

# INCREASING ACCESS TO QUALITY ESSENTIAL MEDICINES AND SERVICES PROVIDED BY DRUG SHOPS IN UGANDA THROUGH ACCREDITATION AND REGULATION

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## Abstract

**Problem Statement:** Most people in rural areas of Uganda often turn to local drug shops for their medicines and health care advice. These shops may be unlicensed, have staff that are untrained, and sell medicines that may be of uncertain quality or that they are not allowed to dispense. Regulatory inspection and supportive supervision are infrequent.

**Objectives:** To transform existing Class C drug shops into well-regulated Accredited Drug Shops (ADS), so that people living in rural communities have access to quality medicines and pharmaceutical services.

**Design:** A quantitative and qualitative pre and post intervention design in Kibaale district, with Mpigi district as the control. We collected baseline (2008) and endline data (2010) using drug shop audits and interviews with owners and shop attendants and measured quality of pharmaceutical services using a mystery shopper scenario (malaria in a 5-year-old child).

**Setting and Study Population:** 45 Class C Drug Shops in Kibaale district; 43 in Mpigi district.

**Intervention:** NDA developed standards for premises, personnel, record keeping and dispensing practice, and established a list of prescription medicines that can be legally dispensed by accredited drug shops. Local monitors and supportive supervision teams from the district were trained and empowered to supplement NDA's routine inspections. Drug shop attendants received training in good dispensing practices and how to handle common medical problems, patient communication, and referrals. Owners also received business skills training and guidance on obtaining loans from microfinance institutions.

**Outcome measures:** Percentages related to indicators of medicines availability, price change, and service quality.

**Results:** Endline results from Kibaale indicate improvement in service quality and dispensing practices. For example, availability of injectables, which are illegal in all drug shops, dropped from 61% to 0% in ADS compared to the control district, where availability remained unchanged at 35% ( $p < 0.05$ ). In addition, the percentage of mystery shopper encounters where the drug seller inquired about prior medicines given to the child rose from 31% to 64% in Kibaale compared to a much smaller increase (from 40% to 43%) in Mpigi ( $p = 0.136$ ).

The legal availability of essential prescription-only medicines has also improved (e.g., availability of essential antibiotics in Kibaale increased from 57% to 84% compared to Mpigi where their illegal availability remained unchanged at 64% ( $p < 0.05$ )).

Medicine prices have not changed on average, despite concerns that costs might rise in ADS because of the expenses associated with meeting new regulatory standards.

**Conclusions:** Results indicate that the accreditation of Class C drug shops has improved access to legally available products and quality services in retail drug outlets that serve populations living in rural areas in Uganda.

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# Background

- In Uganda, most people in rural areas buy medicines from drug shops
- By November 2010, Uganda had 6,363 licensed Class C drug shops and 497 licensed pharmacies (70% of the pharmacies in Kampala)
- However, these drug shops had a number of problems—
  - Selling unauthorized medicines
  - Dispensing of medicines by unqualified personnel
  - Inadequate medicine storage conditions
  - Poor record keeping
  - Inadequate regulatory oversight



# Accredited Drug Shops (ADS) Project

## Goal

Increase access to quality essential medicines and pharmaceutical services, particularly in underserved areas, through accreditation of private drug sellers and drug outlets

## Objectives

- Develop new standards and requirements for drug shops and drug sellers' accreditation
- Strengthen the regulatory monitoring and inspection of drug sellers by national and local authorities
- Improve the quality of drug shop dispensing services and medicines management
- Increase drug shop sustainability through business skills training

# Intervention Overview

- Analysis of the pharmaceutical sector situation in Uganda
- Stakeholder consensus-building to develop an accreditation model based on the Tanzanian ADDO, but adapted to the Ugandan context
- Development of accreditation standards and extended list of drugs allowed for sale in ADS
- Training—
  - 246 sellers in good dispensing practices
  - 82 owners in business practices
  - 18 local monitors and 12 supervisors in accreditation standards and use of supervision checklist
- Accreditation of Class C drug shops into ADS status (73 ADS out of the 85 at baseline).
- Regular inspection, monitoring, and supportive supervision of ADS



# Study Design

- A quantitative and qualitative pre- and post-intervention design
- The baseline (2008) and endline (2010) study in the pilot (Kibaale) and control (Mpigi) measured availability and prices of tracer medicines and quality of pharmaceutical services using a mystery shopper approach (malaria in a 5-year-old child)

