Summary points

Removing user fees for primary care is important in offering financial protection to poor African households

Fee removal must be accompanied by increased national budgets for health care to protect the quality of health care in the face of increased utilisation

Careful and deliberate implementation strategies are needed to ensure that fee removal achieves its objectives

National action must be supported by international action that is sensitive to national circumstances and underpins the sustained mobilisation of resources

Health in Southern Africa, EQUINET, and HEPNet, the Health Economics and Policy Network in Africa). It responds to current calls, such as those of the Africa Commission, for the removal of primary care user fees in Africa. An earlier, substantively different, version of this piece was prepared by the authors as an editorial for the electronic newsletter of EQUINET.

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System and market failures: the unavailability of magnesium sulphate for the treatment of eclampsia and pre-eclampsia in Mozambique and Zimbabwe

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Low cost and effective drugs, such as magnesium sulphate, need to be included in initiatives to improve access to essential medicines in Africa

Ensuring the availability of effective drugs for priority health problems remains a key public health issue in many African countries.[1] Market deficiencies in ensuring drug development for "neglected" diseases affecting developing countries are well described,[2 3 w1] and several global initiatives are attempting to tackle this.[4 w2] Even when low cost, effective treatments exist, however, drug availability for many common health problems remains poor in many settings, limiting progress towards achieving the millennium development goals.[5]

One such health problem is the management of pre-eclampsia and eclampsia, important causes of maternal and infant morbidity and mortality. Over 63 000 women die annually after eclamptic convulsions, with 99% of these deaths occurring in low and middle income countries.[6 7 w3]

Evidence is strong for the effectiveness of magnesium sulphate in treating and preventing eclampsia.[8–10 w4 w5] Magnesium sulphate costs $0.35 (£0.19; €0.29) per ampoule (40 ml of 10% magnesium sulphate; Central Medical Stores, Mozambique, April 2005) and has appeared on the World Health Organization's essential medicines list since 1996.[11] It is of great concern that this effective and low cost drug is

Details of drug regulation, web references w1-w9, and Table 2 are on bmj.com

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TEUN VOERENPANOS

A pregnant woman has a check up at a clinic in a camp for internally displaced people

still unavailable in many countries.[12 13 w6 w7] We describe problems with the registration, approval, acquisition, and distribution of magnesium sulphate, and hence its availability to clinicians, in Mozambique and Zimbabwe, two countries with high maternal mortality ratios (table).[14–16] We draw on a range of sources, including a bibliographical review of policies concerning magnesium sulphate over the past 25 years and qualitative data collected as part of a case study of policy making and procurement for magnesium sulphate in the two countries (box 1),[17] to argue that drug availability has been affected by system and market failures.

Why is magnesium sulphate not widely available in Mozambique and Zimbabwe?

Mozambique

Magnesium sulphate has been used in Mozambique's Maputo Central Hospital since 1981, well before rigorous evidence of its effectiveness became available. An obstetric guideline published in 1985 described magnesium sulphate as the first line drug for treating eclampsia. Until recently, however, it was unavailable outside the hospital, and other drugs, including diazepam, continue to be used as first line treatment.

The key reasons for this lie in the complex mechanisms of approval, acquisition, and distribution of drugs in Mozambique (see bmj.com). The national formulary of medicines lists the essential drugs that can be acquired by, and distributed through, Mozambique's national health system. The 1980 edition did not include magnesium sulphate and this was not updated until 1999. In this period the Central Medical Stores compiled a list of purchases that included both the medicines listed in the formulary and other drugs that clinicians regarded as necessary. Magnesium sulphate had not been requested by clinicians, however, and was therefore not included. This meant that it had to be ordered locally, but this was only done by the Maputo Central Hospital, and only when funds were available. During this period, economic constraints resulting from the war affected the availability of many drugs, particularly those not on the list of the Central Medical Stores. In addition, pharmaceutical companies were poorly represented in Mozambique at this time and participated only in international competitive tenders.

When the formulary was updated in 1999 it was decided that medicines for specialist and hospital use would be included in a special appendix to better control their use. Although magnesium sulphate was seen as important for the management of eclampsia, there was consensus that it should appear only in this list. For reasons that remain unclear, this appendix was not included in the Central Medical Store's list of purchases when the new formulary came into force. Medicines in this appendix could still be acquired, but required special import procedures, including a request by clinicians, review by the Therapeutic Commission, and authorisation from the Ministry of Health. This was a major barrier to procurement.

