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Council Lecture

Cataract, cost: Curious questions

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Abstract

An investigation of the pricing of implantable prosthetic devices in Australia reveals some alarming practices. A governmental mechanism exists to prop up the pricing of 7500 listed devices to levels that are unacceptably high by world standards. Private hospitals and doctors are able, legally, to profit by marking up the cost of these devices from the market price to this artificially inflated price. Even the open market prices of implantable prosthetic items, such as intra-ocular lenses, are high by international standards. In a time of budgetary constraint for health spending and rapidly increasing use of these devices, these issues urgently need to be addressed in Australia.

Key words: cataract, expenditure, government, health, implantable, intra-ocular lens, profit, prosthesis.

Introduction

The present paper is about the cost of implantable prosthetic devices in Australia. Ophthalmologists are most interested in intra-ocular lenses (IOL), but the issues apply to any prosthesis implanted into humans.

There are several timely reasons to discuss these issues.

The first is that, by any criteria, the amounts of money involved are large and growing more rapidly than other categories of health expenditure.[1] Second, as doctors, we are being asked to comply with the principles of evidence-based medicine. The recent Commonwealth Budget called for a 'strengthening of the evidence base' of the Medicare Benefit Schedule. It promised funding for an initiative that '… will assure consumers that new and existing medical procedures have been rigorously evaluated …' and that '… will help ensure that … procedures are thoroughly reviewed before they can attract Medicare benefits'. The document claims that '… decisions (about new listings) rely too little on comprehensive and systematic evaluation of documented research'.[2]

Therefore, it seems appropriate to see what measures, what evaluation, is in place to assess whether implantable prostheses are fairly and reasonably priced, especially in the light of the ongoing marked reductions in Medicare rebates for cataract surgery and 'certain overpriced' ophthalmic item numbers and the rank craziness of item 106.[3]

Third, in the 5 years that I have been associated with the Fred Hollows Foundation (FHF), I have come to learn much about the realities of manufacturing IOL. The FHF can make an all-polymethylmethacrylate (PMMA) single-piece, posterior chamber IOL of contemporary design, certified to comply with the European EN 4600 standard,[4] and sell it at a profit for $A10 in the international marketplace.

Fourth, this is an area of health budget and an industry where almost all the profits go offshore, so it is a matter of national economic interest to look at the basis of this part of our health expenditure.

The Size of the Problem

The amounts of money involved in prosthetic supply are large. The Australian Health Insurance Association figures show that A$168 million was paid out in benefits for listed prosthetic items in the 1996–97 financial year to privately insured patients alone. This is 30% greater than the figure for the 1990–91 financial year.[1]

This $168 million does not include prosthetic costs for public hospital patients or those covered by the Department of Veterans Affairs (DVA). For DVA patients, the cost for the 1996–97 financial year was $36 million, whereas in the 1993–94 financial year it had only been $12.6 million. So, in the space of three financial year periods, the DVA expenditure has increased by nearly 200% (Department of Veterans Affairs, unpubl. data, 1997).

It is difficult to establish the proportion and relative cost of the prosthetic devices that are implanted in public hospitals. However, we do know that a patient in a private hospital is twice as likely to be there for an operation as his

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or her counterpart in a public hospital.[5] For cataract surgery, Keefe and Taylor recently showed that three-quarters of the 70 000 cases of cataract operated on in Australia in 1994 were operated on in private hospitals or day facilities.[6]

For an overall estimate of prosthetic costs to the community, it seems reasonable to assume approximately one-half of all surgery is done under private insurance cover.

Extrapolating the figure paid by private insurers, the total cost of all prosthetic devices in Australia in the 1996–97 financial year was probably more than $300 million. To put this figure into perspective, it is approximately $70 million more than the total of benefits paid out by health funds as gap payments to top up doctors fees from 75 to 100% of the Schedule level, for all patients in all private hospitals and day facilities (R Schneider (Chief Executive Officer, Australian Health Insurance Association Ltd), pers. comm., 1997). The $200 million paid out by private insurers and the DVA is more than twice the $95 million Department of Health appropriation for Aboriginal and Torres Strait Islander Health Services last financial year.[7]

There are several reasons for the rapid increase in expenditure on prostheses. The number of DVA patients receiving prostheses more than doubled from 11 500 in 1993–94 to 26 500 in 1996–97. The number of items implanted nearly trebled from 27 000 in 1993–94 to 76 000 in 1996–97 (Department of Veterans Affairs, unpubl. data, 1997). The DVA patients may be a special cohort, but the trend is similar among privately insured patients. Increasing patient age, new types of implants and increasingly liberal indications for surgery are all undoubtedly contributing to this growth in usage.

