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Malaria Drug Shortages in Kenya:

A Major Failure to Provide Access to Effective Treatment

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Abstract

A key bench mark of successful therapeutic policy implementation, and thus effectiveness, is that the recommended drugs are available at the point of care. Two years after artemether-lumefantrine (AL) was introduced for the management of uncomplicated malaria in Kenya, we carried out a cross-sectional survey to investigate AL availability in government facilities in seven malaria-endemic districts. One of four of the surveyed facilities had none of the four AL weight-specific treatment packs in stock; three of four facilities were out of stock of at least one weight-specific AL pack, leading health workers to prescribe a range of inappropriate alternatives. The shortage was in large part caused by a delayed procurement process. National ministries of health and the international community must address the current shortcomings facing antimalarial drug supply to the public sector.

The widespread failure of chloroquine and sulfadoxine pyrimethamine (SP) in the treatment of malaria in Africa during the late 1990s resulted in a turbulent public health debate, which led to universal acceptance that mono-therapies that failed to cure up to one in four patients should be replaced by highly efficacious artemisinin-based combination therapy (ACT).¹⁻³ More than 40 countries in Africa have now adopted ACT as their first line treatment recommendation for uncomplicated malaria.⁴ Beyond the difficulties of changing national treatment policies, a key bench mark of successful policy implementation, and thus effectiveness, is that the recommended drugs are available at the point of care.⁵⁻⁷ In most countries, ACTs are supplied only to the public, formal health sector managed by the government and its mission sector partners. In 2006, Kenya implemented a change in malaria treatment policy in all public facilities from SP to the ACT artemether-lumefantrine

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(AL), largely supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).⁷

Two years after AL introduction, we carried out a cross-sectional survey to investigate AL availability in government facilities. From August 18 through October 2, 2008, 164 facilities (115 dispensaries, 30 health centers, and 19 hospitals) were assessed in seven districts in Nyanza, Western, and Coast Provinces, Kenya, that were highly endemic for malaria. At each facility, information was collected on the availability of AL packs for the four patient weight groups either through direct review of stock cards or through phone interviews. Health workers were also asked what they prescribed in the absence of AL.

One (25.6%) of four of the surveyed facilities had none of the four AL weight-specific treatment packs in stock, with such complete stockouts more common in dispensaries (30.4%) than in health centers (20.0%) and hospitals (5.3%). Furthermore, three (75.0%) of four facilities were out of stock of at least one weight-specific AL pack (Table 1). It was particularly worrying that packs for the youngest age group, the group most at risk of malaria mortality, were absent in nearly two-thirds (61.0%) of facilities. The median duration of current stock-outs was substantial, ranging from 35 days (interquartile range [IQR] = 12-83 days) for the 12-tablet pack to 52 days (IQR = 22-99 days) for the 24-tablet pack (Table 1). Of the facilities out of stock of all packs, they had been in this state for a median of 52 days (IQR = 16-76 days). Health workers were asked what they prescribed if AL were out of stock (some gave more than one suggestion). Of the 195 alternatives specified, 26.2% were quinine, 25.6% were amodiaquine, 24.6% were SP, and the remaining 23.6% were recommendations for patients to seek various combinations of drugs from the private market including ACTs and artemisinin monotherapies. The frequency of AL stockouts was greater than those documented in 2007, when only 5% of facilities had none of the four packs in stock.⁸

Reasons for the high frequency of drug stock outs are likely to be varied and reflect perennial problems facing weak health systems in resource-poor countries struggling to define procurement needs, manage stock flows with limited information from the periphery, or address funding shortages. However, discussions with government stakeholders indicated that the nationwide shortage of AL during the survey period was in large part caused by delayed procurement. These delays resulted from a range of factors, some stemming from the best intentions.

To increase competition and achieve better value for money in mid-2007, the GFATM decided that 75% of Kenya's annual AL order must be sourced through an international open tender, in contrast to the direct procurement previously used through the special ordering agreement established between Novartis Pharma and the World Health Organization. Confusion in communicating this decision delayed the start of the tendering process to late 2007, and the opening of the tender until February 2008. Further delays arose because of the difficulty in obtaining compliant tender bids.

Finally, evaluating the tender bids took longer than expected because the Kenyan tender committee was being investigated for allegations of corruption. The tender was finally awarded in May 2008 to the Indian firm Ajanta Pharma Limited. The first AL consignment was promised in October 2008, but had not arrived by the end of the year. This delay was reportedly partly due to the slow process of quality assurance testing procedures, which had to be carried out on each batch of AL before its supply. Although the drugs were approximately half the cost of those obtained by direct sourcing, their arrival is going to be too late and the situation described in Table 1 is likely to worsen. This chain of events left

Kenya with disastrously low AL stocks. Similar availability problems have been experienced elsewhere in sub-Saharan Africa.^{9,10}

The international community responded promptly to calls to replace failing medicines but now must turn its attention to failures in supply to fix problems of access and effectiveness of ACT policies in Africa. Lessons should be learned from the recent Kenyan experience. National governments must ensure that procurement processes begin promptly and are administered efficiently. Although open international tenders may have clear benefits in terms of cost, insistence on open tendering should be avoided where this could lead to unacceptable delays. International agencies must recognize that without flexibility around ACT procurement procedures, the public health benefits of ACTs are lost and all other efforts to improve case management will be wasted.

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Table 1

Frequency of artemether-lumefantrine (AL) stock-outs and their durations, stratified by AL pack sizes*

| Type of pack | Stock-out on survey day, n = 164 (%) | No of stock-out days, [†] median (IQR) |
|---------------------------|--------------------------------------|---|
| All AL packs | 42 (25.6) | 52 (16-76) |
| 6-tablet pack (5-14 kg) | 100 (61.0) | 37 (7-73) |
| 12-tablet pack (15-24 kg) | 71 (43.3) | 35 (12-83) |
| 18-tablet pack (25-34 kg) | 71 (43.3) | 43 (6-84) |
| 24-tablet pack (35 kg) | 87 (53.1) | 52 (22-99) |
| Any AL pack | 123 (75.0) | 47 (20-95) |

* IQR = interquartile range.

[†] Denominators include facilities without specific AL pack on survey day for which retrospective stock-out data were available: N(all AL packs) = 25; N(6 tablet pack) = 68; N(12 tablet pack) = 46; N(18 tablet pack) = 42; N(24 tablet pack) = 66; N(any AL pack) = 83.