



**RHD Action**

*United to End Rheumatic Heart Disease*

# NEEDS ASSESSMENT TOOL

User Guide: 2016

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# Contents

- Introduction to the Toolkit..... 2**
  - Objective and uses of this document.....2
  - Index Guide to Data Collection Forms.....7
  
- 1. Situational Assessment Tools ..... 11**
  - 1. Systematic review.....11
  - 2. Site Characterisation .....13
  
- Tips for Conducting Direct Observations ..... 13***
  
- Tips for Conducting Key Stakeholder Interviews..... 14***
  
- 2. Facility-Based Assessment Tools ..... 16**
  
- 3. Understanding the Patient and Provider Experience..... 20**
  - Patient Experience .....20
  
- Patient Interview Tips ..... 20***
  - Provider Experience .....22
  
- Provider Interview Tips..... 22***
  
- 4. Reporting the Needs Assessment and Planning the Intervention ..... 23**
  
- Appendices ..... 26**

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## Introduction to the Toolkit

### Objective and uses of this document

The RHD Action Needs Assessment Tool outlines the processes and tools recommended to conduct a comprehensive needs assessment in local communities in countries where ARF and RHD are endemic. The goal of a needs assessment is to gather baseline information to determine the needs and gaps in care for the development of targeted interventions to prevent and control ARF and RHD.

The NAT Toolkit uses a mixed-methods approach with quantitative and qualitative analyses.

- **The Situational Assessment** (Phase 1), is a Systematic Review of existing data and a Rapid Assessment of candidate sites.
- **The Facility-based Assessment** (Phase 2), involves a detailed epidemiological assessment with quantitative assessment of new and existing data, as well as a qualitative assessment of services around GAS/RF and RHD.
- **Understanding the Patient and Provider Experience** (Phase 3), is a detailed qualitative assessment of patients, healthcare professionals, key stakeholders and policy makers.
- **Planning the Intervention** (Phase 4) introduces Monitoring and Evaluation framework for selected interventions.

**Each phase and each tool requires adaptation to local circumstances and resources; data collection tools must be contextualised within your particular setting. Applying the NAT instruments in different socio-cultural and ethnographic settings requires careful planning, community participation and additional refinement during implementation.**

This User Manual is provided as a general guide to use and implementation of these tools and the techniques by which they can be administered.

## Suggested Resources

Below are the suggested resources in terms of personnel, equipment and services that would be needed to perform all of the activities presented in the NAT. Most sites in RHD-endemic locations are, by nature, under- or poorly resourced, so the listing below is a best-case scenario.

A “Specialised field worker (interviewer)” should be an individual who, at a minimum, has a bachelor’s degree with a focus on social science and 2-3 years of experience conducting qualitative interviews. Master’s students (under direct supervision) or PhD students (conducting interviews independently) are also acceptable.

A “Field worker” should be an individual who, at a minimum, has high school education and 2-3 years of experience working for an organisation that collects health-related data.

### Planning for Resource Needs

#### In Country Personnel

##### Phase 1

- Specialised field worker (interviewer)
- Data analysis
- Field worker: 2 workers for clinical record review
- Field worker: 2 workers for facility surveys

##### Phase 3

- Specialised field worker (interviewer): 2 workers for patient interviews and focus groups
- Specialised field worker (interviewer): provider interviews
- Specialised field worker (interviewer)

#### Equipment

##### Phase 1

- 2 recording devices
- Qualitative software such as Dedoose or Atlas.ti

##### Phase 2

- 2 tablet computers for survey data entry
- Cloud-based data management software such as OpenMRSor REDCap

##### Phase 3

- 2 recording devices
- Qualitative software such as Dedoose or Atlas.ti

##### Phase 4

- 1 tablet computer for data entry
- Multi-criteria mapping software

#### Services

##### Phase 1

- Transcription/translation services
- Literature screening: 2 independent reviewers for the Burden and Health Services reviews
- Literature screening: 2 independent reviewers for the Stakeholder Identification review
- Retrieval of local “grey” literature by site librarian:

##### Phase 3

- Transcription/translation services: patient and provider data

## Suggested Best Practices

### Ethics Committee Oversight

Conducting a needs assessment or program evaluation may be considered research and will then be subject to your country's laws protecting human subjects. To determine whether your project activities constitute human subjects research, consult with your local Ethics Committee in the very early stages of planning your assessment to determine which activities (and data collection techniques) will require Ethics Committee oversight. Please also remember that most journals require official proof of Ethics Committee oversight or waiver of such before accepting any manuscripts for publication.

### Obtaining Informed Consent and Assent of the Child

Most facilities overseen by Ethics Committees are required to implement and follow Standard Operating Procedures (SOPs) for study activities. For example, your facility may have a standardized SOP for obtaining Informed Consent.

In general, the informed consent process should include the following considerations:

- Details regarding the purpose of the study and length of time required for participation should be explained to potential participants in a language and at an educational level that is easily understood by the potential participant.
- Adequate time must be given for the potential participant to ask any questions and to consider whether or not to participate.
- Should the potential participant agree to the interview, s/he should be given an information sheet and asked to provide their consent for participation.
- In the case of a child respondent, local Ethics Committees have standards for when the Assent of the Child is required. Generally, child participants ages 8 years and above should be given the opportunity to "assent" or agree to participating in the study.
- In the case of participants who do not read or write, local Ethics Committees have standards for obtaining verbal or thumb print consents and when and by whom they are to be witnessed.
- Efforts should be made to conduct the interviews in a private and comfortable space that is deemed suitable for the respondent.
- Participants should be given the option to refuse to answer any questions and/or withdraw from the study at any time.
- Confidentiality should be ensured by giving each participant the option of not being quoted in a manner that may identify them individually in any resulting publications; individual sub-groups should be referred to only in general terms.
- It is possible that some sensitivities may occur, related to barriers to effective care which may cause distress to the respondents. The research team should be trained to respond to these situations with appropriate wording, supportive statements and avoidance of excessive probing.

### Selecting Study Sites

The selection of project sites should be discussed and decided with the country teams and will depend on their preferences and time availability. If possible and relevant, different regions/healthcare facility levels and locations can be chosen to provide a more comprehensive picture of the health system barriers and facilitators.

## Identifying Data Analysts for Qualitative and Quantitative Peer Groups

The NAT will generate a wealth of quantitative and qualitative data that require careful analysis by qualified individuals. It is recommended that NAT users consult experts in public health, epidemiology, and qualitative research prior to development of protocols and ethics approval. These individuals should also be included in the data analysis.

## Choosing electronic platforms for data analysis and storage

Electronic, rather than paper-based, recording and storage of all data is recommended for the needs assessment process. A variety of data management systems have been developed that are appropriate for limited resource settings - for example, for quantitative data, Redcap, Open clinica or Filemaker Pro. The choice of database will depend on the prior experience of the NAT user and the available budget. Ideally, the database should be integrated with the data analysis software.

