Durable Lining (DL)
Category Guideline Discussion

A review of WHO guidelines and their application to a proposed new category, Durable Lining (DL)

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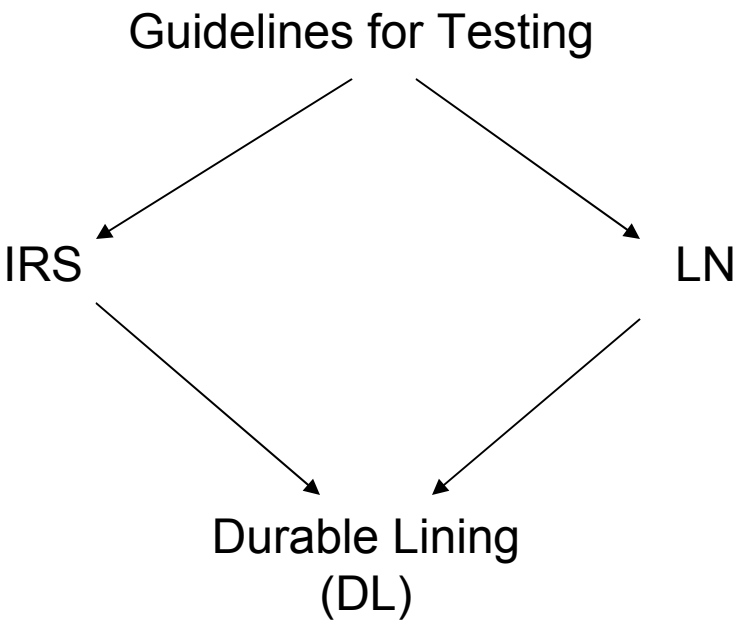
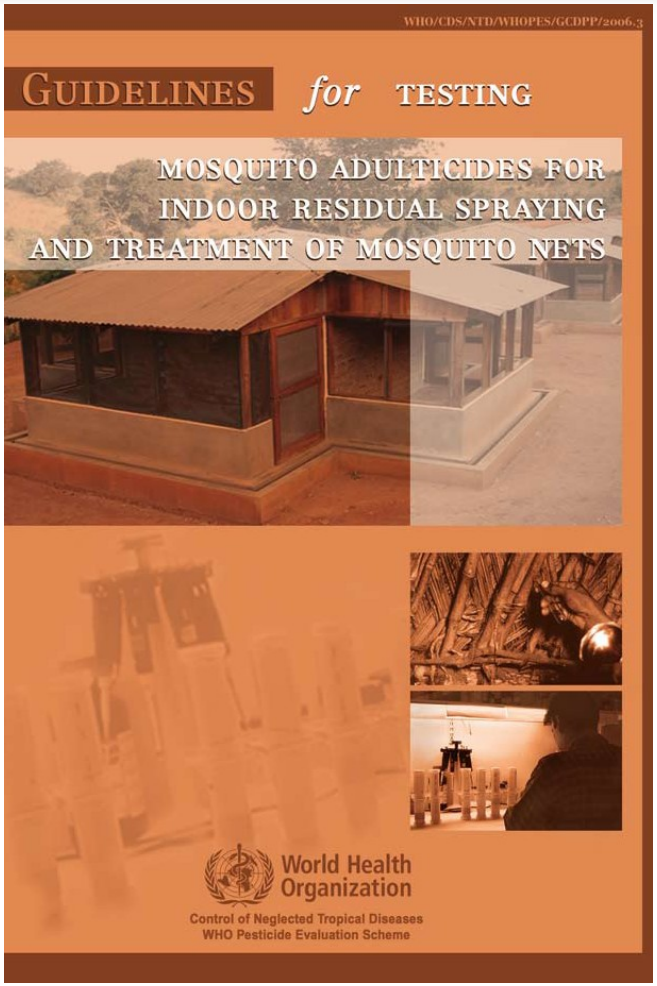
Durable Lining – Guideline development



- hybrid of IRS and LN
- unique features
- range of applications



WHO/CDS/NTD/WHOPES/GCDPP/2006.3

➔ DL fits many WHO-established guidelines but has unique characteristics

What Should Set the Base Lines for Testing Criteria:

Performance Criteria generally set Testing Criteria.

Durable Linings design and performance should logically respond to lessons learnt from malaria control experience today with LLINs and IRS; and provide an effective alternative where current limitations of IRS &/or LLINs may limit their long term suitability if we are to achieve millennium and RBM goals for malaria control.

- **Feasibility** (logistically feasible and suitable for end user/home)
- **Physical durability** (the product will last several years in a condition that continues to afford protection)
- **Insecticide residual durability** (will last at a lethal dose for an acceptable length of time)
- **Acceptability** (end users will want it, use it and maintain it),
- **Effectiveness** (does it work in application)
- **Affordability** ("value for money", cost of obtaining consistent correct usage and protection / families/ year)

Performance challenges / lessons learnt from LLINs and IRS?

LLINs:

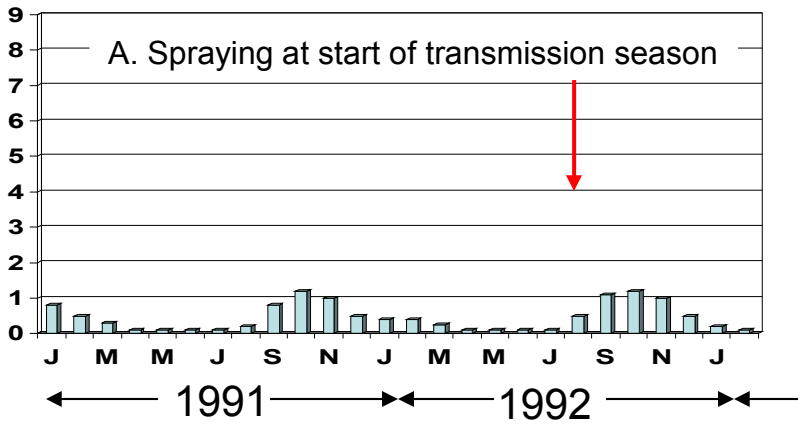
- Chemical durability is generally good and outlasts LLIN material durability.
- Challenges converting numbers “distributed” into nets “hung over sleeping areas” with “sustained and correct usage”.
- LLIN physical durability is proving very variable, but consistently lower than previously assumed = more costly to maintain effective coverage than expected.

IRS:

- Relatively fast to roll out but challenging for logistics, safety and the environment
- Challenging to obtain consistent application quality/coverage and insecticide dosage
- Acceptance / coverage rates are hard to sustain year on year
- Remains a vital tool for short term emergencies : expensive to sustain.
- Short residual life results in sub lethal dosing phases, unprotected periods for households, and its mode of action advances insecticide resistance
- Delays in spray round delivery can result in very serious consequences.

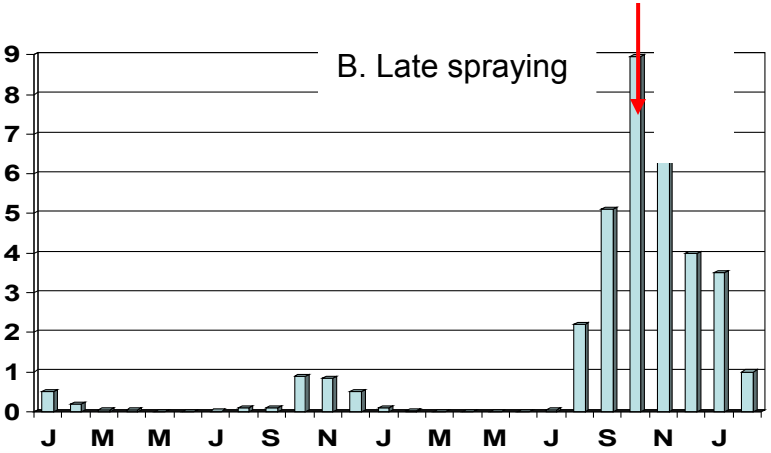
Impact of 2-month delay in spraying on malaria incidence*

Village 1



INCIDENCE
(per 100 person years)

Village 2
(nearby)