Maternal mortality ratios in Mozambique and Zimbabwe

Country	Maternal mortality ratio*	Proportion of mortality attributable to eclampsia (%)
Mozambique	1000	3.2 to 11.3[15 w8]†
Zimbabwe	1100	6.9[16]

*Number of maternal deaths per 100 000 live births.[14]
†Robust national estimates are not available. Range given is based on estimates provided in listed studies.

Box 1: Methods used for case study of policy making and procurement for magnesium sulphate in Mozambique and Zimbabwe

Data collection approach

- In-depth, semistructured qualitative interviews and informal discussions covering:
  - The structure and process of policy making for the management of eclampsia and pre-eclampsia
  - Factors affecting the implementation of policies on the issues of interest
  - Individual's knowledge of evidence related to the use of magnesium sulphate in the treatment of eclampsia and pre-eclampsia

Summary of methods used for case study of magnesium sulphate policy making and procurement in Mozambique and Zimbabwe

	Characteristics of respondents	
Position	No in Mozambique	No in Zimbabwe
Clinicians or researchers	5	7
Senior Ministry of Health officials	4	2
Therapeutic Commission	2	2
Medicine Control Authority	2	2
Pharmacist	1	3
Pharmaceutical company representatives	—	3

Sampling

- Purposive and snowballing approach, based on respondents' involvement in policy making or procurement for magnesium sulphate

Data analysis

- All interviews audio recorded and transcribed
- Categories emerging from the data identified and a coding frame developed
- Coding frame applied to all transcripts
- Country level themes compared and similarities and differences identified

Discussions in 2001 between clinicians, Ministry of Health departments, and the Therapeutic Commission culminated in authorisation for the central purchasing of magnesium sulphate. Since 2003 the drug has been distributed to peripheral units, but again only when requested by the local clinicians. Routine data show that these requests have been sporadic.

In discussing these ongoing problems with the approval, acquisition, and distribution of magnesium sulphate since the publication of the landmark collaborative eclampsia trial in 1995, obstetrician respondents claimed that although they had contributed to the development of guidelines for obstetric care, including the management of eclampsia, and had trained health professionals in using magnesium sulphate, they did not have the authority to ensure a countrywide implementation of the guidelines.

Respondents from Central Medical Stores, however, noted that these problems were the result of obstetricians not requesting the drug. Poor communication between the two groups seemed, then, to be an important obstacle to improving drug availability. Even after formal approval of the drug, difficulties with distribution and management gave the impression to clinicians that the drug was still unavailable. As a result, they continued to use alternative treatments and did not request magnesium sulphate from the Central Medical Stores or the pharmacy in their own health unit.

Zimbabwe

Magnesium sulphate has long been used for the treatment of eclampsia in Zimbabwe, including at Harare Central Hospital since at least 1984-5 (see table on bmj.com). It is still not registered for this use, however, and was listed in 2000 in the essential drugs list as a second line therapy for eclampsia. Respondents cited four key reasons for this. Firstly, the effects of insufficient capacity and resources within the Ministry of Health and Child Welfare: as foreign currency resources are limited, the ministry decided that local (that is, hospital based) arrangements should be made to acquire what they described as "orphan" drugs—those required mainly by hospital based specialists. Priority for central purchasing is given to first line drugs used at all levels of the health service. It was also suggested that the Ministry of Health and Child Welfare does not have sufficient qualified clinicians to monitor drug use or even to prescribe the drug in peripheral hospitals.

Secondly, the ministry and professional obstetric organisations failed to ensure the registration of magnesium sulphate with the Medicine Control Authority of Zimbabwe: the drug was not seen as a priority because it was perceived to be slow moving and because pharmacists at the Ministry of Health and Child Welfare thought that other drugs, such as diazepam, could be substituted.

Thirdly, pharmaceutical companies lacked financial incentives to push for registration and importation: several respondents noted that the low cost of magnesium sulphate, coupled with the low potential volume of use, resulted in low returns. It is unclear to what extent drug registration fees, currently Z$5m (£277; $500; €409) for Zimbabwean applicants per drug or US$1000 for foreign applicants per drug, are a barrier. Although relatively low by international standards,[18] these fees, together with the costs of preparing a submission and bureaucratic barriers, may dissuade commercial companies from applying for registration in this small market.

