

Ensuring Regular Inspection and Enforcement of Standards in Accredited Drug Shops



SDSI Stakeholders Meeting, Entebe
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Background

- Studies revealed irregularities in regulation and operations of class C drug shops which required redress.
- These irregularities were; selling of unauthorized medicines, dispensing of drugs by unqualified personnel, inadequate storage space and conditions for stocking of medicine, poor facilities, poor record keeping, inadequate assortment of medicines for sale, high and variable prices, in-adequate regulatory oversight with infrequent inspections by NDA and irrational drug use.
- In 2008, the Ministry of Health through the NDA in collaboration with MSH piloted the ADS initiative in Kibaale , Uganda.
- This study was therefore aimed at documenting the ADS regulatory model and experience in Kibaale district, so as to enhance the ADS initiative's regulatory systems long-term sustainability by ensuring regular inspection, re-accreditation and enforcement of ADS standards.

Assessment Objectives

- To document the ADS regulatory system and experience in Kibaale, explore options for sustainable ADS regulatory system, and recommend a strategy and needed tools that would help ensure regular inspection, re-accreditation and enforcement of ADS standards.

Methodology

- **Design and methods** ; A descriptive cross-sectional design was used where both quantitative and qualitative methodologies were used i.e.
 - Questionnaires, Key informant interviews, Direct observations, Photography and voice recording.
- **Sample & sample size**; 30 Shops owners or sellers, 1 SDSI staff at NDA, 1 DADI, 5 local monitors, 1 DHO, 2 SDSI staff at MSH.
- **Geographic Coverage**; Kibaale district. we randomly selected 30 shops proportionately from Buyanja, Buyaga and bugangaizi counties.