Manufacturing Costs for IOL

For an example of the manufacturing costs of these devices, let us consider the IOL. To manufacture IOL there are three main areas of cost. These are, first, fixed costs, which include the cost of the building and machinery to make the device.

Second, there are recurrent overhead costs, such as the cost of raw materials, servicing of plant and the like. These are variable input costs. Third, there are direct labour costs. The technical group within the FHF estimates that only the direct labour cost is significantly different in Eritrea and Nepal (the location of its factories) in comparison with the cost of IOL produced in the USA, the Caribbean or in Europe.

The labour input for a FHF lens is approximately A$0.75. When this figure is scaled up to allow for wage differences in the USA or Europe, we estimate that their labour cost for an all-PMMA lens is unlikely to be more than A$8. For IOL that are injection-moulded (e.g. silicone foldable lenses), the marginal cost is probably even lower because the technology is simpler. Allowing for a high side estimate of the cost of the raw polymer, it is likely that the marginal cost of production of a foldable lens (i.e. the cost of production of one more IOL once you are set up) would have great difficulty exceeding A$7–14 in the US or Europe. There is probably no IOL that costs more than A$20 to produce.

Manufacturers of IOL may object to these estimates, but their real costs have never been revealed. This would be counter to normal commercial practice, where profits and costs are subject to secrecy.

Price Overseas

It is revealing to look at the price for which you can buy IOL in some other countries. In India, you can buy a modern US-manufactured all-PMMA IOL from one of the major US companies for between A$50 and 70. In Vietnam, you can buy a pack from a major US company containing an IOL, a vial of methylcellulose and a suture for approximately A$70 or a premium FDA-approved phaco IOL for A$65. In New Zealand, at least one major supplier of high quality IOL has them freely available for purchase by ophthalmologists at A$105 (before GST) and private hospitals have them available to patients for approximately A$200; that's the sort of top premium price.

In San Francisco, the Alta Bates Health Maintenance Organization pays A$89 for all-PMMA lenses and A$171 for silicone lenses. In Britain, all-PMMA lenses are available to health authorities from as little as A$50. Heparin-coated lenses rebatable at A$395 here are available for A$200 and silicone foldable lenses are available for A$125.

None of these figures should surprise you and, at approximately A$70, the price may seem fair and reasonable.

Prices in Australia: The Schedule Versus Free Market

Close examination of the process of setting the prices of implantable prostheses in Australia reveals some startling practices.

The benchmark pricing for IOL in Australia is set by a document called the Basic Table of Benefits for Surgically Implanted Prosthesis.[8] This is a document compiled and published by the Commonwealth Department of Health and Family Services. Its main purpose is to set the maximum price that health funds are obliged to pay for each of the approximately 7500 listed implantable items. In fact, a prosthesis has to be listed in this document in order to attract payment from an insurer.

The pricing of items in this schedule varies from A$2 for very minor items to A$32 980 for one of the implantable defibrillating pacemakers. For IOL, there are a number of categories and prices, ranging from A$271 for a standard

all-PMMA lens through to A$305 for a silicone foldable IOL and up to $395 for a surface-modified IOL. So, how are these prices struck? The answer is very simple. For every one of the 7500 or so items in the schedule, the price of the item has simply been nominated by the supplier.

From the inception of the schedule more than 10 years ago, the procedure for listing in this schedule has been this. First, that Therapeutic Goods Administration approval is gained for the device, second, application is made for listing to the Department of Health, demonstrating that the device fits within the definitions (which are a little loose) of surgically implantable and, third, the difficult task of thinking up a price to write below the bottom line in the letter of application. This price is then transcribed into the Schedule. Until now, in the history of the Schedule, there has never been an item that has been knocked back on the basis of its price.

Furthermore, until now, the suppliers have had the opportunity to revise their prices twice a year, without having to give any reason. Moreover, when an item is listed generically, for example a foldable IOL, when one supplier submits an application for a price increase, that nominated price becomes the rebatable price for IOL in that category from all suppliers.

Even if the figures in the Schedule were reasonable, and I personally believe that for IOL, at least, they are not, the mechanism by which the prices of all these devices are set is demonstrably unreasonable. There is certainly no evidence base for it. This, of course, is the problem: the Department, by its own admission, has no resources and no expertise to go looking for what is a reasonable cost basis for these items. Nor has there been any incentive or official inclination for it to do so, even though there is now a dawning realization in the Department that there is no accountability in pricing these items and no information whatsoever forthcoming from suppliers about what their real profit margins are.

