Drug use in sub-Saharan Africa: quality in processes—safety in use

F Smith

Drug use in developing countries, which has often been described as “irrational”, is influenced by a wide range of factors. Interventions to promote safe and appropriate drug use must be delivered in the context of local services and settings.

Many researchers in developing countries have described drug use as “irrational”, documenting cases of ineffective, unsuitable, sub-optimal or unsafe prescribing, supply and/or consumption of pharmaceutical products. Drug use in these countries is influenced by many factors: health and drugs policy determines the legal frameworks for drug use and its regulation; the organisation and processes of healthcare provision affect access to professionals and drug therapy; and there are commonly big differences in the availability of drugs and services between regions (notably urban and rural areas). Provision and uptake of care are limited by financial constraints on the part of governments and individuals. Problems of access to objective product information, the role of the pharmaceutical industry in production and marketing, the prevalence of counterfeit products, and the difficulties of regulating professional practice and product quality are well recognised. In sub-Saharan Africa traditional and western medical practices commonly operate side by side: drugs are used in the context of local health beliefs, cultural traditions, and individuals’ perspectives and preferences regarding the appropriateness of different courses of action and drug use.

Interventions to promote safe and appropriate drug use are seen as a vital response to the health problems of developing countries. In 1981 the World Health Organisation set up its Action Programme on Essential Drugs to provide operational support and guidance to developing countries in the establishment of national drugs policies.¹ Over 80% of African countries now have national drugs programmes which initially focused on ensuring wider access to essential drugs. However, measures to improve drug use may be conceived at different levels and focus on any of a broad range of issues, from policy and regulation at a governmental

level to prescribing practices and adherence rates at a practitioner/client level.

It is widely recognised, in industrialised as well as developing countries, that adherence to recommended medication regimens is often poor, potentially resulting in treatment failure. Boonstra and colleagues² in this issue of *QSHC* show how the quality in the processes of care—in this case, dispensing procedures and labelling of medicines—affects patient knowledge which is seen as a prerequisite for adherence to medication. In the measurement of patient knowledge of medication researchers generally focus on the name and purposes of the medication, the dose, frequency of dosing, duration of treatment, and sometimes side effects³ because these elements are viewed as essential for safe and appropriate use. Labelling that is both correct and includes the relevant dosage information is also believed to be important. Researchers are generally aware of the tenuous relationship between knowledge and medication-taking behaviour. It is acknowledged that adherence is influenced by many factors including access to care, affordability of medication, and information and beliefs regarding the need for treatment. However, a recent study in public health facilities in Ghana⁴ demonstrated a link between improved patient information and labelling and adherence rates.

The value of trained staff to the quality of the dispensing process is shown by Boonstra *et al.*² In many developing countries the more highly qualified professionals tend to be concentrated in the urban areas—for example, 837 of the 964 pharmacies in Ghana are in and around Accra and Kumasi, the country’s two largest cities.⁵ To obtain data representative of the different locations, Boonstra *et al* selected study sites that would reflect interregional differences in service provision. A more equitable distribution of

trained staff across the country may be contingent on wider socioeconomic development, infrastructure, and amenities. However, Boonstra *et al* concluded that some training, even if limited, may lead to improvements in the quality of the prescribing and dispensing process and consequent outcomes regarding the safety and appropriateness of medication use.

Many researchers, especially social scientists, have described patterns of drug use in the context of local cultural traditions and health beliefs. Practices that may appear to western practitioners as irrational have sometimes been explained in terms of local perspectives and experiences of drug use. In terms of promoting more rational drug use, many of these researchers have highlighted the importance of ensuring that the design and delivery of health programmes take into account the health beliefs and perspectives of local people. In many African countries public sector health personnel (sometimes in comparison with private practitioners) have been perceived as relatively unapproachable, disinclined to spend time with clients, and unwilling to respond to their concerns and views. In their study in Botswana Boonstra *et al*² describe how family welfare educators—who were often members of the communities in which they worked—were sometimes referred to Botswana’s “barefoot doctors”. As such, they enjoyed the trust of their local communities despite their limited training, and thus could play a valuable healthcare role.

Boonstra *et al* also reported a mean dispensing counselling time of 25 seconds. As they point out, if this time was increased it would provide greater opportunity for providing relevant information and for ensuring that this was understood. As a person’s concerns and views regarding drug use are known to influence adherence, increased emphasis on the counselling component of the dispensing process would enable these perspectives to be identified and addressed.