Finally, clinicians' perceptions of the dangers of magnesium sulphate may have contributed to the drug's non-use. Respondents acknowledged that the international trials in which Zimbabwe collaborated showed clearly that the drug saves lives. They also noted, however, that the belief of many Zimbabwean clinicians in the drug's effectiveness is tempered by their perceptions of its dangers to women. This was seen to contribute to its second line listing in the essential drugs list.

Respondents highlighted several other factors affecting the availability of magnesium sulphate. These included the lack of a clinical champion, poor communication between clinicians and pharmacy staff, the ambiguity of clinical guidelines from the Ministry of Health and Child Welfare on the use of magnesium sulphate, inadequate dissemination of guidelines, clinicians' long use of other drugs to manage eclampsia, and constraints on human resources. Consequently, diazepam continues to be used by many clinicians in Zimbabwe as first line therapy for the management of eclampsia.

Although magnesium sulphate remains unregistered, clinicians have since convinced the Medicine Control Authority of Zimbabwe, the Ministry of Health and Child Welfare, and the National Drug and Therapeutic Policy Advisory Committee of its usefulness. It can, therefore, be used without registration but still has to be requested by clinicians from their local pharmacy—a process that depends on the availability of local resources.

System and market failures in ensuring the availability of magnesium sulphate

The issues affecting the availability of magnesium sulphate can be divided broadly into the two categories of system and market failures. We identified several key system failures. Firstly, issues related to drug registration were important in both countries. In Zimbabwe,

Box 2: Criteria for and barriers to the operation of a free market for magnesium sulphate in Mozambique and Zimbabwe

Many independent producers and consumers

Only one major consumer of the drug—the central government purchaser—is responsible for national acquisition

Full information on both sides about prices and quality

Asymmetries in information exist as the central purchaser does not assess need for the drug among clinicians and is therefore unaware of demand.

The central purchaser also does not receive information from the producers on drug effectiveness

No external effects (that is, costs or benefits accruing to individuals or groups other than those undertaking the activity)

If a pharmaceutical company marketed a low cost generic dug such as magnesium sulphate, this could increase the market share of other companies producing the drug—that is, positive external effects. In contrast, branded products have higher profit margins as other companies are legally prevented from selling the same drug. Marketing thus increases the sales of the branded product only.

Incentives are few under a central tendering system for companies to market drugs to clinicians

Box 3: Recommendations to improve the availability of magnesium sulphate

- Governments need to ensure that:
  Bureaucratic processes do not obstruct the delivery of low cost, effective drugs
  Mechanisms are put in place for improved communication between clinicians and agencies responsible for drug procurement and supply at country level
- WHO, international professional organisations such as FIGO (International Federation of Gynaecology and Obstetrics), and international donor agencies, should take a more active role in ensuring that all essential medicines are registered and available in developing countries
- Pharmaceutical companies need to be engaged in initiatives to ensure the supply of low cost, effective drugs for common conditions in Africa; financial and other incentives for marketing these drugs need to be considered by international agencies
- When the conditions for a functional market for pharmaceuticals are not met, governments must be prepared to intervene to support public health, and international organisations should support them in this

long delays in registration were described. In Mozambique, the absence of a registration mechanism before 2001 resulted in the development of a complex drug procurement process, with many opportunities for failure. Secondly, long delays occurred in both countries in including magnesium sulphate in their national formularies. Because drug purchasing is based on these formularies, any failure to include effective drugs such as magnesium sulphate is critical. Thirdly, the numerous opportunities for communication failure within the bureaucratic processes of drug registration, inclusion in the formulary, acquisition, and distribution further contributed to the poor availability of magnesium sulphate. The earlier and current economic difficulties in Mozambique and Zimbabwe, respectively, also affected the procurement of drugs.

As magnesium sulphate is a cheap generic drug, its cost should not be a barrier to its availability in a free market. For a free market to operate, several criteria need to be fulfilled (box 2).[19] It is not unusual for some or all of these criteria not to be met, but the more marked the departure from these criteria, the less likely that a market can function. Several of these criteria were not met for magnesium sulphate in Mozambique or Zimbabwe (box 3), suggesting that market failure contributed to the poor availability of the drug. Similar failures have been described for other pharmaceuticals elsewhere,[3 20 w8] including for other cheap, effective drugs such as thiazides[w9] and ibuprofen.[20]

The low cost of magnesium sulphate had several paradoxical effects. It was suggested that its price retarded its registration in Zimbabwe, as the potentially small profits provided little economic incentive for companies to incur registration costs. Respondents in Mozambique noted similarly that because the drug was cheap and the potential profits from it low, pharmaceutical companies did not actively market it or promote it to the central purchaser.

