health

Department:
Health
Republic of South Africa

Strengthening National and Provincial Capacity for Prevention, Treatment, Care and Support Related to HIV and Tuberculosis

AN ASSESSMENT METHOD AND MANAGEMENT TOOL FOR TB EXPOSURE AT SOUTH AFRICAN HEALTHCARE SETTINGS

(DRAFT 2 Hospitals)

This risk assessment methodology and management tool is supplementary to the National Infection Prevention and Control Policy and Guidelines
And the
National TB Infection Control Guidelines
June 2007

June 2009

Prepared by CSIR for the National Department of Health, Republic of South Africa, CSIR was funded for this project by CDC, South Africa

ACKNOWLEDGEMENTS

Developing this assessment method and tool for TB exposure at all South African healthcare settings would not have been possible without the invaluable contribution by a number of public officials and experts across the nation. The many hours of development and field studies indicated conclusively, that for meaningful outcome, risk assessments for airborne TB exposure must be undertaken by an Infection Prevention and Control Committee comprising a multidisciplinary team with expertise not only in infection control, but also in the fields of public health, healthcare management, architecture and engineering. This assessment method and tool therefore encourages this multidisciplinary approach and has been developed to be supplementary to the National Infection Prevention and Control Policy and Guidelines, April 2007, and the National TB Infection Control Guidelines, June 2007.

The questionnaires utilized in the tool, have been developed after scrutinizing the many excellent existing tools currently being utilsed by certain provinces, such as the Facility Risk Assessment Tool for Tuberculosis (FRATT) tool developed and utilized in the Western Cape and the various risk assessment questionnaires developed by University Research Co., LLC, the University of Natal, the CDC and the WHO. The CSIR team responsible for the development of this document would like to express thanks to those facilities that provided opportunity to test the methodologies included in the document. Finally, a word of appreciation to the Centers for Disease Control South Africa, for providing support and funding for the project.

- S. A. Parsons Ph.D, Pr Eng
- CSIR, Built Environment
- June, 2009

CSIR Built Environment
P O Box 395
PRETORIA 0001
March 2009

TABLE OF CONTENTS

1. PREFACE

People with undiagnosed, untreated and potentially contagious TB are frequently seen in health care settings. In an era of increased access to HIV services such as Voluntary Counselling and Testing, Prevention of Mother to Child Transmission and Antiretroviral Therapy, increasing numbers of HIV-positive clients are also seen in these facilities. HIV-positive clients are particularly vulnerable to TB with a 10% annual risk of developing TB compared to 10% lifetime risk in those with normal immunity. It is estimated too that 10% of those newly diagnosed with HIV have undiagnosed TB; half of these are infectious. The increasing numbers of undiagnosed TB, TB suspects, TB clients and immunocompromised clients all present in the same environment create the potential for high levels of nosocomial transmission of TB.

An increased risk of TB has been documented amongst all categories of health care workers (including facility staff, community health workers and volunteers) compared to the general population. The prevalence of HIV amongst health care workers correlates with that in the general population. Health care workers are at risk due to frequent exposure to clients with infectious TB and because they may also be immunocompromised due to HIV.

It is the responsibility of management and staff to minimise the risk of TB transmission in health settings. Infection control measures should be established to reduce the risk of TB transmission to both the general population and to health workers. Since the majority of clients are seen at primary health care level, it is important to ensure that measures to prevent the spread of infection not only focus on hospitals, but also address all levels of health care.

The first step in developing the TB infection-control program should be to conduct a baseline risk assessment to evaluate the risk for transmission of *M. tuberculosis* in each area and occupational group in the facility. The TB risk assessment determines the types of administrative, environmental, and respiratory-protection controls needed for a setting and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection-control measures.

The aim and purpose of this assessment method and tool for TB exposure is to provide guidance for conducting a risk assessment for a health-care setting. Due the lack of scientific data, the assessment tool does not specify values for acceptable performance indicators. The assessment tool can however be used as part of any facilities quality control and assurance programme to, in consultation with infection control experts, develop an ongoing performance-based evaluation system.

The findings from the risk assessment will form the basis for decisions about the level of administrative, environmental, and respiratory protective measures needed to ensure a safe environment for HCWs, patients, and others.

As an ongoing evaluation tool, the risk assessment can identify the need for improved TB infection controls and can serve as a way to monitor administrative, environmental, and respiratory protective measures to ensure their proper operation.

2. REDUCING THE RISK OF SPREADING *M. TUBERCULOSIS* IN HEALTH CARE SETTINGS

Increased risk of nosocomial transmission has been documented in a variety of countries[1]. The greatest risk of transmission occurs when patients remain undiagnosed and untreated. The magnitude of the risk varies by setting, occupational group, and prevalence of TB in the community, patient population, and effectiveness of TB infection-control interventions.

The risk of TB among HCW in the Pulmonary Hospital in Serbia was 7.6 times higher than in the general population (TB incidence in country 38/100 000)[2]. In Croatia TB morbidity risk among female medical nurses employed in special institutions for lung diseases was up to 17 times higher than among other hospitals[3]. In Estonia TB incidence among HCW was 1.5 to 3 times higher and in a chest hospital 30-90 times higher than in the general population; MDR-TB was detected in 38% of chest physicians sick with TB[4.]

It is very likely that persons with infectious TB will be found in HIV care and other health care settings. There is also a strong likelihood that these persons will spread *M. tuberculosis* to other persons, including immuno-compromised patients or staff. However, there are interventions that can significantly reduce this risk. There are two main ways in which even settings with limited resources can reduce the chances that TB will spread. These two main ways are:

- Work practice and administrative control measures, and
- Environmental control measures.

In general, work practice and administrative control measures have the greatest impact on preventing TB transmission within settings, and they are the first priority in any setting regardless of available resources. These measures prevent droplet nuclei containing *M. tuberculosis* from being generated in the facility, and thus reduce exposure of patients and staff to TB. Ideally, if generation of droplet nuclei is eliminated then exposure is eliminated; no further controls are needed.

However, since it is not possible to eliminate all exposure, environmental control measures must be added to reduce the concentration of droplet nuclei in the air. Although many environmental control measures require resources not always available, some can be implemented, and staff can be trained in their purpose, capabilities, proper operation, and maintenance.

