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'To prescribe generics is to play with the life of the patient': misconceptions of generics in Guatemala

Both pharmacists and doctors in Guatemala lack trust in generic medicines, according to a study carried out by a local non-governmental organization (NGO) [1]. The authors make recommendations for increasing generics uptake, including changing dispensing practices and improving state regulation.

Low-cost generic medicines are key to increasing access to essential drugs in low- and middle-income countries (LMICs), including much of Latin America. As highlighted by a 2005 World Health Organization survey [2], there is a particular need for generic drug programmes in this part of the world. Generic drugs are becoming even more necessary as the burden of chronic diseases, such as cardiovascular disease, cancer and diabetes, increases in Latin American countries.

A recent study [1] focused on the use of generic drugs in Guatemala, the most populous country in Central America. Like many other Latin American countries, although Guatemala has a robust domestic manufacturing market, the vast majority (70%) of its drugs are imported (mostly from Mexico, its border country) and generic drug uptake is limited.

Among the factors limiting access to generics in Guatemala is intellectual property law, which offers significant protection for originator drugs and consequently delays market entry for generics. For example, a generic version of Sanofi's long-acting insulin Lantus would still be restricted in Guatemala even after losing its patent in the US.

Furthermore, most generics sold in Guatemala are branded, i.e. sold under a trade name. These branded versions are aggressively marketed to consumers, allowing a premium to be charged and reducing market share for non-branded and cheaper generics.

Marketing strategies used by branded generics (and originator drugs) capitalize on consumer concern regarding the quality of generic drugs – another major factor impacting their use in Guatemala. One such advert for an originator diabetes medicine reads: 'I have diabetes. If my medicine fails, I could suffer a diabetic coma. I don't play around; I only use the real thing. Trusted brands have studies that back up their quality, efficacy and safety. Respect the medical prescription. Ask your doctor or your pharmacist for originator medicines.'

Quality concerns however are partly grounded in reality, as domestic generics manufacturers operate under out-of-date manufacturing laws and quality can be poor. Data from the International Medicines Quality Database, for example, showed that over 20% of samples submitted from Guatemala failed to pass a quality test. Further studies showed that several generic drugs made in Guatemala were not bioequivalent to their originators.

Finally, there is deep mistrust of the political system and its ability to properly monitor drug supply, exacerbated by a number of high-profile scandals in 2014. At the ground level, doctors – although legally required to include generic names in prescriptions – generally do not do so in practice.

Although there are data available on barriers to entry for generics in Guatemala, it is not clear how the attitudes of generics gatekeepers (physicians and pharmacy staff) impact their use. The authors of this paper therefore set out to explore perceptions among doctors and retail pharmacists on generic medicines, and how these perceptions influence prescribing behaviour.

The authors worked for the Maya Health Alliance, an NGO focused on treating chronic diseases among indigenous people in rural Guatemala. They interviewed 30 pharmacy staff and 12 doctors working in three towns in Guatemala that contain large numbers of patients with chronic diseases.

Retail pharmacy staff, defined as any pharmacy worker who dispenses medicines, were recruited through random sampling of pharmacies across five different categories (national pharmacy franchise; discount local pharmacy; non-discount local pharmacy; hybrid clinic-pharmacy; or government-subsidized pharmacy). Three pharmacies were randomly selected from each category in each of the three towns. Physicians were recruited using a different sampling method (convenience sampling), which involved contacting physicians in each town based on referrals from other healthcare professionals.

Semi-structured interviews lasting up to 45 minutes were used to understand perceptions of low-cost generic medicines and roles in choosing medicines among pharmacists and doctors. While interviews with pharmacy staff focused on training, perceptions of generic medicines and opinions about the roles of pharmacy staff and physicians in care, interviews with doctors also discussed prescribing practices. The data was subsequently analysed to identify the major themes, using a combination of descriptive and quantitative analysis methods.

Pharmacy staff and physicians were doubtful about both the safety and effectiveness of generics, in many cases considering

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ABSTRACTED SCIENTIFIC CONTENT

their low cost as proof of their lower quality. Doctors were generally more likely than pharmacists to be wary of generics, with 55% stating that low-cost generics were not as safe or effective as branded drugs.

The researchers focused on perceptions of generics for two common chronic diseases: diabetes and high blood pressure (hypertension). For these diseases, the decision to use a generic version of a drug was based on several factors, including the patient's income and preferences, but mainly doctor recommendations (as pharmacy staff generally defer to physician prescriptions). Prescribing practices among doctors varied widely and were heavily influenced by perceptions of generics, with one physician even stating: 'To prescribe generics is to play with the life of the patient'.

Overall, the study shows that physician and pharmacist perceptions of generics have a big influence on their clinical use, especially when it comes to chronic diseases such as diabetes. To improve generic drug use in Guatemala, the authors say negative opinions of generics should be tackled. They further suggest laws requiring generic name in prescriptions should be enforced and communication between prescribers and pharmacists improved.

They also say state regulation and monitoring of drug supply should be improved, but note that this may be difficult to achieve

in Guatemala's current political climate. They therefore recommend commitments to increased transparency and accountability, for example, by reporting on compliance with international manufacturing standards. They finally suggest that self-regulation in the generics industry could improve quality and thus public perceptions.

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Reference

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