These problems seem to have been compounded by the lack of economies of scope for the drug. The market for magnesium sulphate is relatively small and the drug is not widely used for other conditions. Economies of scale are also unlikely, given that eclampsia is relatively uncommon and that the drug is already low cost. Economies of scope are important to both the health system and the manufacturer—they give additional incentives to the purchaser to consider the drug and they increase the size of the market (and hence opportunities for profit) for the manufacturer. Alternative drugs for the treatment of eclampsia, while substantially less effective, are also cheap and used widely for other conditions. They are therefore generally available at health unit level, and pharmaceutical companies do not incur costs in promoting them.

Conclusions

The complexity of drug approval, acquisition, and distribution mechanisms in Mozambique and Zimbabwe results in many opportunities for system failures. Cost is also an important factor in the availability of magnesium sulphate, but not because the drug is expensive. Rather, its low cost means that market forces cannot be relied on to ensure its availability in these settings. Box 3 outlines several recommendations to address these system and market failures.

As initiatives are developed to ensure wider access to expensive drugs critical to improving public health in Africa, low cost and effective drugs such as magnesium sulphate for treating eclampsia, should not be forgotten.

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Contributors and sources: This article arose from discussions within our research team while conducting a study of the use of research evidence in policy making in Mozambique, South Africa and Zimbabwe. GW, JC, and SL designed the study. SM, ES, and AM collected the data. ES, SM, AM, JC, and GW led the

Summary points

Evidence from randomised controlled trials shows that magnesium sulphate, a low cost drug, is effective for the treatment of eclampsia and pre-eclampsia

The drug, like many other effective treatments, is still not available widely in many low and middle income countries, but the reasons for this remain unclear

Failures in the registration, procurement, and distribution mechanisms for magnesium sulphate contribute to its poor availability in Mozambique and Zimbabwe

In addition, the low cost of magnesium sulphate means that market forces cannot be relied on to ensure its availability

Governments and international agencies must be prepared to intervene to ensure the availability of low cost, effective drugs in developing countries

analysis, to which the other authors contributed. ES, SL, and ADO led the writing of the paper, to which the other authors contributed. ES and SL are guarantors.

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Gaining a foothold: tackling poverty, gender inequality, and HIV in Africa

Julia C Kim, Charlotte H Watts

Over half of adults infected with HIV in Africa are female—but poverty and social structures still prevent many women from protecting themselves

The United Nations millennium development goals have set out specific targets for 2015, including commitments to reduce extreme poverty, increase women's empowerment, and reverse the spread of the HIV pandemic. In this respect, they clearly recognise what has been called the triple threat facing Africa: poverty, gender inequalities, and HIV and AIDS.[1] Tackling these issues is clearly difficult, and many people have greeted these goals with a sense of scepticism and even futility. We describe why tackling poverty and gender inequalities is central to controlling the HIV pandemic in Africa and suggest how it might be achieved.

Women and HIV

Two years ago, the UN secretary general Kofi Annan declared that "AIDS has a woman's face."[2] Echoing this statement, the Joint United Nations Programme on HIV and AIDS (UNAIDS) has highlighted women, girls, and HIV and AIDS as the theme for their most recent World AIDS Day campaign. Today, women account for nearly half the 40 million people living with HIV worldwide. In sub-Saharan Africa, 57% of adults with HIV are women, and young women aged 15 to 24 are more than three times as likely to be infected as young men.[3]

Contradictory analyses of Uganda's success in tackling HIV and AIDS have sparked debates over the relative prevention merits of promoting condoms, sexual fidelity, or abstinence. The United States has increased its funding for abstinence-only strategies, while the Catholic Church has questioned the efficacy of condoms, raising concerns about the influence of ideological or religious perspectives in shaping global priorities for prevention.[4] Yet a larger question remains. Regardless of their point of emphasis, why are HIV prevention efforts continuing to fail women and girls?

The prevention messages, whether urging women to abstain, be faithful, or use condoms, often fail to reflect the reality of women's lives and, in particular, the broader social forces that contribute to their risk. In settings where limited educational or economic opportunities exist, pressures of poverty lead women and girls to trade sex for survival. Where women have low status and financial autonomy, and depend on their partners for support, abstaining from sex or negotiating use of condoms are simply not realistic options. Moreover, physical and sexual violence affect women's ability to

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