## Assigning Subject ID numbers

To protect the confidentiality of study participants, each participant should be assigned a unique Study Identification Number (SID). The SID can be a combination of the participants' initials (if acceptable to your local Ethics Committee), sequential numbers and/or numbers that might identify a particular site if more than one is used. The purpose of assigning an SID number is to remove identifiers from the data that are entered and used for analysis and is a requirement for all Ethics Committees.

A separate SID number log or key should be maintained that links the assigned SID number to participants' personally-identifying information. This key should be maintained in a secure and confidential manner, and be access-limited to "need-to-know personnel" only. The key is to be used for following up missing or erroneous data points, and should be destroyed once the analyzed data are accepted as clean and complete. The Data Collection forms presented in the NAT call for subject initials, a medical record number and a SID Number. These forms must be modified to fit your particular institution or locale's customary participant privacy process and requirements.

A SID number log is easily set up as an excel spreadsheet and typically includes the following header names:

| Pre-assigned SID Number | Participant Initials | Participant Name                   | Date of Birth | Date of Consent | Chart Number   |
|-------------------------|----------------------|------------------------------------|---------------|-----------------|----------------|
| 001                     | TPM                  | Thandi P Makura                    | 15 Dec 1988   | 01 Mar 2016     | 00882<br>Hosp1 |
| 002                     | SXL                  | Sibanda Legodi<br>(no middle name) | 26 June 1978  | 10 Apr 2016     | 12119<br>Hosp2 |
| 003                     |                      |                                    |               |                 |                |
| 004 an so on            |                      |                                    |               |                 |                |

## Maintaining and Storing Hard Copy Project Data and/or Equipment

Access to signed consent/assent forms, completed data collection/case report forms (CRFs), interview tapes and transcripts should be restricted to the study team members only and stored in a secured manner – preferably in a locked office, in a locked cabinet. Best practice is to keep all project files in a single location. A main project binder or folder should contain a copy of the final Ethics Committee approval, the original approved and all revised versions of the protocol or project plan, Ethics

Committee approval or oversight waiver letter, research team CVs and all related certifications, master copies of all final and approved consent/assent and data collection forms for photocopying purposes. All individual completed hard copy data forms and consent/assent forms should be maintained in a neat and orderly fashion – preferably in file folders or ring binders.

#### [Collecting and Reporting GPS coordinates.](#)

Most of the NAT tools and/or their respective Cover Sheets request site GPS coordinates. Technology is constantly changing with different instructions for each device capable of providing exact site GPS locations. Generally all smart phones have a mapping and/or geo location capability. Google maps includes longitude and latitude coordinates in the web address provided in the results search bar. Consult your favorite search engine for a “how to” based on your particular device or technology for accessing your sites’ geolocations.

## Index Guide to Data Collection Forms

| <b>Phase</b>                        | <b>Form Name/Number</b>   | <b>Type of Tool</b>  | <b>Ethics App Req'd?</b>                                |
|-------------------------------------|---|--|---|
| <b>1. Situational Assessment</b>    |   |  |   |
| 1.1                                 | Systematic review protocol                                      | Protocol   | No  |
| 1.2                                 | Health system assessment  | Desk review – publically available data, electronic or otherwise | No  |
| 1.3                                 | Suggested Key Informants/Stakeholders                           | Stakeholder identification Worksheet                             | No  |
| 1.4                                 | Stakeholder Topic Guides and Interview Schedules                | Qualitative interview  | Yes – recommend EIC/IRB approval or waiver              |
| 1.5                                 | Existing data review  | Desk review – publically available data, electronic or otherwise | No  |
| <b>2. Facility-based assessment</b> |   |  |   |
| 2.1                                 | Primary Care Sore Throat/ARF Cover Sheet                        | Prospective Clinical Record Review                               | NA – Cover Sheet  |
| 2.2                                 | Primary Care Sore Throat  | Prospective Clinical Record Review                               | Yes – need IEC/IRB approval and informed consent/assent |
| 2.3                                 | Primary Care ARF  | Prospective Clinical Record Review                               | Yes – need IEC/IRB approval and informed consent/assent |
| 2.4                                 | Secondary/Tertiary Facility Cover Sheet                         | Prospective Clinical Record Review                               | NA – Cover Sheet  |
| 2.5                                 | Secondary/Tertiary Facility ARF/RHD                             | Prospective Clinical Record Review                               | Yes – need IEC/IRB approval and informed consent/assent |
| 2.6                                 | Secondary/Tertiary Facility Patient Health Services Utilisation | Retrospective Clinical Record Review                             | Yes – need EIC/IRB approval and/or waiver of consent    |
| 2.7                                 | Pregnancy   | Retrospective Clinical Record Review                             | Yes – need EIC/IRB approval and/or waiver of consent    |
| 2.8                                 | Primary Care Facility Survey                                    | Operational data gathering from key facility stakeholders        | Yes – recommend EIC/IRB approval or waiver              |



|   |   |   |
|---|---|---|
| 2.9 Independent Dispensary Facility Survey                            | Operational data gathering from key facility stakeholders                               | Yes – recommend EIC/IRB approval or waiver              |
| 2.10 Secondary/Tertiary Facility Survey                               | Operational data gathering from key facility stakeholders                               | Yes – recommend EIC/IRB approval or waiver              |
| 2.11 Interview Guide for Country Contacts                             | Operational data gathering from key country stakeholders                                | No  |
| <b>3. Understanding the patient and provider experience</b>           |   |   |
| 3.1 Sore Throat Patient Interview Schedule                            | Qualitative interview   | Yes – need IEC/IRB approval and informed consent/assent |
| 3.2 ARF Adult Patient Interview Schedule                              | Qualitative interview   | Yes – need IEC/IRB approval and informed consent        |
| 3.3 ARF Child Patient Interview Schedule                              | Qualitative interview   | Yes – need IEC/IRB approval and informed consent/assent |
| 3.4 RHD Child Patient Interview Schedule                              | Qualitative interview   | Yes – need IEC/IRB approval and informed consent/assent |
| 3.5 RHD Adult Patient Interview Schedule                              | Qualitative interview   | Yes – need IEC/IRB approval and informed consent        |
| 3.6 Health Care Provider Interview Schedule                           | Qualitative interview   | Yes – need IEC/IRB approval and informed consent        |
| <b>4. Planning and reporting the intervention</b>                     |   |   |
| 4.1 Procedure for stakeholder identification, interviews, and mapping | <u>Mixed Methods:</u><br>Lit Review<br>Create Stakeholder Map<br>Qualitative Interviews | NA<br>NA<br>Yes – recommend EIC/IRB approval or waiver  |
| 4.2 Key stakeholder interview Schedule                                | Qualitative interview   | Yes – recommend EIC/IRB approval or waiver              |
| Sample Tool for Quantifying Needs and Setting Targets                 | NA - Example  |   |
| 4.3 a Example calculation tool for setting targets                    | NA - Example  |   |
| 4.4 Intervention Monitoring & Evaluation Worksheet                    | M and E Worksheet   | No  |
| 4.4a-c (Examples 1 – 3)   | NA - Example  |   |
| 4.5 Summary Work Plan   | M and E Worksheet   | No  |
| 4.6 Reporting format - Understanding the barriers                     | NA – Reporting Format   | No  |

|  |                       |    |
|--|-----------------------|----|
| 4.7 Reporting format - Understanding the facilitators                        | NA – Reporting Format | No |
| 4.8 Reporting format - What is missing from TIPS checklist?                  | NA – Reporting Format | No |
| 4.9. Reporting format - Baseline Assessment: Indicators and Benchmarks       | NA – Reporting Format | No |
| 4.10 Reporting format - Stakeholders, interventions, programmes and policies | NA – Reporting Format | No |



