

# LESSONS FROM LOSS



A Guide to Conducting  
TB Patient Mortality  
Audits using a  
Patient-Centered Approach

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## DISCLAIMER

This guide draws heavily from the approach to maternal mortality audits and health systems change literature and in particular, the text *"Beyond the Numbers: Reviewing Maternal Deaths and Complications to Make Pregnancy Safer"* by WHO (2004) ISBN 92 4 159183 8, from which many ideas and large sections of text were adapted.



## ACRONYMS

|        |  |
|--------|--|
| ACSM   | Advocacy, Communication and Social Mobilization    |
| ART    | Anti-Retroviral Treatment                          |
| BCC    | Behavior Change Communication                      |
| CBO    | Community Based Organization                       |
| CBDR   | Community based Death Review                       |
| CPT    | Cotrimoxazole Preventative Treatment               |
| CSO    | Civil Society Organization                         |
| CSS    | Community Systems Strengthening                    |
| DHMT   | District Health Management Team                    |
| DHS    | Demographic and Health Survey                      |
| DOTS   | Directly Observed Treatment Short-course           |
| DTC    | District TB Coordinator                            |
| EPTB   | Extra-pulmonary Tuberculosis                       |
| FBO    | Faith-based Organization                           |
| FBMA   | Facility Based Mortality Audit                     |
| FGD    | Focus Group Discussion                             |
| GIPA   | Greater Involvement of People with AIDS            |
| GIPT   | Greater Involvement of People with TB              |
| HIV    | Human Immunodeficiency Virus                       |
| IEC    | Information, Education and Communication           |
| IPCC   | Interpersonal Counseling and Communication         |
| HCW    | Health Care Worker                                 |
| HMIS   | Health Management Information System               |
| KAP    | Knowledge, Attitudes and Practices                 |
| KNCV   | KNCV Tuberculosis Foundation                       |
| MARP   | Most at Risk Population                            |
| M&E    | Monitoring and Evaluation                          |
| MDR-TB | Multi-drug Resistant Tuberculosis                  |
| NGO    | Non-governmental Organization                      |
| NTP    | National Tuberculosis Program                      |
| PCA    | Patient Centered Approach                          |
| PMDT   | Programmatic Management of Drug-Resistant TB       |
| PPM    | Public/Private Mix                                 |
| PTB    | Pulmonary TB                                       |
| QoC    | Quality of Care                                    |
| RDS    | Respondent Driven Sampling                         |
| SDA    | Service Delivery Area                              |
| TAT    | Turnaround Time                                    |
| TB     | Tuberculosis                                       |
| TB CAP | Tuberculosis Control Assistance Program            |
| VA     | Verbal Autopsy                                     |
| USAID  | United States Agency for International Development |
| WHO    | World Health Organization                          |

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## EXECUTIVE SUMMARY

The purpose of this tool is to collect information on factors leading to mortality among tuberculosis (TB) patients in order to help health professionals, planners, managers working in TB programs, and TB advocates to save TB patients' lives by improving care seeking and the quality of care. The tool offers step by step guidance on how to pinpoint where the problems lie and to build consensus toward feasible solutions. Using a combination of two approaches: the Community-based Death Review (CBDR) and the Facility-based Mortality Audit (FBMA), a coalition of diverse stakeholders can create the changes needed to improve care seeking and quality of care.

Honoring the lost lives of TB patients and trying to derive the programmatic lessons by listening to their families and their challenges is the epitome of *The Patient Centered Approach (PCA)*. This is a philosophy of TB control which places the patients' lived experience at the center of the health care system, in the clinic, and in the community.

High TB mortality is increasingly understood as an indicator of many different problems in the health system and community. Limited awareness of TB in the community, restricted accessibility and/or quality of health services can hamper survival. Evidence suggests that co-morbid TB patients (i.e. those with HIV, hepatitis, diabetes, etc.) are particularly vulnerable when the quality and timing of clinical care services are suboptimal and/or diagnosis is delayed.[1-3] Exploration and analysis of death among TB patients can lead to a clearer and specific understanding of why the deaths happened and where interventions are likely to make a difference in a specific context.

TB mortality proportions can be compared between groups (e.g. HIV negative vs. HIV positive TB patients) as well as within groups in order to understand the impact of any differences in diagnosis or management. In addition, the experiences and care of TB patients who died can be compared with those patients who survived to see if and how patient management (in clinic and community) contributes to survival.

A well executed death audit takes into account many points of view. It yields clues as to the most effective interventions to prevent deaths in the future. Ultimately, the findings of the approach described in this guide can be used to make changes to improve both access to and provision of life-saving health care.

## INTRODUCTION

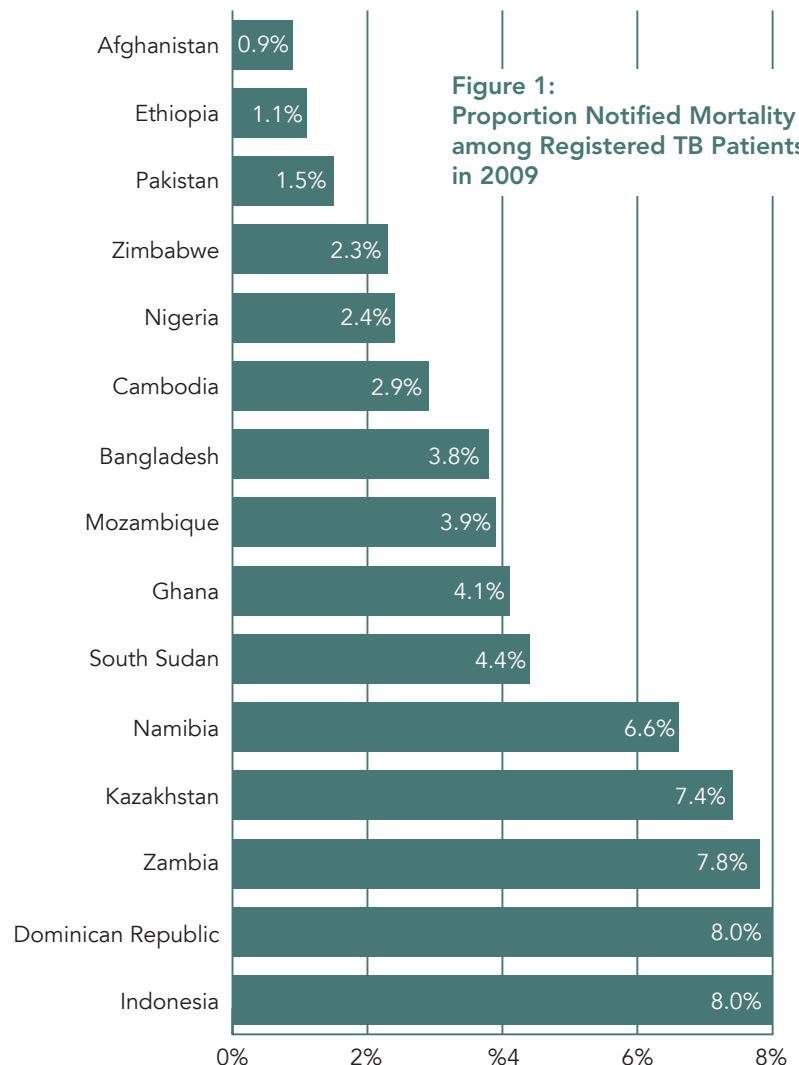
In the era before effective treatment for TB was developed, the average time to death (or self cure) was three years, and case fatality was approximately 70% for smear-positive and 20% for smear-negative TB [3]. However in today's world most deaths among TB patients can be averted, even in cases of HIV co-infection, through timely diagnosis, effective treatment, and proper patient support [4]. Mortality audits can shine a light on issues that have been overlooked due to heavy workloads and competing priorities. In Malawi for example, the national TB program instituted mortality audits at the hospital level, in the spirit of performance improvement<sup>1</sup>. These mortality audits pinpointed problem areas and the results acted as a catalyst to improve the performance of health workers deployed in the TB wards. TB patient deaths were reduced from 16% to 3% following implementation of a simple action plan that ensured a minimum standard of clinical care.

Preservation of life remains the overriding common goal of TB programs worldwide [5]. Preventing mortality among all TB patients is accomplished through discrete efforts on multiple fronts. The international importance of reducing TB mortality is reflected by its inclusion as a Stop TB Partnership target of 50% decline in mortality by 2015. High TB mortality is increasingly understood as an indicator of impoverished living and working conditions, lack of awareness of TB in the community, limited access to and/or quality of the health care services.

Despite the global consensus on the importance of TB patient mortality as a benchmark of health and societal wellbeing, the existing TB register data often offer a confusing picture. With wide variations among countries and almost certainly high rates of underestimation and misclassification it can be challenging to make sense of mortality among TB patients. The graph on the right shows the significant disparities in proportions of TB patient mortality in the national program data from a range of high burden countries in 2009.

These data show a wide range in mortality by country, but may obscure an even wider range among basic management units. The reliability of these estimates is uncertain. It is noteworthy that some fragile states and challenging settings report lower mortality than higher income settings with more stable infrastructure.

Given the lack of confidence in some TB register outcome data and the high proportion of deaths in some settings, further investigation is often warranted. In settings where notified TB patient mortality exceeds the range from 1-3% documented in high functioning TB control programs, information from multiple perspectives can be vital to identify the roots causes of excess



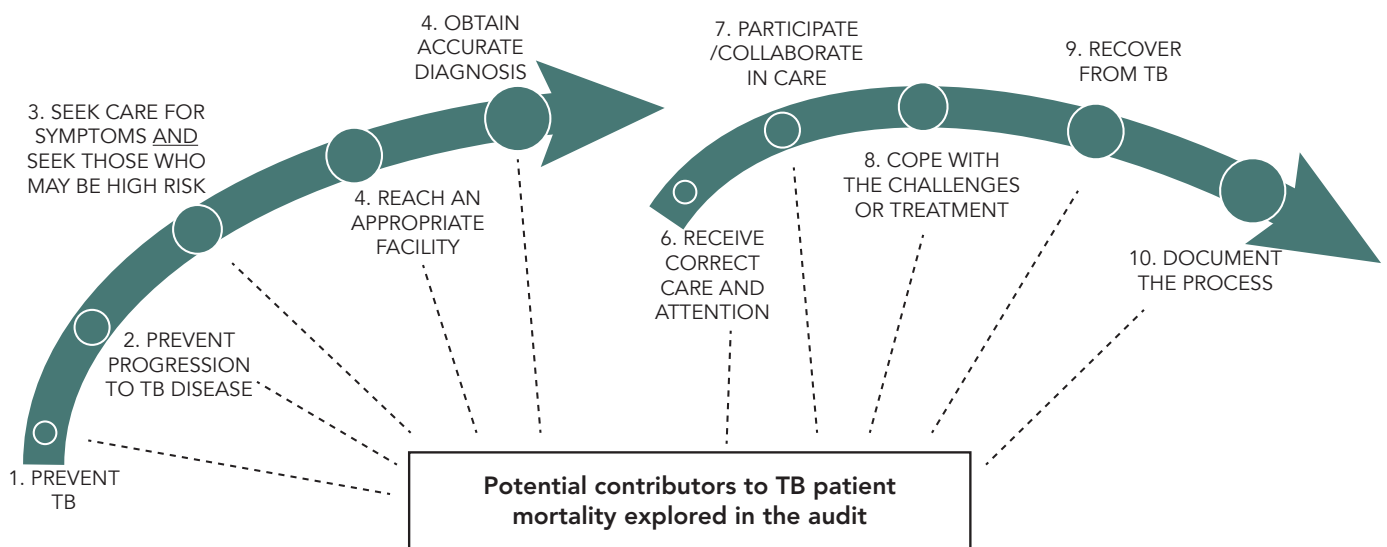
mortality. Insights into the patient's care-seeking itinerary and the chain of social, economic and clinical events that led to his/her death can help us to decide where to focus our improvement efforts. Approaching the problem at the individual level in the context of the patient-centered approach can lead to improvement of the performance of the whole health care system.

For Example:

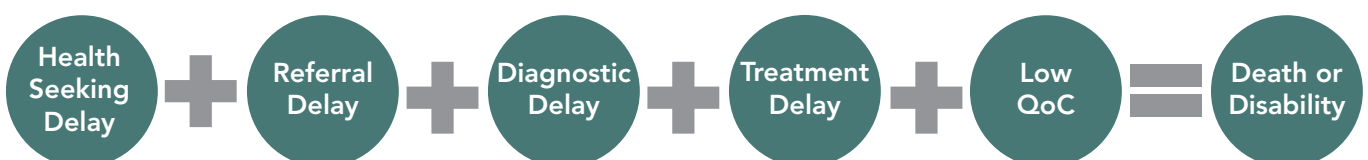
- Are certain types of TB patients dying because they feel unwelcome in the health care system or unaware of the early signs of TB and/or HIV?
- Is there a problem with availability, distribution, or accessibility of the services?
- Are TB patients seeking care early, but not being referred to trained providers?
- Is the care that TB patients receive inadequate or sub-optimal?

