Antimalarial Drug Quality in Senegal

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Acronyms

BASICS	Basic Support for Institutionalizing Child Survival
BP	British Pharmacopeia
CA	Cooperative Agreement
CFA	Unit of currency in Senegal[1]
CNS	Central nervous system
DPM	Direction de Pharmacie et Médicaments
HPLC	High pressure liquid chromatography
IR	Infra Red
ITN	Insecticide-treated net
LNCM	Laboratoire National de Contrôle des Médicaments
MSH	Management Sciences for Health
PNA	Pharmacie Nationale d'Approvissionement
PNLP	Programme National de Lutte contre le Paludisme
RBM	Roll Back Malaria
RPM Plus	Rational Pharmaceutical Management Plus
RS	Reference Standard
SO	Strategic Objective
SP	Sulfadoxine-pyrimethamine
TLC	Thin layer chromatography
USAID	United States Agency for International Development
USP DQI	United States Pharmacopeia Drug Quality and Information
USP-NF	*United States Pharmacopeia-National Formulary*
UV	Ultra Violet
WARO	West Africa Regional Office (BASICS)
WHO	World Health Organization

[1] 1 US$=754 CFA


Senegal
International boundary
Region boundary
National capital
Region capital
Railroad
Road
Track
0 25 50 75 Kilometers
0 25 50 75 Miles
NORTH ATLANTIC OCEAN
MAURITANIA
Nouakchott
Boutilimit
Aleg
Rosso
Richard-Toll
Podor
Bogué
Haïré Lao
Kaédi
Saint-Louis
Lac de Guier
Lac Rkiz
Sénégal
Gorgol
Mbout
Kankossa
Thilogne
Lagbar
Louga
Léona Ndiaye
LOUGA
SAINT-LOUIS
Dara
Linguère
Matam
Tioukougne Peul
Kébémer
Fâs Boye
Darou Khoudos
Darou Mousti
Mékhé
Vélingara
Mamâri
Bakel
Sélibaby
Kayar
DAKAR
Cap Vert
Dakar
Tivaouane
Thiès
DIOURBEL
Mbaké
Diourbel
Rufisque
THIÈS
Popenguine
Mbour
Gossas
Mbar
FATICK
Fatick
KAOLACK
Guinguinéo
Payar
Toubéré Bafal
Nayé
Kayes
MALI
Joal-Fadiout
Ndangane
Kaffrine
Kaolack
Koumpentoum
Goudiri
Nganda
Keur Madiabel
Tambacounda
TAMBACOUNDA
THE GAMBIA
Barra
Kerewan
Banjul
Mansa Konka
Georgetown
Basse Santa Su
Dialakoto
Brikama
Kalagi
Gunjur
Bounkiling
KOLDA
Vélingara
Diouloulou
Diana Malari
Kolda
ZIGUINCHOR
Bignona
Sédhiou
Tanaf
Mako
Saraya
Ziguinchor
Oussouye
Diembéreng
Farim
Koundara
Kédougou
São Domingos
Cacheu
Gabú
Kati
GUINEA-BISSAU
Canchungo
Bula
Mansôa
Bafatá
Mali
Bissau
Enxudé
Gaoual
Buba
GUINEA
Tougué
Labé
ARQUIPÉLAGO DOS BIJAGÓS
Bubaque
Catió
Cacine
Sangarédi
Télimélé
Boké
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Executive Summary

Malaria continues to be a major health concern in the country of Senegal, exacerbated by the free flow of poor quality antimalarial drugs and increasing parasite resistance to traditional first line drug treatment. For this reason, and in the frame of the support that USAID gives to the National Program of Senegal for the fight against Malaria, the surveillance of the parasite resistance to the used antimalarials and their quality is a major component. This study was made in partnership with the Programme National de Lutte contre le Paludisme (PNLP), the Laboratoire National du Senegal, the Direction de la Pharmacie et du Medicament (DPM), the Pharmacie Nationale d'Approvisionement (PNA), and the University of Dakar.

The United States Pharmacopeia Drug Quality and Information Program (USP DQI) was asked to provide an assessment of Senegal's antimalarial drug quality assurance. The scope of work included performing a random sampling of antimalarial drug products and testing them for identity, strength, and quality at USP laboratories in Rockville, Maryland. For this study, USP DQI analyzed samples of amodiaquine, chloroquine, and sulfadoxine-pyrimethamine tablets collected from the public sector health system, private sector licensed pharmacies, and the informal market in different regions of Senegal. The drugs had been manufactured by various companies, local and imported, and were tested according to the standards of the *U.S. Pharmacopeia* and the *British Pharmacopeia*.