# 1. Situational Assessment Tools

|  |
|--|
| 1.1 Systematic review protocol                       |
| 1.2 Health system assessment                         |
| 1.3 Suggested Key Informants/Stakeholders            |
| 1.4 Stakeholder Topic Guides and Interview Schedules |
| 1.5 Existing data review                             |

## 1. Systematic review

### 1.1 Systematic Review Protocol

The NAT has provided a series of systematic review protocols that provide a pre-determined method for screening existing published and local “grey” literature. Grey literature is unpublished data from organizations such as NGOs and philanthropy, academic theses, and government reports. A systematic review team should be organized prior to conducting the review to confirm the primary and secondary objectives, and to review data extraction and analyses.

#### **What is a Systematic Review?**

A systematic review is a protocol-driven, comprehensive literature review for collecting and analyzing multiple research studies or papers using a strict, pre-defined internet search criteria. The key activities of systematic reviews are to identify relevant literature, appraise the quality of the literature/study, select and then synthesise high quality primary articles into a pre-determined reporting format. It is not a quick and simple undertaking.

To successfully carry out a systematic review, the following are required:

- **Access to a reliable and strong internet connection is critical.**
- **There should be at least two team members assigned to address bias issues as they arise.**
- **Time commitment to complete the entire endeavor will likely take several months (6-18 months) to complete.**

Systematic reviews must have an explicit, reproducible methodology, a strategy for assessing and describing bias, a plan for the systematic synthesis and analysis, and finally a plan for the presentation of the findings of the included studies with a Summary of Findings table, as well as a descriptive narrative.

**In general, Ethics Committee approval is not required to conduct a Systematic Review.** Occasionally, the activities of the systematic review may generate a need to analyze or re-analyze already-collected data, especially when it is unpublished data. It is best practice to discuss the need for review and/or approval regarding individual situations with your local Ethics Committee on a case-by-case basis in advance of embarking on data transfer or sharing activities.

The most widely recognized resource for systematic review methodology can be found in The Cochrane Handbook for systematic reviews and is available from [www.cochrane-handbook.org/](http://www.cochrane-handbook.org/) (accessed 8 April 2016)

(Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. )

## 1.2 Health system assessment

The Health System Assessment Tool is meant to be a desk review where publically available data are accessed by internet and/or available printed materials. The purpose of the review is to document the baseline of existing health services infrastructure to be used as a comparator/foundation for the subsequent intervention monitoring and evaluation activities.

Suggested data sources are listed within the various sections of this tool. Data from the Ministry of Health, insurers and public health institutes are likely to be very useful. These sources usually include mortality data, hospital statistics, and national health surveys. Some of the indicators may be available from NGOs or individual facilities, and although they may not be explicitly representative of your target group, they may still be useful in the analyses. Data can also be obtained from the WHO Statistics and other international databases.

Nonetheless, in some cases, the reviewer may still find the need to contact various Ministry personnel directly for specific guidance to the desired data. Your country's National Statistics Office is likely a very valuable source of the kind of information used in this assessment exercise. It is likely that every country/locale will have its own distinctive reporting mechanisms and policies for disseminating their health status and healthcare delivery performance information.

**[“The Global Reference List of 100 Core Health Indicators”](#)** (2015) for results monitoring is a standard set of 100 indicators prioritized by the global community to provide concise information of the health situation and trends, including responses at national and global levels. The Global Reference List reflects indicators of relevance for country, regional and global reporting across the full spectrum of global health priorities relating to the MDG agenda, as well as to new and emerging priorities such as NCDs, universal health coverage and other key issues in the post-2015 development agenda.

Other suggested sources not explicitly listed on the tool:

- [World Health Organization. Global Atlas of the Health Workforce](http://apps.who.int/globalatlas/default.asp) (<http://apps.who.int/globalatlas/default.asp>)
- [The World Bank Open Data](http://data.worldbank.org/) (<http://data.worldbank.org/>)
- [Global Health Observatory data repository](http://apps.who.int/gho/data/node.main.A858?lang=en) (<http://apps.who.int/gho/data/node.main.A858?lang=en>)
- This [Sub-Saharan African Medical Schools Study map](http://www.samss.org/map/default.aspx?medicalschoolsanddocumentsmap.) links to contact information for **all medical schools** in Sub-Saharan Africa, organized by country (<http://www.samss.org/map/default.aspx?medicalschoolsanddocumentsmap.>)

## 2. Site Characterisation

### Country health systems appraisal

**Direct observation** is a data gathering technique of watching a process, behavior, characteristic or interaction in its natural environment; this provides a snapshot picture of a selected location. **Key informant interviews** provide information on critical aspects of community life and meaningful indications about access, risks, priorities, vulnerabilities and capacities at the community level. Both direct observation and key informant interviews can be carried out quickly and with relatively few resources. Both methods are typically used together during primary field data collection for maximum impact.

Although no specific tool for recording direct observations is provided in the NAT, it is recognized that this technique is a critical element of field research. It is recommended to allocate a portion of the data collection instrument for capturing direct observation comments and notes to verify information and correct inconsistencies

#### *Tips for Conducting Direct Observations*

Observe conditions and particular features of an affected community from a range of viewpoints and places to provide a representative view of the selected area. This could be accomplished by making a predefined Transect Walk as a community mapping exercise. Additionally, walking across the community outside of predefined routes such as roads, paths or natural boundaries would produce a cross-section of more points for observation and provide a balanced view of conditions.

Look around and talk with people. Look at what is there, what is not there and what should be there:

- Observe water collection points, latrines, communal washing areas, schools, storage facilities, tea shops, cemeteries, markets, health facilities and religious centres
- In markets, see what people buy and sell as well as what the prices are for basic commodities
- In hospitals and clinics, observe the numbers of patients, their interactions, the methods used to screen, the information collection and recording process, the tools used, the lack of or abundance of resources.
- Note how people relate to one another, especially in light of age, gender, disability, and other minority status
- Observe people's physical condition and activities. Look specifically at children, older persons, the chronically ill, and those persons with disabilities
- Note the conditions of housing, properties, livestock, assets, etc.
- Recognize any impact on daily lives and/or difficulties faced by women and other minorities (where and when culturally appropriate)
- Pay attention to the state and functioning of public services, sanitation systems, and infrastructure (e.g. schools, water points, health posts etc.)
- Be active in observations, use all senses to gather impressions

#### 1.3 Suggested Key Informants/Stakeholders

This tool is an initial site characterisation worksheet for systematically identifying and selecting Key Informants from the community for semi-structured interviews. Ethics approval is not required for this

exercise, but best practice is to include this tool in the Ethics Committee submission for the subsequent interviews to document the participant selection process.