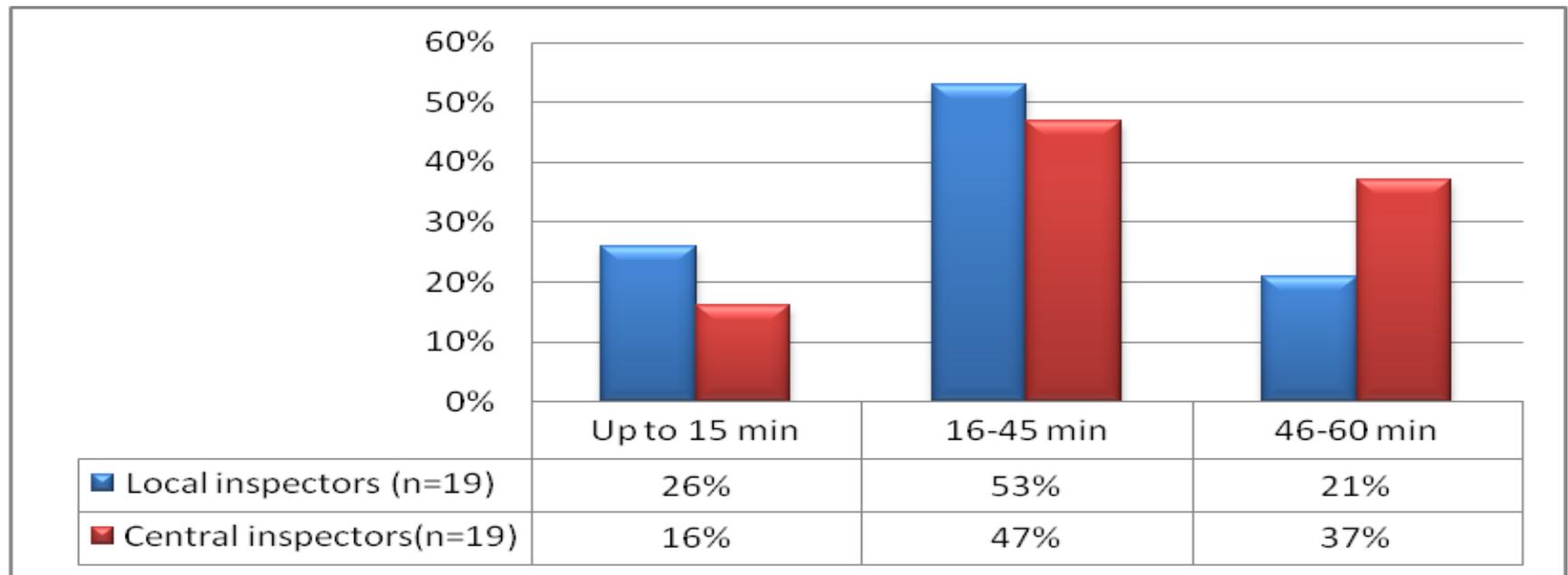
Regulatory system flow processes



- The licensing and accreditation cycle begins in October when the ADS shops collect the forms and pay the fees. By January all shops should have submitted their applications.
- The licenses are issued for one year (January to December).

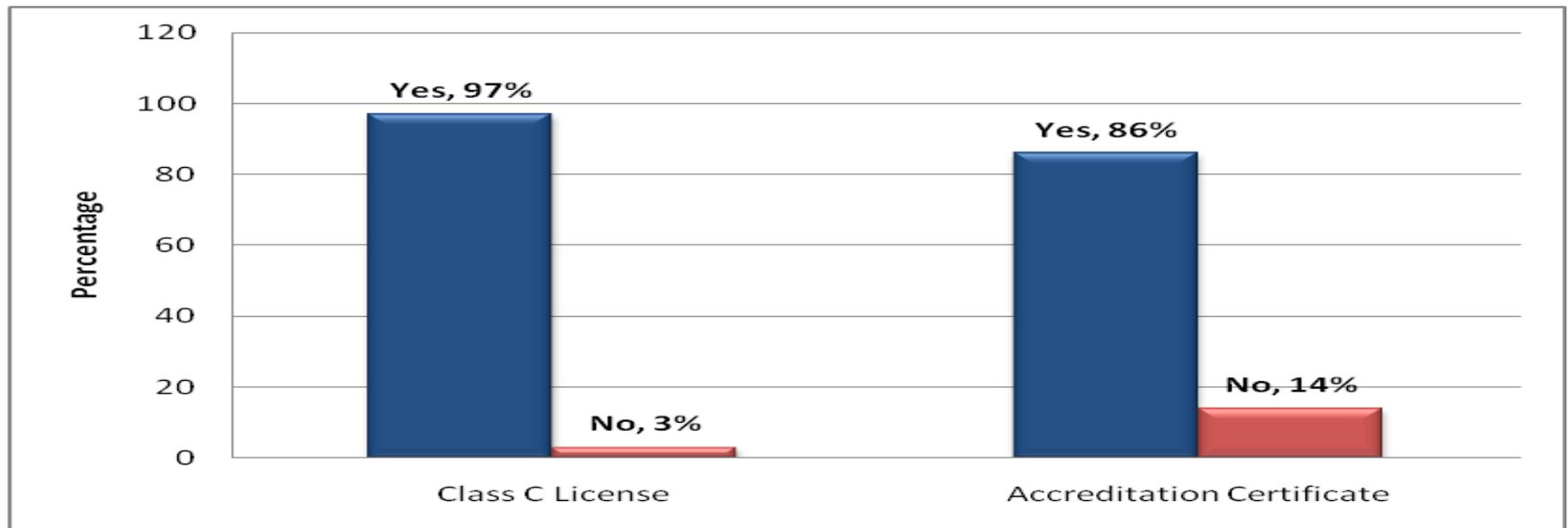
Inspection

- Was done regularly 3-5 times in 2011. More times were inspected by the local/district teams compared to the NDA teams.
- Most inspectors spent between 15 and 45 minutes at premises and the working relationship was described as “very good/friendly”.