Major Findings

Although all the drugs tested contained the active ingredient indicated on the label, the amount of that ingredient varied by sample. Chloroquine tablets contained more than the claimed amount in 35% of the tested samples. Sulfadoxine-pyrimethamine (SP) tablets contained less than the claimed amount in 55% of the samples. All of the amodiaquine samples passed the monograph tests; however, there was a problem with the availability of this drug.

Amodiaquine is the recommended first-line malaria treatment for people who cannot take chloroquine, but it was not available in public outlets. During the sample collection phase, the collection teams found that all three drugs were equally available in the private sector; in the informal sector, all had chloroquine and about 50% had amodiaquine and SP. But in the public sector access points, while most had chloroquine and SP available, none had amodiaquine.

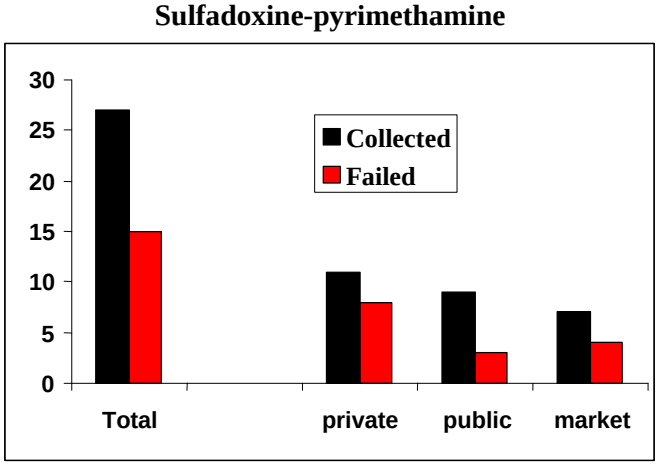

Figure 1.

Contrary to the conventional hypothesis, that drugs sold in the informal market are more likely to be lower in quality, the majority of failed sulfadoxine-pyrimethamine and chloroquine samples came from the formal private sector, 57% and 64% respectively. (See Figures 1 and 2.)

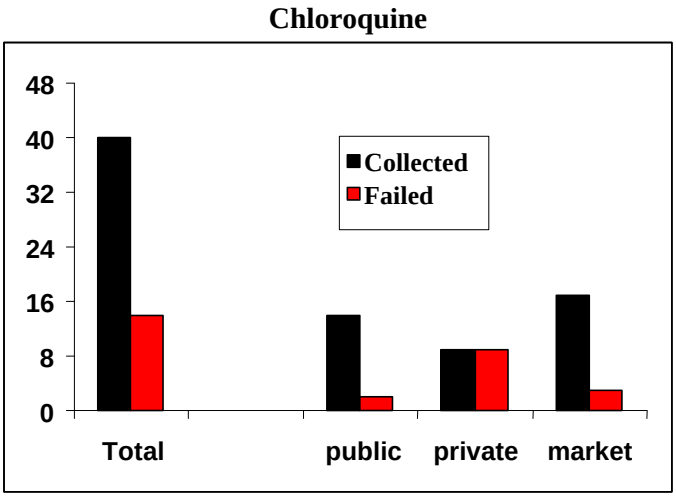

Figure 2.

All of the chloroquine that failed the assay in the monograph was found to contain a higher dose than what was listed on the label. The clinical impact of this is the danger of overdosing, especially for children and pregnant women. Clinical effects of chloroquine overdose include visual disturbances, neurotoxicities (headache, drowsiness), and cardiovascular toxicities (hypotension, cardiac arrhythmias) which eventually lead to cardiovascular and respiratory arrest. Acute overdose of chloroquine is rapidly lethal. Death can occur within a few hours. Ingestion of improperly high dosages also can increase the likelihood and intensity of adverse effects. Unwillingness to suffer adverse effects can cause some people to stop treatment before completing the regimen.

The incorrect dosage also raises questions about the quality control of packaging and labeling. In addition, certain brands of sulfadoxine-pyrimethamine were found to be consistently substandard and need to be further investigated for quality and source.

Recommendations/Next Steps

Addressing the issues of drug quality control in Senegal will require a multifaceted approach that includes training the National Laboratory and University of Dakar staffs to do routine drug quality surveillance around the country; greater quality control over drugs brought into the country and purchased by the government; and improvements in communication among concerned agencies. Establishing routine monitoring of drugs coming into Senegal will afford the opportunity to withdraw substandard drugs from the public health system and from the market.

The problems of chloroquine mislabeling, and possible counterfeiting of chloroquine and sulfadoxine-pyrimethamine, will need to be further investigated. The National Malaria Control Program should consider asking doctors, pharmacists, and consumers to avoid using the specific products identified as substandard in this report.