#### 1.4 Stakeholder Topic Guides and Interview Schedules

To complement the triangulation of the review of secondary data and observations, qualitative semi-structured interviews should be conducted with the Key Stakeholders in the community who were identified during the previous exercise. The topics are a suggested guide format and need to be tailored for the individual respondents. Patients and their families will have a much different perspective and response to the topics than participants selected from the government/ministry.

A total of around 15-20 interviews should be conducted with the community leaders, patients, health care professionals and policy makers and key informants. Selecting respondents can be further based on other characteristics - age, gender, rural-urban, RHD-management status (compliant/non-compliant to secondary prophylaxis, pre-surgical/post-surgical and socio-economic status – in addition to the selection criteria listed on the Identification Tool. The number of interviews are suggestions and should be according to the setting and available resources.

Additional key informants for interviews may be identified by adopting a snowball sampling technique which involves asking interviewees to nominate other people they know who may have knowledge and experience that are particularly relevant to the needs assessment.

This activity should be reviewed by your local Ethics Committee before proceeding with the interviews. Your local Ethics Committee may deem your interview to be an assessment activity that does not meet the requirements of oversight of human subjects research. Conversely, your local Ethics Committee may require informed consent and information sheet presentation to your potential participants. Always get that determination in writing in the early stages of planning your needs assessment activities.

#### *Tips for Conducting Key Stakeholder Interviews*

- Be sure to introduce yourself and identify your organizational affiliation properly.
- Be sure to fully inform your participants about the purpose and potential outcomes of the interviews *as you are building your constituency and supporters for the intervention activities to be developed and implemented.*
- Take time at the beginning of the interview to collect contact details about your respondent.
  - Make sure you have spelled their name correctly and know how to pronounce it correctly.
  - Collect contact details (phone numbers and/or email addresses) so you can get back to that respondent for missing information or clarifications once you have started working on your interview report. You may be required to offer your participation a copy of the final report, long after your interview is completed.
  - Be sure to list the respondent's role in the community, occupation, official title and/or government/institutional role and title or the criteria by which they were selected for the interview.
- **And most importantly, be sure to collect the data without pre-conceived notions or expectations.**

### 1.5 Existing Data Review

As described in the [NAT](#) and publication, [Incidence, prevalence and outcomes of rheumatic heart disease in South Africa: a systematic review protocol](#), Phase 1 should include a review of existing data, including both published and unpublished work. The protocol contains a search strategy to identify and screen published studies as well as some guidance on so-called “grey literature” sources. For NAT users who do not have expertise in conducting systematic reviews and meta-analyses, it is recommended that a health sciences librarian or researcher with expertise in this area be consulted.



## 2. Facility-Based Assessment Tools

|   |
|---|
| 2.1 Primary Care Sore Throat/ARF Cover Sheet                        |
| 2.2 Primary Care Sore Throat  |
| 2.3 Primary Care ARF  |
| 2.4 Secondary/Tertiary Facility Cover Sheet                         |
| 2.5 Secondary/Tertiary Facility ARF/RHD                             |
| 2.6 Secondary/Tertiary Facility Patient Health Services Utilisation |
| 2.7 Pregnancy   |
| 2.8 Primary Care Facility Survey                                    |
| 2.9 Independent Dispensary Facility Survey                          |
| 2.10 Secondary/Tertiary Facility Survey                             |
| 2.11 Interview Guide for Country Contacts                           |

Depending on the resources at your site, you may want to extend the prospective data collection periods to more than the 30-day periods described in these tools. Additionally, it is not required to start prospective data collection on the first day of a given month; it may make more sense to begin and end on a different day. The important thing is to record and abide by the time period you are working within according to your approved assessment plan/protocol.

In addition to the clinical data collection, patients will also be asked to participate in interviews to learn about their health seeking behaviours and experiences from a qualitative point of view (See Section 3 Interview Tools). Patients should be given the choice to opt in or out to allow the clinical record data collection and to participate in the interview as two separate activities on the consent form. (See example in Annexes.)

### 2.1 Primary Care Sore Throat/ARF Cover Sheet

This Cover Sheet is used to document the data collector name, the date range of record review, Ethics Committee approval date and number. It will be used as a Cover Sheet for batching individual CRFs into one data set. It also summarizes some of the facility characteristics should the prospective record review be carried out at more than one site.

### 2.2 Primary Care Sore Throat

This is a prospective study of patients,  $\geq 3$  to  $\leq 15$  years of age, who are presenting to the primary care facility with sore throat. The participant recruitment should be conducted over at least a 30-day period when seasonal sore throat is likely to occur at your site. If you live in an area where there is no seasonal variation contributing to sore throat, choose a start period when you have the resources and time allocation to conduct the assessment activities over the next subsequent 30-day period for the ARF data collection period.

### 2.3 Primary Care ARF

The thirty-day period after presentation for sore throat involves data collection for any patients presenting with ARF as ARF typically develops 2-4 weeks after a Group A Strep sore throat infection. Patients who did not present for sore throat in the preceding period need not be excluded from the ARF data collection period. In many cases, ARF patients do not recall a preceding illness or the illness may have been without noticeable symptoms (subclinical).

This data collection tool is based on the application of the Revised Jones Criteria 2002 that are appropriate for more highly trained healthcare providers. This tool should be adapted according to the resources available at your individual site. If your site has access to echocardiography and have adopted in 2015 Revised Jones criteria which includes echo, you should update the tool.

This tool also requires follow up for collecting mortality information several months after the initial data collection period, so plans for how and when the mortality data will be collected need to be incorporated into your site-specific protocol.

#### 2.4 Secondary/Tertiary Facility Cover Sheet

This Cover Sheet is used to document the data collector name, the date range of record review, and your Ethics Committee approval date and number for batching individual CRFs into one data set. It also summarizes some of the facility characteristics should the prospective record review be carried out at more than one site.

#### 2.5 Secondary/Tertiary Facility ARF/RHD

This is a prospective study of patients of any age who are presenting to secondary/tertiary facility outpatient clinics/casualties/urgent care/emergency with ARF, or outpatient clinics for a new diagnosis of RHD, or care for RHD that has been diagnosed in the past. The participant recruitment should be conducted over at least a 30-day period. It is important to differentiate on the form at the beginning of the data collection process whether your participant is presenting for care for ARF, or new or existing RHD.

This data collection tool involves a comprehensive clinical record review to ascertain dates of symptoms and diagnosis. This tool is based on the application of the Revised Jones Criteria and echocardiography that are appropriate for more highly trained healthcare providers. This tool should be adapted according to the resources available at the individual site.

This tool also requires follow up for collecting mortality information several months after the initial data collection period, so plans for how and when the mortality data will be collected need to be incorporated into your site-specific protocol.

