management and decision support software. The budget initiative has the potential to improve the flexibility of funding, allowing practices greater scope in deciding how diabetes care is provided.

The additional costs of more intensive monitoring may be justified by future savings from a reduced need for hospitalisations to treat the complications of diabetes. The UKPDS included cost-effectiveness analyses for intensive blood glucose and blood pressure management. In both cases, more intensive management was found to be cost saving in the trial setting. It was expected to have additional costs, but still to be cost-effective in a community setting.[5,6] Whether the additional costs of more intensive management for a number of conditions would be considered to be cost-effective is unclear. The pharmaceutical and diagnostic test costs of each condition managed intensively are clearly additive, but the health benefits may not be. Furthermore, the UK results may not be generalisable to Australia.

The Australian example most frequently cited in the co-ordinated care trials was the patient who could not access cheap podiatry services, but then required an expensive hospital admission for the treatment of 'diabetic foot'.[2] The fund-holding model in the trials was intended to provide funding for the additional podiatry services which would be offset by the savings from reduced hospitalisation for complications. The evidence of either reduced hospital admissions or the subsequent savings was not apparent from the trials, partly because of their short duration and partly because improved care was more expensive. Despite up to 60% of all patients in some trials having diabetes, any impact on their health within the two-year period was not sufficient to generate the intended savings.

The only certain and immediate consequence of more intensive management of diabetes is increased pressure on the resources of both general practitioners and the broader healthcare system. Any health benefits for patients may not be for some years. General practitioners may be consistently referring patients to podiatrists, diabetes educators and ophthalmologists, but are these services available in all regions to low income patients? Will preventive advice on lifestyle changes be provided to patients at risk? Will other patients with other needs find themselves less able to access care? If there are insufficient resources to provide intensive management to all patients with diabetes, there will be some patients who will miss out on some or all aspects of this care. It may be that these are the very patients who would benefit most from improved management, better access to allied health services and preventive advice.

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Conflict of interest: none declared

Transparency and the Pharmaceutical Benefits Advisory Committee

Professor Emeritus Lloyd Sansom AO, University of South Australia, Adelaide, and Chair, Pharmaceutical Benefits Advisory Committee

Comment on Professor M.J. Eadie's editorial 'The secrecy of drug regulatory information' (Aust Prescr 2002;25:78–9)

Recent debate about the sustainability of the Pharmaceutical Benefits Scheme (PBS) has again raised the issue of transparency of the decision-making processes of the Pharmaceutical Benefits Advisory Committee (PBAC). The excellent editorial by Professor Eadie entitled 'The secrecy of drug regulatory information' widens the debate about the release of information about drugs into the public domain.[1]

There is no question that the public has a right to know the basis on which decisions are made for the approval or rejection of a drug for marketing and subsidy. In order for those decisions to be able to be debated and discussed, full disclosure of information at the time the decisions are made is needed. Professor Eadie raises a number of critical issues which may be seen by some as barriers to such action. However, they should not be seen as insurmountable, but simply as issues which need to be addressed in the development of a strategy towards the timely disclosure of relevant information.

The PBAC is committed to the release of information regarding its decisions. This includes the reasons for both positive and negative recommendations and in addition the reasons why a

drug has been recommended as a restricted or authority required benefit. It has been suggested that prescribing outside of subsidy-approved indications (i.e. leakage) is a major cause of the cost increases in the PBS. While such prescribing certainly does occur, the PBAC has never been in a position, at the time that a drug is approved for subsidy, to disclose the evidence on which decisions to include such restrictions were made or to be able to place the use of the drug in an appropriate clinical and cost-effective context. The PBAC is hopeful it will be able to initiate these reforms in the near future. However, as Professor Eadie clearly points out, there are matters of 'commercial-in-confidence' which must be acknowledged and attended to, and discussion with the pharmaceutical industry is essential to address their legitimate concerns on this and other issues. Notwithstanding these concerns the overriding consideration must be the right of doctors and the public to have access to information. It is the responsibility of regulatory authorities to provide it in a manner appropriate to each stakeholder group. There is no doubt that disclosure of information will make the decision makers more accountable, but that is how it should be in a transparent system.

The saying 'Don't tell me why it cannot be done but how it can be done' is appropriate in the context of this issue. Professor Eadie's comments are an excellent starting point.

REFERENCE

1. Eadie M. The secrecy of drug regulatory information. Aust Prescr 2002;25:78-9.

Conflict of interest: none declared

Letters

Letters, which may not necessarily be published in full, should be restricted to not more than 250 words. When relevant, comment on the letter is sought from the author. Due to production schedules, it is normally not possible to publish letters received in response to material appearing in a particular issue earlier than the second or third subsequent issue.

Insulins in 2002

Editor, – Regarding insulin and metformin schedules – indeed one size does not fit all. Dr Pat Phillips' excellent update 'Insulins in 2002' (Aust Prescr 2002;25:29–31) nicely highlights inter-individual insulin requirements (e.g. a predicted daily range of 39 to 78 units of insulin for a 78 kg man).

When metformin is factored into the equation, the considerations become even more complex, as when for example a patient has mild diabetes-related renal dysfunction and/or chronic low-grade hepatitis B, both of which are relative contraindications to the use of metformin.

I am also currently looking after a man in his 70s who is mildly overweight, with borderline urea and creatinine, chronic hepatitis B with a slightly raised GGT but normal ALT concentration. His insulin requirements exceed 100 units per day, but metformin is being withheld out of concern for potential adverse effects.

In view of the potential value of metformin with insulin, would Dr Phillips care to comment further on the nuances of this interesting combination of drugs?

Ross Philpot

Consultant Physician

Adelaide

Dr P. Phillips, the author of the article, comments:

Dr Philpot correctly points out the advantages of continuing metformin when starting insulin in patients with type 2 diabetes. Metformin has actions independent of insulin secretion (by reducing gluconeogenesis and insulin resistance) and it has benefits in controlling weight.

However, metformin can cause potentially life-threatening lactic acidosis in patients at risk of metformin accumulation (renal impairment), hypoxic challenges (respiratory or cardiac failure) or reduced lactate clearance (impaired liver function).

The first patient described by Dr Philpot had 'mild diabetes-related renal dysfunction and/or chronic low-grade hepatitis B'. If the patient had one relative contraindication (moderate renal impairment, GFR 30–60 mL/minute) our guidelines[1] would recommend that low doses of metformin are appropriate (500–1000 mg/day). The situation should be reviewed regularly and metformin should be stopped if the patient were to develop an absolute contraindication.

In the second case it appears that the patient might have moderate renal impairment (GFR 30–60 mL/minute) but no functional liver impairment. A metformin dose of 500–1000 mg/day would seem appropriate and might reduce the necessary insulin dose and improve glycaemic control.

REFERENCE

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The evidence-relevance gap

Editor, – I was most impressed by the article 'The evidence-relevance gap – the example of hormone replacement therapy' (Aust Prescr 2002;25:60–2) in which Dr Neeskens gives a sensible and pragmatic approach to dealing with complex information thereby allowing the patient to put it in context for **her** situation. Too often we are confronted with population studies, but what do they mean to the individual person?

There are two other situations, one involving vast expense and the other some serious morbidity, which require similar scrutiny. The first involves the escalating use of 'statins' in the community at a cost which may result in limiting the ability of the Pharmaceutical Benefits Scheme to afford new drugs. Should we **really** be trying to reduce the cholesterol level to some magic number in every adult Australian, even those who are asymptomatic and without a relevant family history? And if so, for how long do we continue this therapy?