Developing consensus SOPs for evaluating next-generation ITNs

Session 3: Enhancing the impact of core interventions

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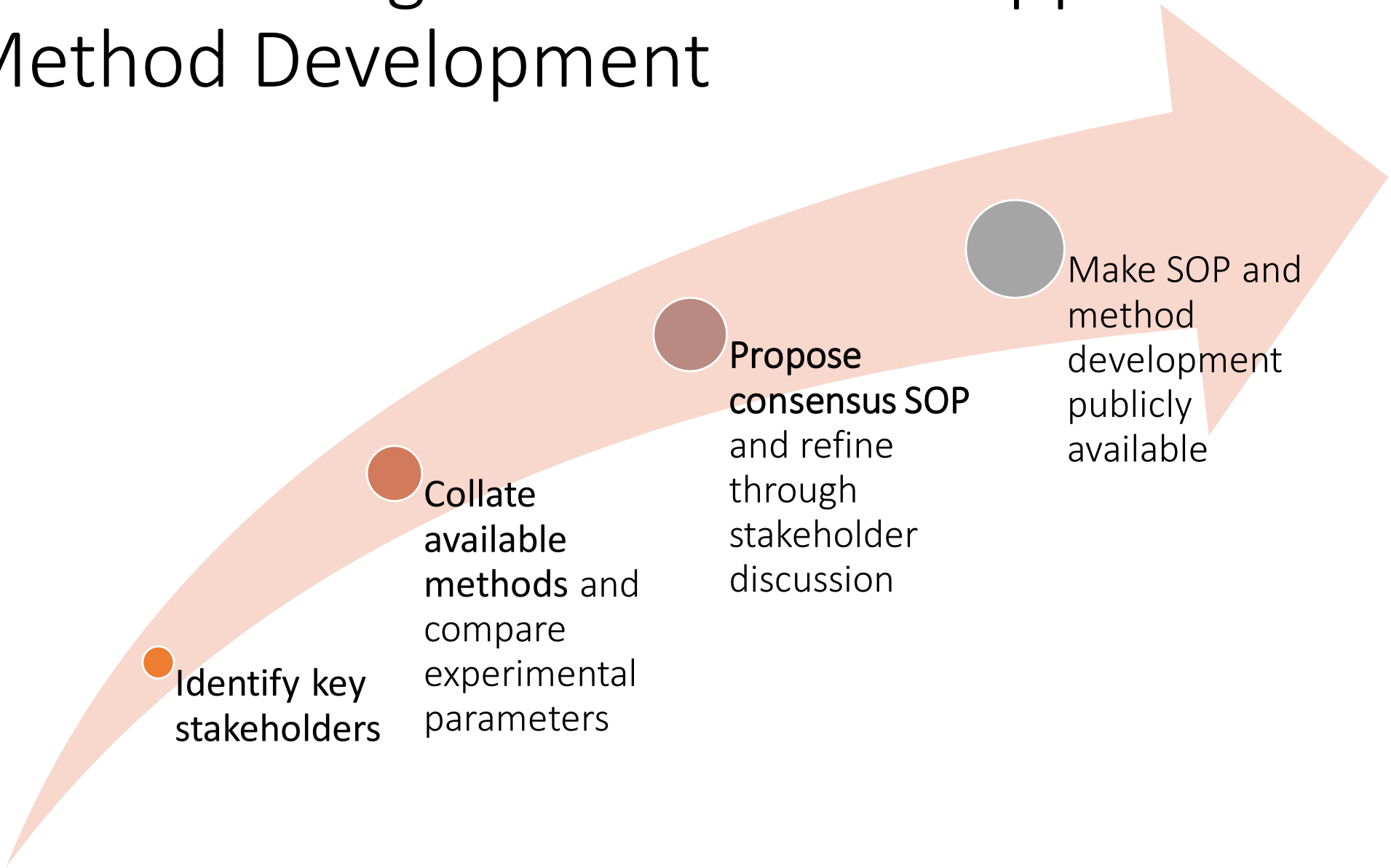
No recommended durability monitoring methods for **next-gen ITNs**, despite products already being PQ listed

- Next-gen ITNs are PQ listed and many are being evaluated in RCTs and pilot deployment schemes.
- All contain two AIs and novel MoA, so methods for efficacy testing necessarily differ from those used for pyrethroid-only ITNs
- Methods for monitoring their durability have not been validated.
- We demonstrate a pipeline to collate and interrogate current methods to produce a ‘consensus SOP’.