2.1. WORK PRACTICE AND ADMINISTRATIVE CONTROLS

Work practice and administrative control measures have the greatest impact on preventing TB transmission within health care facilities. They serve as the first line of defence for preventing the spread of TB in health care settings. Their goals are:

- To prevent TB exposure to staff and patients, and
- To reduce the spread of infection, by ensuring rapid and recommended diagnostic investigation and treatment for patients and staff suspected or known to have TB.

[1] The South African National TB Infection Control Guidelines, June 2007.
[2] Skordic et al. *Occupational risk of tuberculosis among health care workers at the Institute for Pulmonaty Diseases of Serbia.* Int J Tuberc Lung Dis**.** 2000;4(9):827-31.
[3] Babus V. *Tuberculosis morbidity risk in medical nurses in specialized institutions for the treatment of lung diseases in Zagreb.* Int J Tuberc Lung Dis**.** 1997;1(3):254-258.
[4] Krüüner et al. *Spread of Drug-Resistant Pulmonary Tuberculosis in Estonia.* Journal of Clinical Microbiology, Sept.2001, p. 3339-3345

This can best be accomplished through the prompt recognition, separation, provision of services, and referral of persons with potentially infectious TB disease. There are six components to good work practice and administrative controls. They are:

- Conducting periodic risk assessments
- An infection prevention and control plan;
- Administrative support for procedures in the plan, including quality assurance;
- Training of staff;
- Education of patients and increasing community awareness; and
- Coordination and communication with the TB programme.

2.2. CONDUCTING RISK ASSESSMENTS

The findings from the required risk assessments should form the basis for decisions about the level of administrative, environmental, and respiratory protective measures needed to ensure a safe environment for HCWs, patients, and others. As an ongoing evaluation tool, the risk assessment can identify the need for improved TB infection controls and can serve as a way to monitor administrative, environmental, and respiratory protective measures to ensure their proper operation.

3. THE NATIONAL INFECTION PREVENTION AND CONTROL POLICY: LEGAL COMPLIANCE

The stated purpose of the National policy on infection control is to set minimum national standards for the effective prevention and management of health care associated infections, so that hazards associated with biological agents are minimized for patients, visitors and health care personnel in health care establishments.

Every health-care setting should have a TB infection-control program in place that is part of an overall infection-control program. Based on the risk assessment for the setting, proper administrative, environmental, and respiratory protection policies and measures to prevent health-care–associated transmission of *M. tuberculosis* should be adopted. Administrative controls are the most important part of the TB infection-control program.

The specific details of the TB infection-control program will differ depending on whether patients with suspected or confirmed TB disease might be encountered in the setting, or whether patients with suspected or confirmed TB disease will be triaged or transferred to another health-care setting. Administrators making this distinction should

3.1. LEGAL AND REGULATORY FRAMEWORK PERTAINING TO INFECTION PREVENTION AND CONTROL

In the operation of any hospital many regulations, standards (National and provincial standards) and least of all National and Provincial policies, need to be observed. The National Infection Prevention and Control Policy and Strategy (April 2007) makes specific reference to certain acts and their relevant regulations, which bear relevance to the development and implementation of the Policy. These being:

- The South African Constitution, Act 108 of 1996 [sections 2, 24, 27, 36 and 39].
- The National Health Act of 2003, Act No.61 of 2003.
- The Occupational Health and Safety Act of 1993, Act No. 85 of 1993 [Section 8(1)].
- The Environmental Conservation Act of 1989, Act No. 73 of 1989.
- The Foodstuffs, Cosmetic and Disinfectants Act of 1972, Act No. 45 of 1972.
- Government notice R1390 of 27 December 2001 [Hazardous Biological Agents Regulations] as promulgated under section 43 of the Occupational Health and Safety Act of 1993.
- Government notice R908 of 27 June 2003 [Hazard Analysis Critical Control Point Regulations] as promulgated under section 15(1) of the Foodstuffs, Cosmetic and Disinfectants Act of 1972.
- The National Infection Prevention and Control Policy and Strategy, April 2007.
- The South African National TB Infection Control Guidelines, June 2007.

3.2. OBJECTIVES OF THE NATIONAL INFECTION PREVENTION AND CONTROL POLICY

The stated objective of the policy is:

- To encourage and improve effective prevention and management of health care associated infections for the public health sector.
- To prevent and minimize environmental hazards associated with microbes fro all in- and outpatients, healthcare workers and visitors to health care settings.
- To optimize infection prevention and control programmes in health care settings.
- To control and minimize transmission of and colonization by resistant organisms.
- To improve infection control surveillance.

3.3. ISOLATION PRECAUTIONS FOR HOSPITALS

Isolation guidelines were adapted from the 1996 Centers for Disease Control (CDC) Isolation Guidelines for Hospitals by the Infection Control Association of Southern Africa (ICASA), for use in the Southern African region. These Guidelines were subsequently incorporated into the Regulations for Hazardous Biological Agents (R1390), (Dec.2001) section 43 of the South African Occupational Health and Safety Act No: 85 of 1993. The Regulations address the following:

3.3.1 Airborne precautions

In addition to the stated standard precautions, airborne precautions are required for patients known or suspected of being infected with micro-organisms transmitted by airborne droplet nuclei that:

- Remain suspended in the air and
- Can be widely dispersed by air currents with in a room or over a long distance).

3.3.2 Patient placement

Ideally any patient with suspected or known airborne disease should be placed in a private room that has;

- Monitored negative air pressure in relation to the surrounding areas
- 6 –12 air changes per hour
- Appropriate discharge of air outdoors or monitored high efficiency filtration of room air before the air is circulated to other areas of the hospital.

Where this is ***not possible***,

- A room with a simple extraction fan providing at least 6 air changes per hour or
- A room with an open window, and adequate ventilation.

The patient must remain in the room with the room door closed.

- When a private room is not available place the patient in a room with a patient who has active infection with the same micro-organisms, and but no other infection, unless otherwise recommended.
- When a private room is not available and cohorting is not desirable, consultation with infection control professionals as advised before patient placement.

3.4. NON-COMPLIANCE

Failure to comply with the infection prevention and control policy and guideline may result in the following:

- Successful litigation against the state for damages suffered by patients or their families as a result of illness or death from inadequate infection prevention and control procedures.
- Disciplinary action by professional health councils against individuals where their proven negligence caused harm to patients.
- Criminal and/or civil prosecution of individual employees whose negligent actions caused the infection and subsequent death of a patient.
- Loss of public confidence in the health establishment in question.