In many developing countries public health facilities are only one of many sources of drugs. Local pharmacies, drug stores, chemical sellers, and drug peddlers are important suppliers of pharmaceuticals in many communities. However, despite the widely acknowledged pluralism in healthcare provision, interventions (and their assessment) to improve the quality and safety of drug use have generally focused on public sector care. Exclusion of private practitioners from programmes to improve drug use limits their potential coverage and effectiveness, and may also represent a lost opportunity on the part of health policy makers in achieving national or local health policy objectives.

To promote improvements in the quality of health care which meet specific policy objectives, indicators should be continually reviewed. Boonstra *et al* identify simple patient knowledge and labelling scores which, as measures of the quality of the processes of care (in this case prescribing and dispensing), would be expected to reflect improved outcomes—namely, safe and appropriate drug use.

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Adverse drug events

Adverse drug events: what's the truth?

B Dean

Reasons for the wide range in reported adverse drug event rates include discrepancies in the definitions and data collection methods used. Great care must be taken when interpreting the results of studies of adverse drug events and other types of medical harm, and standardised methods and definitions are needed to compare adverse drug event rates.

You don't have to look very far to find that the number of patients being harmed by medication is perceived to be a problem. Nearly every medical, pharmaceutical, and nursing journal frequently publishes articles to this effect. Key documents on medical error—drawing particular attention to the harm caused by medication—have been produced by the US Institute of Medicine and by both the Department of Health and the Audit Commission in the UK. Add to this the widespread coverage at professional conferences and in the media, and it is clear that adverse drug events (ADEs) appear to represent an epidemic.

What is less clear is how often ADEs actually occur. An enormous range of figures have been reported in the literature and are cited regularly—suggesting that ADEs occur in anything from 0.7% to 6.5% of hospital inpatients.^{1,2} In this issue of *QSHC* a further paper is published in which 720 ADEs were identified in 2837 inpatients (25%).³ So why this range of figures and, perhaps more pertinently, does this mean some institutions are safer than others?

Before considering this question it is important to pause for a minute to think about what is being measured, as the definitions and terminology used in the area of iatrogenic harm are notoriously confusing. ADEs refer to instances where patients are unintentionally harmed as a

result of drug use. This includes harm that occurs due to either an adverse drug reaction or a medication error.⁴ Medication errors are generally considered to be preventable whereas adverse drug reactions (or side effects, in common parlance) are less so. Medication errors may or may not result in ADEs, and a separate but overlapping body of literature examines these in more detail.

Returning to our question of why such a range of ADE rates has been reported, there are three possible reasons. The first is that, within the general definition of an ADE given above, there is wide discrepancy in what is considered to constitute "harm". For example, in the Harvard Medical Practice study,¹ one of the most well known studies of iatrogenic injury, harm was defined as "measurable disability at discharge or increased length of stay due to the event". This study therefore included only events that resulted in more serious levels of harm. The US based ADE Prevention Study Group did not define the level of harm they included, but suggest that "all" ADEs were studied; only 8% of the ADEs they identified met the definition used in the Harvard study.² The paper by Rozich *et al*³ also suggests that any degree of harm was included.

The second possible reason is that a wide range of data collection methods have been used. The Harvard study and similar Australian and UK studies^{5,6} were

based on a retrospective review of medical notes. There are many reasons why ADEs may not be documented in the medical notes, and this method may therefore lead to underreporting. The ADE Prevention Study Group instead used targeted self-reporting and daily medical record review, an approach which is likely to identify more ADEs than a retrospective review of medical notes but may still miss those that are not recognised as such or otherwise neither reported nor documented. Another approach is to develop a computer based system to prospectively screen for ADEs based on "triggers"—that is, results of laboratory tests or orders for medication that may indicate that an ADE has occurred. The medical notes for those patients with positive triggers can then be examined in more detail. Using this method, Classen *et al*⁷ found an ADE in 1.7% of patients. The method described by Rozich *et al*³ in this issue of *QSHC* is based on this approach, but involves manually screening for triggers instead of requiring an ADE screening programme to be integrated with computerised prescribing and results reporting systems. These methods may be useful to find evidence of ADEs that are neither reported nor documented clearly in the medical notes, but any ADEs that do not result in a trigger will be missed.