The journey that persons follow from initial infection to recovery or death is depicted in Figure 2. The first arc shows critical intervention points along the way where TB can be averted or addressed. Any potential delays and challenges along this itinerary including health seeking delays, poor accessibility of services, difficulties in diagnosis or initiation of treatment, challenges in coping with the many consequences of illness can be instrumental in a negative outcome. TB stigma is often a barrier to seeking health care and the audit includes a series of questions that can help the user understand the level of stigma in the community and how it may affect the decision to seek care. The continuation of the arc shows the points where challenges can arise while being a TB patient. Taken together, any point along either arc may be the underlying cause of unnecessary mortality.

**Figure 2: TB Journey**



**Figure 3: Delays leading to Death and Disability**



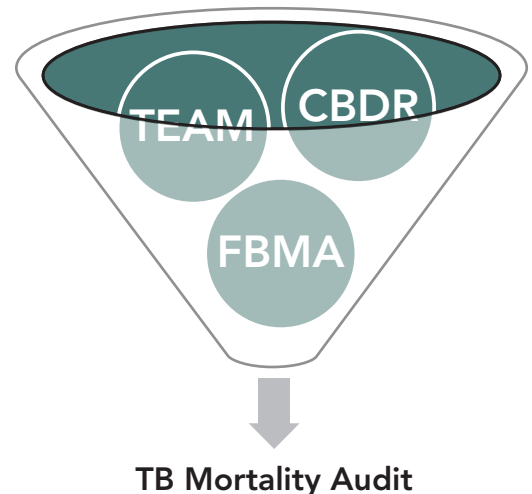
As shown in Figure 3, there are five different types of delays that may contribute to loss of life.

1. Delays in the decision to seek care
2. Delays in being referred to a functioning TB diagnostic center
3. Delays in arrival at a health facility
4. Delays in the diagnostic process
5. Delays in provision of adequate care and treatment.

It is important to distinguish among them because each delay has a different root cause and require a different set of corrective actions to reduce it.

Once a person has a TB diagnosis, the TB patient's treatment journey begins. Sub-optimal collaboration and/or clinical management along the route can contribute to patient mortality.

In order to analyze TB deaths and improve TB services, we introduce the **Community-based Death Review (CBDR)** tool to look at the antecedents, health seeking behavior, and perceptions of care provided and the **Facility-Based Mortality Audit (FBMA)** to review the timing and quality of care provided in health facilities. Exploring the same patient's death from two different points of view can reveal much more than simply a one-sided record review, especially in contexts where the records are poorly kept, poorly designed, or entirely absent.



A TB death is any death occurring to a patient who is diagnosed with TB and who has been on treatment for TB, or who has interrupted treatment not longer than one month ago, regardless of the cause of death.

Successful implementation of the TB Mortality Audit depends on fostering a climate of confidentiality and trust. Using a non-punitive, non-threatening, inquisitive approach to describe and analyze the factors leading to adverse outcomes is essential.

Both health care and community workers and family members should be assured that the sole purpose of the audit is to learn valuable lessons from the tragic death of the patients and to save lives in the future. These reviews seek only to identify barriers to accessing and receiving quality care in the health care system. They must never be used to provide the basis for litigation, management sanctions or personnel decisions.

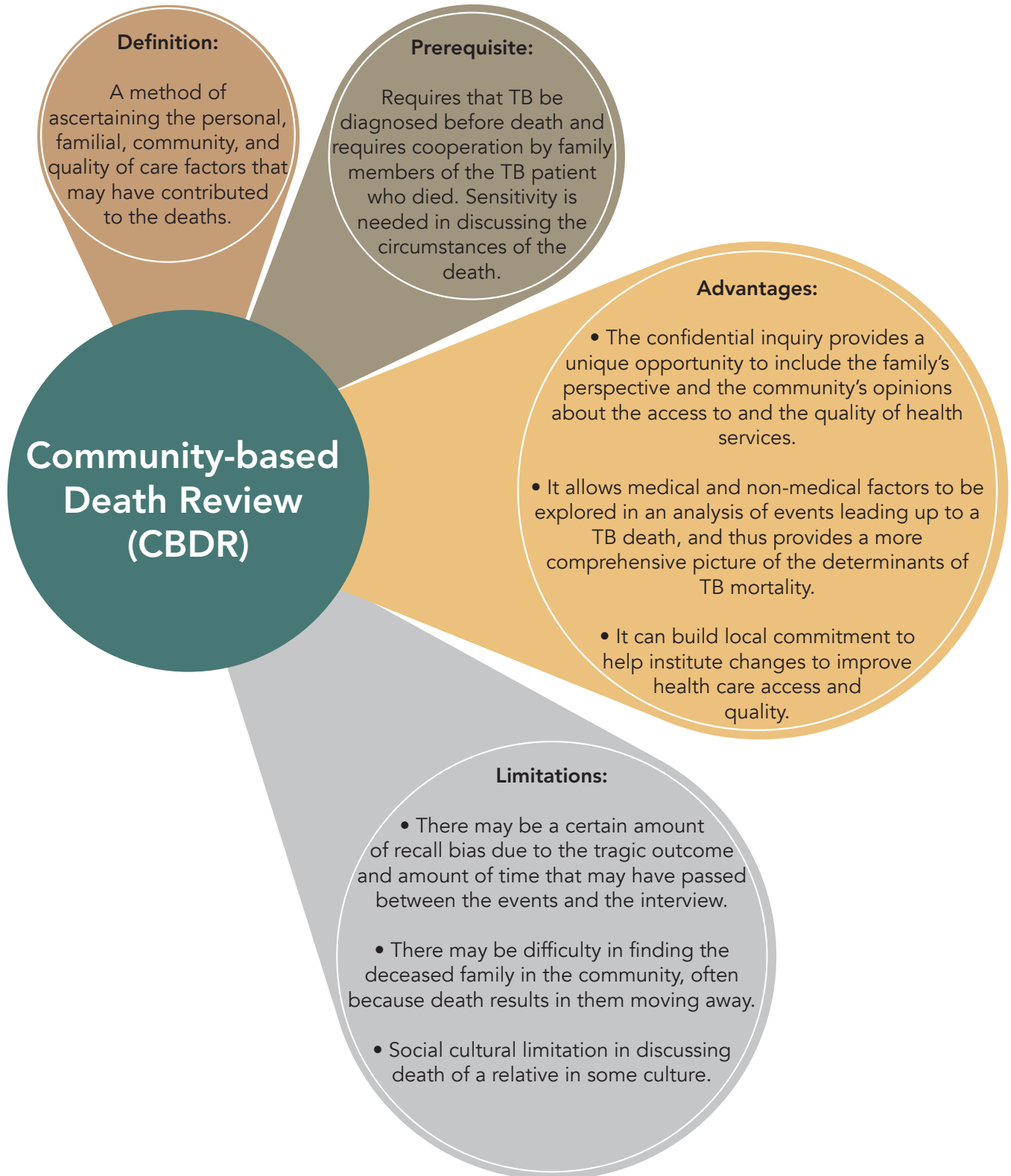
The combined findings of the **Community-based Death Review (CBDR)** and the **Facility-Based Mortality Audit (FBMA)** should be used by local "Change Agents": People with the power and commitment to make improvements in the provision of health care and access. The tools are not intended for use by researchers, but rather by multidisciplinary stakeholder teams committed to reducing TB mortality and morbidity among TB patients. The change process can be similar to the WHO Strategic Approach in that it is a participatory process with stakeholders with diverse research, policy, clinical and community skills [6-8]. Alternatively, experience in Malawi and elsewhere has shown that implementation of improvements can also begin incrementally with quick wins by a local team of committed individuals. These can be expanded and deepened over time leading to profound improvements in patient survival.



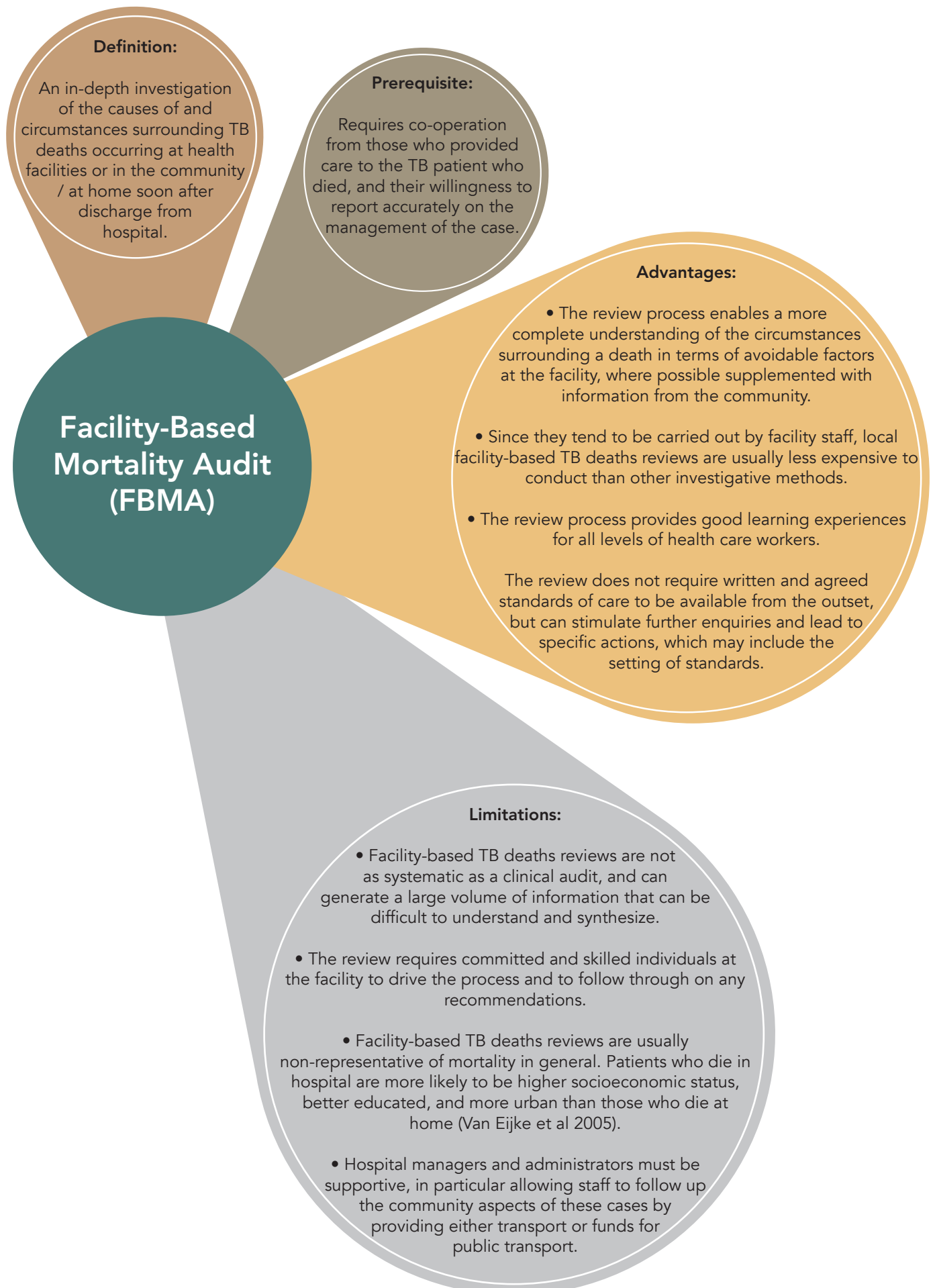
## DEFINITIONS

This section offers simple definitions, prerequisites, advantages and disadvantages of audit methods to facilitate decision making.

