WHO Prequalification of Vector Control Products

Considerations for post-market surveillance (PMS) of WHO prequalified insecticide treated nets (ITNs)

1. Purpose

This document was developed to respond to the requests from stakeholders, including Member States, procurement agencies, and NGOs, for updated guidance on conducting post-market surveillance (PMS) activities for insecticide treated nets (ITNs). PMS can cover a wide variety of activities and be employed to address different questions and interests from stakeholders. The specific technical questions which may be addressed as part of PMS activities are dependent on the stakeholder, and the intent of the monitoring activities.

This document does not specify nor propose exact technical questions around which PMS activities must be conducted. Rather, this document is intended to:

- Present considerations for the development and implementation of PMS activities to all interested stakeholders
- Provide guidance on defining the motivation and questions of PMS activities
- Present the life stages of ITNs in relation to PMS activities
- Highlight the indicators and data that are submitted to WHO PQT/VCP as part of the pre-market assessment of ITNs, those data points that are made publicly available in published WHO Public Assessment Reports (WHOPARS), and the usefulness of specific indicators and data included in the PQ application to address the PMS questions.
- Discuss the management of uncertainty in PMS data, and identify risks to interpretation and usefulness of results

This document should not be viewed as a checklist nor requirement for PMS activities. Instead, it should be considered as guidance information that aids in developing PMS activities in the form necessary to address the needs of the stakeholders. The document is therefore meant to enable and empower responsible organizations in their design of PMS activities as compared to recommending actions which may not be applicable nor valuable to the situational needs.

2. To what does ‘post-market’ refer?

‘Post-market’ refers to the time in a product’s regulatory lifecycle after the premarket authorisation has been established and the product has been marketed/is in the marketplace.

Post-market requirements may include the responsibility of product owners to report changes to the product, submit annual reports, provide specific data required as a condition of the approval/acceptance of the product, and respond to calls for information by the relevant authority.

WHO Prequalification of Vector Control Products
Avenue Appia 20
1211 Geneva 27, Switzerland

For further information, contact:
pqvectorcontrol@who.int
https://extranet.who.int/prequal/vector-control-products

The activities that are generally referred to as 'post market surveillance and monitoring' are those activities that collect information about the safety, quality, and performance of a product when in operational use. The collection of these data may be required by certain authorities, procurers, or other stakeholders. On the other hand, PMS activities may be conducted outside of an expressed requirement, but in order to address questions of interest regarding operational product performance or collect data to support new claims associated with the product. Regardless of the stakeholder, it is crucial that the design of PMS activities is carefully considered such that the interests and requirements of all involved stakeholders can be answered within a single study design, where possible.

2.1. Post-Market and Prequalification

The Prequalification Unit (PQT) of WHO in the Department of Regulation and Prequalification (RPQ) performs premarket assessments of health products. In this context, WHO provides a regulatory function conducting premarket assessments in accordance with established procedures to ensure that eligible products are safe, efficacious, and quality-assured. WHO prequalification is not a global registration. For WHO prequalification of ITNs, the premarket data/dossier requirements are published in the WHO Guideline for prequalification assessment of ITNs.

All manufacturers are required to comply with the relevant requirements for maintaining the validity of a prequalification decision. Examples include submitting change applications, maintaining compliance with established specifications, and responding to submitted complaints/issues.

Depending on the type of health product and/or outcomes of an assessment, there may be post market data requirements established as part of the relevant WHO prequalification procedures with which the applicant must comply. As these commitments are conducted after the prequalification listing decision, they are regarded as 'post-market commitments.' When the need for post-market commitments are identified as part of the prequalification assessment and decision processes, these are presented in the product specific WHOPAR part 2 document available on the prequalification page for that product.

The nature of these commitments is dependent upon the type of health product, the outcome of the premarket assessment, international norms and standards, and the procedures for relevant procedures for prequalification. National Regulatory Authorities (NRAs) responsible for the registration or market authorization of health products at the country level may also impose similar post-market data requirements in accordance with their legislation and regulations.