## Setting and Study Population

- 45 Class C drug shops in Kibaale and 43 in Mpigi

## Outcome Measures

Access to essential medicines as measured by—

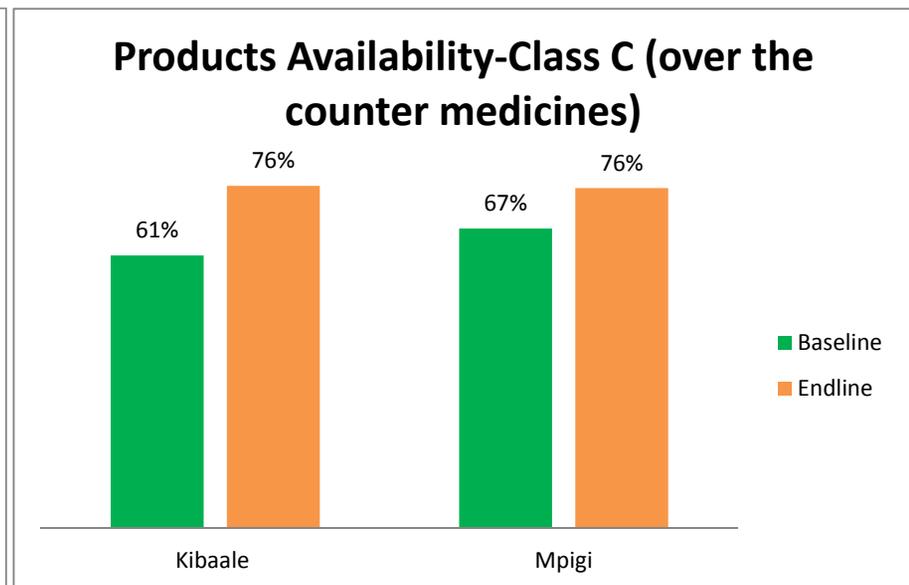
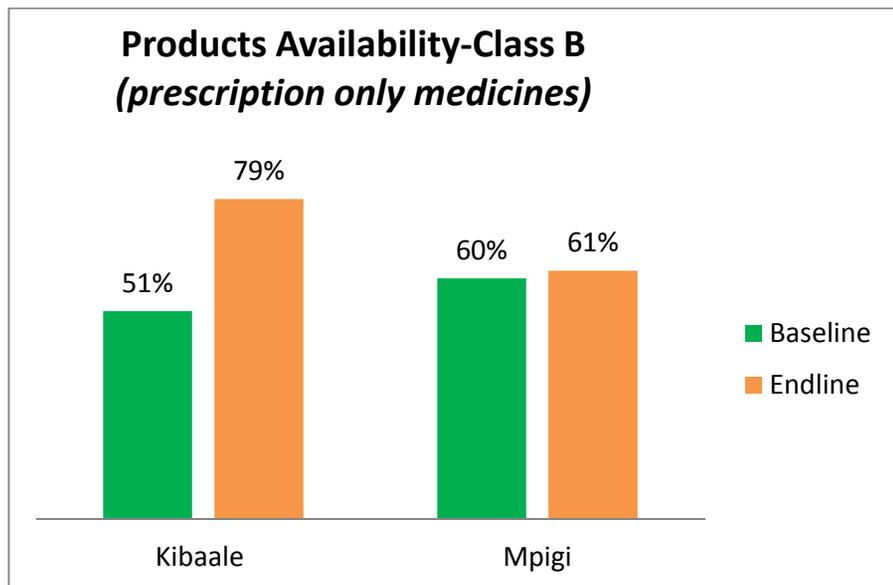
- Percentages related to average availability of medicines
- Median price of medicines compared to international reference prices

Quality of service as measured by—

- Availability of injectables
- Percentage of drug sellers asking about symptoms of the child
- Percentage of drug sellers asking about prior medication given to the child
- Percentage of drug sellers giving instructions for taking medicines