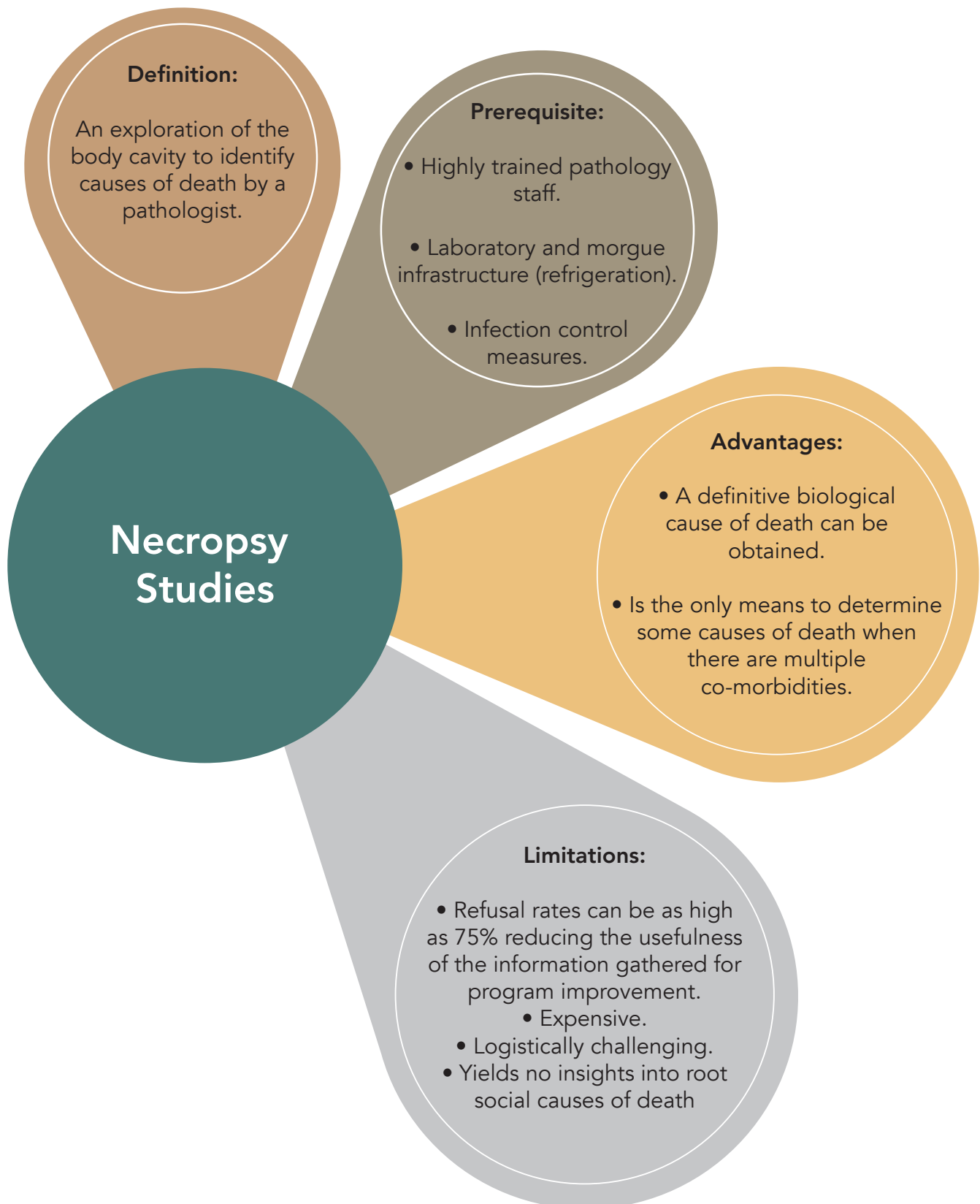
### Part A: Community-based Death Review (CBDR)

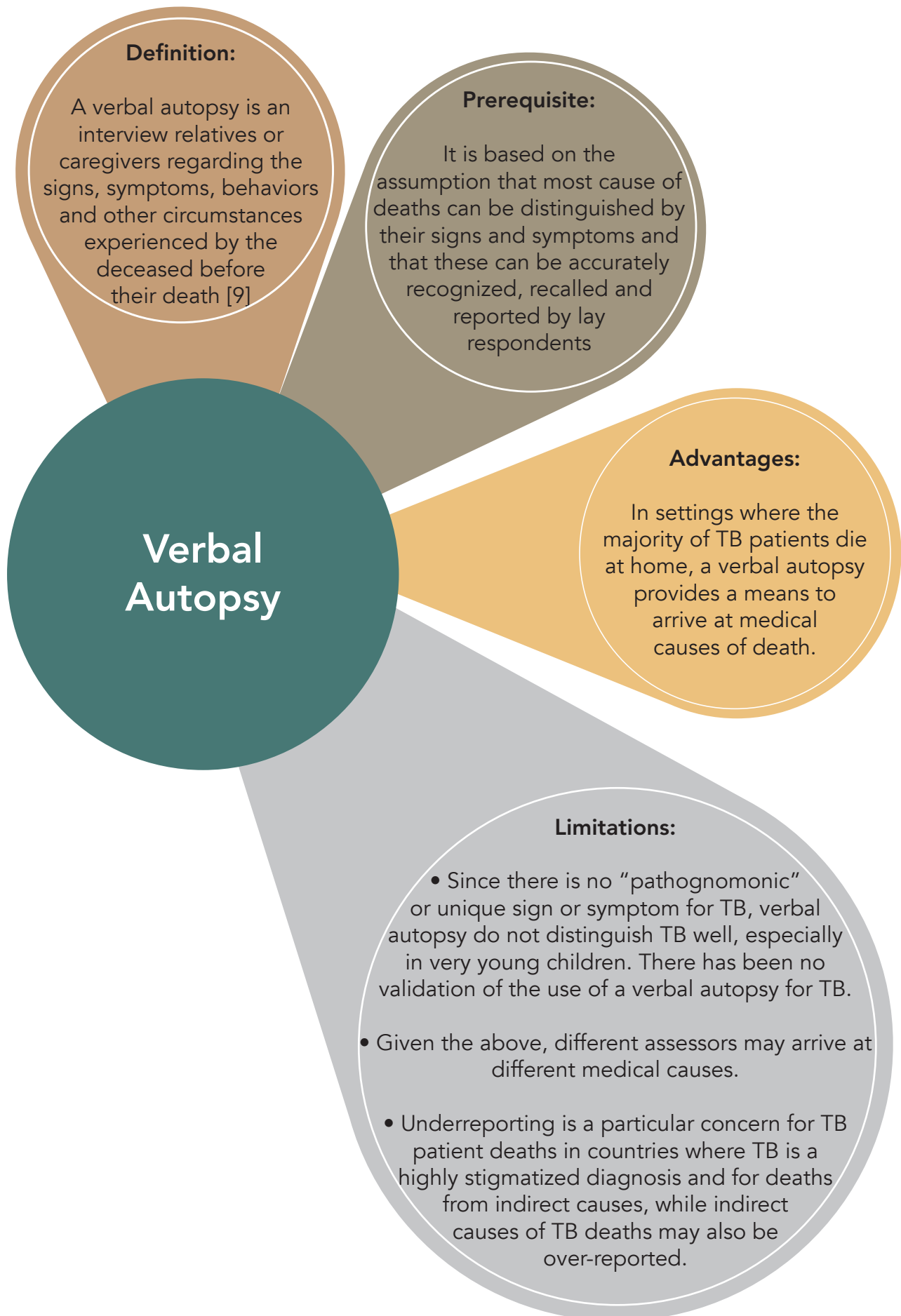


## Part B: Facility-Based Mortality Audit (FBMA)



It is important not to confuse a Mortality Audit process with these related activities:





An important underlying principle for using the approaches suggested in this guide *is to make the best use of whatever methods and data sources are available* in order to improve outcomes for TB and TB/HIV patients. A review involving only the analysis of case notes is still far better than not undertaking any review because there were perceived barriers to implementing the full package of data collection tools. In the next sections we will focus on the **Community-based Death Review (CBDR)** and the **Facility-Based Mortality Audit (FBMA)**.

## A TB MORTALITY AUDIT

The TB mortality audit may be conducted at a single health facility, or periodically across several facilities as part of a district or even regional assessment. In the latter situation, the investigation may include every TB death in each facility for a fixed period of time, such as the last 12 months, or if the number is too large to investigate in-depth, it may be carried out on a (representative) subset of these deaths. For example, it may be important to look at representative proportions of people who died with TB/HIV co-infection and those who were not co-infected in areas of high HIV prevalence to gain an understanding of how the circumstances differ for these two populations. It is well known that social and environmental circumstances often play a decisive role in TB survival. For instance, there may be several reasons why TB patients delay in seeking help for their disease. Therefore, ideally, an attempt should be made to investigate the community factors involved in each case as well as these factors related to the care provided in the facility. In this way, all the relevant medical, social and service factors around the death can be understood.

**What if we want to do an audit, but we don't have a separate budget for this activity? How can we still do this work?**

The Community-based Death Review (CBDR) can (and should) be integrated with existing community work. It is often combined with contact tracing and staff always apply it when they go to screen the pediatric or HIV + household members of a deceased TB patient.

This TB Mortality Audit is used retrospectively to investigate circumstances around the death of a TB patient. The audit is meant for all TB patients who were admitted and died in the hospital, or who died in the community / at home soon after discharge from hospital.

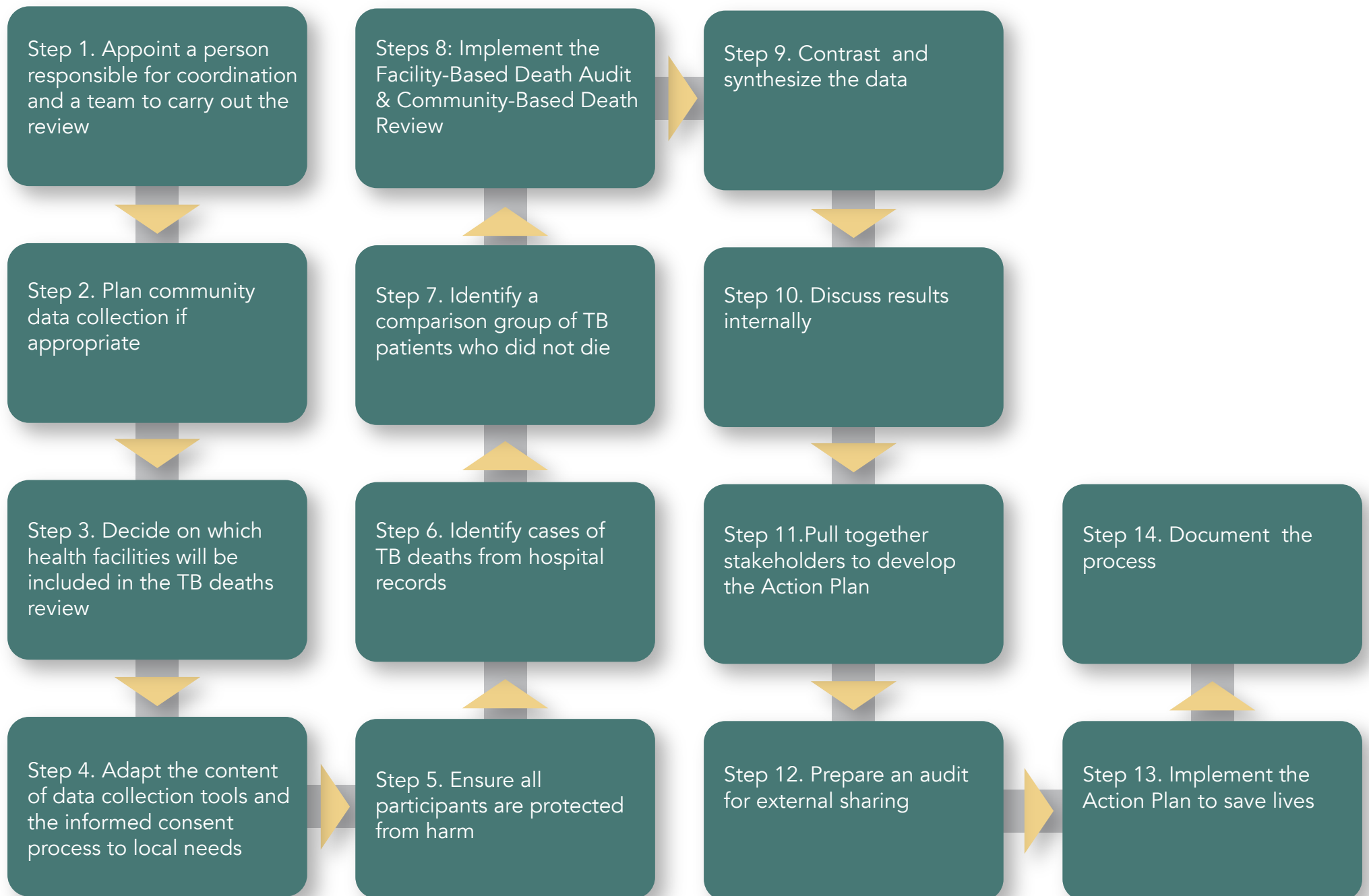


The audit consists of two sections exploring the same death from different perspectives:

**A. Community based Death Review (CBDR)** – Part A is a structured questionnaire to be administered to close relatives with whom the TB patient shared the household. It probes for factors which contributed to the death of the patient, from the awareness of symptoms and motivation to seek health care, to barriers to access of health services, delays in diagnosis, and timing and quality of treatment.