3.5. INFRASTRUCTURE REGULATIONS, STANDARDS, NORMS AND GUIDELINES

The incidence and risks associated with drug-susceptible and resistant forms of TB have recently been given much prominence in medical literature as well as in national and international healthcare management, planning and research circles. While there are guidelines available internationally and in South Africa dealing with treatment policy and protocols, there is little guidance available on the impact of infrastructure on TB and limited design guidance on how to best plan and design facilities for treating cases of TB. What guidance is available is focussed on treatment in first world countries where the incidence is low and full isolation of all TB patients is the norm.

While work has been initiated in South Africa on the development of guidelines for the planning, design and management of facilities where TB is being treated, there is reference in current legislation and existing standards, norms and guidelines which is directly or indirectly relevant to TB.

The following legislation, regulations, guidelines and standards impact and provide guidance on the provision and design of health care facilities.

- The National Health Act no 61 of 2003, as amended
- National Building Regulations and Building Standards Act No. 103 of 1977, as amended
- The Occupational Health and Safety Act 85 of 1993, as amended
- The Pharmacy Act 53 of 1974, as amended
- The National Environmental Management Act 107 of 1998, as amended
- SABS 0400:1990, Code of practice for the application of the National Building Regulations (soon to be replaced by SANS 10400 which is presently under review)
- Good Pharmacy Practice, Board Notice 129 of 2004, as amended
- R158 of 1980 Regulations pertaining to Private Hospitals and Unattached Operating Theatres
- South African Hospital Norms (SAHNORMS)

Much of this legislative and regulatory framework relate to the provision of safe environments or the provision of minimum standards which need to apply in any building or health facility. Health facilities must comply, for instance, with regulations governing fire safety and adequate means of escape – an area often compromised by later introduction of security measures.

Nosocomial infection is a major concern internationally and substantial research has focussed on the contribution of the built environment in addition to the more conventional approach of managing operation to reduce hospital acquired infection. Key issues relate to the design of the patient space, design to support safe processes, ventilation and design to support patient focussed care.

4. THE NEED TO PRIORITISE INFECTION CONTROL MEASURES

Health care facilities comprise complex and diverse environments, often consisting of technically complex and specialized sections. The public interface of health facilities (e.g. outpatient areas or casualty) need to be designed and built according to clinically acceptable standards. During the planning and design phase of any healthcare facility, least of all a facility identified to treat drug - susceptible and resistant TB patients, the need to provide the essential requirements for infection control is fundamental to the principles of ensuring a safe healing environment.

The emergence of drug resistant TB strains has highlighted the call for strengthened infection control measures to interrupt the transmission of TB in healthcare settings. There is probably no difference between the speed of transmission of susceptible TB and resistant TB (MDR or XDR-TB). For this reason, infection control measures apply to all TB strains irrespective of the resistant pattern. The probability that a person who is exposed to *M. tuberculosis* will become infected depends primarily on:

- **the concentration** of infectious droplet nuclei in the air, which is influenced by the number of organisms generated by the TB patient and the amount of ventilation in the area of exposure
- **duration of exposure** to the infectious droplet nuclei
- **proximity to source** of infectious droplet nuclei

Risk for TB infection can be further characterized by patient factors, environmental factors and host (or recipient). Environmental factors that enhance transmission include:

- exposure in relatively **small, enclosed spaces**
- **lack of adequate ventilation** to "clean" the environment through dilution or removal of infectious droplet nuclei
- **re-circulation of air containing infectious droplet nuclei**

Various international agencies such as the WHO, the US Centers for Disease Control and Prevention, provide policy guidance for infection control practices. Common to all, is the need to base these practices on the hierarchy of control measures. In order of priority, these measures include:

1st Priority	**Administrative Control Measures**
2nd Priority	**Environmental Control Measures**
3rd Priority	**Personal Protective Equipment: Respiratory Protection.**

These priorities are also reflected in the South African National TB Infection Control Guidelines of June 2007. These guidelines were adapted from the *"TUBERCULOSIS INFECTION CONTROL IN AN ERA OF THE EXPANDING HIV CARE AND TREATMENT:"* Addendum to the WHO guidelines for the prevention of Tuberculosis in Health Care Settings.

4.1. ADMINISTRATIVE (MANAGERIAL AND POLICY) CONTROL MEASURES

The first and most important level of control is the use of administrative control measures to prevent droplet nuclei from being generated and thus reducing the exposure of HCWs, and patients to *M. tuberculosis*.

Ideally, if the risk of exposure can be eliminated, no further controls are needed. Unfortunately, the risk usually cannot be eliminated, but it can be significantly reduced with proper administrative control measures. Important administrative control measures include early diagnosis of potentially infectious TB patients, prompt separation or isolation of infectious TB patients, and the prompt initiation of appropriate anti-tuberculosis treatment.

One of the most effective means to reduce the risk of transmission of *M. tuberculosis* in hospital settings is to manage TB patients in the outpatient setting whenever possible. Many patients can be managed entirely as outpatients, thereby avoiding hospitalization and the risk of exposing other patients and staff. If hospitalized, patients should be re-evaluated frequently for possible discharge with continuation of therapy as outpatients.

Ideally, infectious TB patients should be isolated from other patients so that others are not exposed to the infectious droplet nuclei that they generate. If sputum smear is performed at the time of admission, those who have positive sputum smear results, and thus most infectious, should be isolated or separated from other patients.

The hospital administration should attempt to:

- Limit the number of areas in the facility where exposure to potentially infectious TB patients may occur.
- Establish separate wards, areas or rooms for confirmed infectious TB patients. These wards/areas should be located away from wards with non-TB patients, especially wards with paediatric or immuno-compromised patients.

As in the outpatient setting, early identification, diagnosis, and treatment of TB cases is the highest priority. Assigning the role of “ward cough officer” to a staff member, who assures sputum specimen collection, rapid transport of specimens to the laboratory, and the delivery of results to the ward medical team, can be effective. The ward cough officer may help to identify patients in need of investigation and to enforce TB infection control policies.

Other important administrative control measures include:

- conducting a TB risk assessment of the setting;
- assigning responsibility for TB infection control in the facility;
- developing and instituting a written TB infection control plan to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease;
- ensuring the timely availability of recommended laboratory processing, testing, and reporting of results to the ordering physician and infection control team;
- implementing effective work practices for the management of patients with suspected or confirmed TB disease;
- ensuring proper cleaning and sterilization or disinfection of potentially contaminated equipment (usually endoscopes);
- training and educating HCWs regarding TB, with specific focus on prevention, transmission, and symptoms;

- screening and evaluating HCWs who are at risk for TB disease or who might be exposed to *M. tuberculosis* (i.e., TB screening program);
- applying epidemiologic-based prevention principles, including the use of setting-related infection control data;
- using appropriate signage advising respiratory hygiene and cough etiquette; and
- Co-ordinating efforts with the sub-district, district or Provincial Health Department.