The evidence base in the Health Department is so low that they do not even have a list of the pricing of comparable items in other countries so that they can keep track of prices when they are falling in the way that IOL prices are around the world.

It will probably come as no surprise to most of you that, for IOL and, indeed, for many of the items in the Schedule, the price quoted in the Schedule document bears little relationship to the price in the open market. A senior executive in the DVA told me that, for an exercise, the Department went through the catalogue prices of a major orthopaedic prosthesis supplier and found that the catalogue cost was, on average, 25% less than the price in the schedule. One item, a hip component, was catalogued at A$2973 cheaper than the Commonwealth Schedule price of A$4000 and another item, also a hip component, is available without negotiation from the suppliers catalogue at A$4708, but the rebatable figure from the Commonwealth Schedule is A$10 000.

Only 20 of the 400 or so items in that catalogue were more expensive than the Schedule figure, usually by quite a small amount. My own enquiries found that one common knee replacement kit can easily be bought from the supplier for A$1760 less than the price quoted in the Schedule. That price difference happens to be almost exactly twice the Schedule fee for the operation to implant the thing.

For IOL, at least one private hospital group buys PMMA lenses for A$120 (the Schedule rebate is A$271) and I know one major supplier of silicone foldable IOL will supply regular customers at A$180 per lens and another at A$160 where the Schedule rebate is A$305.

Price Markups to the Consumer: The Plot Thickens

This would be fine if the cheaper price was passed on to the patient or to their insurer. But, although many hospitals do invoice the health fund or the DVA at the price the item cost them, a substantial proportion of private hospitals bill patients for the maximum amount in the Schedule. In the case of the IOL supplied at A$120, charging at A$271 represents a markup for the hospital of 125%. With foldable silicone IOL bought for A$180, if the patient is charged at A$305, as the Schedule permits, the hospital makes a markup of 70 or 90% if they got them for A$160. These markups represent much more than a reasonable handling or inventory holding charge and are simply a straight profit-generating exercise. As I understand it, when this is done, it is almost always done without disclosure to the patient. It is easy to do it that way because if the patient is insured, they have no direct personal stake in the cost of the prosthesis or the fact that substantial profit is being generated by the selling of the IOL to them. But, if I was an uninsured patient paying my own way, I would certainly be annoyed if I discovered that I was directly contributing A$150 or so to the bottom line of the hospital group's profit in addition to the A$1200 theatre fee, A$290 bed charge, the surgical fee and the A$120 for the Viscoelastic, an item also covered by the Schedule. Fortunately for my blood pressure, the way things stand it would be most unlikely that anyone would tell me. Insurers know that this happens. They do not like it, but it is not illegal and, even if it was, it would be impossible to police. And of course, the markups for IOL pale into insignificance compared with the markups for orthopaedic devices.

Private hospitals are not the only ones doing well from this scheme. Almost all the people I spoke to in my research for this lecture, including the suppliers themselves, assured me, somewhat bitterly, that many ophthalmologists were doing exactly the same thing, insisting on supplying the IOL themselves and, one way or another, billing the insurer or DVA at the full Schedule rate. I am personally unable to

confirm this. I also cannot comment on whether a markup is disclosed to patients when doctors themselves are supplying the lens, but this is certainly an issue that requires further discussion by the College.

It is quite obvious that the marking up of the cost price to the much higher Schedule price is commonplace across the range of items listed in the Schedule and it is quite obvious that the Schedule itself is an artificial and contrived figure, at least for many and, probably, for most of the items. This has led to the bizarre and paradoxical situation where the private health insurance industry faces prices that are artificially fixed at a high level (a non-free market situation), but the public hospital sector is free to negotiate prices of prosthetic items down to whatever they can get them for.

Schedule Manipulation for Profit

There are, apparently, many ways in which to manipulate the Schedule. For instance, a vascular surgeon tells me that when a polytetrafluoroethylene (PTFE) vascular graft is used, and the patient is billed A$1150 for it, the excess is often resterilized and used for another patient who is also billed A$1150 for it. These grafts cost as little as A$387 and the most commonly ordered graft costs the hospital A$977. This seems quite wrong to me. Where a variety of items fall under the one item in the schedule, the price the patient is charged is usually the highest price rebatable in the schedule; in one instance quoted to me by the DVA, the markup was A$3800 on an A$7000 vascular item (DVA, unpubl. data, 1997).