**B. Facility-based Mortality Audit (FBMA)** - Part B is basic information about the quantity, quality, and timing of the clinical care of the TB patient. It is obtained from staff in the hospital, clinical records and the TB registers. Special attention should be given to TB patients who died at home, and to include patients lost to follow up who may have died at home.

Figure 3: Overview of the process for undertaking a TB mortality audit



## STEP 1. APPOINT A PERSON RESPONSIBLE FOR COORDINATION AND A TEAM TO CARRY OUT THE REVIEW

A multidisciplinary team is best equipped to fulfill the main responsibility for conducting the review. The most important criteria are that the members should have a commitment to investigating TB deaths, and be able to devote sufficient time to the process. If a community element is part of the review, they should have knowledge of the local language and cultural norms surrounding mortality as well as an ability to develop respectful rapport with community leaders. The inclusion of at least one senior person is important, to give the team some authority and to facilitate relationships with other agencies. An empowered change agent who can lead the implementation of the recommendations from the audit is also essential. The team could consist of a medical doctor, a nurse, the district TB manager, members of community based-organizations, representatives from at-risk or vulnerable groups, and a social scientist.

Sometimes teams also include members of religious institutions, nursing assistants, students from the local university, and statisticians. The leader of the group should be widely respected within the facility as an early adopter of best practices. He or she should be a charismatic, collaborative leader in whom there is a great deal of trust.

If the audit is limited to one facility, then the review team alone may be sufficient to conduct the process. If, on the other hand, the audit is being conducted across several facilities, a larger collaborating team may be needed. In Malawi, the TB mortality audits were conducted in a weekly clinical meeting in the health facilities; members of the team included all clinical staff (clinicians, nurses etc.).

Including a senior person from all the major facilities involved should enable the review team to gain cooperation within each facility. Otherwise, mid-level staff with about three to six years of professional experience may be the most suitable collaborators and data collectors because they have the appropriate knowledge and maturity, but are usually not heavily engaged in other administrative work.

## STEP 2. PLAN COMMUNITY DATA COLLECTION

The Community-based Death Review (CBDR) is a vital part of the TB Mortality audit. It is important to consider the strategic involvement of some community members in the death review. The aim of community involvement is to ensure quality and uptake of the results. Community leaders are powerful change agents and if they have a sense of ownership of the findings, they can more fully support improvement efforts and catalyze community changes if needed.

Using this approach, the investigation starts by identifying registered TB deaths and then using address information from the record, the team attempts to trace the surviving family members in the community to ascertain the timing and sequence of events leading to death. Data collectors who make these visits to the home after the death should be well trained and understand the importance of sensitivity towards family members.

### **What if there aren't very many TB deaths in our facility? Should we still do a mortality audit?**

In the event that there are very few deaths, it may not be advisable to explore quality of care in this manner. For this, you may use the ISTC (see Appendix D) and/or the *Quote TB Light Tool* as guides to assessing how care was provided and the level of quality.



The CBDR (Part A) uncovers valuable information about the deceased patient's circumstances before help was sought as well the familial perspective on the care he or she received. It also provides an opportunity to ask to see and review any patient-held records that are available.

It is recognized however, that home visits will not always be feasible.

### STEP 3. DECIDE ON WHICH HEALTH FACILITIES WILL BE INCLUDED IN THE TB DEATHS REVIEW

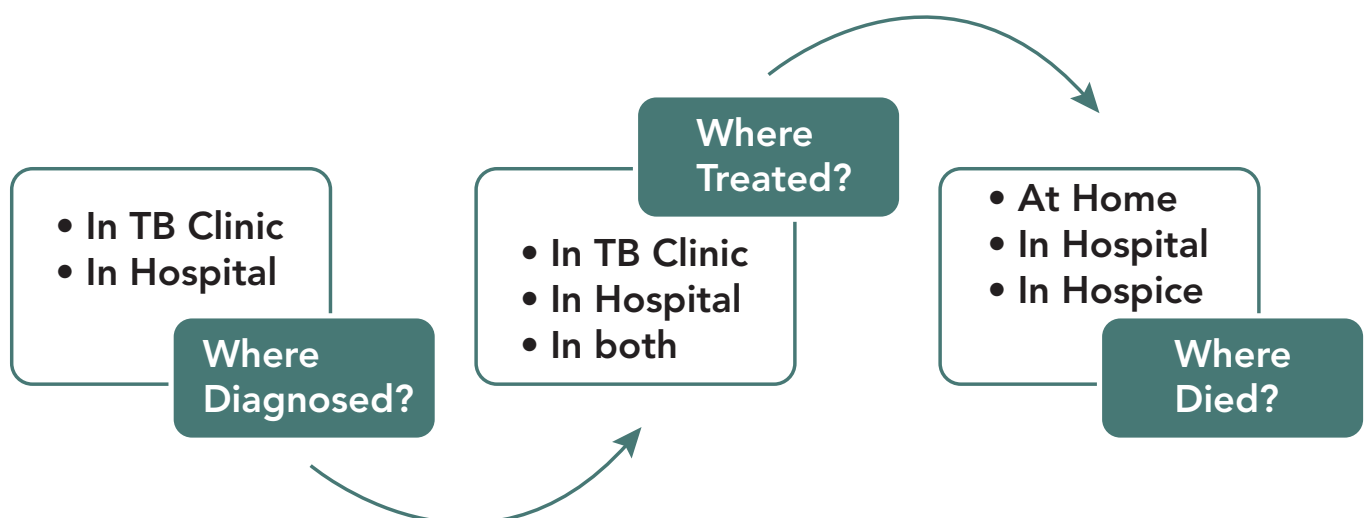
It is important to select TB facilities whose experience can shed light on the functionality of the diagnostic and treatment service delivery, including linkages between levels of care. There are a number of possible diagnostic and treatment itineraries that a TB patient can follow and facilities at various levels of the health system may all play a role. For example, here are some common TB patient trajectories:

- 1. Never hospitalized:** Person is diagnosed and treated in a TB clinic, (i.e. never hospitalized), and dies at home
- 2. Care at all levels:** Patient is diagnosed and treated in TB clinic (ambulatory), then hospitalized for a given period, then discharged, and dies at home
- 3. Deterioration on treatment:** Patient is diagnosed and treated in TB clinic (ambulatory), then hospitalized for a given period, then dies in hospital
- 4. One hospital stay:** Patient is diagnosed while hospitalized, and dies while hospitalized
- 5. Multiple hospital stays:** TB Patient is diagnosed while hospitalized, then discharged to continue treatment in a TB clinic, dies in hospital.

The team should discuss the pros and cons of including different TB patient profiles and justify their decision in their protocol.

It is recommended to seek information on as many deaths as possible, a minimum of twenty cases per patient trajectory. However, any TB death occurring after receiving care from a health facility should be preferentially included to see whether any circumstances surrounding the care of the TB patient by the facility could be improved in the future.

**Figure 4: Potential Patient Trajectories**



## STEP 4. ADAPT, TRANSLATE, AND PRE-TEST THE TOOLS IN YOUR SETTING

The Facility-based audit form and Community-based TB death review are provided in Appendices A and B. Although there are many variables that are listed on these tools, it is not expected that all the data will be entered into a computer and analyzed. The information is collected to support the review team to identify and classify avoidable factors, and recognize which are most common and which can be most easily avoided in future by selected interventions. There may be a need to translate the questionnaires into the language used by the respondents. The interview team should field test the questionnaires in order to gain experience with administering the questionnaire and detect any problems that arise during use, such as questions that are not well understood by the data collectors.

## STEP 5. ENSURE ALL PARTICIPANTS ARE PROTECTED FROM HARM

Although the mortality audit is an internal performance improvement, there exists some possibility of social harms to the reputations of health workers or families who participate if confidentiality procedures fail. Therefore a plan is needed to ensure all participants are protected, data are kept safe, and individuals' privacy and integrity are not compromised. Explicit confidentiality protections and data security protocols are helpful in reducing anxiety on the part of health workers and community members alike. The plan considered by the facility's ethics committee or a relevant ethical review board (if multiple facilities are included or there is no facility ethics committee)<sup>2</sup>. Careful advance consideration of how to protect all participants from negative consequences of participating in the review is both necessary and worthwhile. If the goal is to share the impact of the audit externally, through a peer-review publication for example, ethical review is typically a journal requirement.

**What if the data quality is not sufficient to do a mortality audit? For example, what if the hospital records are so incomplete that we cannot reconstruct the care that was rendered?**

If there are no records, then it is better to talk to current patients (including defaulters and those who transfer to another district or facility) to understand how TB services are provided

## STEP 6. IDENTIFY CASES OF TB DEATHS

TB deaths are usually identified from TB registers, health facility registers (such as ward admission and discharge registers) and mortuary records. Other sources of information that may be available are: vital registration records, religious leadership records (temple, church or mosque files), or informal records kept by health professionals.

Many factors may complicate the identification of TB deaths. For example:

1. A proportion of in-patient TB patient deaths occur in facilities outside TB wards, particularly among patients with extra-pulmonary disease admitted in other wards (Pediatric, Neurology, Orthopedics, etc.).
2. Patient records are often paper-based, disorganized or nonexistent.
3. Many hospital facilities do not have TB wards.

Therefore it is often labor intensive to find TB patient records and use them to identify which TB patients died.

Other TB patients may die at home, after discharge from hospital or even without ever having been admitted. TB deaths often also occur among TB patients who default from treatment.

<sup>2</sup> See: <http://www.wma.net/en/30publications/10policies/b3/index.html>

The latter category is an important one, as the reasons for default may be directly related to the cause of the TB death, such as poor case management by the health facility staff or community health care providers available to them. It is therefore important to explore the occurrence of TB deaths among defaulters and include them in the mortality audit. Budgets and timeline should aim to reflect these realities.

### STEP 7: IDENTIFY A REPRESENTATIVE SAMPLE OF TB PATIENTS WHO DID NOT DIE

In order to conclude that a particular factor was associated with mortality, the audit should also be administered to a sample of the TB patients from the same treatment cohort who were either cured or completed treatment. This comparative information is necessary to understand risk factors for mortality. These TB patients may be selected from the TB Register at random or at random intervals on a list. In cases where comparison is not possible or feasible, the information of the TB deaths alone can still improve the care for TB patients, but one cannot always be fully confident that improvements made will reduce mortality. The decision on whether to use a “matched” case or to select surviving TB case records at random should be made in discussions with an epidemiologist.

**Some of the questions in the CBDR and the FBDR are only applicable for patients who died. How do we adapt the tools to gather information on patients who did not die?**

The Excel template identifies the key variables to be collected from the comparison group of patients who survived.

### STEP 8: IMPLEMENT COMMUNITY BASED DEATH REVIEW (CBDR) AND FACILITY-BASED MORTALITY AUDIT (FBMA)

| Community based TB death review (CBDR)<br>PART A                | Facility-Based Mortality Audit (FBMA)<br>PART B                              |
|---|--|
| A. Train data collectors in confidential inquiry                | A. Train data collectors in record abstraction and in-depth interview skills |
| B. Collect data from relatives and co-habitants of the deceased | B. Collect data from health facilities and staff                             |
| C. Monitor and assure quality of the data                       | C. Monitor and assure quality of the data                                    |

#### A. TRAIN DATA COLLECTORS

The data collectors are members of the TB mortality audit team. It makes sense for all team members to play a role in data collection, because it can be a powerful sensitizing experience. Agreement should be reached about whether or not data collectors can collect data in facilities other than their own. Provided it is apparent that they are carrying out their work with impartiality and with care to maintain confidentiality, this should be permissible. Indeed, when several facilities are included in the review, it is quite important that the same data collectors be used in all the facilities. Otherwise, different results may be obtained merely because of differences in the way the data were collected.

However, for the community-based death review (CBDR), it is preferable to recruit data collectors specifically for this function. In general, non-medically qualified but experienced interviewers are preferred over medically qualified staff as the latter may be too intimidating or directive in their mode of questioning. Moreover families may be reluctant to be candid about quality of care or non-use of care in the presence of senior medical staff. This also ensures that those collecting data in the community do not know details about the management of cases in the facility, and

thus cannot be drawn into possibly controversial discussions on this subject, which may result in conflict of interest. Finally, after having assembled sufficient data collectors, the review team will need to arrange a training course for them. Other factors influencing the choice of interviewers include mobility, acceptability and availability.