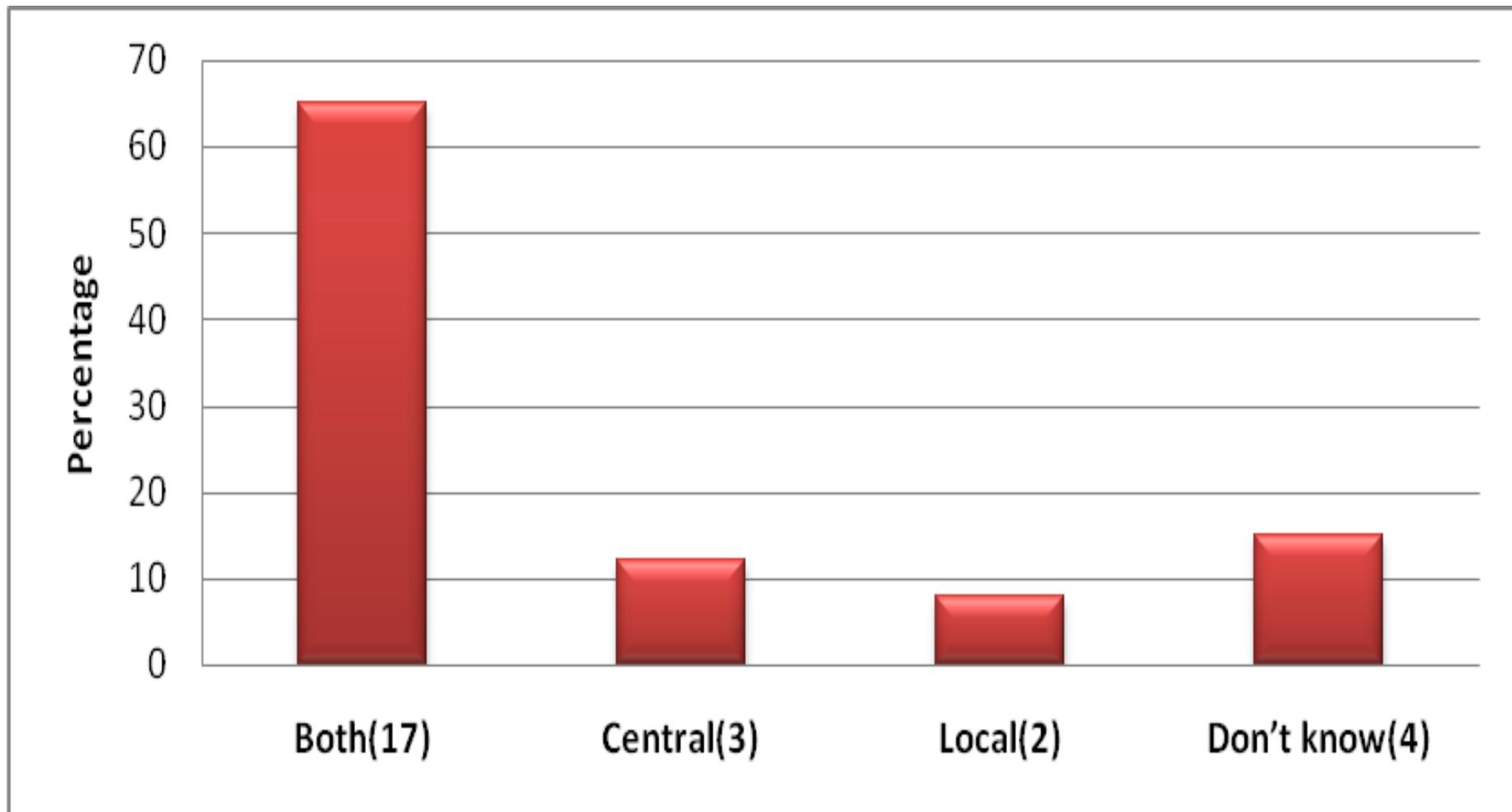


Licensing and Accreditation

- By July 2012 there were 204 licensed drug shops in Kibaale for both human and veterinary medicines.
- The preferred period for re-accreditation was 1 year with the licensing cycle.
- The majority 70% had no difficulty complying with ADS Standards



Preference of central vs. local inspectors



Human Resources

- *Human resources for shops*
 - *The majority of the shop attendants interviewed were seller(26,90%) and only (3,10%) were owners.*
 - *The majority 12,67% worked in the shops for 2 years or less.*
- *Human resource for inspection*
 - The regional inspector, together with the DADI, carried out the inspections. In addition, the NDA had a focal person during the pilot phase. Local monitors were also used to strengthen this function.