For every month of delay
There is a 15% increase
in odds to contract malaria
(Kleinschmidt, et al, 2007)

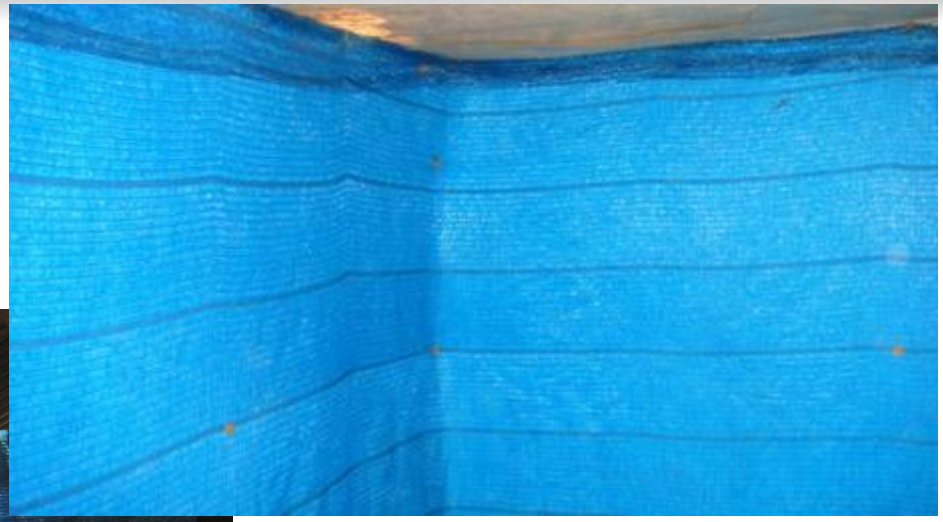
INCIDENCE

*WHO, 2005, Malaria Field Handbook

➔ Late timing can result in dramatic increases in malaria cases

DL Design Feasibility and Material Durability Criteria

Durable Lining (DL) – Feasibility for traditional house design



Specifications of ZeroVector®

- woven shade cloth
- 100% polyethylene, 50% shading
- 55 gm/sqm
- 4.4 gm insecticide a.i./kg material
- 2.35m x 100m rolls
- Color options
- Plastic nail caps
- Nails

➔ DL provides community protection and overcomes many IRS challenges

Durable Lining – Physical characteristics must suit application / durability targets

➔ DART's DL is an insecticide impregnated shade cloth

Durable Lining – operation issues: installation testing

1. Load test

Scenario	Simulate DL fixed on wall for 4 years or has a heavy item hanging on it
Effect	Static load applied to a number of interventions, over a longer time
Sample	30cm wide shade cloth, fixed several places and applied a heavy load, increased by day
Evaluation	The DL should not fall down





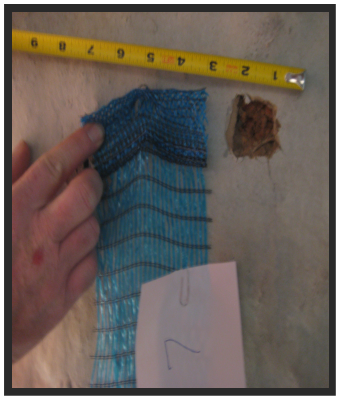
➔ installation methods need to keep material up for years

Durable Lining – operation issues: installation testing

2. Pull test

Scenario	Child pulls on DL unattended
Effect	Increased downward load applied to a very limited area of fixing.
Sample	10cm wide shade cloth, fixed one place. Applied an increasing downward load until fixing failed
Evaluation	Quantified load measure of each fixing products ability to grip DL and wall



➔ installation methods need to keep material up for years

Durable Lining – operation issues: installation testing

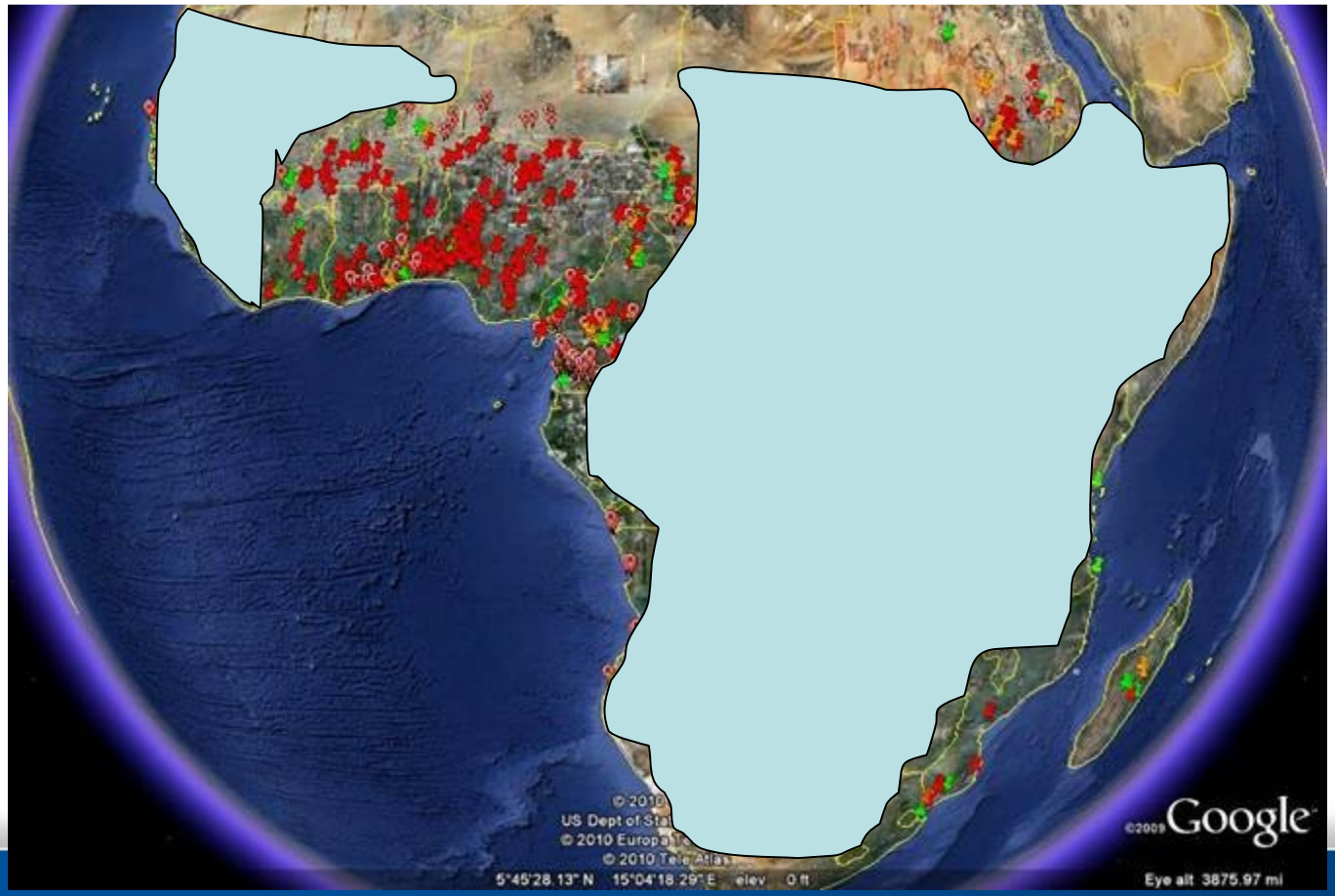
3. Peel test

Scenario	Child pulls on DL unattended
Effect	Increased outward load applied to a very limited area of fixing.
Sample	10cm wide shade cloth, fixed one place. Applied an increasing outward load until fixing failed
Evaluation	Quantified load measure of each fixing products ability to grip DL and wall

➔ installation methods need to keep material up for years

Insecticide Durability in Target Usage Areas

- Intrinsic insecticidal activity – **a.i. deltamethrin, known from IRS and LN studies**
- Diagnostic concentration – **dosage as mg/sqm established**
- Irritant or excito-repellent properties - **deltamethrin**
- Cross-resistance to other insecticides – **same as for other pyrethroids**
- Efficacy and residual activity on relevant substrates – **no limitations noted**



