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Commentry on "The Pharmaceutical equivalence and stability of multisource metronidazole suspensions"

I read with interest the report by Ajala and Colleagues [1] on a post-marketing evaluation of 18 brands of metronidazole suspensions selected from community pharmacies in Ogun state, Nigeria.It is interesting that the authors found only 4 out of 18 brands of the metronidazole suspensions sampled to have met the pharmacopoeial requirement on drug content. Also, the colours and viscosity of the suspensions changed within a lesser time-period than expected and there were significant increase in particle size. As a paediatrician, these findings raise some concerns.

In Nigeria, the use of metronidazole suspension for treatment of bacterial and protozoal infections among children is common,especially in the general medical practice settings. The taste notwithstanding, effectiveness and affordability make physicians prescribe metronidazole so frequently [2], especially in the treatment of diarrhoea.Metronidazole suspensions, being a common household item and often purchased by parents off the counter, I would like to communicate the significance of these findings in clinical practice and to public health.

The main purpose of any oral suspension is to deliver a certain and defined amount of drug to the human body through gastrointestinal system. The findings from the study by Ajala *et al.* [1] suggest that the quality the metronidazole suspensions in the Nigeria market do not meet official standards for strength, quality, purity, and storage. The use of counterfeit and substandard drugs in clinical practice have serious health implications; including treatment failure, adversereactions, drug resistance, increased morbidity and mortality. In my years of practice, I have observed that metronidazole suspensions are routinely given by caregivers to children who complain of abdominal pain or pass loose stool at home before hospital consultation. This home treatment practice suggests that some of the caregivers might have administered left-over metronidazole suspensions which duration of storage could be longer than can guarantee its efficacy or purchase the drugs from community pharmacies of the calibre which Ajala and Colleagues collected their researched samples.

A good oral metronidazole suspension ought to maintain its stability for at least a year in ambient storage. Better preservation is achieved at refrigerated condition, and therefore it is the recommended storage temperature for most preparations. This condition is often not attainable in a typical Nigerian household because of poor electricity supply. The most significant effect of storage is the loss of solvent from the suspension due to evaporation and/or permeation, which could be accelerated at higher temperaturesand in dry environment such as often occur in the tropics, where ambient temperature could be as high as 40 to 50 degree Celsius [3]. It is therefore important that the manufacturers of metronidazole suspensions in Nigeria consider the use of impervious glass containers which would likely reduce solvent loss and may further extend the shelf life.

A safe medicines supply is fundamental for public health. Children are particularly more vulnerable when exposed to substandard drugs. One of the most compelling impacts of substandard or poor quality drugs is that of guileless poisoning of children. It would be recalled that between November 2008 and February 2009, "84 Nigerian children died from acute kidney failure brought on by the industrial solvent diethylene glycol in teething syrup" [4,5]. One of the reasons for this untoward event was the weakness of thedrug regulatory systems in Nigeria. The potential fallout of such system weakness, in respect of substandard metronidazole suspension includes poisoning, resistance of initially sensitive infectious agents, early death, and treatment failure[6].In combating such type of problems there is the need for drug regulatory authorities in Nigeria to pay more attention to quality assurance and continuous monitoring of drugs at community pharmacies.

I think the efforts made by Ajala and Colleagues[1] are commendable. There is a growing universal concern regarding substandard medications in developing countries. In particular, substandard antimicrobial drugs are a threat to public health with many distressing consequences for patients. Over time, physicians treating patients may lose confidence in the use of metronidazole suspension if drastic measures are not taken to curb the deterioration in number of brands meeting the pharmacopoeial requirement on drug content. Moreover, to implement effective countermeasures against substandard drugs, there is the need for more research and evidenced-based information to define the extent of the problem in the community.

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