For some health products, there may be explicit requirements for PMS activities to be conducted. In accordance with the WHO Guideline for prequalification assessment of ITNs, there is a requirement for manufacturers of ITNs to submit long-term community studies to characterize the performance of ITNs in operational use. The available guidance on conducting these studies provides information specific to the needs and use of generated data within the context of the prequalification assessment and as such may not align with nor cover all the potential interests of other stakeholders. Where PMS activities are conducted out of interest or to comply with requirements of other stakeholders, WHO PQT/VCP does not mandate specific designs, nor questions, for these PMS activities.

3. Post-market surveillance in relation to the ITN lifecycle

There are three stages in the lifecycle of ITNs (Fig 1). These can be referred to as:

- Manufacturing – begins with the receipt of raw materials, production process, packaging and preparation for release
- Before use – the time between release, e.g. certificate of analysis (CoA) generation, to the distribution of the product
- In-use – the time from receipt of the product by the end user to the product's end of life and disposal.

PMS activities are applicable to the in-use life stage of ITNs (Fig 1).

Fig 1. Life stages of an ITN

Manufacturing		Before use				In-use		
Manufacture/ Packaging	QC Testing/ Release	Storage (Includes sites of manufacturer or third parties)	Transport	Storage (on-site prior to distribution)	Distribution	Initiation of use	Continuation of use	End of life/ disposal

Note: the life stages leading up to the initiation of use may not be discretely identifiable. Furthermore, the opening and first use of a product may not happen immediately after distribution/receipt to the user. To represent these situations, dotted vertical lines are presented and additionally, the "Distribution" stage is split between before use and in-use. For simplicity, "end of life/disposal" is included within the In-use stage for the purposes of this document as PMS activities may include investigation of the determinants for defining "end of life" and practices for disposal.

4. Why might organisations conduct PMS?

PMS activities may be initiated to address regulatory or contractual requirements from specific stakeholder bodies, or the PMS activities may be initiated to address questions of interest regarding operational product performance. There are a variety of organisations that may either require data from, or conduct, PMS activities. These may include funders, procurement agencies, charitable organisations, country disease programmes, country research organisations and NRAs (Table 1).

Given limitations in funding and resources for PMS activities, and the variety of reasons for conducting PMS, there is no 'one size fits all' design for PMS activities that can be implemented to address all possible interests. It is therefore critical that any organizations interested in implementing PMS for ITNs understand and characterize the rationale for conducting these activities, in order to ensure that the collected data can adequately address the primary objectives.

Table 1. Potential motives for conducting PMS and examples of organizations that may be interested in such information or activities

Potential Motive for PMS activities	Organisation/Type
Market shaping and forecasting	Charitable organisations, Product development partnership(s), Product manufacturers, Procurement agencies
Compliance with regulatory decision	NRA
Collecting information to inform novel product designs	Product development partnership(s), Product manufacturers, Country disease programmes,
Collecting information to inform human centred design of new products and preferred product characteristics	Product development partnership(s), Product manufacturers, Country disease programmes, Research organisations, Civil society groups
Infection trend analysis – selection of the best product for the particular situation	Country disease programmes, Research organisations, Procurement agencies, Charitable organisations, NGOs
Product performance and durability, inc. physical durability in a particular use context	Country disease programmes, Procurement agencies, Civil society groups, Research organisations, NGOs, Charitable organisations, Product manufacturers, Product development partnerships,
Product performance under different use scenarios or settings	Country disease programmes, Product manufacturers, Research organisations
Suitability of particular products for national programme use	Country disease programmes, Research organisations
Cost-effectiveness of ITN products	Country disease programmes, Procurement agencies, Research organisations
Acceptability/ Product preferences	Country disease programmes, Research organisations
Duration of efficacy in different settings	Country disease programmes, Product manufacturers, Research organisations
User behaviour e.g., washing/handling	Country disease programmes, Product manufacturers, Research organisations

4.1. Identifying partners for PMS activities

Stakeholders wishing to conduct PMS activities may need to establish partnerships to develop and implement such activities. Partnering with donors and implementing organizations may be critical in ensuring that funding and data collection capacity for PMS activities are available and sufficient over the expected duration of activities.

Although PMS activities should be designed to ensure that the specific questions of interest are investigated and answered, there is value in standardising the approach to answer certain questions of interest. Stakeholders who partner with organizations, including donors, that have experience in collecting such information may benefit from access to standardised, well-validated protocols for certain PMS questions.