➔ DL should be placed where pyrethroid resistance is not advanced

Related Published Studies:

- Insecticide treated polyethylene sheeting for prevention of malaria in acute emergencies: A phase III cluster randomised trial in a refugee setting in Sierra Leone. **Burns, M. et all.** Submission July 2010.
- *The indoor use of polyethylene sheeting pre-impregnated with insecticide for control of malaria vectors.* **Diabate, A, et al.** 2006, Tropical Medicine and International Health, Vol. 11, pp. 597-603.
- *Evaluating insecticide-treated polyethylene sheeting for malaria control in complex emergencies: an intersectoral approach.* **Burns, M.** 2005, Humanitarian Exchange, Vol. 31, pp. 14-16.
- *New tools to control malaria in refugee camps.* **Graham, K.** 6, 2004, The Journal of the Royal Society for the Promotion of Health, Vol. 124, pp. 253-255.
- *Cash and Crisis: Motivating the private and public sector to establish common goals.* **Allan, R, Burns, M and Frandsen, M.V.** June 2003, International Aid and Trade Review, pp. 90-91.
- *Rolling Back Malaria amongst Displaced People in Complex Emergencies: Innovative Public/Private Partnerships*. **Allan, R** and Guillet, P. 2003, Multilateral Initiative on Malaria (MIM). Abstract 433. (alanr52783).
- *Changes in house design reduce exposure to malaria mosquitoes.* **Lindsay, S.W, et al.** 6, 2003, Tropical Medicine and International Health, Vol. 8, pp. 512-517.
- *Roll back malaria challenges in complex emergencies.* **Allan, R and Guillet, P.** 2002, International Aid and Trade Review, Vol. 1, pp. 27-29.
- *Insecticide treated polyethylene tarpaulins for control of malaria vectors in refugee camps.* **Graham, K, et al.** 2002, Medical and Veterinary Entomology, Vol. 16, pp. 404-408.
- *Reducing malaria by mosquito-proving houses.* **Lindsay, S.W, Emerson, P.M and Charlwood, J.D.** 11, 2002, Trends in Parasitology, Vol. 18, pp. 510-514.
- *Parasites & Guns: Waging War Against Malaria*. **Allan, R**. 2001, African Health Journal, Vol.24, pp.12-13.
- *Roll Back Malaria: The challenges in complex emergencies.* **Allan, R**. 2001. International Health Exchange. Dec: pp. 4-9

Durable Lining – Phase I (laboratory studies)

Aim of WHO Guidelines for Phase I:

- Intrinsic insecticidal activity
- Diagnostic concentration
- Irritant or excito-repellent properties
- Cross-resistance to other insecticides
- Efficacy and residual activity on relevant substrates

IRS residual testing:

- 30 minute exposure, 24 hr mortality
- cutoff at 80% mortality
- evaluate @ 1 wk, monthly until below cutoff
- hold substrates @ 30°C between tests
- mud, concrete, plywood, bamboo, thatch

LN residual testing:

- 3 minute exposure, 1 hr KD, 24 hr mortality
- cutoff at 95%KD, 80% mortality
- wash 20X
- evaluate after each wash until below cutoff

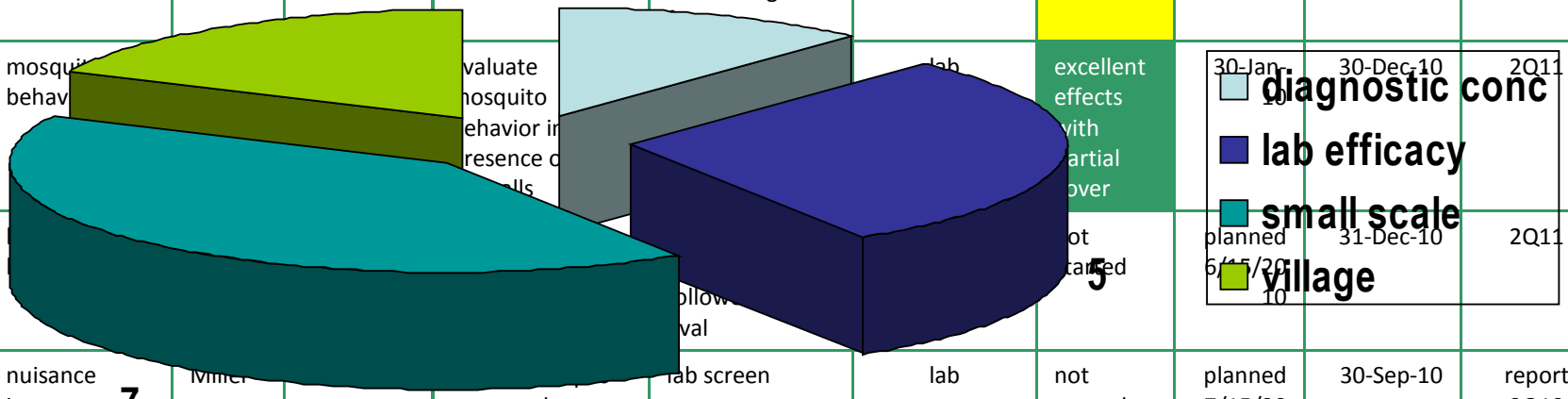
Durable Lining residual characteristics:

- expected to be a replacement for IRS, so, 30 minute exposure?
- structure surfaces infrequently washed but do get covered with dust, washing?
- Covers variety of wall surfaces, should all be tested?

➔ What should be the Phase I testing criteria?

Durable Lining – field trials / study overview

Country	Study objectives	Name of PI	Institutional affiliation	Study title	Study outline	Scale (units with DL)	Results	Timing: Study start	Timing: End of study	Publication
Laboratory and hut studies	**Development trial program, 2006-10**									
Burkina Faso	Phase II hut study	Corbel	IRD	DL evaluation in Phase II huts in resistance area	typical hut study in area with high DM resistance, entomological	6 huts	susceptible ok; resistant not	01-Nov-08	30-Mar-10	report 2Q10
USA	mosqui… behav…			…valuate …osquito …ehavior i… …resence o… …lls		lab	excellent effects …ith …artial …over	30-Jan-10	30-Dec-10	2Q11
USA					…ollow… …val		…ot …tarted	planned 6/15/2010	31-Dec-10	2Q11
USA	nuisance insects	Miller		pests such as cockroaches, ants, bedbugs, flies	lab screen	lab	not started	planned 7/15/2010	30-Sep-10	report 3Q10



➔ Laboratory and hut studies validate efficacy

Current Durable Lining – Lab and Hut Studies

Country	Study objectives	Name of PI	Institutional affiliation	Study title	Scale (units with DL)	Results	Timing	
							Study start	End of study
Laboratory and Hut studies								
Burkina Faso	**Phase II hut study**	**Corbel**	**IRD**	**DL evaluation in Phase II huts in resistance area**	**6 huts**	**susceptible ok; resistant not**	**01-Nov-08**	**30-May-10**
USA	**mosquito behavior**	**Achee**	**Uniformed Services Univer**	**Evaluate mosquito behavior in presence of DL on walls**	**lab**	**excellent effects with partial cover**	**30-Jan-10**	**30-Dec-10**
USA	**behavior and hut study**	**Clark**	**USDA**	**lab and hut evaluations of DL**	**lab + 4 huts**	**not started**	**planned 6/15/2010**	**31-Dec-10**
USA	**nuisance insects**	**Miller**	**Va Tech**	**test against pco pests such as cockroaches, ants, bedbugs, flies**	**lab**	**not started**	**planned 7/15/2010**	**30-Sep-10**