Remedial Action Needed

One may have expected that the private health insurance industry would move to rectify this situation. Yet, until now, they have been strangely quiet. They explain their apparent inertia by the fact that, until now, the amounts of money have been small relative to their total expenditure and that they have many more important issues to deal with. Second, and more importantly, they say that they too have lacked the expertise and resources to track down what reasonable prices they should be happy to pay for prostheses and also the reasonable additional costs that they should pay to private hospitals for handling the prostheses and carrying inventory stock. The people who know about the real costs and real profits in both the supply of the prostheses from the manufacturer and the way in which they are handled commercially to the end-user are simply too few and most are unwilling to talk to the insurance industry. While the Schedule exists in its present form and while there is so little information about real costs, the few attempts that have been made to control marking up have been unsuccessful. If the health insurers were to insist upon payment of the invoice cost into the hospital store, for instance, even if there is, say, a 10% surcharge for handling and inventory costs, this would immediately remove any incentive for the hospital or hospital group to negotiate a lower price with suppliers. In reality, this would present a great temptation to hospitals to agree with suppliers to accept the suppliers invoice at full Schedule levels but come to some 'arrangement' regarding discounts on other items or receive some other benefit that does not appear on an audit of accounts pertaining to prostheses.

These sorts of practices present a scenario that is far removed from the sort of evidence base that the Health Minister is calling for in the setting of medical fee rebate levels.

There is no evidence base at all for the price of any of the items listed in the schedule and no obvious way to acquire one. I think we, not just as doctors, but as a community, need to look at what we accept as a reasonable markup for medical devices over their manufactured cost. For a bottle of wine in a restaurant we readily accept 100% markup; for designer clothes, perhaps 300–400%. But, for medical devices, are we to accept 500, 1000 or 3000% as a reasonable figure? I am told that markups of 3000% are commonplace in the pharmaceutical industry and I suspect that the same order of magnitude presently applies to prosthetic devices. But, if you can buy a Daewoo car, drive away no more to pay, for A$15 000, including the dog, can A$16 000 possibly be a reasonable figure for a knee replacement kit?

Marketing

Most drug and prosthetic companies spend a great deal of money on marketing, much of which is spent merely trying to get us to switch to their brand. Obviously these costs will be factored into the retail cost of the items they are selling. It is reasonable to factor-in research and development costs and the costs of compliance with national regulatory authorities. But, the cost of a marketing blitz for a new IOL or shoulder system should not be borne by patients via inflated pricing that is reflected in their insurance premiums or tax contributions.

The community deserves transparency in understanding how marketing research and development, sponsorship of academic meetings and cross subsidization of other products are figured in to prices.

Summary

The issues boil down to these: first, our community is faced with an explosion in the cost of prosthetic devices: A$300 to 350 million a year, rising at 30% each year.

Second, there is no logic, no accountability, no sense, but very probably huge profits, in the way in which the benchmark pricing of prosthetic devices is set by the Commonwealth Department of Health and the way in which this Schedule distorts the market for these things. There is certainly no evidence to suggest that the price of an IOL should be half the Medicare Schedule fee for cataract surgery.

Third, nobody in the Health Department, the private health insurance industry or the private hospital industry has been able to seriously confront the issue, even though costs have been rising alarmingly for years. The efforts that I have heard about as to how to address the issue have been pathetically irresolute, underresourced and ineffectual and have achieved nothing or nearly nothing up until now. Until last week, not one person I spoke to in any of the government or insurance groups had any idea of what you could buy an IOL for in other countries, even New Zealand. They certainly did not have any form of systematic way to compare prosthetic costs in any other country with local prices as a basis from which to work.

Fourth, the existence of a Schedule listing the maximum amount private funds must pay to patients or hospitals for prostheses virtually guarantees that this is what they will end up paying. Even with the development of contracts between insurers and private hospitals that purport to cover these things, there still seems to be widespread marking up of prosthetic devices without disclosure to patients or their insurers.

The time has come to address this matter before it reaches crisis point. As doctors we sometimes feel impotent when faced with the apparent monoliths of government or the health insurance industry or with the macro-economics of health politics. But, with this issue, we actually know quite a lot on a microlevel, which can help to achieve reform and, therefore, benefit the community. Maybe we should also talk about the cost of spectacles. As individual doctors, whether we are ophthalmologists or orthopaedic surgeons or vascular surgeons, most of us have talked to our patients at some time or another about their hospital bills. We actually know what it is that insurers are buying on their policy holders' behalf and we can help to work out what is fair.

Above all, doctors, hospitals, insurers and the Health Department have a responsibility to act collectively in the best interests of the community they claim to serve.

If we do not act, the community may well respond with growing cynicism about the health industry and its regulators. The public has a right to insist on fairness and accountability in this as in other aspects of their medical care.

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