#### 2.6 Secondary/Tertiary Facility Patient Health Services Utilisation

This is a limited retrospective clinical record review activity to capture the healthcare utilisation of the ARF and RHD patients identified in the prospective activity of Data Collection Tool 2.5. Data collection includes capturing detailed information related to prior visits for regular follow-up care as well as for urgent/emergent care. The form also captures details around the patient's adherence to secondary prophylaxis, anticoagulant use and management for post-surgical patients, past medical history, procedures and outcomes. Mortality outcomes are captured that include cause of death as well as maternal mortality-related details.

#### 2.7 Pregnancy

The intent of this data collection tool is to provide a mechanism for capturing pregnancy-related outcomes for pregnant ARF/RHD patients identified during the prospective activity of Data Collection Tool 2.5. Applying this tool requires a plan for following up on these pregnancy outcomes that can occur well after the initial data collection activities are complete.

## 2.8 Primary Care Facility Survey

This data collection tool is quite complex and will likely require multiple respondents from several departments within a primary care facility. This form begins with a cover sheet to collect basic information about the facility, the time frame in which information is collected, Ethics Committee Approval or Waiver information and contact details for the primary person providing information. There are respondent information lines at the end of the sections of the form where information regarding individual respondents is captured. A facility or clinic manager would likely be a good person to start with for this section of the data collection tool, since a person at that level will have the authority to introduce you to the other staff members appropriate for the subsequent sections of the tool so that set up interview sessions can be arranged.

The first section focuses on costs to patients for medication and diagnostic tests in the primary care setting. Staffing structure and resources, hours of operations, a health seeking behaviours around sore throat is captured here. A nurse manager may be an appropriate respondent for this section of the data collection tool.

Information for the next section regarding the facility's use of guidelines and training for the diagnosis and management of sore throat/ARF/RHD, use of an RHD Register, practices around secondary prophylaxis that would be appropriately discussed with the clinical manager. Interviewing the facility pharmacist or senior pharmacy technician if applicable would be appropriate for collecting information required in the next section that deals with pharmacy issues and so on for the subsequent sections on laboratory issues, INR management, referral options for surgery and post-surgical care.

## 2.9 Independent Dispensary Facility Survey

This data collection tool has been designed for instances where the site utilizes the services of an independent dispensary. The information collected is the same basic information collected in the Pharmacy section of the preceding Primary Care Facility Survey. This form suggests taking photos of BPG vials that indicate stock on hand and expiry dates. Be sure to ask permission/have approval before doing so.

## 2.10 Secondary/Tertiary Facility Survey

This data collection tool is quite complex and will likely require multiple respondents from several departments within a secondary/tertiary facility. This form begins with a cover sheet to collect basic information about the facility, the time frame in which information is collected, Ethics Committee Approval or Waiver information and contact details for the primary person providing information. The emphasis of this tool is to capture information on the facility's capacity to treat ARF, manage a secondary prevention registry, and diagnose and treat RHD, including heart valve surgery at referral facilities. Information regarding affiliated training programs for physicians, nurses and other allied health professionals is captured, types of available services, as well as RHD Guidelines currently in use. Patient service utilization and mortality are also captured.

There are respondent information lines at the end of the sections of the form where information regarding individual respondents is captured. A facility or clinic manager may be an appropriate respondent for this section of the data collection tool since a person at that level will have the authority to introduce you to the other staff members appropriate for the subsequent sections of the tool so that interview sessions can be arranged.

### 2.11 Interview Guide for Country Contacts

This interview guide is designed to gather contextual information to complement the information captured in the facility reviews and focuses on diverse issues; so only a few informants who have an overall perspective, should be interviewed at length as they will have an overview of multiple aspects of the system. It is directed to key stakeholders such as director/managers of local NGOs, academic partners, Ministry based or other health services partners – people working in health care delivery who may have a higher-level perspective than people working or seeking care in the facilities themselves. Even so, for example, some respondents will be familiar with human resource issues only while others will know about the use of clinical guidelines, etc.

While not intended to undergo a formal qualitative data analysis, these interview sessions should be recorded or at least summarised with “field notes” and thematically categorized within the CoC framework. This information captured during these sessions should be shared with the data analysts for inclusion into the final report.

## 3. Understanding the Patient and Provider Experience

### Patient Experience

#### *Patient Interview Tips*

Basic interview practices should be considered when conducting patient/parent interviews:

- Mutually agree on an acceptable time and location for conducting the interview and confirm with the participant in advance of the planned session. If the length of time required is not agreeable to your respondent, negotiate or reschedule a mutually acceptable time frame that will meet the objectives of the interview.
- The interview should be semi-structured as an informal conversation.. The interviewer should familiarise themselves with the questions or the areas of inquiry and ask them when appropriate taking into account how the interview is evolving and the needs of the interviewee. One can have a printed version of the interview guide when conducting the interview, but it is recommended to not to read or look very often while interviewing.
- The most important aspect of an interview is that the interviewee feels comfortable and shares their story with you. In some instances, you will have to share information with the interviewee to make them at ease and so they understand about your background and your motives for doing the interview. If they ask you a question, reply and move to a question that links with what they have just asked, and then start again asking questions about the information we are interested in eliciting.. The comfort and wellbeing of the interviewee is the priority rather than the information we are interested in eliciting. If you sense the interviewee feels uncomfortable, sad, worried or embarrassed with the questions being asked, move to another question and if appropriate, return to the question later in the interview.
- Another key aspect of a successful interview consists of actively listening, showing empathy, not judgement, when the interviewee is sharing problems or difficult situations with you. When the interviewee asks for advice, it is better not to engage but suggest instead where he/she could follow up for further advice. The interview should be organized like a conversation where the interviewee trusts that the information she/he is giving will be anonymous and confidential.
- When talking to a patient try to understand the story of the condition and as much information on when the first symptoms emerged; what happened; who helped within the family or/and community; then the experience of accessing services; how the treatment and prevention was provided; the experience with the healthcare provider; discuss the health system barriers and facilitators to accessing services and receiving care (e.g. coordination, waiting times); and things that the interviewee would like to see improved. It is advisable to follow a chronological order and go step by step through the experience of the illness.
- In some cases the interviewee might talk about other issues not relevant to the questionnaire, in these cases let them speak and then go back to the interview once the interviewee has finished explaining what he/she wanted to tell you.

- When the interview is finished thank the interviewee for their time and emphasize how important it is for the study that the participant has shared their experiences with you and explain that you will follow up with them with the preliminary results (if relevant).

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| 3.1 Sore Throat Patient Interview Schedule |
| 3.2 ARF Adult Patient Interview Schedule   |
| 3.3 ARF Child Patient Interview Schedule   |
| 3.4 RHD Child Patient Interview Schedule   |
| 3.5 RHD Adult Patient Interview Schedule   |

Patient participants for the following interviews are selected from the same patients who were recruited for the prospective clinical record reviews in Section 2 (Tools 2.2 through 2.7). Whether or not the patient agrees to the clinical data extraction portion of the assessment, this qualitative interview is a separate exercise. Consent forms should explicitly describe both components of the activity and give the patient/parent the choice to opt in or opt out to one or both of the components.