➔ Laboratory and hut studies validate efficacy

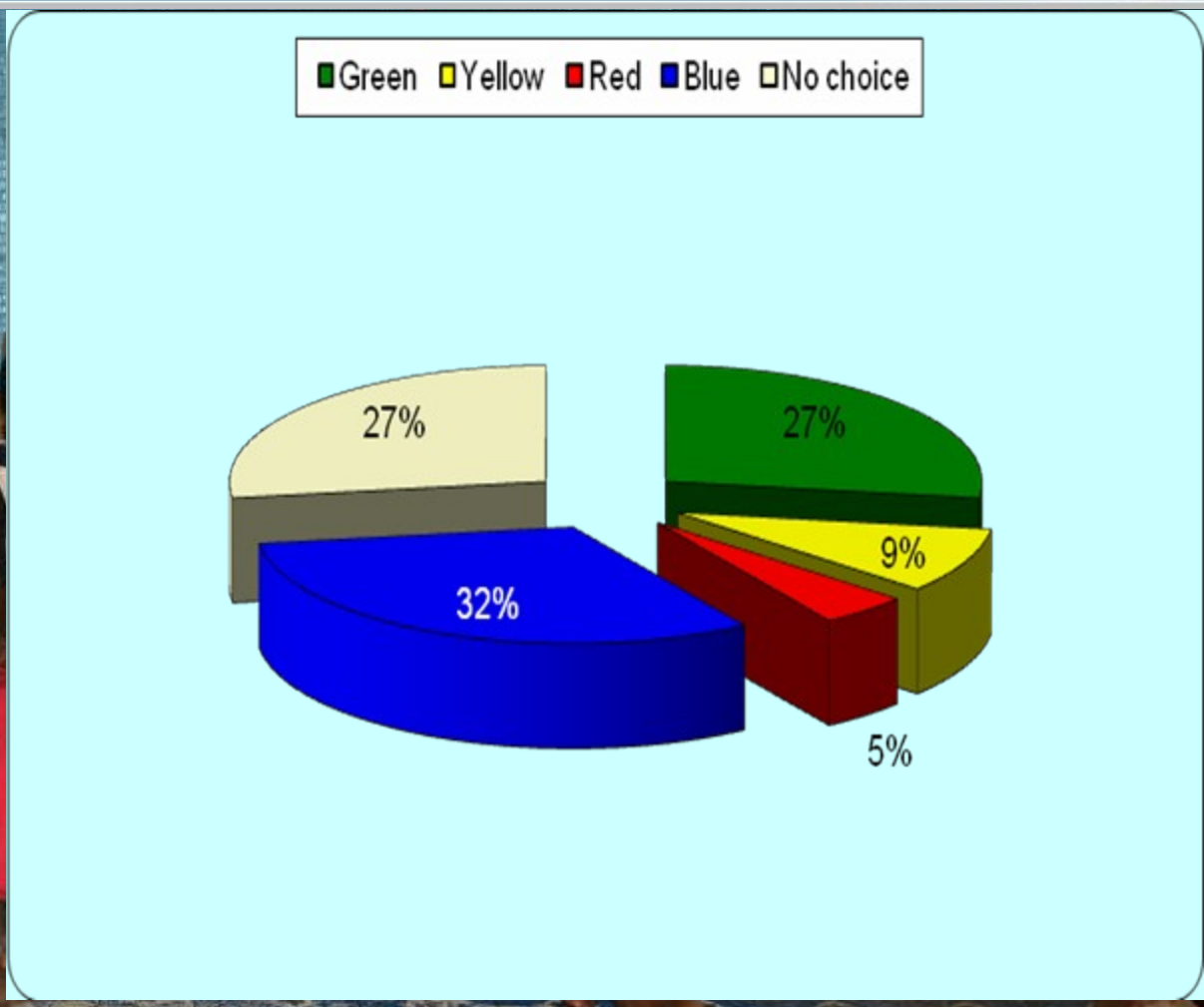
Country	Study objectives	Name of PI	Institutional affiliation	Study title	Scale (units with DL)	Results	Timing	
							Study start	End of study
Small-scale trials (<50 houses) to determine feasibility, acceptability, entomological + chemical durability								
Equatorial Guinea	acceptability, durability, efficacy	Abrahan + Rowland	MCDI +LSHTM	comparison of DL, IRS, and LN curtains, small scale	20 huts	excellent on all measures	15-Oct-08	30-Jan-10
Ghana	acceptability, durability, efficacy	Knowles + Rowland	AngloGold + LSHTM	STA&D, small scale	30 huts	excellent on all measures	09-Oct-08	30-Oct-09
Mali	acceptability, durability, efficacy	Coulibaly + Rowland	MRTC + LSHTM	STA&D, small scale	20 huts	excellent on all measures	05-Sep-08	01-Oct-09
Nigeria	user acceptability	Knox	VF	long-term evaluation of DL, demo type small scale	50 huts	excellent on all measures	07-Nov-06	01-Nov-11
South Africa	acceptability, durability, efficacy	Mulder + Rowland	Agricultural Research Station + LSHTM	STA&D, small scale	17 houses	excellent on all measures	09-Oct-08	30-Jun-09
Vietnam	acceptability, durability, efficacy	Hoan Le	VF	STA&D	25 houses	excellent on all measures	15-Mar-09	30-Jun-10

Durable Lining – Village / Large Scale Studies

Country	Study objectives	Name of PI	Institutional affiliation	Study title	Study outline	Scale (units with DL)	Results	Timing		Publication
								Study start	End of study	
Village-scale trials (500 or more houses) to compare conventional tools and determine disease impact										
Angola	**village trial, evidence of disease reduction**	**Carneval e**	**IRD, Sonamet**	**Comparison of vector control interventions**	**multiple villages with DL, IRS, PN, ZF**	**200 huts**	**excellent at interim**	**23-Dec-08**	**30-Sep-10**	**2Q11**
Kenya	**village trial, evidence of disease reduction**	**Vulule**	**KEMRI**	**Evaluation of DL for community protection**	**multiple villages comparing DL with IRS for disease reduction**	**500 huts**	**excellent at 6 mo.**	**30-Sep-09**	**01-Oct-11**	**2Q12**
Large-scale trials (501 - 3,000 houses)										
Kenya	**village trial, evidence of disease reduction**	**Gimnig**	**CDC**	**Phase III type village trial comparing DL and nets for disease impact**	**large trial (2700 huts) to compare DL with nets over multiple years**	**2,700 huts**	**Data not collected**	**15-May-10**	**01-Apr-12**	**2Q13**

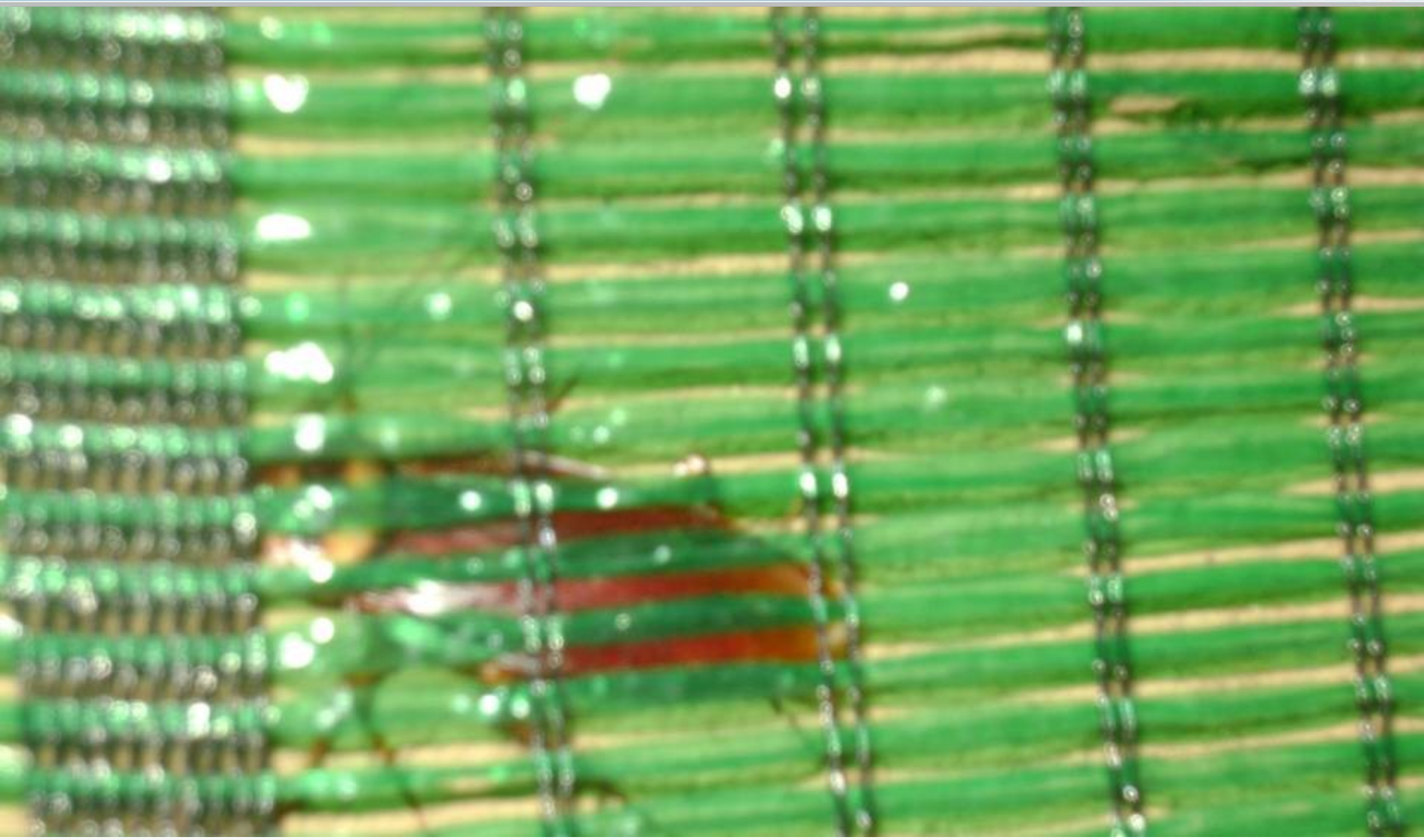
Durable Lining – Feasibility : house installation testing

