PERSONAL VIEW

Prescribed minimum benefits or minimum prescribed benefits?

Brian Rayner

On 1 January 2004 the government introduced the policy of Prescribed Minimum Benefits (PMBs) into the health care sector. This system obliges health care funders to cover fully a minimum of 25 conditions for all members of the medical aid scheme, regardless of the level of scheme. In addition, in terms of an amendment to the Medical Schemes Act, 1998 (Act No. 131 of 1998), health care funders were allowed to introduce managed health care protocols provided that these were developed on the basis of evidence-based medicine taking into account considerations of cost-effectiveness and affordability, and provided that provision be made for appropriate exceptions where the protocol has been ineffective or causes or would cause harm to the beneficiary *without penalty to the beneficiary*. Furthermore, if managed health care entails use of a formulary or restricted list of drugs, such formulary or restricted list must be developed on the basis of evidence-based medicine taking into account considerations of cost-effectiveness and affordability, and must make provision for appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause harm to the beneficiary *without penalty to the beneficiary.* With this in mind I would like to comment on the implementation of the PMBs in relation to hypertension and also use a case study to illustrate the serious problems facing doctors trying to implement good clinical practice.

The Southern African Hypertension Society (SAHS) recently published the Hypertension Guideline 2003 in this *Journal*.[1] This guideline represents a consensus statement of the SAHS Executive, international speakers at the 13th Scientific Meeting, South African special interest groups, African hypertension special interest groups, and invited local national Department of Health delegates, taking careful consideration of the balance between best clinical practice and affordability. It should be the model for the management of hypertension in South Africa. Yet there is another guideline for hypertension created by the medical schemes, which although broadly similar to the Southern African Hypertension Guideline has several important differences. For instance, the South African guideline recognises the following compelling indications for angiotensin receptor blockers (ARBs) — angiotensin-converting enzyme (ACE) inhibitor intolerance, chronic kidney disease, left ventricular hypertrophy, cardiac failure, type 2 diabetes with micro-albuminuria or proteinuria, and prior myocardial infarction.[1] The only compelling indication for an ARB in the PMBs is type 2 diabetes with micro-albuminuria or proteinuria. Although ACE inhibitors are also compelling (and sometimes preferred indications) for these conditions (e.g. heart failure, prior myocardial infarction), the PMBs take no cognisance of ACE inhibitor intolerance. It is not appreciated that ACE I intolerance is not an uncommon problem. A controlled prospective clinical trial[2] found that overall 0.68% of all patients and 1.62% of black patients may develop angio-oedema (a life-threatening complication). Cough may occur in up to 20% of patients, leading to discontinuation of therapy.

The Hypertension Guideline Update also explicitly states that only long-acting calcium channel blockers (CCBs) should be used for the treatment of hypertension.[1] It is well established that short-acting CCBs may in fact cause harm.[3,4] Furthermore we have previously reported in the *Journal* serious problems caused by substituting CCBs either generically or therapeutically in high-risk patients with hypertension.[5] The Medicines Control Council has also issued an advisory warning on substituting dihydropyridine CCBs either generically or therapeutically.[6] In my opinion, considering the above, only CCBs that have proven benefits based on prospective clinical trials should be used for the treatment of hypertension,[7-10] but few of these are available on PMB formularies. On occasion I have been indirectly pressurised by medical aids to substitute CCBs for cheaper and unproven 'equivalents' contrary to the Medicines Control Council's advisory warning.[6]

The following case study illustrates many problems facing medical practitioners trying to follow good clinical practice guidelines. I have treated Mr PT for the past 6 years in conjunction with his vascular surgeon, cardiologists, and general practitioner. Briefly, he has widespread vascular disease. He has had a coronary artery bypass graft for ischaemic heart disease, carotid endarterectomy for transient ischaemic attack, surgery for abdominal aortic aneurysm, stenting of the renal arteries for severe bilateral renal artery

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stenosis, stenting of the femoral arteries for claudication, recent athero-embolus to the left eye, ACE inhibitor intolerance and severe allergic skin reaction to generic simvastatin. He also has significant hypercholesterolaemia and mild chronic renal failure (creatinine 170 µmol/l) with proteinuria and hypertension. Despite all these chronic conditions he remains in good health. He has four conditions covered by PMBs, namely hypertension, chronic renal failure, ischaemic heart disease, and hypercholesterolaemia. He is a member of Discovery Health, and I made the following motivation for non-formulary drugs in a letter to the medical advisor because I was unable to find appropriate choices on the Discovery Health formulary or guideline for PMBs:

1. Bisoprolol. The patient has peripheral vascular disease and atenolol worsens his claudication. As he has a compelling indication for a β-blocker (ischaemic heart disease and hypertension), the highly selective β-blocker bisoprolol is considered the appropriate choice as it has limited effect on claudication.

2. Losartan. The patient is intolerant to ACE inhibitors and therefore requires an ARB according to compelling indications (hypertension, prior myocardial infarction and chronic kidney disease). Losartan was suggested as he also has hyperuricaemia.

3. Zocor. The patient was previously on Zocor 30 mg for significant hyperlipidaemia and ischaemic heart disease. Switching to generic simvastatin resulted in a severe allergic skin reaction. Therefore Zocor 30 mg was suggested.

4. Indapamide SR. The patient has a creatinine of 170 µmol/l. Thiazide diuretics become ineffective at this level of renal function. The suggested substitution was indapamide SR in view of its efficacy with impaired renal function and slow onset of action.

5. Clopidogrel. Despite all these measures for vascular protection the patient suffered an atherosclerotic embolus to the eye. He is, therefore, aspirin-resistant and according to his cardiologist and vascular surgeon requires clopidogrel 75 mg daily.

At the time of writing in April 2004, the patient informed me that the motivation had not been accepted in its entirety. I have yet to receive a reply or phone call from the medical advisor of Discovery Health to discuss the motivation or consider alternative options. His general practitioner has been following this up without success. A formal complaint was lodged with the Council for Medical Schemes on their electronic website 6 weeks before I wrote this letter, but I am still awaiting an acknowledgement.

Besides the common courtesy of a reply to a doctor's motivation, the entire issue of the PMBs raises several important questions: (*i*) who should be responsible for the designing of guidelines and determination of appropriate formularies?; (*ii*) what protection is available to members of medical schemes against the denial of properly motivated considerations for treatment; and (*iii*) how will the patient obtain medication until these disputes are resolved?

Additionally the financial implications of using non-formulary drugs is an important issue as it is appropriate for medical funders to contain costs of chronic medication. I accept this principle, but this must be in accordance with current clinical guidelines, must not be to the detriment of the patient, and should not ignore that the short-term savings in medication costs may in some cases result in greater costs in the long term. This is a complex issue and sometimes difficult to quantify, but in the case presented above it is self-evident that the minimal differences in cost of generic and ethical simvastatin cannot be a factor in the overall cost-effectiveness of statin therapy in high-risk patients. Additionally, failure to provide appropriate drugs to prevent progressive renal disease will ultimately result in the need for dialysis. In relation to the cost of dialysis, the extra money required for the ARB pales into insignificance.

I am sure this is not an isolated problem and look forward to a speedy resolution of these difficulties without compromising patient care. Issues relating to use of guidelines and formularies by managed health care companies were on the agenda of the executive meeting of the SAHS held in June this year.

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