PATH has developed two curricula that can be adapted and used for data collector training. The first builds skills in assuring privacy and confidentiality for providers. It was intended for reproductive health care providers but the main principles are applicable to interviewing on any sensitive topic, including mortality. The second curriculum is aimed at improving health workers' TB communication and counseling skills and some of the exercises can be used to strengthen data collectors non-verbal communication skills, etc. These materials can be found at [www.path.org/](http://www.path.org/):

- Ensuring Privacy and Confidentiality in Reproductive Health Services: A Training Module and Guide. For Service Providers: [http://www.path.org/publications/files/RH\\_ensuring\\_privacy.pdf](http://www.path.org/publications/files/RH_ensuring_privacy.pdf)
- Interpersonal Communication and Counseling for Clients on Tuberculosis and HIV and AIDS. PATH, 2009. <http://www.path.org/publications/detail.php?i=1770>

FHI 360 has also published an international Research Ethics training materials in English, Spanish, French, and Portuguese that can help the team to understand the ethical dimensions of the mortality audit: <http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm>

In addition, the following websites have important tools on clinical quality and patient centered approaches that can be used to prepare data collectors:

1. [http://www.tbcare1.org/publications/toolbox/tb\\_hiv/](http://www.tbcare1.org/publications/toolbox/tb_hiv/)
2. <http://www.tbcare1.org/publications/toolbox/me/>

## **B. COLLECT DATA AT HEALTH FACILITIES AND IN THE COMMUNITY**

Data collection forms can be filled electronically or in duplicate paper form (one to be kept in the patient's file and one is used in the audit). For more details on the specifics of data collection for each part see Appendix A and B.

## **C. MONITOR AND ASSURE QUALITY OF THE DATA COLLECTION**

Quality control procedures are needed to ensure collection of accurate data. Mistakes can occur at several points in the process, for example, misreporting information from case notes. It is particularly important to detect such errors where small numbers of deaths are being reviewed. For example, a mistake in recording the time between when a person was admitted until when he or she began treatment for just one death would result in misleading conclusions where there were only a small total number of deaths.

One method of quality control is to provide good quality training for data collectors and to run refresher courses for them if problems emerge. Other measures that can be taken include double-checking entries in data collection forms and repeating some of the data collection with different data collectors.

Data quality assurance is critical to maintaining internal consistency and validity of data. For some deaths, very little information may be available. However, these deaths should not be omitted. Indeed, a special effort should be made to find out why there may be a lack of information, and to describe relevant events by collecting data in the community. A large volume of missing data is a very important finding suggestive of the need to improve recording and reporting.

## STEP 9: CONTRAST AND SYNTHESIZE THE DATA

The first step in making sense of the data is to review of individual TB deaths. To achieve, this one must first compare data from the two data collection exercises: **Community based TB death review (CBDR)** and **Facility-Based Mortality Audit (FBMA)**. This includes analysis of the circumstances in which the individual TB patient died: the clinical care and attention during admission, compliance with treatment, side-effects of drugs, complications, multiple organ failure, etc. It is important to triangulate the data on each patient. Triangulation refers to a process of contrasting diverse sources of information to reveal disparities, identify divergent perspectives, and validate key information. Triangulation often yields a richer, more nuanced analysis.

Second, the results of all TB cases should then be synthesized to identify any common patterns. The analysis can be guided by a cascade of key questions:

### How complete are the data from the different sources of data used to complete the forms?

- Are any patient data consistently missing from the forms? For example, were the data collectors able to find and record patient characteristics such as age, sex, smear status, risk factors, co-morbidities, etc. for all deaths included in the audit?
- Are the dates of diagnosis, start of treatment, and death available for each patient?

Below is an example of a comparison of data quality at four hospitals. Highlighted cells are areas where missing data exceeds 5%. This highlights both patterns as well as individual trouble spots.

**Table 1: Comparison of the Proportion of Missing values from TB patient charts by Facility**

| Information                             | Facility 1 (%) | Facility 2 (%) | Facility 3 (%) | Facility 4 (%) |
|---|----------------|----------------|----------------|----------------|
| Sex                                     | 0.2            | 2.0            | 0.0            | 0.0            |
| Age                                     | 0.7            | 0.9            | 0.0            | 0.2            |
| Type of patient                         | 0.0            | 0.9            | 0.0            | 0.0            |
| Disease classification (e.g. PTB, EPTB) | 0.0            | 0.9            | 0.0            | 0.2            |
| Smear results (Before treatment)        | 0.8            | 5.4            | 8.2            | 0.8            |
| Date of start of treatment              | 0.8            | 3.6            | 0.0            | 0.2            |
| Treatment category                      | 0.0            | 4.0            | 3.0            | 1.0            |
| Date of death                           | 9.0            | 12.0           | 7.4            | 27.4           |
| HIV status                              | 13.6           | 18.8           | 14.3           | 0.8            |
| ART status                              | 6.7            | 31.0           | 13.2           | 5.0            |
| CPT status                              | 12.6           | 24.0           | 2.7            | 3.4            |
| Weight                                  | 16.0           | 8.0            | 4.5            | 3.4            |

Use of the Lessons from Loss tool can help to identify any gaps in the facility's recording and reporting systems.

### How many are dying?

The first step should be to calculate a crude mortality proportion among the registered TB patients.

**Table 2: Example of a Comparison of TB Mortality in Two Districts.**

|   | Q 1 2007     | Q 2 2007     | Q 3 2007     |
|---|--------------|--------------|--------------|
| Deaths of Presented by Quarter for District A |              |              |              |
| Number Registered TB patients                 | 405          | 566          | 570          |
| Number of Deaths                              | 65           | 72           | Missing Data |
| Proportion                                    | <b>16%</b>   | <b>12.7%</b> | <b>N/A</b>   |
| Deaths of Presented by Quarter for District B |              |              |              |
| Number Registered TB Patients                 | 253          | 266          | 204          |
| Number of Deaths                              | 43           | 41           | 31           |
| Proportion                                    | <b>17.0%</b> | <b>15.4%</b> | <b>15.0%</b> |

### Who is dying?

- Are there particular types of patients who are dying? Most At-risk Populations (MARPS) such as people living with HIV, injecting drug users, or other vulnerable groups such as migrants, ethnic minorities, refugees? What is the gender distribution – did more women or men die? Exploration of who is at highest risk of death should lead to additional questions about their overall trajectory. Do women face particular barriers? What are the special challenges for quality care of different age groups such as children and the elderly?
- Compare those who died and did not die by gender, age, type of TB, co-morbidities, especially HIV, hepatitis and diabetes.

The table overleaf is an example of the type of analysis that an audit team might perform to find out which TB patients are more vulnerable. The numbers in bold indicate a significantly higher risk of death, the bigger the number the greater the risk. It appears at first glance that in this district – young children, older patients, those with extrapulmonary TB and those with HIV are most at risk. However, the team also sees that there is so much default and missing data that the true picture of mortality is likely to be obscured, so they decide to work on this also. The annexes provide more details on how to analyze the results, including what statistical tests need to be performed.

Table 3. Treatment outcome by disaggregated by sex, age and HIV status

|                   | Total | Success* | Other (e.g. default) | Died | Died vs. cured/completed      |                  |
|-------------------|-------|----------|----------------------|------|-------------------------------|------------------|
|                   | N     | %        | %                    | %    | Unadjusted Odds Ratio (95%CI) | P-value          |
| <b>Total</b>      | 3287  | 79%      | 18%                  | 3%   |                               |                  |
| <b>Sex</b>        |       |          |                      |      |                               |                  |
| Male              | 1867  | 79%      | 18%                  | 3%   | Ref.                          |                  |
| Female            | 1420  | 79%      | 18%                  | 3%   | 0.92 (0.62-1.36)              | 0.67             |
| <b>Age Group</b>  |       |          |                      |      |                               |                  |
| 0-4 years         | 89    | 82%      | 7%                   | 11%  | <b>3.37 (0.05-2.73)</b>       | <b>0.03</b>      |
| 5-14 years        | 195   | 86%      | 11%                  | 4%   | 1.15 (0.52-2.52)              | 0.74             |
| 15-49 years       | 2689  | 79%      | 18%                  | 3%   | Ref                           |                  |
| ≥50 years         | 314   | 72%      | 22%                  | 7%   | <b>2.55 (1.54-4.21)</b>       | <b>&lt;0.001</b> |
| <b>TB Type</b>    |       |          |                      |      |                               |                  |
| Pulm sm+          | 1120  | 83%      | 15%                  | 2.1% | Ref.                          |                  |
| Pulm sm-          | 952   | 83%      | 13%                  | 4%   | 1.90 (1.13-3.19)              | 0.15             |
| EP                | 854   | 80%      | 16%                  | 4%   | <b>1.75 (1.02-3.01)</b>       | <b>0.04</b>      |
| Unknown           | 361   | 53%      | 44%                  | 4%   | <b>2.63 (1.13-5.26)</b>       | <b>0.006</b>     |
| <b>HIV Status</b> |       |          |                      |      |                               |                  |
| Negative          | 1543  | 87 %     | 11%                  | 2%   | Ref.                          |                  |
| Positive          | 1164  | 80%      | 14%                  | 6%   | <b>4.44 (2.76-7.17)</b>       | <b>&lt;0.001</b> |
| Unknown           | 580   | 54%      | 43%                  | 2%   | 2.42 (1.21-4.82)              | 0.12             |

\*Treatment Success = the proportion cured + proportion completed

In interpreting these tables it is vital to remember that some groups, such as the elderly, have a higher back ground risk of mortality. So the higher mortality seen in this analysis may not necessarily be due to program-related factors.

### **Where are patients dying? What is the distribution of deaths in terms of location?**

- Compare districts
- Compare facilities to determine if specific facilities or facility types have a particularly high proportion of the TB deaths during the time period

### **When are patients dying?**

Below is an example of an audit from three communities. The audit team looked for smallest values to find patients who were dying soon after diagnosis. They noted that women were more likely to die in the intensive phase of treatment than men and concluded that they were not being diagnosed early enough. They noted that district 2 seemed to have more early deaths overall and began to think that the emphasis of the action plan in that district should be early case-finding. They noted with satisfaction that the difference in time of death did not vary by HIV status and they felt this was because they have a very comprehensive and well-integrated TB/HIV program.

**Table 4. Time to death by sex, TB type and HIV status for patients who died during TB treatment in 3 districts over a 5 year period.**

|                   | District 1 |                                  | District 2 |                                  | District 3 |                                  |
|-------------------|------------|----------------------------------|------------|----------------------------------|------------|----------------------------------|
|                   | N          | Time to death, median days (IQR) | N          | Time to death, median days (IQR) | N          | Time to death, median days (IQR) |
| <b>Overall</b>    | 621        | 45 (12-103)                      | 323        | 23 (6-49)                        | 184        | 40 (9-88)                        |
| <b>Sex</b>        |            |                                  |            |                                  |            |                                  |
| Male              | 410        | 42 (11-101)                      | 212        | 23 (5-50)                        | 114        | 38 (14-78)                       |
| Female            | 201        | 26 (13-103)                      | 111        | 17 (6-49)                        | 70         | 20 (7-92)                        |
| Unknown           | 10         | 66 (58-145)                      | 5          | 15 (1-29)                        | 4          | 6 (2-8)                          |
| <b>TB Type</b>    |            |                                  |            |                                  |            |                                  |
| Pulm sm+          | 220        | 32 (9-76)                        | 77         | 27 (7-51)                        | 59         | 27 (7-65)                        |
| Pulm sm-          | 360        | 57 (15-123)                      | 128        | 24 (6-56)                        | 105        | 53 (15-92)                       |
| EP                | 33         | 40 (8-100)                       | 58         | 18 (6-42)                        | 20         | 20 (4-83)                        |
| Unknown           | 8          | 23 (0-80)                        | 60         | 24 (4-50)                        | 13         | 8 (4-83)                         |
| <b>HIV Status</b> |            |                                  |            |                                  |            |                                  |
| Negative          | 138        | 45 (11-106)                      | 35         | 27 (8-67)                        | 63         | 49 (11-92)                       |
| Positive          | 96         | 43 (13-84)                       | 284        | 25 (5-49)                        | 109        | 42 (7-69)                        |
| Unknown           | 387        | 48 (12-104)                      | 4          | 14 (3-34)                        | 12         | 38 (21-102)                      |

In order to address the issue of the timeliness of care more precisely, it may be strategic to compare the timing of patients' care seeking and diagnosis against pre-determined time-windows or benchmarks to detect if delays occurred. For example, turnaround time (TAT) for smear results is often established as part of the targets in a national strategic plan.