Acceptability



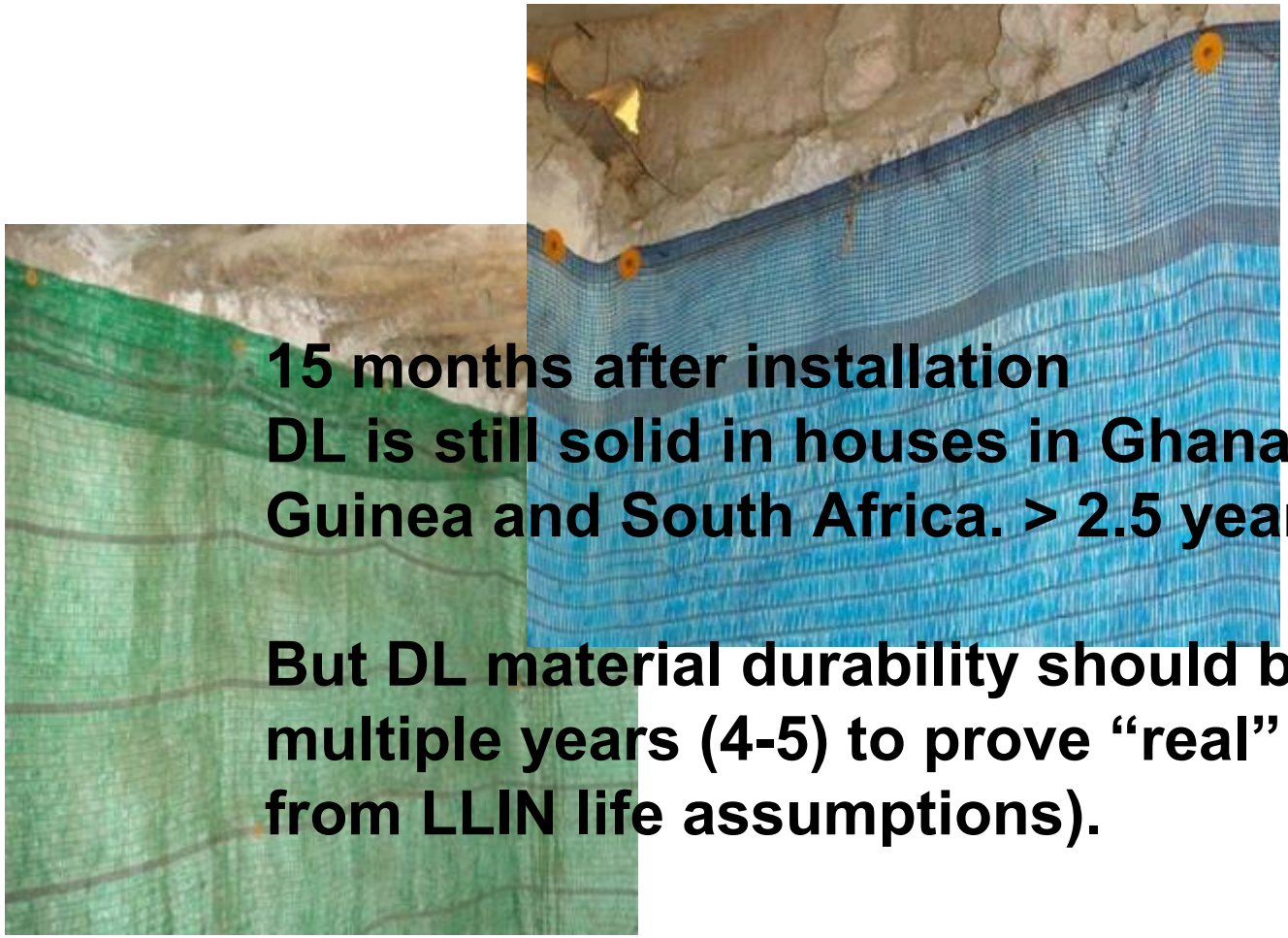
Significant community and family acceptance in every study to date

Durable Lining (DL) – resident acceptability



Residents have a very positive impression that DL improves the interior of the house and controls mosquitoes and nuisance insects

