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PHARMAC and EpiPen for anaphylaxis

In response to the 'Special Series' article by Dr Penny Fitzharris and colleagues on the EpiPen® delivery device for anaphylaxis (http://www.nzma.org.nz/journal/119-1233/1965/), we acknowledge the risks and anxiety related to anaphylaxis.

In essence, EpiPen is a device designed to deliver a cheap product (adrenaline) and improve compliance; however the evidence to hand suggests that this is anything but the case. Its cost utility of $650,000 per quality-adjusted life year gained (when last estimated) reflects this lack of effectiveness in practice, with health gains being less than 1/30th of medicines that PHARMAC typically funds.*

Notwithstanding the very high price charged for a relatively simple device by the supplier, the relatively poor cost-effectiveness is driven by the inefficient and inappropriate usage of the device.

As the authors acknowledge, empirical data suggest that many patients do not know how to use the auto-injector device – let alone a caregiver or bystander unconversant either with the device, the disease process or the indications for urgent use. Overall, it seems that less than a third of patients and parents alike have adequate knowledge of the indications and how to use the device (see endnote†), with similarly infrequent use in practice in children when needed.‡[1] Overseas evidence suggests that patients are reluctant to self-administer,§ many potential prescribers are unversed in its use,** and schools may not have adequate first aid measures to safely manage young children at risk.††

There is also good evidence that patients at significant risk who have been prescribed this device do not carry it with them—or carry expired devices—thus negating the point of prescribing it.‡‡ Although allergy diseases impact on quality of life,[2,3] there is some evidence too that indicates that EpiPen auto-injectors do not appear to reduce the anxiety surrounding anaphylaxis.[4]

PHARMAC is committed to achieving the best population health outcomes within the funding provided.[5] We have a finite health budget and competing needs, and funding one item can mean not being able to fund something else. If funded, annual expenditure on EpiPen could reach $1 million by the year 2010. An ampoule of adrenaline costs $5.25, so it is fair to ask why an auto-injector device costs patients $120 to $190.

Again acknowledged by the authors, it is likely that many patients will carry this device even though they don't need it. As well, there are issues of possible over-use for non-anaphylactic symptoms.§§ Such use is in the context of small but important device-related risks of adverse events.***

PTAC most recently considered the funding of EpiPen at its November 2005 meeting, including cost-effectiveness, continuing to recommend that it be listed with a medium priority. The full PTAC minutes can be found at http://www.pharmac.govt.nz/pdf/1105.pdf

We agree that simply restricting access to defined specialists could risk serious inequities for those patients unable to access or afford them – without necessarily fully addressing other aspects of effective use. Along with access, any future programmes that funded EpiPen would need at least to demonstrate appropriate targeting—alongside rigorous education and anaphylaxis management plans,[6–9] etc. including training.[10]

Adrenaline ampoules, syringes and needles continue to be available fully funded for patients. PHARMAC will remain open to the funding of Epipen devices and examining any further evidence or proposals for a workable system.

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Endnotes:

* Comparative health gains (measured in quality-adjusted life years (QALYs)) relate here to the QALYs gained for the same net spending of DHB funds. Net spending of DHB funds in turn is the combination pharmaceutical costs and nominal savings to other DHB services (http://www.pharmac.govt.nz/pdf/pfpa.pdf).

The cost per QALY of pharmaceuticals funded by PHARMAC within the last five years has generally been less than $20,000, i.e. for every $1 million net spent at least 50 QALYs would be saved. By contrast, every $1 million spent on EpiPen would save 1½ QALYs (i.e. $650,000 per QALY).

† Overseas studies[1,11—13] have consistently estimated that fewer than half of patients and parents are able to demonstrate proper use of the device. When parents were asked to indicate the symptoms of anaphylaxis, 'the majority reported skin rash and shortness of breath but few parents reported specific symptoms that may have indicated upper airway obstruction or hypotension.[1]

‡ In practice, EpiPen seems to be infrequently used in children when needed, e.g. in a retrospective survey in Australia, the device was used in only 29% of recurrent anaphylactic reactions in children prescribed it.[1]

§ 23% of adult patients in one series stated that they would probably not be brave enough to self administer adrenaline—half would seek medical assistance and the other half would ask another person.[14]

** Studies in primary and secondary care settings overseas have shown that most doctors are themselves uncertain about the correct method for use of auto-injectors.[17]

†† Children, especially the very young, will need to have at least one person at their school able to operate the device when needed. One paper[11] found that 77% of children had a device kept at the school, but in 19% of these nobody had ensured that the school had adequate knowledge of both the method of administration and the symptoms of anaphylaxis.

‡‡ In overseas studies, only 50–75% of patients had a device at all times,[14–17] with lower rates in another retrospective series (22% at the time of anaphylactic episodes). In another study,[11] while 86% of families claimed to carry a device at all times, only 71% of this group had one at the time of the clinic-based survey. In addition, 10% of devices were expired—so only 55% of all patients had an unexpired device with them at the time.

§§ In one series, for example, 19% of parents of patients with previous severe anaphylaxis stated they would give adrenaline with the onset of isolated hives, and 11% stated they would give adrenaline without the onset of any symptoms.[11]

*** As patients are often not familiar enough with the device to select the correct end,[11] patients may be at risk of injecting adrenaline into their thumbs – potentially fraught, both because the adrenaline has not been correctly administered when it is needed, and because patients can experience digital ischaemia with consequent sequelae. Although this is a small risk, it again highlights the importance of patient education.

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