### 3.1 Sore Throat Patient Interview Schedule

The purpose of the interview is to explore themes surrounding health seeking behaviour for sore throat including reasons for seeking healthcare, other sources of care they may have visited or consulted, progression of the child’s symptoms and impact on daily life. The final theme is an exploration of and opportunity to increase the patient/parent’s awareness of the potential impact of sore throat leading to RHD.

### 3.2 ARF Adult Patient Interview Schedule

Adult patients should be recruited from among those presenting to a primary care facility or hospital for ARF. The purpose of the interview is to explore the patient’s experiences around health seeking behaviour for ARF. The interview schedule explores themes around the patient’s history of the disease and admission to the hospital, their relationships with their healthcare providers, the patient’s understanding of their disease, and the impact of having ARF on daily life. Again, the final theme is an exploration of and opportunity to increase the patient’s awareness of the potential impact of ARF developing into RHD.

### 3.3 ARF Child Patient Interview Schedule

Paediatric patients should be recruited from among those presenting to hospital facilities for ARF. The purpose of the interview is to explore the patient’s/parent’s/carer’s experiences around health seeking behaviour for ARF. The interview schedule explores themes around the patient’s history of the disease and admission to the hospital, their relationships with their healthcare providers, the patient’s understanding of their disease, and the impact of having ARF on daily life. Again, the final theme is an exploration of and opportunity to increase the patient’s/parent’s awareness of the potential impact of ARF developing into RHD.

### 3.4 RHD Child Patient Interview Schedule

Paediatric patients should be recruited from among those presenting at a hospital for RHD.

The purpose of the interview is to explore the effect of RHD on a family that has a child with RHD. The interview schedule explores themes around the patient's history of the disease and admission to the hospital, their relationships with their healthcare providers, the patient's understanding of their disease, and the impact of having RHD on daily life. Again, the final themes are an exploration of and opportunity to increase the patient's/parent's awareness of their disease, as well as parent's expectations and concerns about their child's future.

### 3.5 RHD Adult Patient Interview Schedule

Adult patients should be recruited from among those presenting at a hospital for RHD. The purpose of the interview is to explore the patient's experiences around RHD. The interview schedule explores themes around the patient's history of the disease and admission to the hospital, their relationships with their healthcare providers, the patient's understanding of their disease, and the impact of having RHD on daily life. Again, the final themes are an exploration of and opportunity to increase the patient's/parent's awareness of their disease, as well as patient's expectations and concerns about their future.

## Provider Experience

### 3.6 Healthcare Provider Interview Schedule

#### *Provider Interview Tips*

Basic interview practices should be considered when conducting healthcare provider interviews:

- **Know in advance how much time will be needed for conducting the interview and inform the respondent in advance of the interview.** If the day of the week or length of time required is not agreeable to your respondent, negotiate a mutually acceptable time frame that will meet the objectives of the interview.
- Interviews with health care professionals should focus on their expertise and the role they play in the prevention and treatment of Sore throat/ARF/RHD, as well as understanding their relationship with the patient; how the care is coordinated; the information they provide to the patient; and what are the areas that need improvement.
- The interviewer should try to find out what is the health professional's knowledge of the existing regional, national programmes/initiatives to prevent and treat Sore Throat/ARF/RHD. The interviewer should also ask questions on the use and implementation of clinical guidelines for diagnosis and secondary prevention.
- The questions will be tailored to whether the interviewee is a community worker, nurse, GP or secondary care specialist.

### 3.6 Health Care Provider Interview Schedule

Recruitment from all levels of care and specialties should be considered, from primary to secondary (hospitals, specialist dispensaries, emergency services) to regional and national institutions. Both public and private sectors should be considered.

The purpose of the interview is to explore the healthcare provider’s perspective on what they think their role is and their knowledge about GAS, ARF and RHD. The interview begins with eliciting information about local facility utilization and proceeds with asking the respondent how they would react to two patient care scenarios. The interview ends with asking follow up questions, or probes, to complete any gaps in the responses around how the healthcare provider perceives his/her relationships with patients.

## 4. Reporting the Needs Assessment and Planning the Intervention

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| 4.1 Procedure for Stakeholder Identification, Interviews and Mapping         |
| 4.2 Key Stakeholder Interview Schedule                                       |
| Framework for Monitoring and Evaluation                                      |
| 4.3 Sample Tool for Quantifying Needs and Setting Targets                    |
| 4.3 a Example calculation tool for setting targets                           |
| 4.4 Intervention Monitoring & Evaluation Worksheet                           |
| 4.4a-c (Examples 1 – 3)  |
| 4.5 Summary Work Plan  |
| 4.6 Reporting format - Understanding the barriers                            |
| 4.7 Reporting format - Understanding the facilitators                        |
| 4.8 Reporting format - What is missing from TIPS checklist?                  |
| 4.9. Reporting format - Baseline Assessment: Indicators and Benchmarks       |
| 4.10 Reporting format - Stakeholders, interventions, programmes and policies |

### 4.1 Procedure for Stakeholder Identification, Interviews and Mapping

This form builds on the Key Stakeholders identified during the systematic review activity completed in Phase 1. If your site would like to use dedicated software to map stakeholders in a more detailed fashion, we have suggested using MCM software which will objectively grade the responses from stakeholders. This software was developed to assist in the technical assessment process by “systematically ‘mapping’ the practical implications of alternative options, knowledges, framings and values.” <http://www.multicriteriamapping.com/#!/packages-and-pricing/ca4p>

### 4.2 Key Stakeholder Interview Schedule

This interview guide is to be tailored for the categories of Key Stakeholders identified in 4.1 above. The basic themes covered in the Country Partner (2.11) interview topic guide are explored here as well. Health Systems issues cover topics such as Human Resources for Health, the existing referral system and related costs for patients. Policies and Procedures is designed to illicit information about existing guidelines for ARF/RHD care and if/how they are integrated with other policies and procedures at the national, regional and local levels. Knowledge and practice of clinical guidelines is explored and the opportunity is made to cultivate stakeholder engagement for the developing intervention. This interview will take approximately 60-90 minutes.



These interviews are to be transcribed, coded and analysed for exploring interactions among stakeholders, identifying uncertainty, agreement and solutions among stakeholders, and creating the opportunity for engagement and commitment.

#### 4.3 Sample Tool for Quantifying Needs and Setting Targets

This form provides brief examples of generic RHD interventions at primary, secondary and tertiary levels and presents them in the context of the CoC framework. The examples are meant to encourage the user to quantify measurable outputs. This is key to successful monitoring and evaluation.

The sub-form also provides an example of a method for setting target numbers for outreach activities using baseline case information collected during the needs assessment.

#### 4.4 Intervention Monitoring & Evaluation Worksheet

The Intervention worksheet is a template that can be adapted to monitor and report progress on individual interventions. It is designed to be used for periodic reporting according to the adapted M and E plan as well as for the final report.

