Medicines shortages in Australia—the reality

Simon Quilty

Faculty of Medicine, The University of Sydney

EDITORIAL

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Corresponding Author:
Dr Simon Quilty
Menzies School of Health Research, Darwin
Email: simon.quilty@nt.gov.au

The challenge posed by shortages of essential medicines is an international problem that appears to have increasing dimensions over the last decade.[1] Here in Australia, however, the issue remains understated and we are yet to have a national response to this real, but as yet hypothetical, threat to health care.

As a physician working in Katherine Hospital in remote Northern Territory, it is not an unusual scenario to be faced with the reality of being a long way from lifesaving therapeutic options. Shortages are an everyday event, and like flooded roads and cyclones, the realities of expiry dates, complex formularies, and supply chain challenges are a part of day-to-day practice.

Often these shortages merely reflect the realities of a small hospital that does not stock rarely used and expensive drugs. But increasingly it seems that the lack of supply comes from complex trade and manufacturing circumstances beyond our shores and completely beyond our control.

The changing pattern of shortages in our remote hospital is not unexpected, reflecting the well-documented burden of international drug shortages.[2] What is alarming though, particularly with the vulnerabilities of supply in a remote setting, is the lack of national response from government or industry to reduce the occurrence and mitigate the impact of shortages.[2–3]

As a recent example, in May 2013 there was an acute shortage of the generic injectable antibiotic ticarcillin/clauvulanate in Katherine Hospital and the entire region. This antibiotic is used primarily for the treatment of complex diabetic infections. With the wave of metabolic syndrome and diabetes that is washing across indigenous people in this region, this shortage posed a serious problem.

A statewide response was implemented, initially to rationalise and reduce the prescription of this drug, and when stocks had expired, switch to a clinically equivalent alternative, piperacillin/tacobactam. Although there are some theoretical long-term risks associated with such clinical practice, no harm was done. After enduring a few weeks of this shortage, there were warnings from pharmacists that due to the subsequent increase in demand for piperacillin/tacobactam, stocks of this alternative were also running low.

Fortunately, ticarcillin/clauvulanate began to trickle back to pharmacy shelves after a six-week period; however, within a few months the product again became unavailable through national suppliers. Supplies of the alternative piperacillin/tacobactam have not been subsequently compromised.

There were probably no adverse outcomes as a direct result, but the follow-on impact of shortages is complex, and adverse outcomes are probably happening without recognition. For instance, it has been clearly documented that with this kind of switching to alternative treatments to get around a shortage, medical and nursing staff unaccustomed to the use of the replacement could easily make consequent errors in prescription and dosing.[4]

From the point of view of a remote physician, there are serious concerns about the relative lack of transparency regarding the cause of the shortage, where the bottleneck was, and how long it would take to resolve. Despite the subsequent resolution of this particular problem of piperacillin/tacobactam, it has now been suggested that this product will become permanently unavailable.

The lack of transparency regarding shortages of essential medicines and other medical equipment here in Australia is particularly apparent when comparing responses to this problem internationally. For example, the Food & Drug Administration (FDA) in the United States has a dedicated website listing all drugs in short supply, the reason for the shortage, and expected date of resolution.[5] Likewise in Europe, the European Medicines Agency has officially recognised this global phenomenon and has short- and medium-term actions to counter these trends.[6]

Medicines at greatest risk of short supply include off-patent drugs that have reduced profit margins associated with manufacture and marketing, and injectables, particularly those that are off-patent like ticarcillin/clauvulanate, that are challenging and expensive to manufacture.[8]

It is reassuring that Australia's Therapeutic Goods Administration (TGA) has recently launched the Medicines Shortage Initiative website that directly deals with some of these issues—identifying drugs vulnerable to short supply and estimating a date where normal supply will recommence.[7] This initiative allows sharing of information and enables health services to coordinate a transparent and national approach to known shortages. However, shortages can come upon a supply chain with very little notice, and while this is a very valuable initiative, the global causes of shortages still need to be addressed in a nationally strategic manner.

In a region like Katherine in Australia's remote Northern Territory it is these drugs—long-acting penicillin, anti-TB medicines, injectable generic medications—invented years ago and still very useful for diseases of poverty, that are most vulnerable to short supply.

In the last 10 weeks, there have been two young Aboriginal men present to this hospital dying from advanced pulmonary tuberculosis. With the use of old-fashioned anti-TB medications their lives have been saved, yet there have been recent articles in the medical literature and popular international press alluding to critical shortages of anti-TB medications worldwide.[9-10]

Yet still no one in my network seems to clearly understand why the Northern Territory experienced critical shortages of ticarcillin/lauvulanate, adrenaline mini-jets, injectable haloperidol, phenytoin, or benztropine at this hospital and presumably across Australia over the past few months. Hopefully the new TGA website will ease this uncertainty, but there remains a general and blissful unawareness amongst my profession that a shortage of critical anti-TB medications in India could potentially be the harbinger of shortage of critical medicines and subsequent preventable deaths in Katherine.

The vast distances in Australia's remote outback make for forced reflection of the critical need for timely provision of essential medicines and supplies. After the lead of the US and Europe, it is vital that Australia and the region recognise this issue and develop short- and long-term strategies to ensure sustainable supply chains, and the TGA's recent progress is reassuring. We are already slow off the mark, as attested by the growing body of literature on this subject in reputable international medical journals and the relative absence here in Australia. It is time to build on this recent initiative by the TGA to ensure sustainability of supply of the most important medicines into the future.

References

1. Chabner BA. Drug shortages – a critical challenge for the generic-drug market. N Engl J Med. 2011;365(23):2147–9.
2. Kuehn B. Despite curbing new drug shortages, shortfall of drugs a persisting problem. JAMA. 2013;309(6):532–3.
3. Quilty S, Harris LM, Kewley J, Jones A, Pearce R, James R, McGain F. A pandora's box: sustainable pharmaceutical supply. Med J Aust 2011;195:510–11.
4. Pearce R, Kewely J, Quilty S. Letter: A Pandoras Box: sustainable pharmaceutical supply. Med J Aust. 2011;195(9):510–1.
5. Rochon PA, Gurwitz JH. Drug shortages and clinicians: no time for complacency. Arch Intern Med. 2012;172(19):1499–500.
6. US Food and Drug Administration. Current Drug Shortages. [cited 2014 April 24] Available from: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm314743.htm.
7. Australian Government. Department of Health Therapeutic Goods Administration. Available from: http://www.tga.gov.au/hp/MSI/search/.
8. European Medicines Agency. Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice compliance problems. November 2012. EMA/590745/2012.
9. Warkentin J (CDC). Impact of shortage of first-line antituberculosis medication on tuberculosis control – United States, 2012–13. MMWR. 2013;62:398–400.

10. Mascarenhas A. City runs short of anti-tuberculosis drugs for children. The Indian Press. 2013 June 25. [cited 2014 Apr 24]. Available from: http://www.indianexpress.com/news/city-runs-short-of-antituberculosis-drugs-for-children/1133423/.

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CONFLICTS OF INTEREST

The author declares no conflict of interest.