*“We feel that the name **local monitors** be changed to **health Inspectors**, the word local is demoralizing. We like our work and it’s easy to do” ----A local monitor*

“They know their work and they are always in touch with me. They help me reach far places I take long to go” ---DADI Kibaale

Enforcement of standards

- Three ways were found to be the most effective in the enforcement of the ADS standards:
 - 1. Dialogue, *“they change when we talk to them”*
 - 2. Closure of premises & the impounding of drugs
 - 3. Litigation, only in extreme circumstances.

Case Study: Uganda versus Muhendo, a drug seller

Court Case : Uganda versus Muhendo, a drug seller

DPP case Number: Kib-CO-124-2011

Court case No: 73-2011

Count 1: Unlawful possession of government stores according to Section 316 (1) and (2) PCA

Count 2: Places from which restricted drugs may be supplied sub section (b)
of the NDP Act and Authority Act.

Judgment: Overall Count1 was dismissed

Count 2 was charged 30 currency points equivalent to UShs. 600.000/=
or face 10 months imprisonment.

Concluding the court case: The drug seller paid UShs. 600.000/= and was free to go.

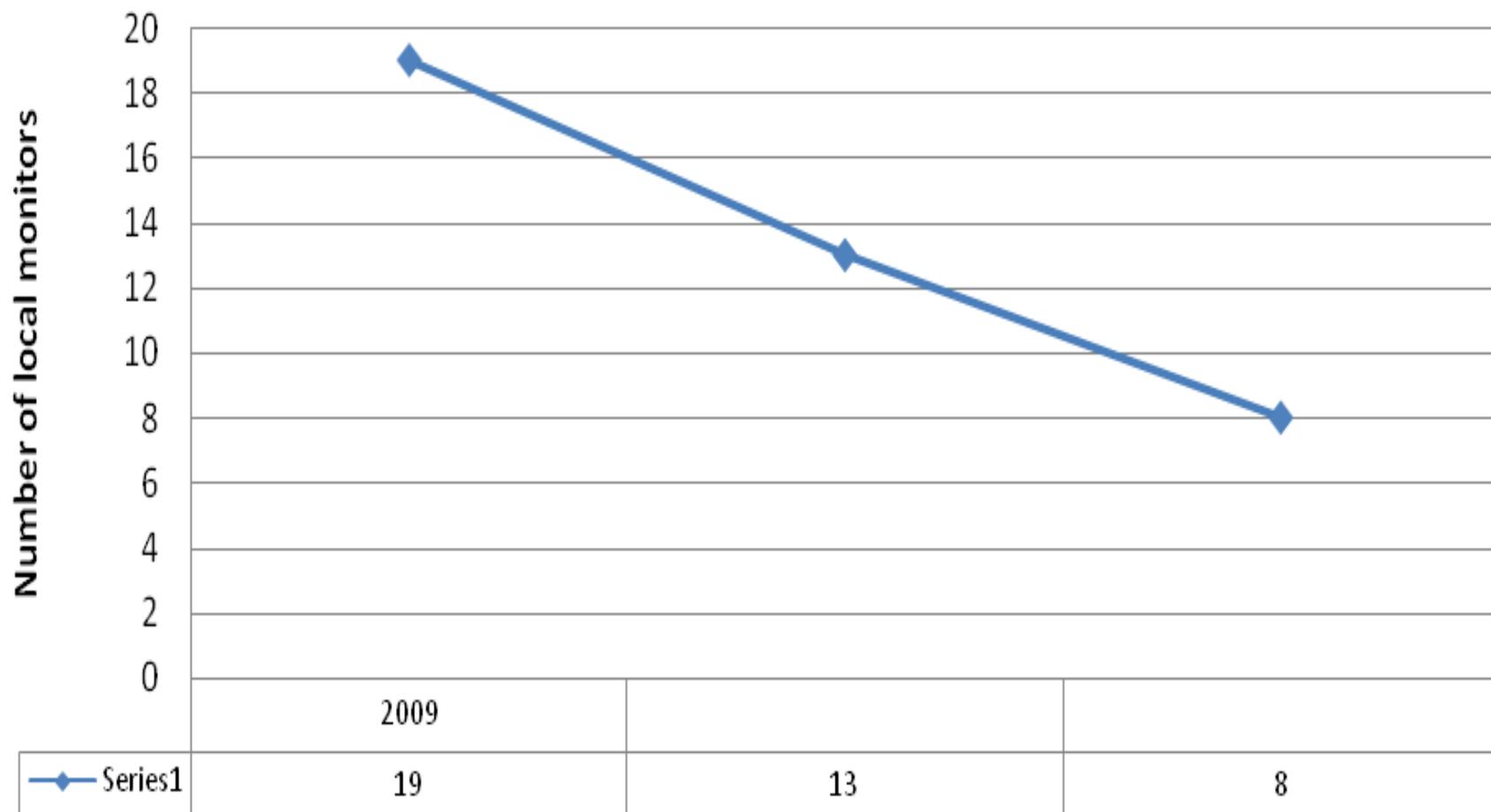
“The outcome of such cases is very demoralizing. It takes long, and you are called to court on short notice. Look the first count was dismissed! This option doesn’t help us; it’s not the best” ---- DADI Kibaale.