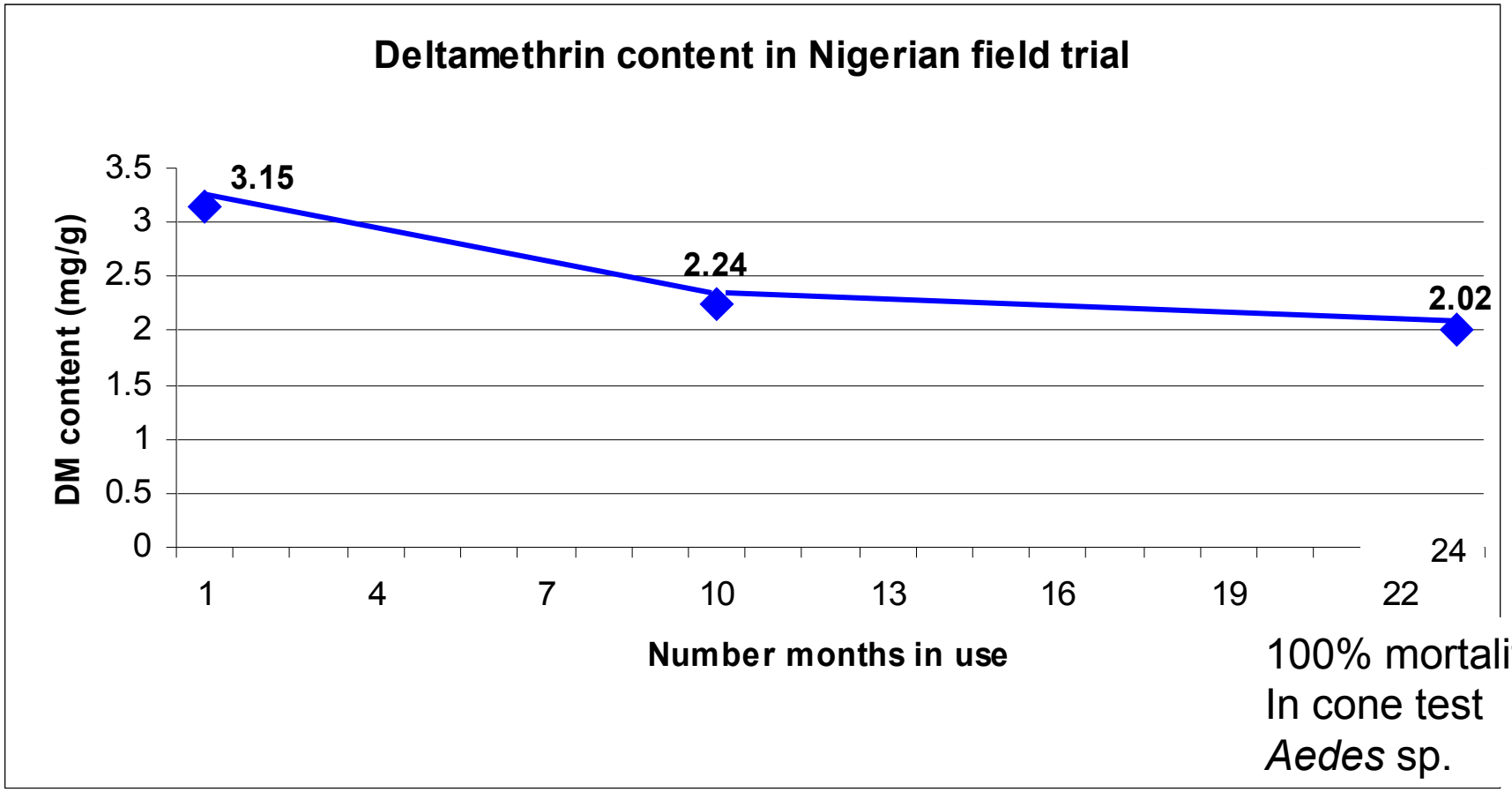
Durability: Physical and Chemical



15 months after installation
DL is still solid in houses in Ghana, Mali, Equatorial Guinea and South Africa. > 2.5 years in Nigeria

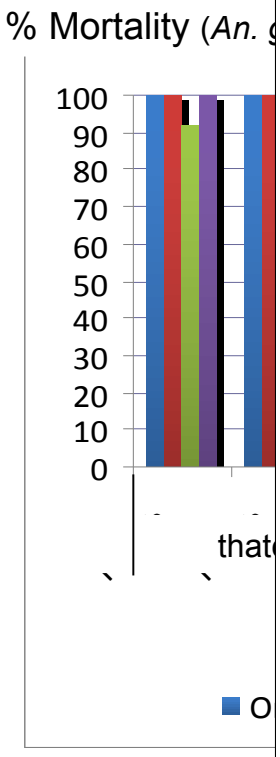
But DL material durability should be monitored over multiple years (4-5) to prove "real" life (learning from LLIN life assumptions).

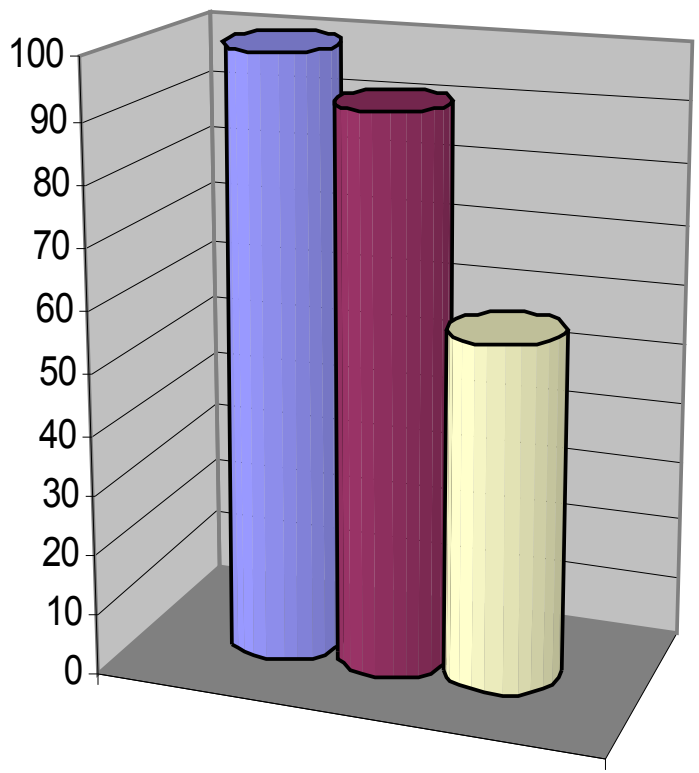
Durable Lining (DL) – insecticide residual activity n should ideally be equivalent to the material durability



➔ DM rate of loss slows over time leading to conclusion reservior is sufficient for 5 yrs

Durable Lining (DL) – Insecticidal activity should not vary with substrate (as IRS does)





Durable Lining – Phase II (small-scale studies)

Aim of WHO Guidelines for Phase II:

- Efficacy and persistence under different ecological settings
- Dosage of application
- Handling and application
- Perceived side-effects

IRS hut testing:

- no rotation between huts
- cover walls, ceilings, doors
- test papers to evaluate spray coverage & dose
- no washing of sprayed surfaces
- use different surface types
- evaluate spray safety & operational issues
  - adverse effects, ease of application

LN hut testing:

- rotate nets between huts
- cut holes deliberately in nets
- use washed nets
- compare to negative control

Durable Lining characteristics:

- surface coverage, need for ceiling questionable
- coverage of open eaves?
- what pre-test handling needed?
- compare to IRS? LN?
- installation considerations

➔ DL has characteristics similar to both IRS and LN, with some additional unique

EFFECTIVENESS

DL large trial – malaria impacts in Angola

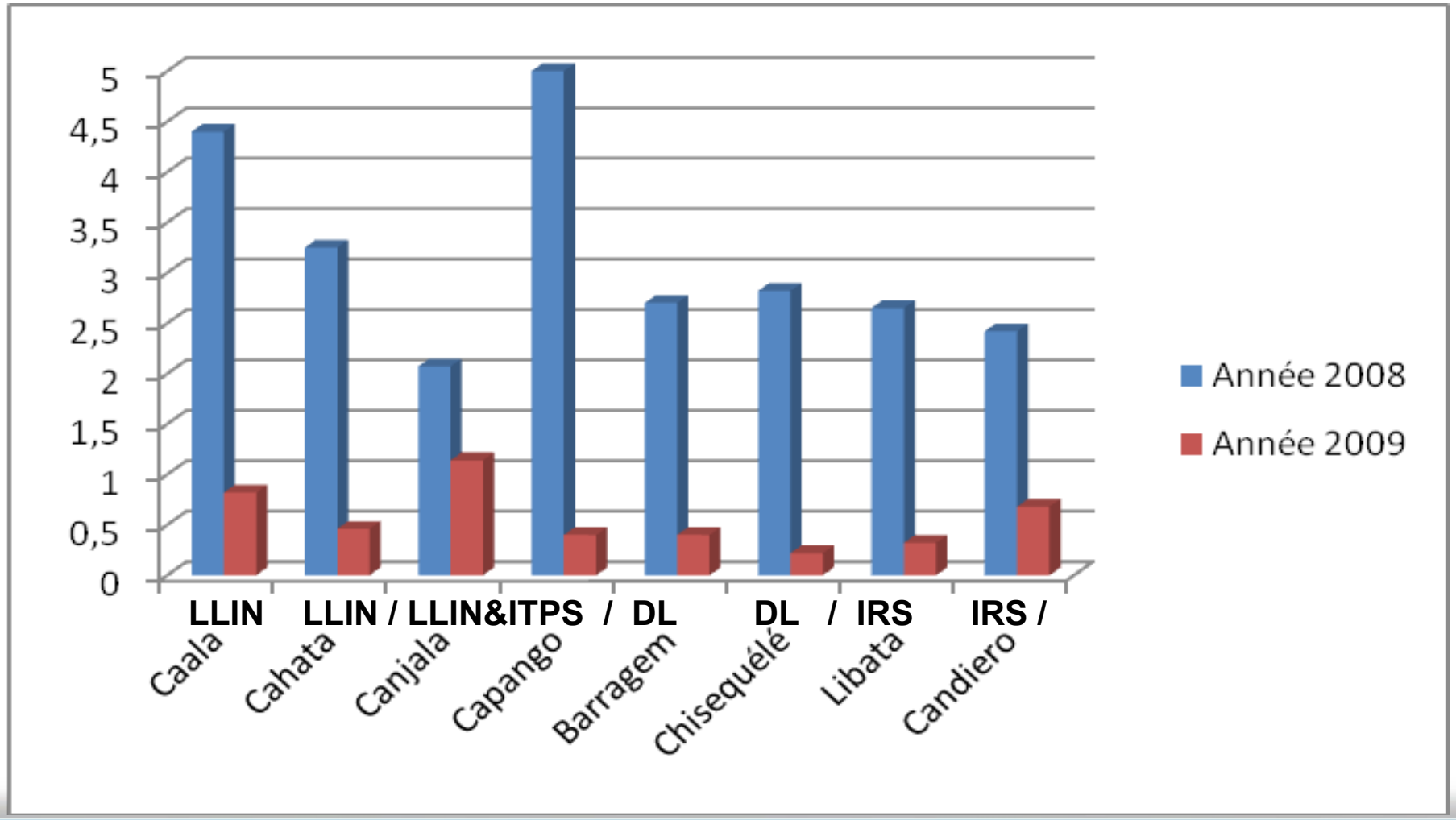
- Paired villages (large), multi-year study
- Designed to measure reduction in malaria impact.
- Two villages per treatment to be assessed for vector control and parasiteamia.