Partnerships between country disease programmes and procurement agencies can allow the tailoring of standardised protocols for specific contexts to ensure that the data generated through PMS activities are relevant and robust. In a similar manner, partnerships among country disease programmes and local organisations in respective countries can ensure that study protocols are designed to maximise engagement with the recipients and users of ITNs.

Research institutions, including contract facilities and/or academia-based programs, may be valuable and necessary partners in designing activities, implementing data collection and generating analytical/laboratory data on samples taken from operational use. Furthermore, these partnerships may be beneficial in exploring, developing, and validating new methods related to the analysis of ITNs.

5. Defining the specific questions in relation to the motives for conducting PMS

In conducting PMS, specific questions should be developed to align with the motives for conducting the activities. In developing the questions, the following should be considered to ensure that the questions are clear and reflect the interests, motives and goals of the program.

- Is the question specific to a single product or a class/type of ITN product?
- Is the intent that the results from the PMS are generalizable across a subset of all ITN products?
- Is the question specific to a particular geographic setting, e.g. region, country, locality?
- Is the question specific to a particular use setting?
- Is the question related to a specific timepoint or stage in the ITN lifecycle post-distribution, i.e. start of useful life, in-use, end of life?
- Does the product batch/lot of interest need to be identified prior to distribution?
- Can specific products be identified reliably when sampling from operation use?
- Can sampled products be linked to batch production data/information?

The points above are not exhaustive, but can be relied upon to develop other relevant considerations when advancing a plan for PMS activities.

The questions which are developed should also be the catalyst for considering the timepoints, sample size, and duration for sampling of products from operational use.

Entities/organisations who regularly conduct PMS activities may wish to develop standardised procedures/study designs that can be used to answer specific questions.

5.1. Defining the required information and indicators to address the identified PMS question(s)

In designing objectives for PMS activities, the availability of product specific information that may help to inform the question should be considered.

This is because, depending on the specific questions that are formulated, there may be a need to consider which additional baseline data/information may be available, or needed, to aid in the analysis and interpretation of results collected in PMS activities. After identifying the necessary baseline/reference data which may be needed, a plan should be developed to identify ownership of those data and how such data can be accessed. This may lead to augmentation of the questions and/or establishment of partnerships within the PMS activities when determining if access to such information is possible.

5.1.1. Information available from WHO PQT/VCP

Availability of product specific assessment reports, such as WHO Public Assessment Reports, and the information included may serve as important baseline information in developing the question(s) and interpreting collected information during PMS activities.

The data generated in long-term community studies for ITNs, which are studies conducted using ITNs that have been distributed in communities and have been operationally aged through routine use, may include baseline data on operationally aged ITNs that may be useful in linking active ingredient concentrations with expectations for the duration of further useful life. It is important to consider that long-term community studies are a post-prequalification commitment to be conducted by manufacturers, therefore this kind of information may not be available at the time of prequalification. Engaging with the manufacturers can be useful to understand if any new data are in the process of being generated and how the coming availability of this information may impact plans for PMS activities.

5.1.2. Other information that may be available

CoAs and pre/post-shipment testing reports may be available and serve to confirm or dispute the fitness of the product in advance of the distribution. Access to such information would need to be requested through the responsible organisation, in most cases the manufacturer or procurement agency, in accordance with their respective procedures. If there are indicators of product divergence from specifications either as a result of manufacturing quality or uncontrolled handling prior to distribution, these factors can have significant impact on the interpretation of the data collected during the in-use stages of the product life (Fig 2). The information in Figure 2 identifies common points within the life stages of ITNs when identity and physical/chemical characteristic data may be generated. These data would typically be generated by the manufacturer, procurement agencies, and/or implementing partners in accordance with relevant contractual requirements for quality control.

Fig 2. Life stages of ITNs and points in the life stages where manufacturer and shipment-associated testing may be conducted.