Appropriate architectural design to support the functional and operational processes required for the first level of the hierarchy of control, namely the administrative measures, must be investigated and ensured via the design of the facility. This requirement in turn should not be inhibited by unilateral management decisions without consultations with all role players in the design and operational needs of any facility.

4.2. ENVIRONMENTAL CONTROL MEASURES

Since the exposure to infectious droplet nuclei usually cannot be eliminated, various environmental control measures can be used in high-risk areas to reduce the concentration of droplet nuclei in the air. Such measures include:

- Direct source control using local exhaust ventilation (Sputum collection booths etc.).
- Dilution and removing contaminated air via controlled (artificial), ventilation systems.
- Controlling the airflow within buildings to prevent contamination of air in areas adjacent to the infectious source, via contaminant source isolation techniques when designing appropriate ventilation systems. An overview of ventilation processes for environmental control is provided in Annexure B.
- The removal of contaminants from the air via filtration. The CDC allow the use of portable High Efficiency Particulate Arrestance (HEPA) filter units in TB isolation rooms, as a means of achieving the desired air change rate for the occupied space, thus augmenting the mechanical ventilation system.

The National Infection Prevention and Control Policy, attempts to address the possible differences in resources, that may exist between the classified facility levels. Consequently, infection control guidelines for the lower level classification of facility may emphasize the less expensive administrative (managerial) control measures (e.g. patient identification, diagnosis, and the initiation of prompt treatment for TB) in lieu of expensive infection control measures more appropriate for referral centres (level one to tertiary hospitals).

Regardless of the level however, studies suggest that addressing administrative control measures may be the most effective interventions at all levels (Blumberg ’95).

4.3. PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORY PROTECTION)

In addition to administrative and environmental control measures (discussed below), the recommended personal control measure for protection of the health care worker (HCW), from inhaling infectious droplets in high-risk TB settings, is the use of respiratory protective devices. These are designed to fit over the mouth and nose and filter out infectious TB particles.

Respiratory protective devices for HCWs that are capable of adequately filtering out infectious particles are more expensive than surgical or procedure masks. Nevertheless, their use in high-risk TB settings is recommended, particularly in high burden HIV settings where many health care workers may be HIV infected. In addition, respiratory protection should be used only when all other administrative and/or environmental control measures are fully implemented.

5. CONDUCTING THE TB RISK ASSESSMENT

5.1. THE PURPOSE OF A TB RISK ASSESSMENT

While all new facilities must be planned and designed taking account of the risk posed by drug-sensitive or -resistant TB, there is an extensive estate of existing facilities which predate the development and spread of M(X)DR-TB, where drug resistant TB will be encountered with increasing frequency and where there is currently and will be an increasing risk of cross infection to staff and other patients alike. Risk assessments must be taken at all facilities to identify potential risk areas so that proper protocols can be developed and administrative, environmental and personal protection measures can be introduced.

Every type of health-care setting should conduct initial and ongoing evaluations of the risk for transmission of *M. tuberculosis* regardless of whether or not patients with suspected or confirmed TB disease will be encountered in the setting. The TB risk assessment determines the types of administrative, environmental, and respiratory protection controls needed for a setting, and serves as a tool for the ongoing evaluation of the quality of TB infection control and the need for improved infection-control measures. (Parts of the risk assessment are similar to a program review that is conducted by the Provincial or District TB control program.) Collaboration with the Provincial or District TB controller(s) is recommended. A TB risk assessment for health-care settings should be conducted and documented at least annually.

The TB risk assessment determines the risk for health-care–associated transmission of *M. tuberculosis* in the setting by examining a number of factors, including 1) community rate of TB disease, 2) number of patients with TB disease encountered in the setting, regardless of whether they stay in the setting or are transferred to another health-care setting, 3) timeliness of the recognition, isolation, and evaluation of patients with suspected or confirmed TB disease, 4) evidence for transmission of *M. tuberculosis* in the setting, and 5) the types and conditions of the environmental controls present in the facility.

The TB Risk Assessment Worksheets (Addendum E) may be used as a guide for conducting a risk assessment for any health-care setting. As an ongoing evaluation tool, the risk assessment can identify the need for improved TB infection controls and can serve as a way to monitor administrative, environmental, and respiratory protective measures to ensure their proper operation.

5.2. THE TB RISK ASSESSMENT METHODOLGY

The Tuberculosis (TB) risk assessment is the foundation of the TB infection control plan. The risk assessment involves an evaluation of community TB rates and areas within a facility to determine if potential for TB transmission exists.

The TB risk assessment should be conducted as a first step in the process of developing the TB infection control programme. The risk assessment should be repeated at least annually so that areas of increased risk can be identified and corrective action taken to prevent TB transmission.

The seven principles of the Risk Assessment using the Hazard Analysis Critical Control Point (HACCP) risk analysis[5] and subsequent control of Airborne Infections as recommended by the SA National Infection Prevention and Control Policy and Strategy are:

1. Plan the risk assessment in order to inform the HACCP process and to determine what sections of the risk assessment tool will be used.

[5] The National Infection Prevention and Control Policy and Strategy, April 2007.

2. Assemble a risk multi-disciplinary assessment team
3. Establish procedures to document all activities and results of the proposed assessment.
4. Establish procedures to confirm that the intervention actually works under operating conditions (validation), and is being implemented properly (verification) and is periodically reassessed.
5. Conduct a hazard analysis by investigating all patient pathways to identify critical control points (the last opportunity to eliminate the hazard or prevent it from harming people).
6. Establish what (or if any) appropriate IC intervention for each critical control point has been implemented by using the risk assessment questionnaire (Annexure C) to:
    - Evaluate the management of the various infection control programmes in the facility in order to reduce risk against infection (in particular at the identified critical control points identified via the HACCP process).
    - Evaluate compliance with personal protection practices
    - Evaluate facility engineering controls and maintenance practices, and to determine their effectiveness in reducing or preventing the likelihood of infection transmission within the facility.
    - Establish what monitoring plan for the applied IC intervention at each of the critical control points has been implemented (or is needed)
7. Identify and recommend corrective action.