Méthode de lutte	IP « moyens »			IP « élevés »		
	villages	IP	Population estimée	villages	IP	Population estimée
LLIN	Caala	60%	1836	Cahata	80%	678
LLIN + ZF	Canjala	65%	2166	Capango	86%	413
IRS	Candieiro	63%	2987	Libata	95%	2856
WL	Barragem	70%	3251	Chisséquélé	84%	2517

% Parasiteamia in children in 8 paired villages, Lobito Angola

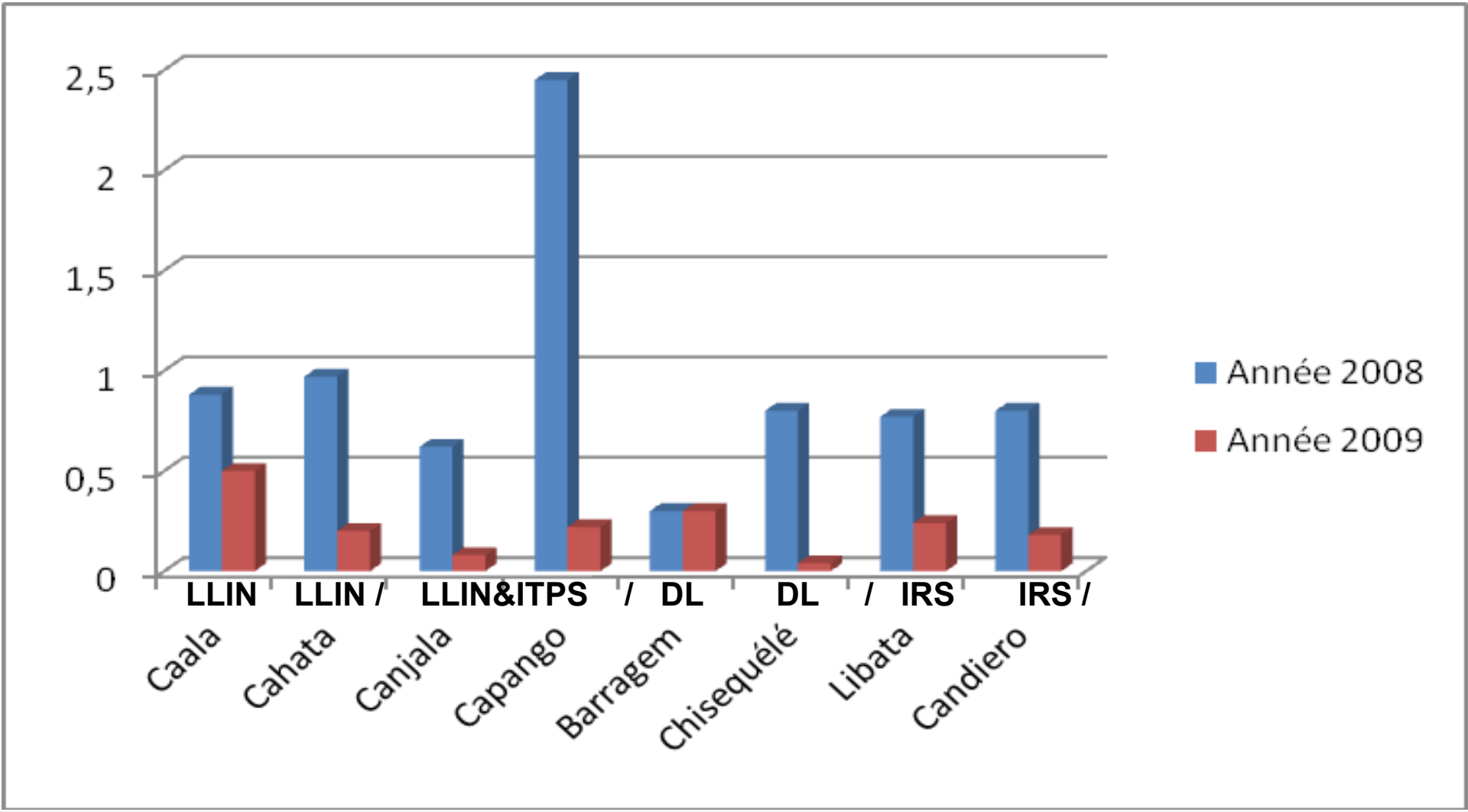
15,006 blood slides examined; 4,828 parasite +ve. Children 2-9