Certificate of Analysis (CoA) Pre-shipment testing Post-shipment testing

Manufacturing		Before use				In-use		
Manufacture/ Packaging	QC Testing/ Release	Storage (Includes sites of manufacturer or third parties)	Transport	Storage (on-site prior to distribution)	Distribution	Initiation of use	Continuation of use	End of life/disposal

Other responsible authorities such as national regulatory bodies may also hold relevant data regarding the pre-market performance of ITN products, for example, studies that may have been conducted locally to meet country registration requirements. If available, these data may be useful in refining PMS questions to better reflect the local context.

5.1.3. Potential indicators and associated methods which may support the design of PMS activities

Table 2 was developed to present example indicators along with methods and considerations which may support PMS activities. This should not be viewed as an exhaustive list of all possible indicators which may be necessary or of interest in the specific PMS activities. Those organizations who may be developing and implementing PMS activities are encouraged to review the examples provided in the table and utilize the concepts presented to critically consider these and other indicators which may be envisioned for use.

Where applicable, points of reference in the WHO public assessment reports (WHOPARs) have been included to identify where and when additional background information may be available. Please refer to the relevant implementation guidance documents, including IG-Community Studies, for current guidance considerations in the generation and reporting of data.

Depending upon the motive for conducting PMS activities and the specific questions which have been identified, it may be that a validated method is not currently available to generate reliable data for use in the investigations. In these cases, appropriate approaches may be considered to couple multiple methods or rely on experimental methods, ensuring that an analysis of the uncertainty/impacts on the resulting data interpretation is undertaken.

The information in Table 2 is provided to support stakeholders developing PMS plans to identify and consider those pieces of information that have the greatest utility in answering the defined goals/questions.

The table includes indicators for which methods may not be currently available. In the absence of methods, questions to be investigated in PMS may need to be reconsidered in order to ensure PMS activities are focused and achievable.

Table 2. Indicators which may support the design of PMS activities

Indicator	Method/data collected	Considerations/Limitations	Inclusion in WHOPAR
Appearance	Visual inspection of samples of constructed ITNs to identify potential quality issues related to aspects such as: knitting, fabric integrity, sewing at seams, improper shape/size, discoloration, damage from environmental exposure, damage due to shipping/handling, etc. Results may be collected and issues characterized/quantified based on the size of sampling as compared to the batch size.	Visual inspections of appearance may provide important insight into the quality of the production batch as well as any issues related to handling, shipping, and storage. Depending on when visual inspections are conducted, and if previous inspections have been conducted/documented, there may be challenges in determining the root cause for identified issues. Visual inspections of ITN appearance may be selected to be utilized in PMS programmes. Ensuring that baseline data are collected, especially at the time of distribution (and/or previous time points) is critical so as to aid in the interpretation of results and identification of possible cause.	Pre-market: Manufacturer's description Long-term community study: Characterisation of the appearance at periodic intervals, e.g. baseline, 6-, 12-, 24-, 36-month
Attrition	Surveys to record presence or absence of ITNs in households. Can be measured at multiple timepoints if funding/logistics allows, e.g. 18-, 24- and 36-months post-distribution to allow analysis of rates and reasons for attrition over time.	The methods and approaches available to characterize the attrition of distributed ITNs may not enable analyses which can characterize if the attrition is a function of the factors such as: distribution cycles, ITN quality, user handling, etc. These data may inform investigations into: • Suitability of particular products for national programme use • Acceptability/ Product preferences • Product performance under different use scenarios • Product performance and durability, inc. physical durability	Pre-market: No Long-term community study: Characterisation of the attrition at periodic intervals, e.g. 6-, 12-, 24-, 36-month
Point estimate of net survival in a serviceable condition	The analysis using results from investigations of attrition and Proportional hole index, is utilized to estimate of retention time and include uncertainty intervals.	This analysis requires robust household data to derive an informative estimate. These data may inform investigations into: • Suitability of particular products for national programme use • Product performance under different use scenarios • Product performance and durability, inc. physical durability	Pre-market: No Long-term community study: No (median functional survival)
Total AI	In utilizing the appropriate method for the identification and quantification of the active ingredient(s), this provides information about the total AI content, i.e., surface + reservoir, present in the product at the time of sampling. In order to generate meaningful data and statistical analyses, sampling plans must be developed to meet the intent. If measured at multiple timepoints, provides an indication of the reduction in total AI over time	The reliability of the data generated, and statistical certainty, is dependent upon the sampling plan, number of samples, and analysis at the levels of sample, fabric (if fabrics in ITN are different), single ITN, and batch/community. With this method, investigators cannot measure bioavailable AI on the surface of the ITN. There are then further limitations/difficulties in connecting results from total AI testing with bioassay results. Interpreting total AI results to identity low or high loss rates of AI over time may be challenging without reliable data on how many times each sampled ITN has been washed. These data may inform investigations into: • Maintaining validity of the regulatory decision • Suitability of particular products for national programme use • Product performance under different use scenarios • Product performance and durability, inc. physical durability	Pre-market: Modules 3 and 5 Long-term community study: Characterisation of the total at periodic intervals, e.g. baseline, 6-, 12-, 24-, 36-month