5.3. UNDERTAKING THE TB RISK ASSESSMENT

5.3.1 Planning the risk assessment of a facility.

A risk assessment should be carried out in each facility identified by the various District Infection Prevention and Control Committees. Each District Infection Prevention and Control Committee should submit their risk assessment and management plans to Provincial Infection Prevention and Control Committees[6].

When planning for a risk assessment of a district or metro clinic, it is necessary to accept that the risk of *M. tuberculosis* transmission should be evaluated for the entire facility.

In addition to district clinics, community health centers, gateway clinics and wards, there are a number of settings where risk of TB transmission to HCWs and patients may be increased, and special consideration should be given to reducing nosocomial and cross infection of TB transmission in such settings where patients, HCWs, or both, have HIV infection[7].

At the district and referral level hospital, the risk assessment should be conducted in both outpatient and inpatient settings. The risk of *M. tuberculosis* transmission should be evaluated for the entire hospital with specific focus on areas within the facility where TB patients might receive care (e.g., examination rooms, medical wards, HIV wards, radiology, emergency departments, bronchoscopy suites, etc.) or where HCWs otherwise may be at risk (e.g., in laboratories).

5.3.2 Assemble a risk assessment team

Ideally a multi-disciplinary co-ordination team should be assembled and trained to undertake the Infection Control Assessment of any facility. Case studies have indicated that such

[6] The South African National TB Infection Control Guidelines, June 2007
[7] WHO's Tuberculosis infection-control in the era of expanding HIV care and treatment, 2006.

assessments, when undertaken by an infection control HCW (or occupational health staff persons) without the support of facility administrative staff, environmental engineers, or building professionals do not always present conclusive factual outcomes.

The assessment team should be well equipped in measuring, or validating the functions and performance of the building, its functionality and whatever building systems are required to minimise the risk of transmission. It is not possible to measure infectiousness of *M. tuberculosis* or drug resistant *M. tuberculosis* directly[8], nor can the efficacy of environmental infection control interventions to reduce or prevent transmission be measured directly. It is therefore necessary that the operational compliance of the environmental control systems be tested and validated by the assessment team.

Further, the presence of administrative staff may assist in resolving issues related to administrative control decisions such as staff needs, space utilisation and financing.

The functions and responsibilities of the identified members of the Assessment team should, where possible include:

- Facility administrators or their designated representatives and facility managers
- Infection-control personnel, including hospital epidemiologists, risk-management personnel and laboratory personnel (microbiologist).
- Employee safety personnel, industrial hygienists and regulatory affairs personnel
- The facilities management, architectural and engineering maintenance personnel (These may be provincial and not facility specific personnel).

Should the facility (clinic, community health centre or hospital) not have a hospital engineer and architect to serve on the team, the District (or Provincial) Infection Prevention and Control Committee should arrange access to the services of such an engineer and architect with their provincial health department.

5.3.3 Establish procedures for the risk assessment.

The objectives of the team should be to:

- Undertake a facility risk assessment utilising the techniques of “root cause analysis”, or hazard analysis and control (HACCP) in an identified facility. Identify the critical control points where above normal risk of nosacomial or cross-infection exist and where special precautions need to be taken.
- Evaluate the management of the various infection control programmes in a facility in order to reduce risk against infection (in particular at the identified critical control points identified via the HACCP process) in terms of the guidelines[9].
- Review the existing infection control programmes with respect to relevant control protocols in terms of the guidelines.
- Evaluate compliance with personal protection practices in terms of the guidelines.
- Evaluate facility engineering controls and maintenance practices, and to determine their effectiveness in reducing or preventing the likelihood of infection transmission within the facility.

[8] Mastorides SM, Oehler RL, Greene JN, Sinnot JT, Kranik MK, Sandin RL. 1999. *The detection of airborne Mycobacterium tuberculosis using micropore membrane air sampling, and polymerase chain reaction.* Chest 1999; 115:19-25.
[9] The South African National TB Infection Control Guidelines, June 2007

5.3.4 The Hazard Analysis and Critical Control Point (HACCP) methodology.

By following the patient referral pathway through the hospital with a team from the hospital, the multi-disciplinary assessment team, using the techniques of "root cause analysis" and the methodology of Hazard Analysis and Critical Control Point (HACCP)[10], as recommended by the National Infection Prevention and Control Policy[11], areas within the facility can be identify where there is an above normal risk of cross-infection and where special precautions need to be taken.

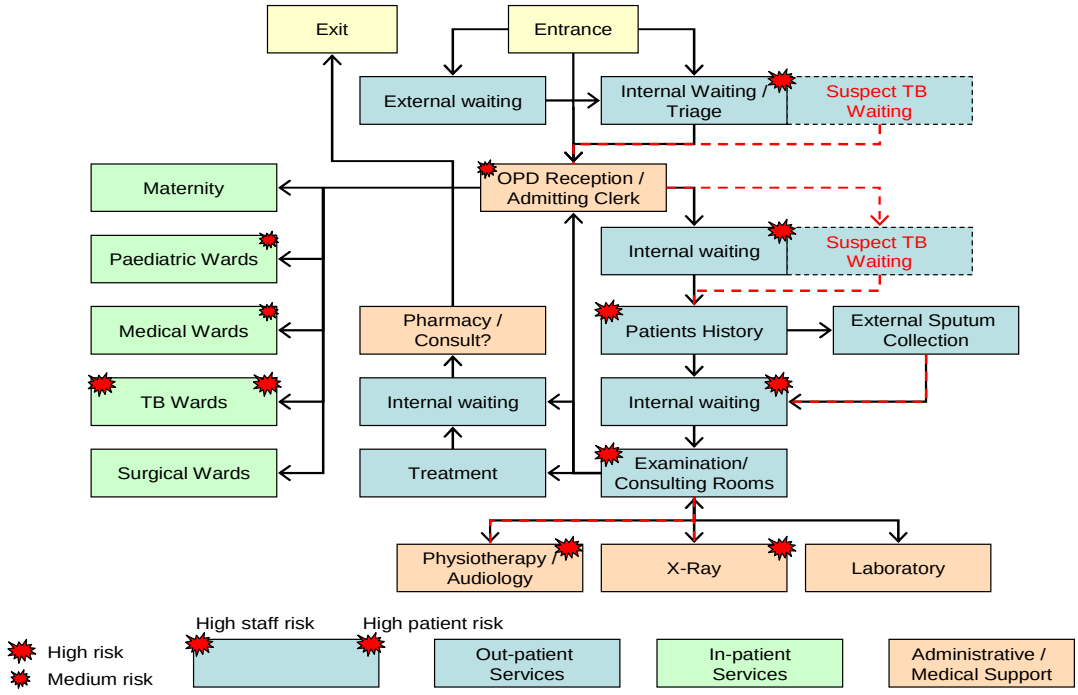

Figure 1: Patient flow in District Hospital with specific reference to TB and suspect drug-resistant TB patients and identification of risk areas (Abbott GR, Parsons SA, CSIR, 2008).