A team might choose to determine how many TB patient deaths occurred within 28 days of initial TB diagnosis (likely related to delayed diagnosis) and those that occurred 28 days or more after diagnosis (likely related to quality of care). This will help the team to decide at what point along the pathway more intervention is needed. Here is an example of 4 time targets that could be used to detect 4 common types of delay that are known to lead to mortality.

To find out if delays play a role in patient mortality, compare the proportion of patients experiencing different types of delays among those who do die and those who do not.

**Table 5. Definitions and Example Values for Four Types of Delay**

| Delay                          | Definition  | Target   | Form          |
|--------------------------------|---|----------|---------------|
| <b>Health Seeking</b>          | Time interval between 1st symptom to 1st provider   | ≤30 days | CBDR (PART B) |
| <b>Referral</b>                | Time interval between seeing 1st provider and having 1st TB diagnostic test   | ≤1 day   | CBDR (PART B) |
| <b>TB Diagnosis</b>            | Time interval between 1st TB diagnostic test and patient receiving the TB diagnosis   | ≤2 days  | FBMA (PART A) |
| <b>Initiation of Treatment</b> | Time interval between when TB diagnosis was given to patient and when medicines were dispensed to the patient (treatment start) | ≤1 day   | FBMA (PART A) |



What are the main barriers prior to diagnosis?

- Compare TB patients who died versus those who did not
  - » Distance to facility, and other relevant socio-demographic characteristics
  - » Transportation barriers
  - » Costs to the patient

What are the main challenges following diagnosis (quality of care)?

- Compare TB patients who died versus those who did not by
  - » Type of TB, HIV status, co-morbidities
  - » Type and timing of clinical management of HIV positive TB patients by CPT, by ARVs, by discharge status, etc.
- How is the laboratory performing? (Analyze the length of diagnostic delays)
- How are TB drugs and other commodities being handled? Stock outs? (Analyze the time between diagnosis and start of treatment)
- How well were the TB patients' rights and responsibilities upheld? What were the perceptions of the families with regard to the quality of care?

Here is an example of the type of comparison that should be done to evaluate quality of care:

**Table 6: ART and CPT Provision in HIV-positive TB patients**

| No of HIV+ patients                  | Died |   | Lived |   | Outcome Unknown |   |
|--------------------------------------|------|---|-------|---|-----------------|---|
|                                      | N    | % | N     | % | N               | % |
| <b>Anti-Retroviral Therapy (ART)</b> |      |   |       |   |                 |   |
| Yes                                  |      |   |       |   |                 |   |
| No *                                 |      |   |       |   |                 |   |
| Unknown                              |      |   |       |   |                 |   |
| <b>Cotrimoxazole (CPT)</b>           |      |   |       |   |                 |   |
| Yes                                  |      |   |       |   |                 |   |
| No *                                 |      |   |       |   |                 |   |
| Unknown                              |      |   |       |   |                 |   |
| <b>Both ART and CPT</b>              |      |   |       |   |                 |   |
| <b>No ART or CPT *</b>               |      |   |       |   |                 |   |
| <b>ART and CPT unknown</b>           |      |   |       |   |                 |   |

Highlight the *avoidable* factors related to the process of diagnosis and treatment that happened before admission, issues related to the availability of health facilities, and potential programs related to the care given by health professionals. Other factors include deterioration of the condition of TB patients under treatment, due to adverse effects of anti-TB drugs or co-morbidities, that may not have been recognized by community health care providers or recognized too late.

Identify recurring themes and common problems in the data, including problems found within and outside the health care system. Avoid the temptation to reduce a death to a single "cause" since typically more than one root factor is present in a specific death.

Audit teams will need to compare what *actually* happened to the patients throughout the diagnosis and treatment process to what *should have* happened according to local diagnosis and treatment guidelines. (See Appendix B for key quality standards).

Data gathered about the same TB patient from the two very different perspectives will provide a fuller understanding of what happened to the patient – the results from the facility based records may be quite different from the information revealed by the community audit. This is because the people involved often do not share the same beliefs about what causes disease, or TB transmission, and they may have different opinions about or knowledge about the quality of care or treatment adherence. This is not a weakness, but a rather a strength of combining facility and community level data. It requires triangulation of data. Avoid trying to seek a singular truth, but rather seek to understand what the different views can teach you about how care can be improved.

One or two members of the multidisciplinary team should first prepare the initial synthesis of the findings using the Excel reporting functions, which is then presented to the team. The broader team should work together to reach agreement about the significant findings and what they mean.

### **STEP 10: DISCUSS THE FINDINGS WITH THE TEAM AND STAKEHOLDERS**

After analyzing the data and developing preliminary conclusions, the review team should meet with a larger group that includes all individuals who were involved with the management of TB patients included in the audit. All health workers who cared for TB patients included in the study before admission to the hospital should be invited to attend. Laboratory staff, pathologists and all those who may have relevant information on the death should also be included. The details of the death or deaths should be presented in a factual, comprehensive, and precise manner without any judgments. It is critical to avoid blame so that the discussion is honest and participants do not have to worry about whether or not they will lose their jobs or be punished for their actions (or failure to act). This peer review should be a non-anonymous but confidential procedure, that is, it is appropriate to use individual health care workers' or others names but only if they are not shared outside the review team. The review team members must understand that the provision of feedback to the appropriate people is a moral and ethical requirement. If done well, this step can improve accountability and the participants' willingness to cooperate in the action plan (Step 11). Nevertheless, the code of confidentiality has to be enforced within the peer group participating in this step of the review. The one exception would be a situation in which patterns of gross negligence are uncovered. These cannot remain unaddressed until the action plan is developed, and the procedures that are used in a facility for investigating such instances and acting upon the findings must be followed. It is important to agree ahead of time how such findings will be documented and who on the team will be responsible for following up using the standard procedures used to report gross negligence.

### **STEP 11: MAKE AN ACTION PLAN BASED ON THE RESULTS**

It is critical to bring the right people to the table to develop the action plan. The audit results will provide insight as to who should be included in this process. For example, if the results indicate that TB patients are being diagnosed late in their disease process, then some action may be needed by community leaders and it would be important to include them in the action plan development. On the other hand, the results may point to the need to work with organizations or ministries that one is not accustomed to working with such as the correctional system or the transportation ministry or even the education ministry. Make sure that the right people are invited to make the action plan and not just the groups that are easy to involve or traditionally invited. It is possible that an advocacy, communication, and social mobilization strategy may be needed to encourage earlier diagnosis. The results may be presented in the tabular formats in the Excel data sheet ([http://www.tbcare1.org/publications/toolbox/tools/hss/LfL\\_Excel\\_Data\\_Sheet.xls](http://www.tbcare1.org/publications/toolbox/tools/hss/LfL_Excel_Data_Sheet.xls)). For each negative finding, an appropriate solution or strategy can be proposed, including the responsible persons at different levels.

Too often, we underestimate the effort and support needed to make a lasting change. The following suggestions/scenarios provide guidance as to possible next steps related to findings of the mortality review.

1. Healthcare managers can help staff to recognize the challenges to providing high quality TB diagnosis and treatment and discuss what action needs to be taken in order to close the gap between desired and actual performance and achievement (in terms of indicators). A root cause analysis of current obstacles can be helpful as part of the discussion.
2. Identify relevant promising practices that have succeeded elsewhere and that can be reproduced and/or adapted in the local context. If potential solutions are not found locally, extend the search to regional and international resources. Choose those that best match the challenges and the needs, mission and budget.
3. Identify successful local users of the promising practices (aka early adopters, champions). This might involve a study tour to a high performing facility, a mentorship, a training.
4. Adapt and test one promising practice or set of practices at a time. Focus the initial phase of the action plan on those issues that are under the control of the hospital staff and community members to correct. That will give the team some “quick wins” to build the momentum for more complex or long term changes. Reach consensus on what you will change first, how you will achieve the change, and what you expect to be different as a result of that change
5. Choose proper monitoring and evaluation (M&E) indicators and systems that can provide convincing evidence to support adoption of successful practices but also inspires providers to do their best work. Identify a range of easy and more challenging benchmarks that are measurable and within control of the change team.

Here is an example from Malawi:

| Interventions   | Targets for Hospital A | Targets for Hospital B |
|---|------------------------|------------------------|
| 1. Increase the frequency of monthly rounds in the TB wards | 4 to 13                | 4 to 8                 |
| 2. Increase number of TB ward nurses                        | 2 to 4                 | 2 to 3                 |
| 3. Record patient weight and hemoglobin                     | 33% to 90%             | 41% to 90%             |

## STEP 12: PREPARE A REPORT FOR EXTERNAL AUDIENCES

An external report combines the synthesis of the results of all cases with the action plan. The important findings from patient deaths are combined with the detailed solutions that have been agreed upon. Only anonymous aggregated data and results should be presented and without detail that would permit deductive disclosure (i.e. allow readers to determine the identities of patients and providers discussed in the report).

Often a mortality audit raises as many questions as it answers. Identify areas for operational research and identify local partners in universities and NGOs who may be able to take up these questions.

In Ghana, the national TB program conducted a review of TB register data to better understand mortality among TB patients in 2009 and identified the following areas that merited further exploration via operations research:

### Examples of Potential Operations Research Questions following a Mortality Audit

- a. How frequently are TB patients offered the opportunity to be reviewed by doctors while on TB treatment?
- b. What is the potential role of nutrition in preventing TB patient deaths (in Ghana 51% of the TB

- patients at the time of TB registration have moderate to severe malnutrition)
- c. What is the role of Rifampicin in early TB deaths?
  - d. What is the association between TB deaths and poverty in Ghana?
  - e. Do smear-negative TB patients really have TB or do they have other conditions that are not managed properly?
  - f. How does patients' satisfaction influence mortality among TB patients (e.g. *QUOTE TB tool*)?
  - g. What is the role of non-communicable diseases (i.e. diabetes) in mortality among TB patients?
  - h. How does integration TB and HIV Care impact mortality among TB Patients?
  - i. How does active TB case finding impact mortality among TB Patients?

### STEP 13: IMPLEMENT THE ACTION PLAN TO SAVE LIVES

1. Form a change team to implement the Action Plan and pilot the planned strategies in a limited number of settings. This will be a different group than those who carried out the audit, but with some of the same members.
2. Implement the new practice in additional settings beyond those included in step 1 by involving other facility managers and agreeing on the process of implementation, and how implementation will be monitored, and who will be responsible for following up on specific steps.
3. Find ways to generate ownership among staff members who carry out the practices, including routine sharing of the M&E data. Ensure recognition and experiment with friendly competition if culturally appropriate.
4. Discuss these key questions:
  - Are available data or TB/HIV indicators at local level being put to productive use to improve performance? Once data are recorded, who is it shared with, in what form? And how often?
  - What TB/HIV data/ indicators are reported to the MoH or partner organizations by the facility?
  - Are there mechanisms for cross checking the data to ensure that people with TB and HIV are on both HIV and TB registers?
  - What can be done to improve the flow of information to those who can put it to use to save lives?

Over ten years ago, the National TB Programme of Malawi instituted a biannual TB mortality audit for all hospitals which engaged a wide range of stakeholders. This brought people together regularly to focus on a shared goal and allowed them to chart progress together.

Scale up the successful practices internally and to other facilities and providers. This may involve handing over responsibility to more senior managers with broader authority and contacts.