Indicator	Method/data collected	Considerations/Limitations	Inclusion in WHOPAR
Surface AI (before and after method for surface AI approximation - BAM)	Provides information about the fraction of AI that is present on the surface of the ITN fabric. In order to generate meaningful data and statistical analyses, sampling plans must be developed to meet the intent. If measured at multiple timepoints, provides an indication of the presentation of bioavailable AI on the ITN fabric surface over time	The reliability of the data generated, and statistical certainty, is dependent upon the sampling plan, number of samples, and analysis at the levels of sample, fabric (if fabrics in ITN are different), single ITN, and batch/community. As there are no methods currently available to directly measure the surface concentration the BAM method is used as a proxy to characterize the surface concentration by means of total AI quantification on larger samples which are then split and one sub sample being subjected to a single wash. Interpreting total results may be challenging without reliable data on how many times each sampled ITN has been washed or when the last wash was conducted. These data may inform investigations into: • Maintaining validity of the regulatory decision • Suitability of particular products for national programme use • Product performance under different use scenarios • Product performance and durability, inc. physical durability	Pre-market: Modules 3 and 5 Long-term community study: Characterisation of the total at periodic intervals, e.g. baseline, 6-, 12-, 24-, 36-month
Wash resistance Index (WRI)	The WRI test provides quality control information about the loss of AI from the reservoir in response to the specific washing series used in the test, i.e. 4 washes with ~1 day interval. If measured at multiple timepoints,, the results can provide information which may indicate if the release behaviour of the fabric is consistent with or has changed since manufacturing. A change in the WRI is not necessarily an indicator of decreased product performance, but may indicate that with the reduction of the AI reservoir, the dynamics for translocation/presentation of the AI have changed.	The reliability of the data generated, and statistical certainty, is dependent upon the sampling plan, number of samples, and analysis at the levels of sample, fabric (if fabrics in ITN are different), single ITN, and batch/community. Interpreting total results may be challenging without reliable data on how many times each sampled ITN has been washed. These data may inform investigations into: • Maintaining validity of the regulatory decision • Suitability of particular products for national programme use • Product performance under different use scenarios • Product performance and durability, inc. physical durability	Pre-market: Module 3 Long-term community study: Characterisation of the total at periodic intervals, e.g. baseline, 6-, 12-, 24-, 36-month
Imaging of ITN surface to understand changes in AI presentation over time	If a practical and accessible method were developed, this could support the contextualisation of bioassay results and correlation with observed biological effect(s)	No validated methods currently exist.	N/A
Evaporative loss	Existing methods for AI analysis could be relied upon to investigate changes in AI content as a result of storage/use conditions which are designed to focus on evaporative loss.	No validated methods currently exist. If study designs were developed, this would allow a more complete understanding of the ways in which AI is lost from the ITN fabric. This could be integrated with total/surface AI content and wash resistance data to enable better predictions of ITN duration of performance and survival.	N/A