These points are referred to as Critical Control Points (CCPs), and should be plotted onto a plan of the facility as indicated in Figure 1, and detailed assessments undertaken of the critical control points. The assessment must systematically ascertain whether the specific control measures, that could be applied to prevent, eliminate or reduce the hazard, has and is being applied at each CCP.

- By using the HACCP process, the CCP's in the Hospital are identified and are then listed in Section 9 of the Administration Controls form (*RA ADM-1 Hospitals*), see Fig C1 below. A risk assessment form for Environmental Controls (RA EC-Hospitals) and Personal Protection Equipment (RA PPE-Hospitals) must be completed for each CCP identified (or identified service area).

[10] *The goal is to eliminate or reduce the hazard thereby preventing it from harming people by identifying critical points of risk and then implementing an action to reduce the identified risk. The Hazard Analysis Critical Control Point (HACCP) system has been proven successful for preventing food borne disease and is endorsed by the World Health Organization (WHO) in the Codex Alimentations.*

[11] The National Infection Prevention and Control Policy and Strategy, April 2007.

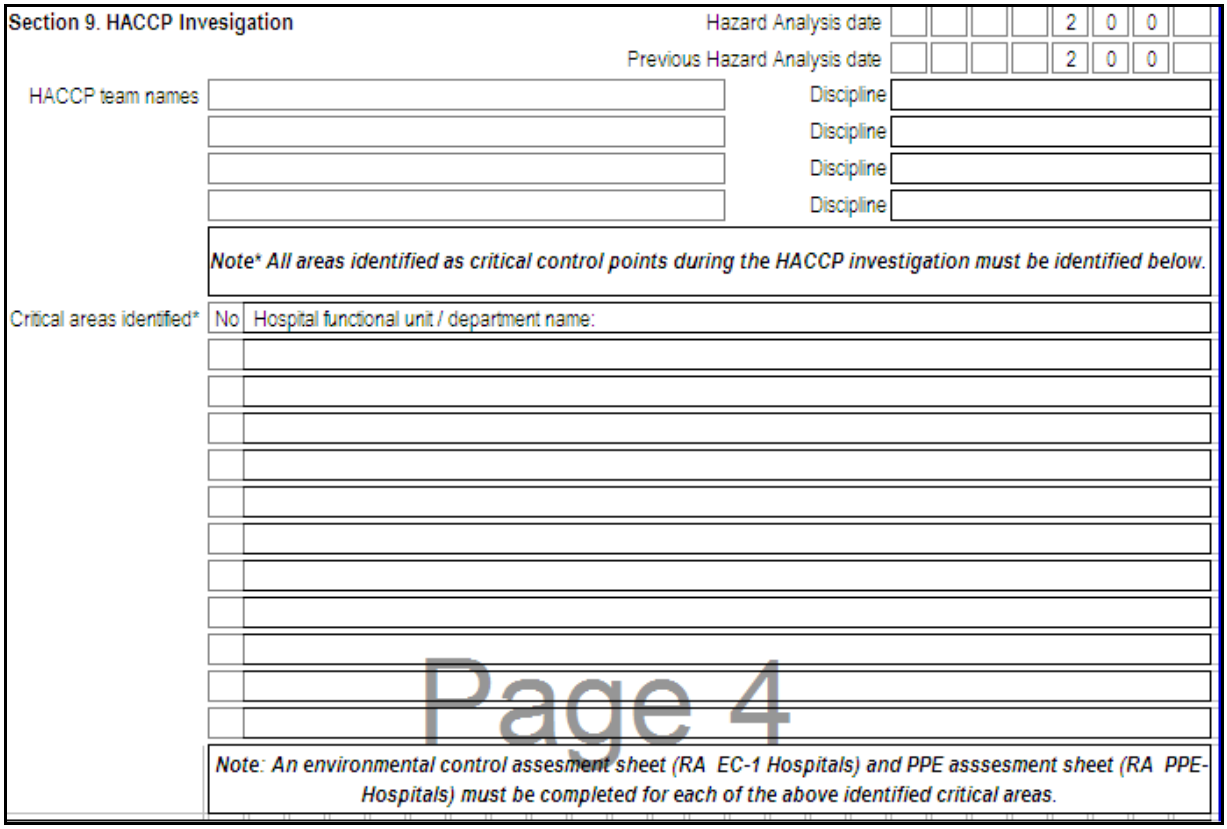

Figure 2: Section 9 of the Administration Controls form (RA ADM-1 Hospitals).

5.3.5 Utilising the risk assessment questionnaire and reporting methodology.

- A risk assessment questionnaire is to be completed for each of the areas identified as CCP's (Note a general questionnaire per facility must be completed in addition to the questionnaire(s) for the identified CCPs for each of the service areas per functional unit.

- Based on the outcome of the assessment, using the risk assessment questionnaire provided in Annexure F, the report on the identified risks (if any), should provide the location where a risk has been identified, the control recommended (namely, administrative, environmental or the use of personal protective equipment). These identified risks, which need to be addressed, are classified as follows:

- **Administrative (A):** These are risk items that can be addressed by an administrative process.

- **Transient (T):** These are risk items that need hospital management intervention (They may have administrative and cost implications).

- **Fundamental (F):** These are risks that have been identified due to the absence of required controls. These may require Sub- or District – Provincial Department Assistance such as Financial or even Professional Expertise relate to Buildings for example.

It should be emphasised that the intention of undertaking a risk assessment is to identify possible risk to airborne infection, and that each of the above three categories for each of the locations assessed that require attention, and to provide suggested resolution to risks identified.

5.3.6 Recommend corrective action to the TB Infection Control Plan for the facility.

As the Provincial Infection Prevention and Control Committee should monitor the implementation of the risk management plans, a standardised reporting system should be developed to enable the district, provincial and national structures to extract instant data on the outcomes of each of the assessments, with recommended corrective action by the assessment team.