There are four stages to Method Validation

Method Development	• Define desired outcomes, and design and refine methodologies
Feasibility Experiments	• Quantify inherent error in the method
Internal validation	• Evaluate the ability of the method to accurately characterize VC product(s)
External Validation	• Affirmation of results by two external laboratories

We are taking a collaborative approach to Method Development



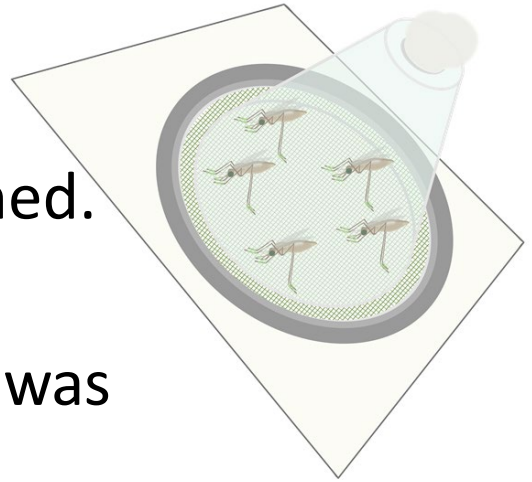
Potential methods for durability monitoring were identified through literature search and stakeholder discussions

ID	Project/Trial	Timeline	Durability monitoring	Methodology
1	PMI VectorLink project	Ongoing(?)	Y	Provided
2	New Nets Project in Burkina Faso	Ongoing	Y	Provided
3	LLINUP Trial – durability testing in Uganda	Complete(?)	Y	Provided
4	LLINUP Trial – durability testing in LSTM	Ongoing	Y	Provided
5	Awolola 2014, Nigeria village trial	Complete	Y	Published
6	RCT, Kenya, SMART trial (NCT04182126)	Ongoing	Y	Provided
7	RCT, DRC trial, Weetman (ISRCTN99611164)	Ongoing	Y	Not determined
8	RCT, Kenya (UMIN000019971)	Ongoing	N	-
9	RCT, DRC trial, Ilombe (NCT03289663)	Ongoing	Unknown	Unknown

Searching the historical, on-going, and planned trials we identified **six** accessible SOPs monitoring durability

- Three other pyrethroid-PBO net RCTs trials were identified, and authors were contacted:
  - For one study it was not possible to ascertain if they were measuring durability
  - One will not be conducting durability monitoring
  - One had not set its methods for durability monitoring
- Method development also considered the WHO guidelines on conventional cone tests
  - However, no guidance on PBO thresholds or interpretation of data are provided

We conducted a collaborative process of method development and iterative drafting of an SOP



1. Key experimental parameters for the bioassay were established.
2. Parameter data were extracted from the accessible SOPs.
3. Extracted data were compared and a ‘consensus parameter’ was suggested for each experimental element.
4. Other methodological considerations and remaining questions were identified.
5. The method development was shared with stakeholders for feedback.
6. Feedback was used to prepare a draft ‘consensus SOP’.
7. This SOP will be shared with stakeholders for a second round of feedback before a final SOP is agreed on to take forward for validation.

The **WHO cone test** appeared to be a suitable method for monitoring durability of pyrethroid-PBO nets

- Currently 6 pyrethroid-PBO nets are PQ listed.
- These vary in pyrethroid AI, PBO concentration, and location of PBO on the net (e.g. roof only).
- Need to consider: control nets and the characteristics (resistance) of mosquito strain tested.
- Data is already being generated which can be used to validate an SOP, and provide guidance on interpretation of data.

Thank you for listening

Participants so far:

Alison Reynolds, Angus Spiers, Christen Fornadel, Jackline Martin, Jennifer Armistead, John Gimnig, Joseph Wagman, Katherine Gleave, Lilia Gerberg, Louisa Messenger, Melissa Yoshimizu, Natacha Protopopoff, Sarah Moore, Sarah Zohdy, Seth Irish, Stephen Poyer