

of hand hygiene (appendix). An appropriate hand hygiene programme can prevent ten nosocomial infection episodes in very low birthweight infants admitted to a neonatal intensive care unit every year, with a cost saving of US\$10 000 per episode (reference 7 in appendix). Hand hygiene is very effective in combating nosocomial respiratory pathogens (reference 8 in appendix).

Rupp and colleagues<sup>6</sup> noted no significant reduction in rates of nosocomial infection with improved hand hygiene. However, they suggested, probably correctly, that this finding might be a result of the fact that their study was underpowered, the original baseline level of nosocomial infections in the hospital was low, and the 70% rate of adherence to hand hygiene was not high enough to reduce rates of infection.

The US Center for Disease Control and Prevention's guidelines for prevention of intravascular catheter-related infections include hand hygiene and other aseptic measures. In China, a handwashing campaign has been acclaimed as the most effective yet economical method for prevention of infections (reference 8 in appendix). As WHO states, handwashing is a starting point of infection control.<sup>7</sup>

The conclusion of the Comment by Sepkowitz, that the infection control community might do well to move on, does not seem such good advice when the aforementioned evidence is considered.

We declare that we have no conflicts of interest.

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## Counterfeit antimalarial drugs

Medicines for Malaria Venture (MMV), a not-for-profit research foundation, agrees with Gaurvika Nayyar and colleagues in their appraisal of the poor quality of antimalarial drugs available in southeast Asia and sub-Saharan Africa.<sup>1</sup> MMV is committed to the discovery and development of high-quality antimalarial drugs, and works to facilitate their delivery to vulnerable populations and health-care systems as widely as possible in countries where malaria is endemic.

We at MMV recognise that that counterfeiting of antimalarial drugs is a multi-billion-dollar business, with very sophisticated operators and an excellent ability to evade detection by drug-regulatory authorities in Africa and other continents. Similarly, we understand that the global trade in fake medicines supersedes billions of dollars' worth of real drug products and potentially kills up to 100 000 people every year.<sup>2</sup> Counterfeit traders mainly operate in developing countries, but developed countries are not safe from this threat.

We agree with Nayyar and colleagues that production and distribution of counterfeit antimalarial drugs, or indeed any drug, should be deemed a crime against humanity. Drug counterfeiters prey on susceptible people at their weakest moments. Therefore, we support WHO's call<sup>3</sup> for

countries to take extra measures to try to quash the manufacture of illegal and substandard malaria products, which endanger patients and put the effectiveness of authentic artemisinin at risk. Moreover, we support the call for greater national capability to control the quality of drugs at the point of import and by random sampling of the retail chain, which will enable drug-regulatory authorities to protect the worldwide drug supply.<sup>1</sup> We welcome the development of innovative technologies, such as Sproxil, which uses point-of-sale scratch codes and short message service (SMS) technology to allow buyers to send an SMS to verify the legitimacy of the drugs they are purchasing, thus helping consumers to protect themselves from counterfeit products.

DR is a former employee of Roche and holds stock in the company. JB declares that she has no conflicts of interest.

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## Universal access to quality medicines: prioritisation of a-priori solutions

In the June issue of *The Lancet Infectious Diseases*, Michael Seear<sup>1</sup> discussed the extent and consequences of poor pharmaceutical quality. We fully agree that sustainable actions are urgently needed to address the scourge of poor-quality medicines, which disproportionately hits developing countries, where drug regulation is

often inadequate or insufficiently enforced—even in middle-income countries.<sup>2</sup> The 20-year-old political controversy about the various non-mutually-exclusive definitions of counterfeit and substandard continues. However, since the 65th World Health Assembly, which approved a new member-state mechanism proposing international collaboration on so-called substandard, spurious, falsely-labelled, falsified or counterfeit medical products,<sup>3</sup> momentum to shift the prime considerations from intellectual property rights to public health is building. Seear appropriately points out that, despite the absence of accurate estimates, counterfeits are probably only a small proportion of all the poor-quality medicines worldwide.

These observations should lead to the right choice of remedial measures. For instance, if the bulk of poor-quality medicines are from legitimate manufacturers who occasionally or systematically neglect quality standards (which is often the case in low-income countries), priority should be given to a-priori actions to prevent the production and distribution of substandard drugs. A-posteriori detection would spot some bad medicines, but would not address the root problem. Validated

field detection methods are useful for research purposes (to estimate the extent and distribution of the problem) and very basic random quality control, but they cannot systematically prevent poor-quality medicines from reaching patients. The role of technology, such as radiofrequency tags, seems limited to tracing and detection of illegal production of counterfeits; effects on so-called legitimate substandard medicines are negligible.

Structural investments supported by a strong political commitment are needed to develop and enforce efficient regulatory oversight of pharmaceutical products in low-income and middle-income countries. Furthermore, stringent repercussions, such as temporary or definitive withdrawal of manufacturing or import licences, need to be enforced for manufacturers that do not implement corrective actions to adhere to quality-assurance standards. If such actions are not taken, the problem of multiple (and variable) quality standards<sup>4</sup> will not be redressed. In a 2012 Editorial,<sup>5</sup> *The Lancet* provided a stark example of this problem. In India, nine officers staff the national drug regulatory authority headquarters and have to

deal with 20 000 new applications per year. As long as regulatory oversight is not equally enforced everywhere, detection technologies might help to monitor the problem but cannot make any substantial changes to the status quo in which the most vulnerable patients remain exposed to the serious and often fatal consequences of substandard medicines.

We declare that we have no conflicts of interest.

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