The third reason why there may be differences in reported ADE rates is that there may be differences in the underlying ADE rates in the different institutions. However, without a standardised method for identifying ADEs we do not know the extent to which this is the case. The data of Rozich *et al* suggest that the differences are not great, with a range of 2.47–4.81 ADEs per 1000 doses reported across the 86 hospitals studied (mean 2.68).

These issues clearly demonstrate two points: firstly, that great care needs to be taken when interpreting the results of studies of ADEs and other types of medical harm; and, secondly, that we desperately need standardised methods and definitions to compare ADE rates in different institutions and in the same institution following large scale changes

designed to reduce them. As well as being practical for routine use, such a method would have to be tested in terms of its validity and reliability. The extent to which a method could be used in countries outside the one in which it was developed would also require careful consideration; prescribing practice, laboratory reference ranges, and drug names can differ immensely. These issues represent major challenges for those wanting to show a reduction in the number of patients being harmed by drug use.

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Nursing home quality

Rights, risks, and autonomy: a new interpretation of falls in nursing homes

A Ryan

Achieving the balance between safety and the right of nursing home residents to dignity, choice and self-determination is a challenging issue.

Families caring for older people worry particularly about the safety of their vulnerable relatives. It is often such concern about safety that prompts the final decision to seek nursing home care. In many cases this follows a lengthy period of care in the community where the physical safety of older people may be compromised to respect their right to self-determination and choice. For many families, underpinning the decision to opt for institutional care is the belief that at least their relative will now be safe.

With demographic trends predicting an increase in the number of older people and a reduction in the number of carers,¹ it is likely that admission to nursing homes will continue to increase. In light of this, initiatives such as the National Service Framework for Older People² and the "Essence of Care" benchmarking project³ are setting new standards of care for older people. In his paper in this issue of *QSHC*, Kapp⁴ highlights many issues that people with an interest in the health and social care of older people will readily appreciate. Few will disagree that the issue of safety is as complex as it is poorly defined. While there can only be a consensus that care homes should provide safety and security, the issue of what exactly constitutes a safe environment warrants further exploration. Clearly, there are many instances where the safety

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even in the face of real or perceived physical risk? Is it the nursing home owners whose determination to avoid negative publicity and litigation overrides any concern for resident autonomy? Perhaps the problem rests with families who may be uncomfortable about the physical safety of their relative being jeopardised. This is especially pertinent in situations where concerns about falls may have triggered the nursing home admission. In such instances, relatives are perhaps justified in expecting to see a decrease in the frequency of such falls following nursing home placement. If this does not occur, relatives may understandably question the merits of their decision. However, at a more realistic level, it is likely that the genesis of the problem rests with all key parties (residents, relatives and staff) and, this being the case, so too does the solution.

There is a general consensus that a good nursing home is one that provides a homely environment. Should residents with mobility problems therefore have the right to walk freely and unsupervised (as they would at home), even if this brings with it an increased risk of falling? From a nursing perspective, this is a difficult and challenging issue. The negative consequences of immobility have been well documented. However, initiatives aimed at promoting mobility carry a risk of falls. Falls in turn lead to immobility and ultimately the negative consequences that one initially sought to avoid. Of course, no family member wants to hear of a relative falling, and openly addressing safety problems may subject a nursing home to negative publicity. However, more effort should be made to contextualise safety with due regard to the maintenance of a home-like environment and the residents' right to dignity, participation, and self-determination.

It would be naïve to underestimate the real risks in adopting such a position, and cynics are justified in believing that some institutions may abuse this liberal approach. However, if we are serious in our effort to address residents' autonomy, a

tripartite approach involving residents, relatives, and nursing home staff will have to be the norm. This is wholly consistent with the concept of “relationship-centred” care^{5,6} which proposes that the enhancement of relationships should be at the centre of education and practice. Nursing home staff who show a genuine willingness to respect residents’ autonomy cannot continually live in fear of litigation. Similarly, residents and relatives must appreciate the fine balance between rights and risks that will continuously have to be negotiated in a client-centred environment.

Fostering the innovation and creativity that is required to address the issue of resident safety in such a broad context is

a huge challenge. In an ever increasing client-centred environment, it will continue to gain momentum and, as the older people of the future, we would be well advised to take note!

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