Average No. Mosquitoes (anopheles + culex) trapped / home / night, Lobito Angola



1080 house trap nights; 2065 moustiquitoes caught of which 754 were anophèles

Average No. Anopheles mosquitoes trapped / home / night, Lobito Angola

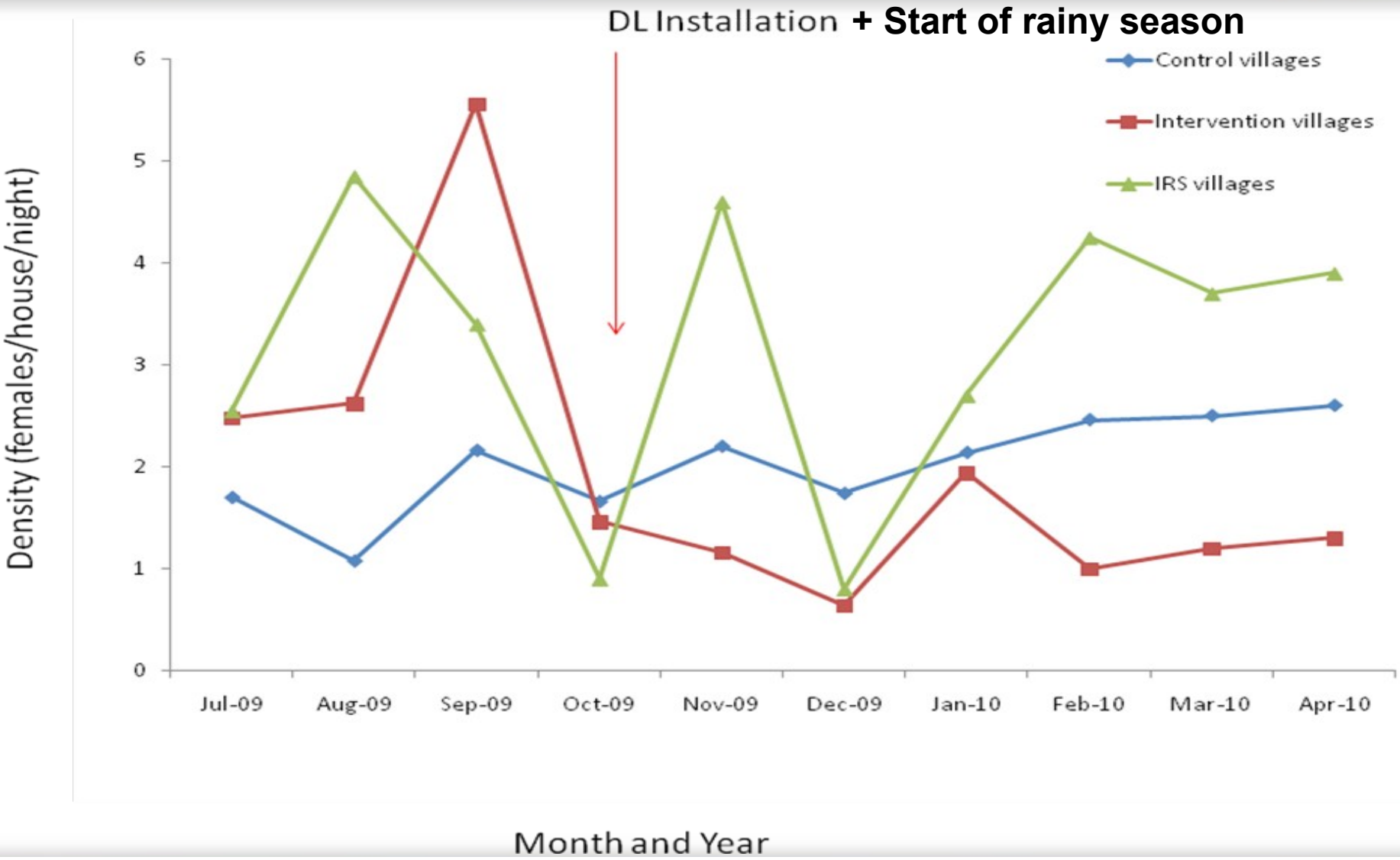


80% reduction from 2008 to 2009 **(0,9 anopheles per house to just 0,2)**

KENYA: Densities of *An. gambiae* female mosquitoes in KEMRI 12 paired village study

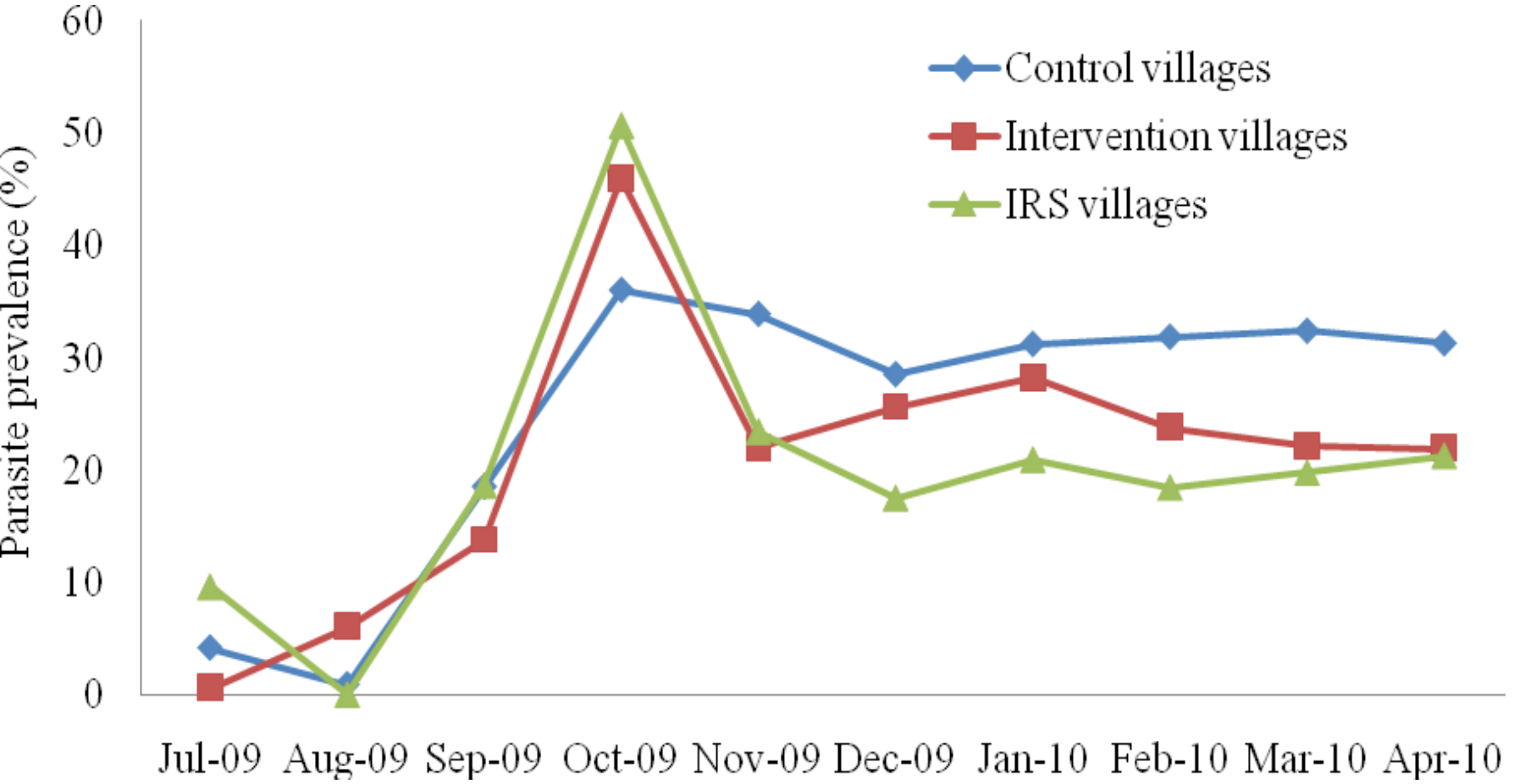
Density (females/house/night)

Densities of *An. funestus* female mosquitoes in KEMRI 12 paired village study



4565 mosquitoes: 61.8% *Culex quinquefaciatus say*; 28.1% *Anopheles gambiae s.l.;* 10.5% were *An. funestus*.

P. falciparum parasite prevalence in control, intervention and IRS villagers, KEMRI Kenya



Durable Lining – Phase III (large-scale trials)

Aim of WHO Guidelines for Phase III:

- Efficacy and residual activity
- Operational issues
- Community acceptance

IRS village testing:

- human landing rates
- density reduction
- residual on different wall surfaces
- acceptability by operators & residents

LN village testing:

- user compliance
- mass killing effects
- impact on vector density

Durable Lining characteristics:

- surface coverage, need for ceiling questionable
- coverage of open eaves?
- what pre-test handling needed?
- compare to IRS? LN?
- installation considerations

➔ Village scale tests combine all aims for IRS and LN

Design of a potential study: What to measure if 10,000 people were targeted for each intervention?

IRS

- Spraying time
- Coverage rate
- Delay in spraying
- Acceptance rate (push back from the households)
- Insufficient cycles of spraying
- Program cost

DL

- Installation time
- Coverage rate
- Delay in installation
- Acceptance rate (push back from the households)
- Program cost

Cost Effectiveness of Prevention Tools

- Global Fund TRP want prevention tools to use at national level that give "Value for Money"
- What are the indicators to consider for "value for money"?
- Basic tool costs alone?
- Cost of ensuring families receive and correctly use and maintain an effective tool?
- Cost of maintaining adequate community level coverage and usage.
- Impact on lives and suffering (added treatment costs) caused by timeliness or delay in tool delivery
- Impact on lives and suffering caused by lack of continuity of "protection" (resulting from limits of tool chemical and material durability or family usage duration)
- Cost implications on resistance management from annual sub lethal dosing cycles with IRS or longer lasting insecticidal activity (with materials).
- Suitability of the tool for long term malaria prevention at household level once malaria transmission control/eradication has been achieved, and the tools cost an usage implications

Durable Lining (DL) – SUMMARY

Durable Lining is an alternative prevention tool, a hybrid between IRS and LN:

- Coverage for surfaces, and mosquito entry points
- High acceptability within communities,
- Aesthetic qualities ensure maintenance and long term acceptance
- Long residual activity
- Physical durability for many years
- Breaks malaria transmission cycle and likely to be a good tool for maintaining malaria control gains with minimal need for external input.

➔ Durable Lining warrants a separate category for vector control