All TB stakeholders can play a role in implementing the Action Plan:

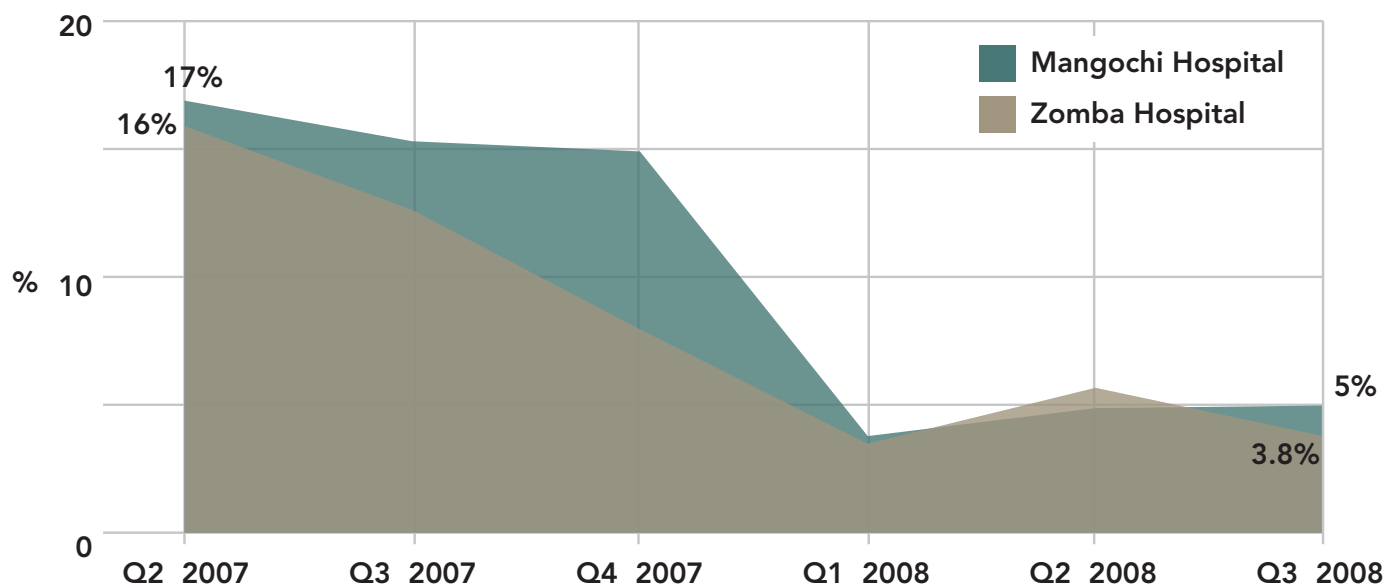
- **Clinicians** apply effective practices in their delivery sites to save lives and reduce the impact of illness. They can make substantial improvements in maternal health, child health, reproductive health, family planning, and infectious diseases.
- **Community members** can support and monitor the implementation of the change process in facilities and give feedback on local perceptions of the changes.
- **Mid-level managers** can lead and champion changes in health delivery practices.
- **Senior management** needs to visibly support the changes and those who are leading the change process.

- **National, regional, and international decision makers** support these changes in health delivery practices. They act as matchmakers, creating a marriage between: Effective practices for clinical and programmatic work and strategies for implementing change and scale-up.
- **Researchers** can help to resolve the lingering mysteries that the audit reveals.

#### STEP 14: DOCUMENT THE PROCESS

It is important to be able to tell the story of how improvements were made and share the experience widely with others so that they can benefit from it. A story can be told easy via a graph such as this one from Malawi:

**Figure 5: Mortality in Two Malawian Hospitals Following the Implementation of Action Plans**



In October 2007, the USAID-funded Tuberculosis Control Assistance Program (TB CAP) assisted in conducting audits in Zomba and Mangochi districts. By ascertaining the chain of events and patterns of care related to the deaths among patients admitted in TB wards, facility staff were able to take the decision to improve clinical care of admitted TB patients as well as the classification, recording and reporting of TB deaths.

#### APPENDIX A: COMMUNITY BASED DEATH REVIEW (CBDR)

The goal of the community TB death review is to look at “root causes” and challenges to TB diagnosis and treatment that patients experience beyond the facility doors. These community inquiries are focused on more social, political, cultural, financial, and structural issues. They reveal important information about barriers to health seeking and quality and access to TB care from the patients’ family’s point of view. Honoring the lost lives of TB patients and trying to derive the programmatic lessons by listening to their families and their challenges is part of The **Patient Centered Approach (PCA)**. This is a philosophy of TB control which places the patients’ (and family’s) lived experience at the center of the health care system, in the clinic, and in the community.

Community based TB death reviews may be conducted in addition to (or independent of) facility based mortality audits. The CBDR will mainly consist of a key informant interview with people who are knowledgeable about the circumstances leading to the death, thus, it is critical to identify the individuals who were in contact with him or her just before the patient died and preferable, throughout his or her illness. In general, therefore, the community based TB death inquiry will

mostly rely on information provided by the family. There may also be cultural barriers to paying visits during a period of mourning. This will vary by setting.

The community-based death review tool is also called “Part B”. A question-answer format is often used to reconstruct the circumstances leading to death, while a more open respondent-led or semi-structured approach is used to identify the contributing factors.

It is often helpful to use graphics, maps and interactive techniques, particularly where low literacy and language diversity may limit the utility of written measurement tools. Be sure to pre-test the guide well before setting out to collect data.

## IDENTIFY RESPONDENTS

The respondent is a person who knows about the TB patient’s experiences. The respondent may be the partner, sister, parent, in-law, child, neighbor, employer or traditional healer. The number and selection of key informant interviews conducted often depends on budget, time constraints and the complexity of a particular case.

To identify the contributing factors to a specific patient’s death, it is useful to interview those people who cared for the TB patient during the illness. To arrive at the non-medical factors contributing to death, it may also be useful to interview people who were not necessarily present at the time of death, but who knew the patient well enough to report on her general health status, health beliefs, care-seeking behavior, and experiences with transport, costs, waiting times, and the quality of medical attention.

## A Note About Stigma

In some settings, TB disease is considered a discrediting condition that carries with it a negative “taint” or stigma. TB stigma can undermine the perceived value of a person, regardless of whether they are infectious or successfully cured. We measure TB stigma because it is known to have an influence on health seeking behavior, quality of care, and treatment adherence.

The CBDR uses the Van Rie Stigma scale. Stigma can be measured through a variety of methods and this topic is worthy of its own guidelines, so this paragraph summarizes current thinking on measurement of stigma and provides direction for more detailed resources on evaluation of stigma reduction. Regardless of the quantitative or qualitative method used to measure stigma (ex, KAP surveys, focus group discussions, diaries used to record experiences of stigma), evaluators should be comprehensive in their attempt to identify the underlying cause of TB related stigma in the context. For example, stigma often results from lack of information about TB, such as how it is transmitted, so it is important to listen for common misperceptions about TB among the target audience. Similarly, TB stigma can often be compounded by ageism, racism, xenophobia, homophobia and discriminatory attitudes toward groups at elevated risk for TB such as prisoners or sex workers.

At times it can be challenging to differentiate between TB stigma and negative attributes ascribed to those most at risk populations (MARPs). Interviewers should capture not only experiences of discrimination (often referred to as “enacted stigma”) among TB patients, but also listen for stigmatizing attitudes.

### What if we have an address of the deceased, but the family no longer lives there?

This is also a common dilemma. Families where there has been a death are at high risk of dissolution and/or further deaths. Try to find out from neighbors if it is possible to locate key persons. It may require visiting multiple homes.

## Who to interview? How? And How Many?

In many settings, it may not be appropriate or even possible to restrict the interview to a single respondent. In addition, interviewing a number of respondents might provide useful insights into the nature of relationships that may have affected decisions to seek care. Multiple respondents often discuss the facts among themselves, and this may help to obtain a more complete picture of the circumstances preceding the death. Some respondents might withhold information when interviewed in a group, and it might be necessary to return later and interview them alone.

The way this dilemma will be handled should be discussed before the field work with community representatives and locally acceptable approach should be agreed upon.

For tips on gathering information from a group, we recommend the following sources:

*Burrows D & Kendall S (1997) Focus groups: What are they and how can they be used in nursing and health care research? Social Sciences in Health 3, 244–253.*

*Krueger RA & Casey MA (2000) Focus Groups: A Practical Guide for Applied Research, 3rd ed. Thousand Oaks, CA: Sage Publications.*

*Fatemeh Rabiee Focus-group interview and data analysis. Proceedings of the Nutrition Society (2004), 63, 655–660*

## APPENDIX B: FACILITY-BASED MORTALITY AUDIT (FBMA)

The staff of all the facilities involved need to be certain that the review process does not involve apportioning blame for anything that happened. They need to know that all findings will be recorded and reported completely anonymously. Health workers can be reassured about this at preliminary meetings, or through a brief written account of the working methods of the review. Specifically, staff may need to be assured that confidential codes will be assigned to each staff member for the purpose of data collection and that only the review team will have access to the codes. Even with the above reassurances, data collectors need to demonstrate tact, sensitivity and attention to detail if they are to be successful. All team members should sign a confidentiality agreement (see Appendix H for a template).

### General Instructions:

- Introduce yourself to everyone and be transparent about what you are doing, who has authorized your work, and how it will benefit the facility
- Assure all staff of confidentiality
- Demonstrate respect and proper care of the facility records and materials, even if they are in poor order
- Do not criticize health facility staff or patients
- Ideally each FBMA should be filled in triplicate, one to be kept in the patient's file, one for data entry, and one for to facilitate the community based death review

### What if there are no valid addresses to find families of the deceased?

This is a common problem. If you have a community representative on the team, perhaps they can help you to identify other sources of address information –such as mosque or temple records, municipal files, school records, etc. If locating the family is not possible, then it is better to just conduct the FBDA and not implement the CBDR. You may instead conduct focus groups in the community to explore their more general views on health services access and quality.

- For all responses answers with multiple pre-coded options: Check or circle the answer(s) that apply (applies) and enter the code number in the box at the left side
- Questions are written in a normal font, Interviewer instructions in *Italic*, instructions on skip patterns are underlined.

In some facilities it will not be possible for patient records to be removed. In this instance, you must either do data entry at the site or capture the data using a digital camera or scanner.

### Data Capture of Facility-based Data

Data capture can occur via a digital camera (10+ megapixels) or via portable scanner technology. Both create digital images that can be sent by email back to the entry clerks, so data entry can be simultaneous with data collection.

Simple steps will assist you in keeping the data capture high quality and the data in order.

Conduct a pre-test:

- a. Take a picture of any handwritten piece of paper,
- b. Print it out, and
- c. Attempt to transcribe the contents of the picture.

### At the TB program

#### General Instructions

If the pages in the log book are not numbered, as if you can write numbers in pencil on the edge of log book before you begin.

#### If using a portable scanner:

Make sure that there is electricity at the facility you are going before choosing this option. Bring a digital camera for back up. USB cables and plug converters may be required.

1. Make sure the glass is clean of debris
2. Set the scanner to high quality scanning, especially if the ink is light
3. Make sure the scanner is connected to the laptop and the destination of the scanned files is clear before you begin (i.e. In which folder on your laptop will the scanner save the files?)
4. Develop a file labeling system to help prevent mixing up the order of the files. For example:

*First 2 letters for the facility – e.g. "or" for facility named "Orange "*  
*Second 2 letters for the patient e.g. "BL)" for patient named "Blue"*  
*Then 2 numbers for the year- e.g. 09 for 2009*  
*Then the page number being copied. e.g. pag 324*  
*The name of the file would be: ORBLO09324.jpg*

#### If using a digital camera:

Be prepared with battery charger, spare batteries, spare memory sticks, an external hard drive, and a USB cable to transfer the information from the camera as needed.

1. Make sure there are no smudges on the lens of the camera before starting
2. Make sure that the camera smart card is clean and has enough space
3. Set the camera to "portrait" or other setting that gathers details
4. Make sure that the flash is either off or covered with tape to avoid glare from the white paper.



## APPENDIX C: REFERENCES FOR STANDARDS OF TB CARE:

Treatment of Tuberculosis: guidelines for national programs, fourth edition. Geneva, World Health Organization, 2010 (WHO/HTM/TB/2009.420).

[http://whqlibdoc.who.int/hq/2003/who\\_cds\\_tb\\_2003.313\\_eng.pdf](http://whqlibdoc.who.int/hq/2003/who_cds_tb_2003.313_eng.pdf)

Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva, World Health Organization, 2010 (WHO/HTM/TB/2010.11).

[http://whqlibdoc.who.int/hq/2010/WHO\\_HTM\\_TB\\_2010.11\\_eng.pdf](http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)

International Standards for Tuberculosis Care (ISTC). The Hague: Tuberculosis Coalition for Technical Assistance, 2006.

<http://www.tbcare1.org/publications/toolbox/tools/access/ISTCReport2ndEdition.pdf>

Interpersonal Communication and Counseling for Clients on Tuberculosis and HIV and AIDS. PATH, 2009.

[http://www.path.org/publications/files/CP\\_ukraine\\_tb\\_hiv\\_ipcc\\_hnd.pdf](http://www.path.org/publications/files/CP_ukraine_tb_hiv_ipcc_hnd.pdf)

Handbook for Using the International Standards for Tuberculosis Care. The Hague, Tuberculosis Coalition for Technical Assistance, 2007.

[http://www.tbcare1.org/publications/toolbox/tools/access/ISTC\\_Handbook.pdf](http://www.tbcare1.org/publications/toolbox/tools/access/ISTC_Handbook.pdf)

Implementing the WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households. A framework to plan, implement and scale-up TB infection control.

[http://www.tbcare1.org/publications/toolbox/tools/ic/TB\\_IC\\_Implementation\\_Framework.pdf](http://www.tbcare1.org/publications/toolbox/tools/ic/TB_IC_Implementation_Framework.pdf)

Guidance for National TB and HIV programs on the Management of TB in HIV-infected children: Recommendations for a public health approach. Paris, International Union Against Tuberculosis and Lung Disease (The Union), 2010.