Indicator	Method/data collected	Considerations/Limitations	Inclusion in WHOPAR
Resistance to hole formation	The resistance to hole formation test characterizes the response of the fabric to stressors by capturing the presence and degree of hole enlargement and secondary damage.	The results for the fabric are a function of the formulation and manufacturing process. The results are influenced by the integral materials and the nature/pattern of the fabric formation/knitting. The results may be used in indices to predict the physical durability of the fabric under normal use. Inclusion of this test in long-term community studies is to determine if the fabric response changes over the operational life of the product. These data may inform investigations into: • Product performance and durability, inc. physical durability	Pre-market: Module 3 Long-term community study: Characterisation of the total at periodic intervals, e.g. 12-, 24-, 36-month
Fabric and seam bursting strength	The bursting strength test characterizes the response of the fabric to a direct stressor of pressure to characterize the pressure needed to induce failure, by capturing the presence and degree of hole enlargement and secondary damage.	The results for the fabric are a function of the formulation and manufacturing process. The results are influenced by the integral materials and the nature/pattern of the fabric formation/knitting. The results may be used in indices to predict the physical durability of the fabric under normal use. Inclusion of this test in long-term community studies is to determine if the fabric response changes over the operational life of the product. These data may inform investigations into: • Product performance and durability, inc. physical durability	Pre-market: Module 3 Long-term community study: Characterisation of the total at periodic intervals, e.g. 12-, 24-, 36-month
Bioassays (cone test, tunnel test, or other developed method) appropriate for the mode of action of the AI(s) of the product.	Provides indications of surface bioavailability via the induced biological effect after exposure of test system(s) to the ITN fabric	Difficult to link to Total AI content. Cannot be used for estimations of entomological efficacy. Results need to be considered within the context of the selected test system(s), e.g. different species/strains and varying resistance profiles. These data may inform investigations into: • Maintaining validity of the regulatory decision • Suitability of particular products for national programme use • Product performance under different use scenarios • Product performance and durability, inc. physical durability	Pre-market: Modules 3 and 5 (unwashed and washed fabric/ITNs) Long-term community study: Characterisation of the total at periodic intervals, e.g. 12-, 24-, 36-month
Semi-field evaluation (experimental huts, IACT)	Provides entomological efficacy data using free-flying mosquitoes. Best source of efficacy data. Enables comparison of artificially aged nets, e.g. 20 washed nets, with sampled distributed ITNs	Expensive. May not be logistically feasible. Requires high number of ITNs to be sampled from communities in order to capture the true operational variability of the product. These data may inform investigations into: • Maintaining validity of the regulatory decision • Suitability of particular products for national programme use • Product performance under different use scenarios • Product performance and durability, inc. physical durability • Duration of efficacy in different settings	Pre-market: Modules 3 and 5 (unwashed and washed fabric/ITNs) Long-term community study: Characterisation of the total at periodic intervals, e.g. 12-, 24-, 36-month

The information in Table 3 is provided to support stakeholders developing PMS plans to identify and consider those pieces of information related to how products are used which may impact the state of sampled ITNs and thereby influence data generated for the indicators described in Table 2.

Table 3. Indicators which may be collected based on user experience for the purpose of informing interpretation of results

Characterisation of use pattern	
Number of times that an ITN has been washed	Allows contextualisation of where the product may be in the cycle of it intended useful life.
UV exposure	Allows for an understanding of exposure to UV in normal use and/or handling and compliance with recommendations for best practices in the use of ITNs.
Environmental risk index (household environment)	Provides information on the environment in which the net is used, inc. indoor cooking, storage of food in sleeping rooms, rodent prevalence, type of sleeping space
Net use risk index	Provides information on the use practices of the net, inc. tying up nets, net washing
Net use	Provides information on who uses the net and how often it is used. Can include intensity of use, e.g. how many people use a single net, and demographic information on the age groups (children/adults) using nets.
User acceptability to communities	Provides information on net users' perceptions of the product in use
Reasons for attrition	Aims to captures the reasons for attrition of ITNs distributed in communities. May allow the analysis of product specific acceptability and use, including analysis by textile type.
Product specific acceptability and use	Allows determination of specific factors in communities that influence net usage and the appropriateness of the distribution of specific products in specific locations. May enable a meta-analysis of the acceptability of products by textile type, mesh size, etc.
Number of people protected by ITNs	Allows countries and programmes to identify products that provide the most protection to the population in a specific context.

Note: Collection of these points of information is typically done through self-reporting. As such, the information collected must be weighted appropriately based on the inherent uncertainty. Furthermore, it is important to consider if the information collected is reflective of the whole household or of an individual who may be solely responsible for providing this information

5.2. Data interpretation

Where feasible, as much background information as is possible should be collected so as to rule out other factors which may be driving results and thereby facilitate interpretation of the results.

