed care packages could include planned and targeted increases in such costs based on evidence of effectiveness rather than indiscriminate expansion

Box 3: Draft quality standards for use by public sector organisations when considering packages for disease management from companies with a commercial conflict of interest

1. Is the company or organisation "legitimate"—that is, is it a registered company, capable of being independently audited?

2. What does the package offer in relation to the following aspects of health care?

- Diagnosis and referral
- Investigations and measurements (who would make them, and how?)
- Informing and educating patients (is the educational material non-promotional, accurate and culturally appropriate, and how would this be checked?)
- Informing and educating health professionals (is the information valid, complete, balanced, and up to date?)
- Therapeutic menu, which should include options for no specific treatment and non-drug treatment, as well as those of drug treatment, for the condition (where possible, the effectiveness of therapeutic interventions should be expressed in terms of absolute, not relative, benefit for specific subgroups)
- Monitoring or review of patients (who will monitor the patients, and at what time points? By what criteria will therapeutic success be judged, and will these specifically include patients' perceptions?)
- Audit of the service (how will this be done, by whom, and with what outcome measures?)

3. How will patients be informed about the package?

4. What interests does the organisation and the NHS have in relation to each of the aspects of the package listed in point 2 above? Where do these interests coincide, and where are the potential conflicts of interest?

5. Who "owns" the data generated by audit and monitoring for the managed care package—for example, number of patients, proportion enrolled, proportion completing the programme (successfully or not), drugs used, and so on:

- Who has access to the data, bearing in mind the Data Protection Act and the requirements for patient confidentiality of healthcare records?
- How and for what purposes will the data be used?

6. Has the scheme been piloted or are there plans to do this?

7. Is there valid and relevant information on the cost effectiveness of the package? If so, does this take into account indirect and opportunity costs and does it include one or more sensitivity analyses? If so, has value for money been shown?

8. Who would have designated clinical responsibility for the patient at each stage in the package?

9. How would the package relate to, and mesh with, existing systems of care in the primary or secondary care sectors?

10. Has this package been compared with other packages currently on offer and with "usual care" as currently provided? (Competing tenders should preferably be heard at a multilateral meetings)

11. Will there be joint management of the scheme throughout its duration by a committee or working group, with representation from all parties?

12. On completion of the scheme, how will it be evaluated in terms of:

- What have been the costs and benefits to patients?
- What has each side learnt and gained?

Results of pilot

The company completed the list of questions we sent them, which was based on the checklist in box 3, and this began a dialogue through which the original offer was changed considerably. The initial proposal had been for an activity that was heavily directed towards cholesterol testing and prescription of statins. After several meetings and letters with reference to the draft guidelines for the "disease management package," we were able to shape it, with the agreement of the company, into a broader (and, we believed, more evidence based[5]) secondary prevention initiative. The changes negotiated included:

- A more explicit focus on overall cardiovascular risk, with an extended range of initiatives for lifestyle modification
- Widening of the entry criteria for secondary prevention to include cerebrovascular and peripheral vascular disease as well as coronary heart disease
- Facilitating the review of patients already taking a statin drug to ensure that treatment is targeted appropriately
- Incorporation of a locally agreed algorithm for risk factor management (including lipid lowering).

Discussion

We report a single example of how, forearmed with a checklist of quality standards we had constructed previously, we were able to develop a package for disease management that suited both the commercial interests of the sponsor and our own aim to provide evidence based and cost effective care for a group of patients at risk. Health authorities, hospital trusts, and primary care groups are likely to come under increasing pressure to enter into quasicommercial relations with pharmaceutical companies. We suggest that open dialogue, in which all parties explicitly present their conflicts of interest and potential common ground is explored in a structured manner, may produce greater overall health gain than a combination of official condemnation and clandestine liaisons. Healthcare providers should consider modifying the standards and recommendations in this paper as part of their clinical governance programmes.

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1 Royal Institution of Chartered Surveyors. *The private finance initiative; the essential guide*. London: Royal Institution of Chartered Surveyors, 1995; 1-30.
2 Fairfield G, Hunter DJ, Mechanic D, Rosleff F. Managed care: implications of managed care for health systems, clinicians, and patients. *BMJ* 1997;314:1895-8.
3 Pringle M. Beware of Greeks bearing gifts. *BMJ* 1987;295:738-9.
4 NHS Executive. *Commercial approaches to the NHS regarding disease management packages*. Leeds: Department of Health, 1994. (EL 94/94.)
5 Anon. Secondary prevention of ischaemic cardiac events. In: *Clinical evidence*, issue 2. London: BMJ Publications, Dec 1999;73-98.

Box 4: Draft recommendations if the public sector organisation decides to pursue a partnership in disease management

- A written agreement should define the exact nature of the support provided and its duration or time frame
- Clinical aspects of care, including the development of guidelines or protocols, should be under local control, although local groups may choose to use or adapt information produced elsewhere
- The company must agree not to promote or advertise its own products within the work it is supporting
- Work should proceed on a project by project basis, not as part of an ongoing relation
- All patient identification should be removed from data before they are given to the company
- Reports or information from the work should not be used or published elsewhere without explicit permission from the health authority, hospital department, or general practice concerned