Trend of litigations to enforce ADS standards

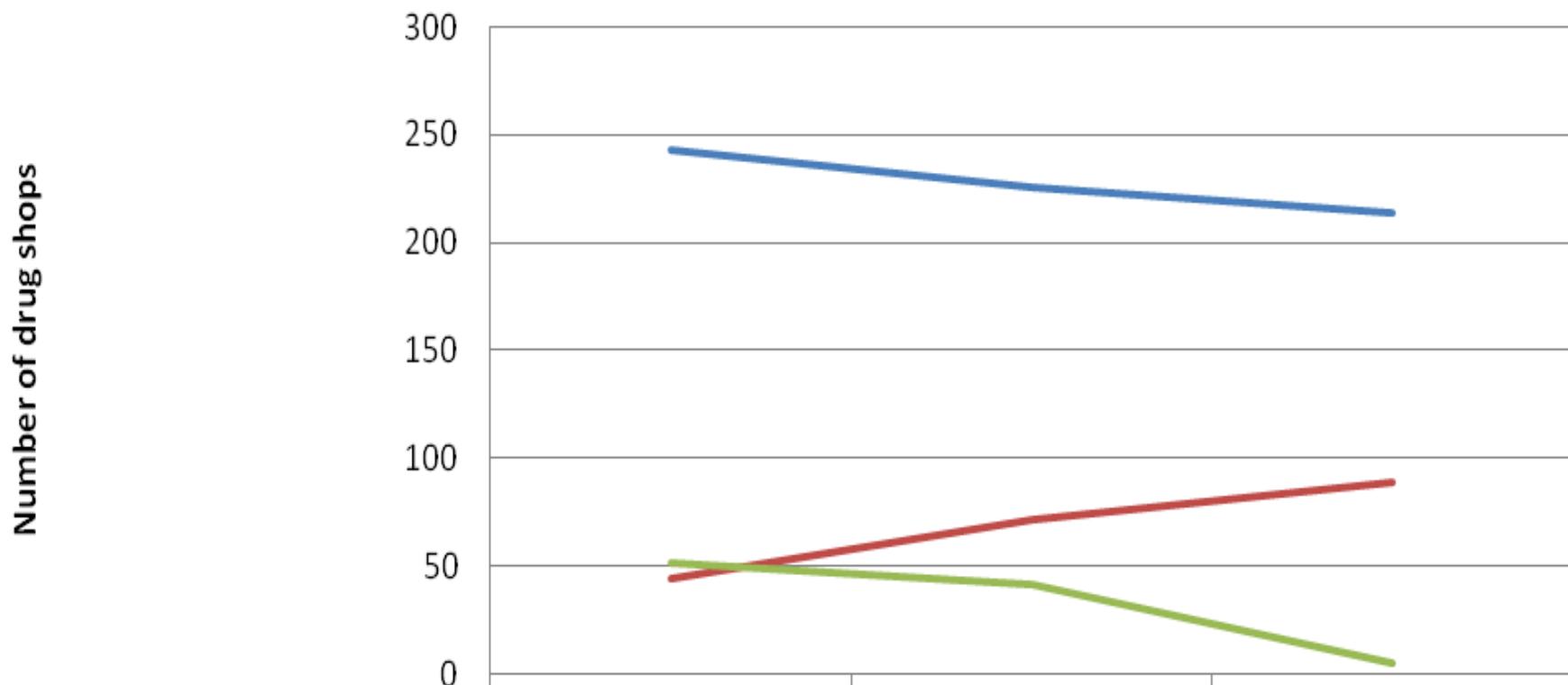


- There were three main counts which the shops were taken for; Operating drug shops in unsuitable premises, unlicensed persons and Illegal possession of restricted drugs.
- The convictions and penalties for these cases was; a fine of 100,000/- to 300,000/- or Conviction of 6 months to 14 months imprisonment.