##### 4.4a-c (Examples 1 – 3)

Examples 1 – 3 illustrate applications of potential RHD programme scenarios to the forms and provide examples of crafting objectives in quantifiable terms within time bounds. The form is designed to encourage the users to think about and discuss potential challenges to achieving the objectives, and to be proactive in devising strategies to manage them.

#### 4.5 Summary Work Plan

The Summary Work Plan is a reporting tool to communicate interim project status to the Stakeholders at pre-determined intervals or as a final report. It provides the opportunity to note successes as well as obstacles encountered toward achieving the objective within the desired time frame. Informed Stakeholders will have both the authority and responsibility to address the challenges (within their limits), as well as to modify interventions during the administration of the interventions. It is a hands-on approach that ensures that projects stay on track and are managed properly.

Five reporting templates are provided in this section of the NAT to give users examples and format for organizing, summarizing and reporting results from the Needs Assessment process. These formats provide a presentation schema for reporting and discussing the findings with Key Stakeholders. Summary reports can be synthesized from these formats to a few major key findings – especially where common themes are identified in multiple areas.

Format 4.9 can be used to report baseline findings and to formulate goals and benchmarks.

#### 4.6 Reporting format - Understanding the barriers

#### 4.7 Reporting format - Understanding the facilitators

Formats 4.6 and 4.7 provide reporting architectures for summarizing both quantitative and qualitative findings based on the CoC© Framework. This format is most likely to illustrate common themes in multiple areas and lends itself to summary reports of key findings from both the barrier and facilitator perspectives.

#### 4.8 Reporting format - What is missing from TIPS checklist?

Format 4.8 is based on the [Tools for Implementing rheumatic heart disease control Programmes](#) (TIPS) checklist. TIPS is a priority-based conceptual framework for evaluating and formulating RHD control programmes by assessing strengths and opportunities and providing a “menu of options.”

#### 4.9. Reporting format - Baseline Assessment: Indicators and Benchmarks

Format 4.9 provides a structure to list the baseline findings of the Needs Assessment in a manner that includes both qualitative and quantitative aspects at all levels of care.

#### 4.10 Reporting format - Stakeholders, interventions, programmes and policies

Format 4.10 provides a structure to report and summarize opportunities to leverage existing interventions that may be able to support new RHD programme interventions. Common examples are leveraging existing NCD, MCH and/or HIV programmes that have an established infrastructure and place in the community or health system.

#### 4.11 More resources for reporting results

**SRQR** - <http://www.ncbi.nlm.nih.gov/pubmed/24979285>

Standards for reporting qualitative research: a synthesis of recommendations.

O'Brien BC1, Harris IB, Beckman TJ, Reed DA, Cook DA.; Acad Med. 2014 Sep;89(9):1245-51. doi: 10.1097/ACM.0000000000000388

**COREQ** - <http://intqhc.oxfordjournals.org/content/19/6/349>

Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.

Tong A1, Sainsbury P, Craig J.; Int J Qual Health Care. 2007 Dec;19(6):349-57. Epub 2007 Sep 14

**PRISMA Website** - <http://www.prisma-statement.org/>

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

**STROBE Website**- <http://www.strobe-statement.org/index.php?id=strobe-home>

STrengthening the Reporting of OBservational studies in Epidemiology STROBE for record review/surveys

## Appendices

**The samples provided here must be adapted to include the elements required by your local IEC/IRB.**

### 1. Sample Information Sheet for Stakeholder Interviews

Local Title of Project

Local Investigator(s) and Research Team Members Name

Name of Facility/Ethics Committee

A team of researchers here at (add institution) is conducting a needs assessment project on the barriers and facilitators to the prevention and treatment of Sore Throat/Acute Rheumatic Fever (ARF)/Rheumatic Heart Disease (RHD) in (your country/community).

The objectives of the assessment are *(Use the objectives from your protocol/project plans and write them in a way that is easily understandable for your local patients):*

- Describe existing policies and practices for the prevention and treatment of Sore Throat, ARF and RHD
- Describe the system for Sore Throat/ARF/RHD diagnosis, treatment and control in (your country) and learn about the linkages between primary health care and treatment activities
- Describe how patients with Sore Throat and ARF seek and obtain health care, and how follow-up and secondary prevention of RHD is provided.
- Identify barriers experienced by both patients and health professionals involved in Sore Throat, ARF, and RHD treatment and prevention, with implications for adherence, and how they seek to overcome them.
- Assess how well RHD care and prevention is integrated within the health system.
- Describe barriers and facilitators to the provision of Sore Throat/ARF/RHD services.

#### **Stakeholder Interview**

We would like to talk with/interview you about your community – who lives here, how it is organised, as well as what are the financial, health, educational and social issues for members of your community. We hope the information we learn from you will help us to understand the current and potential capacity of the community for setting up an intervention around Sore Throat/ARF/RHD. The interview will take about an hour and we would like to record our conversation so we can go back and write down, word-for-word, what we talked about today.

All transcripts of the interviews will be stored in password-secured files. These might be quoted in scientific publications or a country report with no reference to your name, age, gender or profession, in order to ensure confidentiality. However, you have the option of not being quoted anonymously. Along with this information sheet, you will be provided with a separate form giving consent to your participation in the interview.

Taking part in the research is entirely voluntary and withdrawal is possible at any time without having to give a reason. If at any point you feel uncomfortable and would like to stop, you may withdraw from the interview without giving a reason.

The Ethics Committee of the (your facility) has approved the study.

My contact details are written below. You can contact me at any point with any questions or comments.

Research Team Member Name and Title  
Research Team member Email and Phone

## 2. Sample Stakeholder Interview Consent Form

Local Title of Project

Local Investigator(s) and Research Team Members Name

Name of Facility

For the Participant:

- I have read the information sheet concerning this assessment project [or have understood the verbal explanation] and I understand what will be required of me and what will happen to me if I take part in it.
- My questions concerning this study have been answered.
- I understand that at any time I may withdraw from this study without giving a reason.

### PLEASE TIC AS APPROPRIATE

- I AGREE TO BE INTERVIEWED
- I AGREE TO THE INTERVIEW BEING RECORDED
- I AGREE TO BE QUOTED ANONYMOUSLY IN ANY PUBLICATIONS ARISING FROM THIS STUDY

Participant Signature

Date

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### 3. Sample Information Sheet for Patient Interview

Local Title of Project

Local Investigator(s) and Research Team Members Name

Name of Facility

A team of researchers here at (add institution) is conducting a needs assessment project on the barriers and facilitators to the prevention and treatment of Sore Throat/Acute Rheumatic Fever (ARF)/Rheumatic Heart Disease (RHD) in (your country/location).