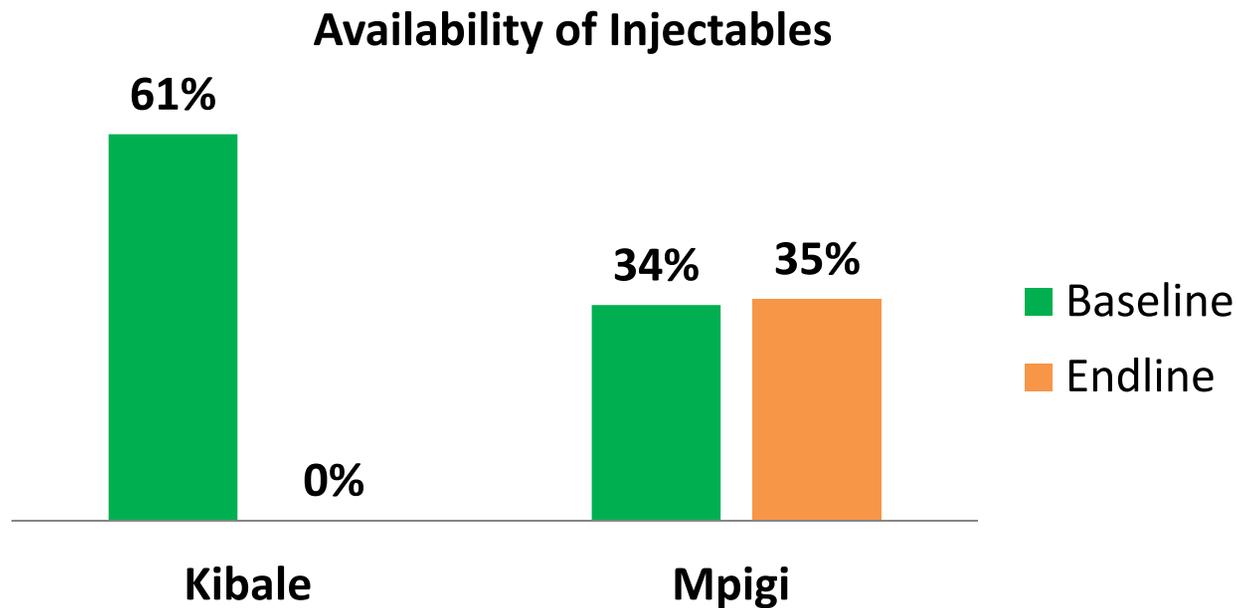
# Results: Availability of Quality Pharmaceutical Products

- Prescription-only medicines (Class B) are sold only in pharmacies and non-prescription medicines (Class C) can be sold in pharmacies or drug shops
- NDA provisionally allowed ADS to sell a limited list of Class B medicines, such as antibiotics, as part of the pilot initiative
- The availability of Class B and Class C drugs increased in Kibaale, with smaller increases for Mpigi. The greatest increase was for Class B drugs in Kibaale ( $p < 0.05$ )



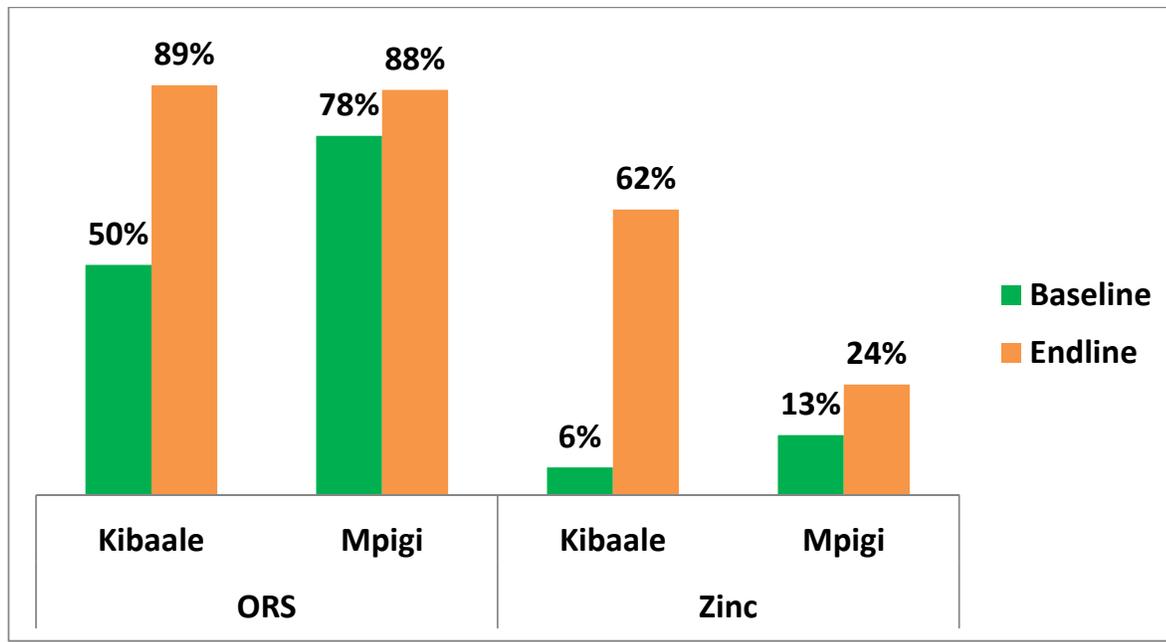
## Results: Availability of Injectables

- It is illegal to sell injectables in either Class C shops or ADS
- At endline, ADS had no injectables available.
- Practices in Mpigi, on the other hand, remained unchanged ( $p < 0.05$ )