The report should provide the location where a risk has been identified, the control recommended (namely, administrative, environmental or the use of personal protective equipment).

6. CONCLUSION

Field studies have conclusively indicated that for meaningful outcome, risk assessments for airborne TB exposure must be undertaken by a multidisciplinary team with expertise not only in infection control, but also in the fields of public health, healthcare management, architecture and engineering. This assessment method and tool therefore encourages this multidisciplinary approach.

The successful application of this risk assessment methodology and management tool depends on the establishment of the required infection control and public health staff structures in each province, and making available the necessary resources for correct implementation of the recommendations. The assessment of risk to TB exposure must be undertaken by an Infection Prevention and Control Committee comprising a multidisciplinary team appropriately trained with an appreciation of internationally accepted guidelines for the prevention of tuberculosis in the health care facilities, with special consideration MDR-TB settings. Every effort should be made to build and improve capacity for the implementation of the assessments which are foundation of any facilities TB infection control programme.

This risk assessment methodology and management tool has been developed to be supplementary to the National Infection Prevention and Control Policy and Guidelines, April 2007, and the National TB Infection Control Guidelines, June 2007.

GLOSSARY AND ABBREVIATIONS

Disinfection: A process of reducing microbial load without complete sterilization. Disinfection refers to the use of a physical process or chemical agent to destroy vegetative pathogens, but not bacterial spores.

Droplet nuclei: Microscopic particles that are estimated at 1-5 microns in diameter and are produced when a person coughs, sneezes, shouts or sighs. Such particles may remain suspended in the air for hours.

Environmental control measures: Measures that can be used in high-risk areas to reduce the concentration of droplet nuclei in the air (e.g., maximizing ventilation or controlling the direction of airflow).

Hospital-associated or nosocomial infection: An infection acquired in a health care facility by a health care user, health care worker, or a visitor to a health care facility, who was in the facility for a reason other than that infection. Such an infection should have neither been present nor incubating at the time of admission or at the time when the initial contact with the health care facility was made. This includes infections acquired in the hospital, but appearing after discharge, including any infection in a surgical site up to six weeks post operatively. Also included are occupational infections among staff of the facility.

Health care workers: A group of people that includes nurses, physicians, nursing and medical students, laboratory workers, counsellors, and others who work in health care facilities and may be exposed to patients with communicable diseases.

HIV: Human immunodeficiency virus, the causative agent of AIDS.

Infection with *M. tuberculosis*: The sub-clinical, latent infection with the organisms that cause TB, manifested by a positive tuberculin skin test, but without clinical evidence of disease.

Infection prevention and control: Specific measures and work practices that reduce the likelihood of transmitting *M. tuberculosis*.

Infection Prevention and Control Committee: A multidisciplinary committee that deals with infection prevention and control issues. Each member of the committee makes inputs as they relate to his /her discipline in order to share information and to cooperate. The committee is made up of medically trained microbiologists, clinicians, management representatives, and other health care workers representing, pharmacy, sterilizing service, housekeeping and training services.

Infection Prevention and Control Programme: A comprehensive programme that encompasses all aspects of infection prevention and control, covering education & training, surveillance, environmental management, waste management, outbreak investigation, development and updating of infection prevention and control policies, guidelines and protocols, cleaning, disinfection and sterilization, employee health, and quality management in infection control.

Infection Prevention and Control Team: The team of health care workers involved in carrying out the day-to-day infection prevention and control programme activities.

Isolation room: A single patient room with dilution and negative pressure ventilation where an infectious TB patient can be isolated from other patients.

Artificial ventilation: Methods used to direct airflow to dilute and remove air, and to produce negative pressure in isolation rooms.

Medical devices: All equipment, instruments and tools, used in health care for diagnosis, prevention, monitoring, treatment or rehabilitation. Devices could thus include products such as contact lenses, condoms, heart valves, hospital beds, resuscitators and radiotherapy machines, surgical instruments and syringes, wheelchairs and walking frames, etc.

Multidrug-resistant tuberculosis (MDR-TB): TB caused by strains of M. tuberculosis that are resistant to both Isoniazid and Rifampicin with or without resistance to other drugs.

M. tuberculosis: The bacterium (Mycobacterium tuberculosis) that causes TB.

Natural ventilation: Defined as natural air movement to achieve dilution and air exchange in an area with free-flow of ambient air (e.g. through the open windows).

Personal protective equipment: This refers to items specifically used to protect the health care worker from exposure to body substances or from droplet or airborne organisms. Personal protective equipment includes gloves, aprons, gowns, caps, masks and protective eye wear.

Respirators: A special type of closely fitted mask with the capacity to filter particles 1 micron in size to protect from inhaling infectious droplet nuclei.

Risk management: All the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress.

Smoke tubes: Devices used to monitor proper airflow direction and to determine the correct function of ventilation systems.

Sterilisation: A process that destroys or removes all viable micro-organisms, including spores. Sterilisation can be achieved by the use of heat, stream, gas or chemicals.

Tuberculosis (TB): A clinically active, symptomatic disease caused by bacteria belonging to the M. tuberculosis complex (*M. tuberculosis, M. bovis, M. africanum*).

VCT: Voluntary counselling and testing for HIV infection.

Work practice and administrative controls: Defined as managerial or administrative measures that guide work practices to reduce significantly the risk of TB transmission by preventing the generation of droplet nuclei. These include early diagnosis, prompt isolation or separation of infectious TB patients, prompt initiation of appropriate anti-tuberculosis treatment.

ANNEXURES

ANNEXURE A: A review of the transmission and pathogenesis of M. tuberculosis

The following is a brief review of some important facts for understanding risk of nosocomial transmission of TB:

- *M. tuberculosis* is mainly transmitted through the air.
- *M. tuberculosis* is carried in airborne particles, called droplet nuclei, which can be generated when persons who have pulmonary or laryngeal TB disease coughs, sneezes, shouts, or sings.
- The infectious droplet nuclei are an estimated 1-5 microns in diameter. If there are no air currents they settle down at an estimated rate of ca 1 cm per minute and remain airborne for many hours. Air currents carry them around throughout a room or building until they land onto some surface and attach onto it.
- Infection, which is usually asymptomatic, occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis* and the organisms reach the alveoli of the lungs.
- Once in the lung, the organisms are taken up by the alveolar macrophages and may spread further throughout the body.
- Disease, which is usually accompanied by focal and generalised symptoms, may develop soon after infection. In most persons, however, an immune response is generated within 2-12 weeks after initial infection that limits further multiplication of *M. tuberculosis*. At this point in time the immunological test results for *M. tuberculosis* infection become positive.
- Some of the bacilli may remain dormant and viable for many years. This condition is referred to as latent TB infection (LTBI) i.e. latent infection with *M. tuberculosis*. Tuberculosis skin tests become mostly positive in persons with LTBI. Persons with latent infection do not have symptoms of active TB and are not infectious.