- These were considered light and required a lot of follow-up time and resources by the enforcement staff which was not sustainable.

Numbers of active local monitors

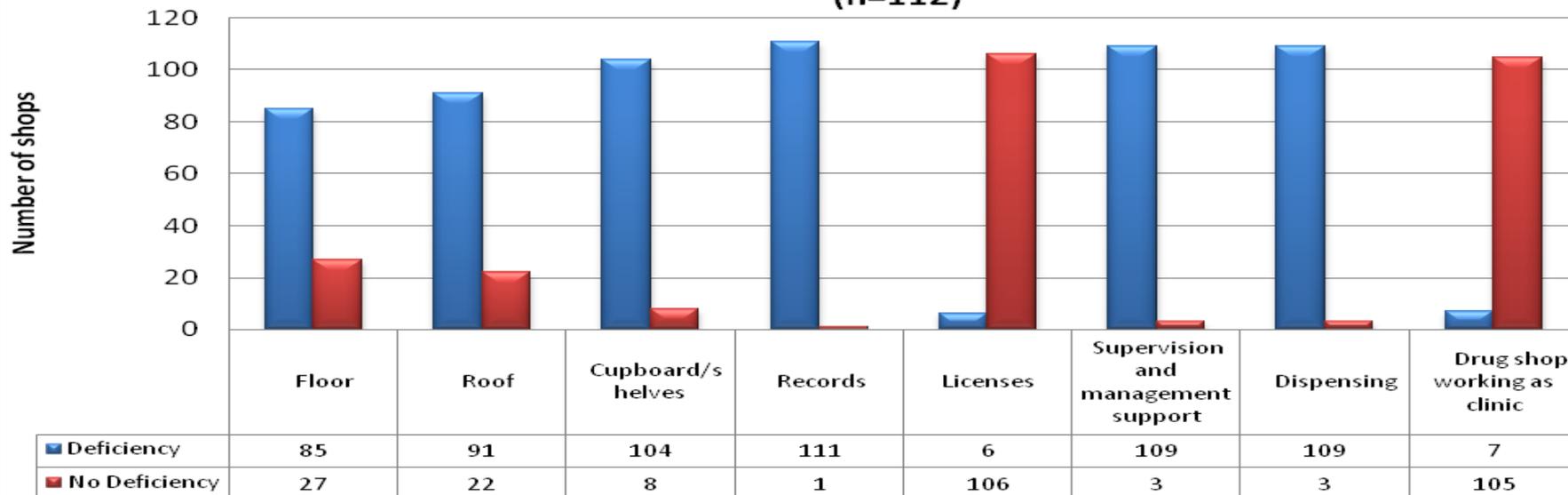


Trends in inspection, accreditation and enforcement



	2009	2010	2011
Number of drug shops Inspected	243	226	214
Number of drug shops Accredited	44	72	89
Number of drug shops closure recommended	51	41	5