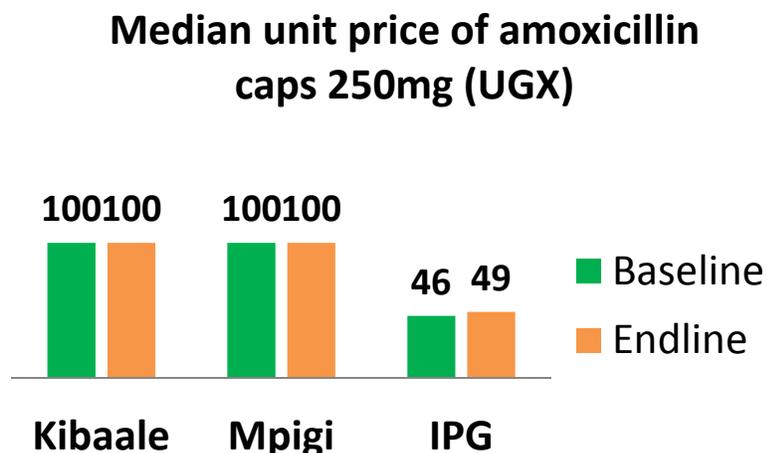
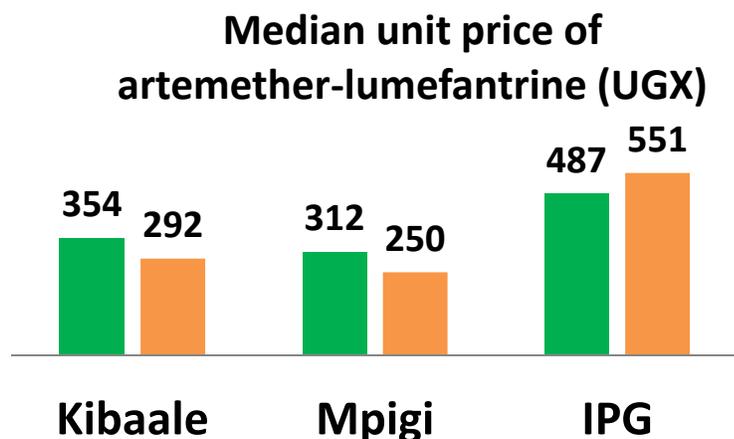
# Results: Availability of Antidiarrhea Medicines

- The availability of oral rehydration solution (ORS) and zinc tablets increased in ADS
- The number of drug shops in Mpigi also experienced increases, though of smaller magnitude (78% to 88% for ORS and 13% to 24% for zinc ( $p < 0.05$ ))



# Results: Price Changes

- The median unit prices for most products changed slightly (both increases and decreases) after implementation of ADS in Kibaale.
- The median price for artemether-lumefantrine decreased by about 19% in both Kibaale and Mpigi reflecting a nationwide increase in supply.
- The median unit price for amoxicillin capsules 250mg showed no changes from baseline to endline in either district.



# Results: Dispensing Services

Dispensing practices generally improved in Kibaale after the advent of ADS, but none of the results were statistically significant.

<b>Variable</b>	<b>Kibaale difference in percentage points (before and after)</b>	<b>Mpigi difference in percentage points (before and after)</b>	<b>Between group difference</b>	<b><i>P-Value</i></b>
Provider asked about child symptoms	+8	-32	22%	<i>P=0.136</i>
Provider asked if the child was taking any other medicines	+33	+3	21%	<i>P=0.136</i>
The provide gave instructions on how to take the medications	-7	-18	16%	<i>P=0.271</i>

# Policy Implications

- Drug sellers complement the public sector by improving access to medicines
- An accreditation and regulation program requires review of the existing regulations
- Drug shop renovation is costly and yet drug sellers find it harder to get loans from financial institutions compared to other sectors (e.g., agriculture). Policies need to be developed that facilitate financing for drug sellers



# Conclusion

- The ADS project was shown to work in increasing access to medicines and quality pharmaceutical services.
- The medicine prices did not increase significantly despite the shop renovation costs that were borne by the owners.