The objectives of the assessment are *(Use the objectives from your protocol/project plans and write them in a way that is easily understandable for your local patients):*

- Describe existing policies and practices for the prevention and treatment of Sore Throat, ARF and RHD
- Describe the system for Sore Throat/ARF/RHD diagnosis, treatment and control in (your country) and learn about the linkages between primary health care and treatment activities
- Describe how patients with Sore Throat and ARF seek and obtain health care, and how follow-up and secondary prevention of RHD is provided.
- Identify barriers experienced by both patients and health professionals involved in Sore Throat, ARF, and RHD treatment and prevention, with implications for adherence, and how they seek to overcome them.
- Assess how well RHD care and prevention is integrated within the health system.
- Describe barriers and facilitators to the provision of Sore Throat/ARF/RHD services.

There are two activities that require your consent to participate.

#### **Clinical Record Data Collection**

We want to collect medical information from your medical chart about the treatment you received here today. If your visit today is related to Acute Rheumatic Fever / Rheumatic Heart Disease, we also want to collect past and future information about your care and what happens to you. Information about your symptoms, diagnosis, treatment and outcomes for your condition will be recorded and analysed with information about other patients at this facility who have a similar medical condition. Information about you will be recorded in a way that no one outside of the project team will be able to identify you personally. We will maintain the information that does identify you in a secure manner and will not share it outside of the study team. Along with this information sheet, you will be provided with a separate form giving consent to us to collect information from your medical record.

#### **Patient Interview**

We would also like to talk with/interview you about your health seeking behaviour before you arrived at this clinic/hospital today. We'd like to know your reasons for seeking treatment here, what other medicines/treatment and healthcare providers you may have tried before coming here, the impact of your condition on your daily life, and your awareness about sore throat, acute rheumatic fever and rheumatic heart disease. The interview will take about 45 minutes and we would like to record our conversation so we can go back and write down what we talked about today.

All transcripts of the interviews will be stored in password-secured files. These might be quoted in scientific publications or a country report with no reference to your name, age, gender or profession, in

order to ensure confidentiality. However, you have the option of not being quoted anonymously. Along with this information sheet, you will be provided with a separate form giving consent to your participation in the interview.

Taking part in the research is entirely voluntary and withdrawal is possible at any time without having to give a reason. If at any point you feel uncomfortable and would like to stop, you may withdraw from the medical record review and/or the interview and study without giving a reason.

The Ethics Committee of the (your facility) has approved the study.

My contact details are written below. You can contact me at any point with any questions or comments.

Research Team Member Name and Title  
Research Team member Email and Phone

#### 4. Sample Information Sheet for Children/Minor Participants

We are doing this research to find out more about sore throat, an illness called acute rheumatic fever and a heart disease known as rheumatic heart disease.

If you decide to be in our study, we would ask you to do the following:

- Allow us to take past, current and future information from your medical chart about healthcare you received for sore throat / ARF/ and/or RHD. We will not share personally identifying information about you outside of the research team.
- Agree to talk with us and your parent(s) about your illness. It will take about 45 minutes.

Some of the questions might be hard to answer and might make you feel uncomfortable. We will try to make sure that no bad things happen. It is OK to say yes, and then change your mind later. You can stop being in the interview at any time. Please tell the person who is conducting the interview if you want to stop at any time.

You can also say “no” to participating in our research. No one will be mad if you say “no.” The doctors and nurses will still take care of you. If you don’t want to be in the study, you don’t have to be.



## 5. Sample Patient Record Review and Interview Consent Form

Local Title of Project

Local Investigator(s) and Research Team Members Name

Name of Facility

For the Participant:

- I have read the information sheet concerning this assessment project [or have understood the verbal explanation] and I understand what will be required of me and what will happen to me if I take part in it.
- My questions concerning this study have been answered.
- I understand that at any time I may withdraw from this study without giving a reason.

### PLEASE TIC AS APPROPRIATE

- I AGREE TO LET THE STUDY TEAM COLLECT INFORMATION ABOUT MY PAST, CURRENT, AND FUTURE MEDICAL TREATMENT RELATED TO SORE THROAT, ACUTE RHEUMATIC FEVER AND RHEUMATIC HEART DISEASE FROM MY MEDICAL CHART.
- I AGREE TO BE INTERVIEWED
- I AGREE TO THE INTERVIEW BEING RECORDED
- I AGREE TO BE QUOTED ANONYMOUSLY IN ANY PUBLICATIONS ARISING FROM THIS STUDY

Participant Signature

Date

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ASSENT of the CHILD

Child/Minor Participant Signature

Date

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## 6. Sample Information Sheet for Healthcare Provider Interview

Local Title of Project

Local Investigator(s) and Research Team Members Name

Name of Facility

A team of researchers (add institution) is conducting a needs assessment project on the barriers and facilitators to the prevention and treatment of Sore Throat/Acute Rheumatic Fever (ARF)/Rheumatic Heart Disease (RHD)..

The objectives of the assessment are: *(Use the objectives from your own protocol/project plan.)*

- Describe existing policies for the prevention and treatment of Sore Throat, ARF and RHD
- Describe the system for Sore Throat/ARF/RHD diagnosis, treatment and control in (your country) and assess linkages between primary health care and curative activities
- Describe how patients with Sore Throat and ARF seek and obtain health care, and how follow-up and secondary prevention of RHD is provided.
- Identify barriers experienced by both patients and health professionals involved in Sore Throat and ARF treatment and prevention, with implications for adherence, and how they seek to overcome them.
- Assess how well RHD care and prevention is integrated within the health system.
- Describe barriers and facilitators to the provision of Sore Throat/ARF/RHD services.

### **Healthcare Provider Interview**

We would like to talk with/interview you about your role, relationships with, and knowledge about taking care of patients with sore throat / ARF / RHD. We will present you with two patient care scenarios and ask how you would manage the patients. The interview will take about 45 minutes and we would like to record our conversation so we can go back and write down what we talked about.

All transcripts of the interviews will be stored in password-secured files. These might be quoted in scientific publications or a country report with no reference to your name, age, gender or profession, in order to ensure confidentiality. However, you have the option of not being quoted anonymously. Along with this information sheet, you will be provided with a separate form giving consent to your participation in the interview.

Taking part in the research is entirely voluntary and withdrawal is possible at any time without having to give a reason. If at any point you feel uncomfortable and would like to stop, you may withdraw from the interview without giving a reason.

The Ethics Committee of the (your facility) has approved the study.

My contact details are written below. You can contact me at any point with any questions or comments.

Research Team Member Name and Title

Research Team member Email and Phone

## 7. Sample Healthcare Provider Interview Consent Form

Local Title of Project

Local Investigator(s) and Research Team Members Name

Name of Facility

For the Participant:

- I have read the information sheet concerning this assessment project [or have understood the verbal explanation] and I understand what will be required of me and what will happen to me if I take part in it.
- My questions concerning this study have been answered.
- I understand that at any time I may withdraw from this study without giving a reason.

### PLEASE TIC AS APPROPRIATE

- I AGREE TO BE INTERVIEWED
- I AGREE TO THE INTERVIEW BEING RECORDED
- I AGREE TO BE QUOTED ANONYMOUSLY IN ANY PUBLICATIONS ARISING FROM THIS STUDY

Participant Signature

Date

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