**Number of shops with or without deficiencies at pre-inspection, 2009
(n=112)**



<i>Key component</i>	<i>Attributes</i>
1. Floor	floor is cracked, shelves and floor dusty
2. Roof	ceiling peeling off, ceiling of papyrus, walls and shelves dusty
3. Cupboard/shelves	No lockable cupboards
4. Records	no records for sales, purchase, expiries
5. Licenses	No NDA license
6. Supervision and management support	No sign post, no hand washing facility, no reference materials, no drinking water, no hand washing facility, misleading sign post
7. Dispensing	No counting tray, no drug envelopes, more than one drug mixed in one tin, re- labeling of tins
8. Drug shop working as clinic	Drug shop used as clinic, has bed for injections, lab services offered.

Financing

ADS Activity	Cost met by donors	Cost met by the shop	Cost met by NDA	Cost met by Kibaale district
Inspection	X		X	
Support supervision	X		X	
Mobilization	X		X	X
Training	X			
Licensing and accreditation	X	X	X	

•For sustainability the drug shops and the districts need to be more involved in meeting the costs to ensure regular inspection and enforcement of standards with NDA as the lead.

Recommendations and Options

Ensuring regular inspection

- **Self regulation;** Strengthen the association .
 - Borrow provisions from success full shop associations like MITYANA district where all drug sellers including herbalist's drug shops and pharmacies are controlled and standards enforced by the association whose membership is compulsory.
 - This group self regulation is cheaper, friendlier and less prone to corruption and is sustainable.
- **Community policing;** Community sensitization e.g. radio talk shows will institute community policing so as to uphold the ADS standards. *“Once you empower the community work becomes easy, the people are on our side”*---- Inspector of drugs.

Recommendations and Options

Ensuring enforcement of standards

- **Revocation or denial of license/accreditation certificate in next issuance;** Certification should be **revocable** or **next issuance** of accreditation certificate in cases when standards (HR, premises, practice) are not upheld. Specifically tag the recommendations by the association, local monitors, DADI, SDSI coordinator and the RID to denial of Accreditation certificate if recommendations not worked upon.
- **Incorporate ADS in existing laws and regulations;** specifically rescheduling the expanded list of medicines, standards of premises and practice to improve medicine regulation within the legal realms of Uganda.

Recommendations and Options

Crosscutting

- ***Constant Supplies for accreditation(Dispensing logs, reference books and job aids, referral books, white coats);*** be developed, updated, and issued by NDA at a reasonable fee or through the association at a further subsidized fee. This will ensure standardization.
- ***Foster Multi-sectral linkages;*** NDA, the district local governments, MOH, drug sellers associations and development partners is critical since the interventions proposed are not under one core regulatory body.
- ***Gender sensitive planning, ethics & integrity ; Should be considered when recruiting local regulatory personnel.***

Conclusion

- Inspection and enforcement of standards among the ADS drug shops was regular and structured and has resulted in significant improvements in standards of practice and premises of drug shops in Kibaale district during the pilot phase.
- Despite the success shown during the pilot phase, when regular inspection and support supervision is lacking, the standards of practice and premises among the ADS deteriorate.
- Three ways were found to be the most effective in the enforcement of the ADS standards:
 - Dialogue, *“they change when we talk to them”*
 - Closure of premises and the impounding of drugs
 - Litigation, only in extreme circumstances
- To sustain and improve the model for ensuring regular inspection and enforcement of standards, the **financial** and **human resources** base needs to be supported

THE END

Thank you for listening