A potential situation where the interpretation of PMS collected information can be challenging is when incomplete quality checks are available from pre-shipment, post-shipment, and pre-distribution time points. In such situations it can be difficult to correlate the findings of the PMS data to the operational use as compared to issues with the product as a result of manufacturing and/or handling during transport/storage.

There are many other factors which can lead to challenges in the interpretation of results. Some examples include, but are not limited to:

- Number of washes at the time of sampling – estimating where a product may be in its lifecycle is influenced by how many times the product has been washed.
- Washing and drying (inside vs outside) methods – the use of different detergents or bleach not in accordance with the recommendations of the manufacturer can have an impact on the performance and longevity of an ITN. Exposure to UV light during use and/or drying can also have negative impacts.
- Time since last wash - if an ITN was recently washed, testing may underestimate surface concentration and bioassay results or lead to a difference in results across samples if insufficient time for stabilization/presentation of the AI on the surface has been allowed.

6. Communication

Assuming that data collected are of good quality, address the questions and motivations of the study, and can be reliably interpreted, it is the responsibility of the study sponsors and investigators to determine how the results of the study should be disseminated and if specific engagement with NRAs and/or WHO may be of relevance.

In cases where results and conclusions pertain to specific products which are prequalified, any identified issues pertaining to the quality, safety, efficacy, and/or duration of product performance may be submitted to WHO PQT/VCP in the form of a complaint. Complaints can be submitted by any person or organization. This is the process through which additional information pertaining to a prequalified product can be submitted by an entity other than the manufacturer. Complaints are submitted by email to rapidalert@who.int. If the investigation of a submitted complaint further characterises general properties of the prequalified product (rather than, for example, issues pertaining to specific manufacturing batch(es) of the product), the product WHOPAR may be updated with this information.

Results from PMS studies that are in the domain of the product manufacturer and which provide additional information about the quality, safety and/or efficacy of a prequalified product can be submitted to WHO PQT/VCP for assessment and possible inclusion in the product WHOPAR using the established communication channels.

Apart from the regulatory considerations of post market data analysis, results which inform general aspects of product design, handling, use, product selection in specific contexts, etc., should be disseminated throughout the stakeholder community.

6.1. Communication of product specific findings to WHO

If there are indications that the ITN is not performing as expected, a complaint should be submitted to rapidalert@who.int. Complaints may be submitted by any organization and/or individual.

Further details regarding the process of submitting a complaint, and the supporting data required, can be found at https://extranet.who.int/prequal/vector-control-products/submission-complaints

6.2. Partner communications

Engaging partners in the development of the PMS activities and maintaining open communication can aid in the value of data collection through PMS, regardless of the questions.

7. Annex I Example considerations for PMS design

Example motivation

NMCP wishes to collect data on the current ITN distribution in their region → *Refer to Section 4, Table 1 for examples*

Example question of interest

Is ITN x performing as expected in country/region y for the current distribution cycle?

Example considerations for identification of data/indicators and for protocol design

Identification of available and/or necessary baseline data and partnerships

- CoAs
- Storage conditions
- Pre- and post-shipment testing reports

→ *CoAs and pre- and post-shipment testing reports verify that the ITNs as received met the manufacturing release specifications as defined in WHOPAR part 3 for that product*

→ *Information on the duration and conditions of storage prior to distribution allows for the assessment of influence on the characteristics of the distributed product*

Are external or additional partnerships necessary to access the relevant data or to conduct planned testing?

→ *Refer to section 4.1 for additional details*

Identification of product characteristics(s) of interest

Identification of the product characteristic(s) that are of the most interest

→ *e.g.*
- *Physical durability, and/or*
- *Retention/loss of chemical content, and/or*
- *Entomological efficacy*
- *Median functional survival*

Identification of informative and relevant data indicators to measure the identified product characteristic(s)