<http://www.tbcare1.org/publications/toolbox/tools/access/GuidanceForManagementofTBinHIVInfectedChildren.pdf>

Guidance for national tuberculosis programs on the management of tuberculosis in children. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.371, WHO/FCH/CAH/2006.7).

Rapid advice: treatment of tuberculosis in children. Geneva, World Health Organization, 2010 (WHO/HTM/TB/2010.13).

[http://whqlibdoc.who.int/hq/2006/WHO\\_HTM\\_TB\\_2006.371\\_eng.pdf](http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.371_eng.pdf)

Guidance for national tuberculosis programs on the management of tuberculosis in children.

Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.371, WHO/FCH/CAH/2006.7).

Ethambutol efficacy and toxicity: literature review and recommendations for daily and intermittent dosage in children. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.365).

[http://www.stoptb.org/wg/dots\\_expansion/assets/documents/EMBreviewFinal070406.pdf](http://www.stoptb.org/wg/dots_expansion/assets/documents/EMBreviewFinal070406.pdf)

## APPENDIX D: RESOURCES FOR COMMUNITY INVOLVEMENT

Engaging communities in owning the problem of TB mortality and the search for solutions is very important. A participatory approach to a mortality audit is very helpful. For hints on how to avoid the pitfalls and address the challenges this entails, see the following resources:

Van der Werf, Mitchell, and Heumann. *Community Engagement in TB Research*. STOP TB Partnership Research Movement

Community involvement in tuberculosis care and prevention. Towards partnerships for health. Guiding principles and recommendations based on a WHO review WHO/HTM/TB/2008.397. [http://whqlibdoc.who.int/publications/2008/9789241596404\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241596404_eng.pdf)

Somesh Kumar (2002) *Methods for Community Participation: A Complete Guide for Practitioners* London:ITDG

TB CAP TB/HIV tools (TB CAP report at [http://www.tbcare1.org/publications/toolbox/tools/hss/Malawi\\_Factsheet.pdf](http://www.tbcare1.org/publications/toolbox/tools/hss/Malawi_Factsheet.pdf))

Parks et al. *Communications for Social Change Consortium*. 2005. *Who measures change? An introduction to participatory monitoring and evaluation of communication for social change*. [http://www.communicationforsocialchange.org/pdf/who\\_measures\\_change.pdf](http://www.communicationforsocialchange.org/pdf/who_measures_change.pdf)

Guy Bessette. *Involving The Community: A Guide To Participatory Development Communication*. [http://web.idrc.ca/en/ev-52226-201-1-DO\\_TOPIC.html](http://web.idrc.ca/en/ev-52226-201-1-DO_TOPIC.html)

## APPENDIX E: GLOSSARY

|                             |   |
|-----------------------------|---|
| <b>Change Agent</b>         | Any person within an institution that has enough social capital, respect, and leadership to catalyze new behaviors among the staff, through example, mentoring, advocacy or other means.  |
| <b>Change Process</b>       | An effective change process is a recipe for selecting, adapting, implementing, and scaling up effective practices in a way that will achieve health results and sustain those results over the years.   |
| <b>Commitment to Change</b> | Commitment to change is the determination to carry the process to the end. The change is complete when all program levels, working together, continually produce desired results as they implement, or support, the changed practices. When stakeholders are committed to change, they don't give up when they encounter barriers – nor do they stop when donors turn their resources toward other needs. |
| <b>Diagnostic Delay</b>     | Time interval between 1st TB diagnostic test and patient receiving the TB diagnosis if it exceeds 2 days  |
| <b>Health Seeking Delay</b> | A long time interval between feeling initial symptoms and arrival to 1st health care provider, e.g. more than 30 days   |
| <b>Referral Delay</b>       | An excessive time interval between arrival at first point of care and first TB diagnostic test e.g. length over 1 day   |
| <b>Treatment Delay</b>      | A long time interval between the date that a TB diagnosis was given to patient and when TB medicines were dispensed to the patient (treatment start) e.g. in excess of 1 day  |
| <b>Triangulate</b>          | Refers to a process of contrasting diverse sources of information and different data to identify divergent perspectives, validate key information, explore disparities, and yield a richer, more nuanced analysis of a situation.   |

## APPENDIX F: INSTRUCTIONS FOR DATA ENTRY

Data entry should be done systematically and accurately. Data entry is not a coffee break activity but serious work; if data are entered poorly the results will have no meaning.

1. There should be two trained data clerks involved.
2. Data should be double entered, so each clerk will enter all the datasheets, resulting in two databases of the same data. Both the CBDR and FBMA are entered and merged twice.
3. Each data entry clerk will get a copy of each of the databases labeled with his/her initials and 'entry 1' or 'entry 2' to distinguish the databases.

The following procedures should be followed when entering data:

- a. Data should be entered sheet by sheet of each questionnaire. Each questionnaire should include multiple photocopied pages that are clipped together
- b. The data clerk should ensure that both photocopy sheets for every one page of the register should be fully entered before moving on to another page of the questionnaire.
- c. When a questionnaire is completely entered, that data clerk signs and dates the questionnaire to indicate it has been entered.
- d. Clear piles should be kept not to confuse the data already entered with those still to be entered.
- e. It is advisable to start with one database, complete it and then start with the next one. For example the first data clerk can start with first entering all CBDR, then all facility FBMA. The second data entry clerk starts with first entering the FBMA and then finishes with the CBDR. This avoids mixing up of the piles between the two data clerks.
- f. It is important data are entered exactly as indicated; there should be no interpretation or correction of the data based on further knowledge or guessing on the part of the clerks. The objective of this audit is to explore data quality; therefore it is important the database gives an exact copy of what is found.

### Coding/specific entry values

- ✓ Enter -99 for fields not filled in the register (missing), for dates fill 01-01-1099
- ✓ In case you have difficulties deciding what the field reads check with NTP staff. If together you cannot decide on what it reads please fill -98 (see below); if agreement was reached, note on the paper sheet near the field what you decided it reads and put your name, sign and date to indicate you are the one making the change.
- ✓ Enter -98 for fields where the information is not readable, for dates fill 01-01-1098.
- ✓ The district number is formatted in different ways, please enter as filled in the district register.
- ✓ Age should be entered in years, if below 1 year fill 0 for age.
- ✓ If a data field is not applicable to entered, for example if disease classification is PP or NP there is no need to fill the field "if EP which site?" In this cases fill N/A. This also holds for the data fields if other, please specify, these fields can only be filled if the in the field in such cases
- ✓ For the smear result fill as recorded, if + is recorded enter +, if ++ is recorded enter ++, if +++ is recorded enter +++, if negative is recorded enter negative etc. In some cases instead of giving +, ++, +++ just positive is recorded, in these cases just enter positive as recorded. In some instances there is written positive as well as + in the register, in this cases enter the + (the most detailed level).

## Data Management

Determine in advance who will also serve as the Data Manager of the project. Data entry files for both data clerks should be backed up by the Data Manager daily. This means there should always be at least two copies of the database, one on his/her computer and one on another computer or a flash drive kept at the office. The two back-ups should never leave the office together, i.e. both taken home. One backup should always stay in the office.

On a weekly basis data entry files should be backed up by the Data Manager in the shared server space. Each file should be labeled with the date of backup. For example the back up for the data entry set of data clerk Ellen Mitchell for 20th May will be labeled as 'EasternRegiondbase-DistrictReg\_EMentry1\_20May2011'

## Procedures for data validation

1. Once the data are entered as two complete sets (entry1 and entry2) the different databases will be compared using the compare function in Epi Info to find fields where the databases do not match.
2. If there are inconsistencies between the two versions, the source questionnaire (CBDR or FBMA) should be checked to decide what the correct value should be for that field.
3. When making corrections, both versions should have the correct values, so that the compare function can be used again until all inconsistencies are identified and fixed in all three databases.
4. Once both sets of the databases are in line with each other, one database each for district and health facility should be selected as the version for use in data analysis and clearly labeled as such, i.e. EasternRegiondbase-DistrictReg\_validated with the date added

## APPENDIX G: REFERENCES FOR SCALING UP INTERVENTIONS

World Health Organization, ExpandNet. Practical guidance for scaling up health service innovations. Geneva: World Health Organization; <http://www.expandnet.net/>.

World Health Organization, ExpandNet. Beginning with the end in mind: Planning pilot projects and other programmatic research for successful scaling up. Geneva: World Health Organization; 2011.

## APPENDIX H: DATA USE AND CONFIDENTIALITY AGREEMENT

The Mortality Audit team member \_\_\_\_\_, agrees to safeguard the confidential data provided to him/her by the Mortality Audit team and to use said data ONLY for the explicit purposes described in the protocol.

(Name) promises not to disclose any information about the circumstances surrounding any TB patient's demise to any person, institution, or authority beyond those identified in the protocol.

(Name) will maintain the data in a secure, password protected location to prevent inadvertent data loss or theft.

At the termination of the audit, \_\_\_\_\_ will return the final data set, associated documents and output and destroy any copies in his/her possession.

(Name) will be included in any reports or publications deriving from this work in accordance with the norms of international biomedical journal editors.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## APPENDIX I: ADDITIONAL DATA ANALYSIS

In addition to using the excel tool for simple, rapid results, bivariate and multivariate analysis of information can be conducted to identify demographic, clinical, and temporal associations with death. The following examples of high quality TB/HIV mortality analysis provide insights into how to do more advanced exploration of the data you have collected.

Egger M, Spycher BD, Sidle J, et al. Correcting mortality for loss to follow-up: a nomogram applied to antiretroviral treatment programs in sub-Saharan Africa. *PLoS Med* 2011;8(1):e1000390.

Gadkowski LB, Hamilton CD, Allen M, et al. HIV-Specific Health Care Utilization and Mortality among Tuberculosis/HIV Coinfected Persons. *Aids Patient Care and Stds* 2009;23(10):845-851.

Gandhi NR, Shah NS, Andrews JR, et al. HIV Coinfection in Multidrug- and Extensively Drug-Resistant Tuberculosis Results in High Early Mortality. *American Journal of Respiratory and Critical Care Medicine* 2010;181(1).

Grange J, Adhikari M, Ahmed Y, et al. Tuberculosis in association with HIV/AIDS emerges as a major nonobstetric cause of maternal mortality in Sub-Saharan Africa. *International Journal of Gynecology & Obstetrics* 2010;108(3):181-183.

Komati S, Shaw PA, Stubbs N, et al. Tuberculosis risk factors and mortality for HIV-infected persons receiving antiretroviral therapy in South Africa. *Aids* 2010;24(12):1849-1855.

Manosuthi W, Chottanapand S, Thongyen S, Chaovavanich A, Sungkanuparph S. Survival rate and risk factors of mortality among HIV/tuberculosis-coinfected patients with and without antiretroviral therapy. *J aids-Journal of Acquired Immune Deficiency Syndromes* 2006;43(1):42-46.

Mugusi FM, Mehta S, Villamor E, et al. Factors associated with mortality in HIV-infected and uninfected patients with pulmonary tuberculosis. *Bmc Public Health* 2009;9.

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1. Waitt, C.J. and S.B. Squire, *A systematic review of risk factors for death in adults during and after tuberculosis treatment*. Int J Tuberc Lung Dis, 2011. 12: p. 12.
2. Straetemans, M., et al., *The Effect of Tuberculosis on Mortality in HIV Positive People: A Meta-Analysis*. Plos One, 2010. 5(12).
3. Peterson, K., et al., *Interventions to reduce mortality in sub-Saharan Africa among HIV-infected adults not yet on antiretroviral therapy*. Expert Rev Anti Infect Ther, 2012. 10(1): p. 43-50.
4. Straetemans, M., et al., *Systematic literature review to assess tuberculosis case fatality rate* Plos One, 2011.
5. Coleman, C., Jaramillo, E, Reis, A.;Selgelid,, *Guidance on ethics of tuberculosis prevention, care and control*, W.H. Organization, Editor. 2010, World Health Organization: Geneva.
6. Simmons, R., et al., *The strategic approach to contraceptive introduction*. Stud Fam Plann, 1997. 28(2): p. 79-94.
7. Alshishtawy, M.M., *Strategic approach to improving maternal survival in oman*. Oman Med J, 2008. 23(3): p. 179-86.
8. Tsogt, B., K. Seded, and B.R. Johnson, *Applying the WHO strategic approach to strengthening first and second trimester abortion services in Mongolia*. Reprod Health Matters, 2008. 16(31 Suppl): p. 127-34.
9. Chandramohan, D., P. Setel, and M. Quigley, *Effect of misclassification of causes of death in verbal autopsy: Can it be adjusted?* International Journal of Epidemiology, 2001(of Publication: 2001): p. 30 (3) (pp 509-514), 2001.

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