→ *Refer to Section 5.1.3, Table 2 for examples*

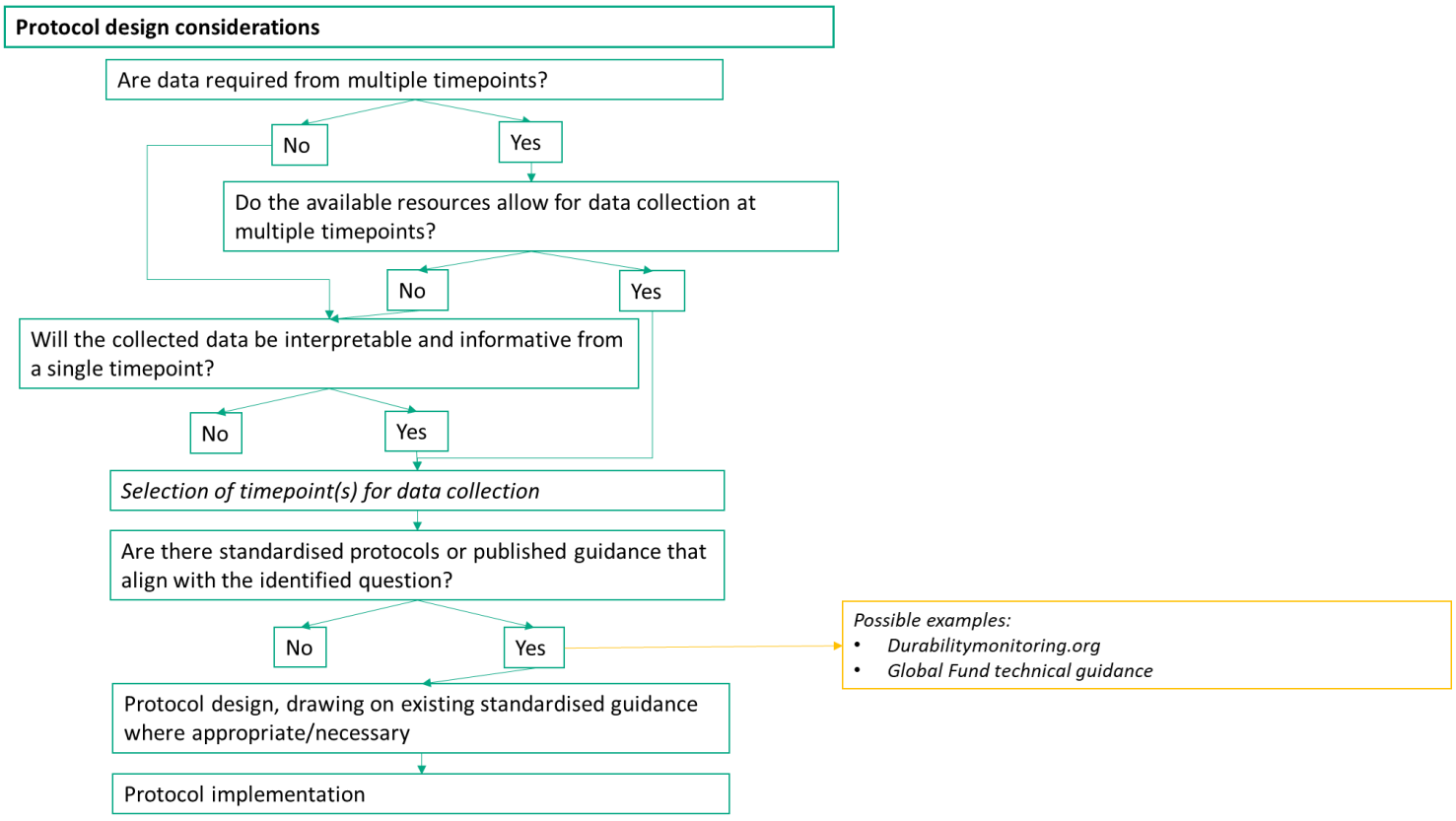
Identification of product use/community factors of interest and/or use in interpreting the collected data

→ *Refer to Section 5.1.3, Table 3 for examples*

WHO Prequalification of Vector Control Products
Avenue Appia 20
1211 Geneva 27, Switzerland

For further information, contact:
pqvectorcontrol@who.int
https://extranet.who.int/prequal/vector-control-products

Example considerations for identification of data/indicators and for protocol design (continued)



Example considerations for data interpretation and dissemination