Factors affecting the risk of mycobacterium tuberculosis infection

The probability that a person who is exposed to *M. tuberculosis* will become infected depends primarily on:

- The concentration of infectious droplet nuclei in the air, which is influenced by the number of organisms generated by the TB patient and the amount of ventilation in the area of exposure.
- Duration of exposure.

The dose of droplet nuclei required to cause infection depends on the probability of success by alveolar macrophages in each encounter with tubercle bacilli, that is, their microbial capacity relative to the virulence of inhaled tubercle bacilli[12]. The infecting dose will be high in persons whose macrophages generally have great innate microbial capacity, where bacilli are of low virulence. In persons whose macrophages generally have relatively low innate microbial capacity, where bacilli are virulent, the infecting dose will be low, probably a single droplet nucleus. Characteristics of the TB patient influence the number of organisms generated and thereby increase the risk of transmission. Such characteristics include:

- Location and extent of disease in the lungs and/or airways including the larynx;

[12] Dannenberg 1989.

- Presence of acid-fast bacilli in the sputum;
- Unprotected cough, i.e. failure of the patient to cover the mouth and nose when coughing or sneezing;
- Forceful unprotected expiration during bronchoscopy, anaesthesia.

Patients with TB, caused by drugs sensitive *M. tuberculosis* usually become non-infectious within a short period of time (2 weeks- 3 month) after initiating treatment. Thus, health providers may contribute to TB transmission by:

- Delaying initiation of therapy;
- Failing to initiate treatment with an adequate regimen;
- Performing procedures that can induce coughing or cause aerosolisation of *M. tuberculosis* (e.g., sputum induction).

The patients with multidrug resistant tuberculosis remains infections (e.g. sputum smear positive) after initiating treatment much longer than those infected with drug susceptible *M. tuberculosis.*

Risk of disease following infection

In most persons who are infected with *M. tuberculosis*:

- The lifetime risk of a newly infected young child (1-3 years) of progressing to active TB is estimated to be approximately 10%;
- The risk of developing disease is greatest in the first five years following infection.
- The risk of developing disease among persons, with a long-standing infection, with not other recognisable risk factor, is estimated to be 10 times less than in case of recent infection.

Factors affecting the risk of disease:

- Recent infection with *M. tuberculosis*.
- Infection with HIV; Persons with *M. tuberculosis* infection who are co-infected with HIV have approximately an 8%-10% risk per year for developing active TB.
- Persons with HIV infection who become newly infected with *M. tuberculosis* are at high risk for progression to active TB; such progression can occur very quickly after infection.
- Other conditions may pose a modest increase in the risk of progression (e.g., spontaneously healed TB with fibrotic residuals i.e. TB scars in X-ray in an untreated patients, diabetes, and probably malnutrition).

Environmental risk factors that enhance the probability of transmission of mycobacterium tuberculosis

Environmental factors that enhance the probability of transmission of *M. tuberculosis* include:

- Exposure in relatively small enclosed spaces;
- Inadequate local or general ventilation to “clean” the environment through dilution or removal of infectious droplet nuclei;
- Re-circulation of air containing infectious droplet nuclei;
- Inadequate cleaning of equipment;
- Characteristics of persons exposed to *M. tuberculosis* that might affect the risk for infection

ANNEXURE B: Ventilation for environmental control

- It is generally accepted that Environmental controls are the second line of defence for the prevention of *M. tuberculosis* transmission to Health Care Workers within the facility. In the face of inadequate administrative controls, environmental measures will not eliminate the risk.

- When employed in conjunction with administrative controls however these environmental controls will be effective to reduce the concentration of infectious droplet nuclei to which health care workers or other patients may be exposed.

- The theoretical dilution of air contaminated with droplet nuclei by ventilation, follows an exponential die-away curve, which can be described by the expression: via

- $$N_t / N_o = e^{-kt} \qquad \text{(B1)}$$

  Where:

  N_o = initial concentration of droplet nuclei
  N_t = concentration at time t
  K = rate of removal in air changes / hr

  When converted to natural logarithms, the above equation becomes:

  $$\ln N_o - \ln N_t = Kt \qquad \text{(B2)}$$

  Hence:

  $$K = \frac{(\ln N_o - \ln N_t)}{t} \qquad \text{(B3)}$$

  Now since logarithms to the base e = 2.3 times logarithms to the base 10

  $$K = \frac{2.3 (\text{Log}_{10} N_o - \text{Log}_{10} N_t)}{t} \qquad \text{(B4)}$$

- K therefore depends on the die away curve after droplet nuclei have stopped being generated.

-

- From tests carried out by Riley, O'Grady et al, using counts of infectious airborne samples taken every five minutes with a one-minute interval between samples, giving an interval of six minutes, an average slope of 1.0405 in 12 minutes was obtained. Thus resulting in K = 12 air changes per hour (approximately). This is the result of removal of droplet nuclei by actual dilution ventilation and natural death. This is the rate of air changes per hour that has been used by CDC.

-

- The South African Government notice R1390 of 27 December 2001 [Hazardous Biological Agents Regulations] as promulgated under section 43 of the Occupational

Health and Safety Act of 1993, requires that a K value of 6 to 12 air changes per hour be achieved.

- Environmental infection control, require that any system comprise not only achieve dilution (supply air) and exhaust (extraction) systems but be designed to achieve directional airflow:

-
- Dilution ventilation, combined with contaminant exhaust, is the accepted process of lowering the concentration of airborne contaminants.
- Directional air flow is the control of airflow into or out of a room, according to the specific functional requirement. The creation of directional airflow into (or out of) one space from the adjoining spaces is achieved by the establishment of a relative differential pressure between the spaces across doorways.
- Directional airflow out of a space (positive relative pressurization) is utilized when there is a need to protect room occupants from the airborne hazard outside the space, whilst airflow into a space (negative pressurization) is utilized when it is desired to prevent airborne contaminants released in the space from spreading to adjoining areas. A generally accepted practice to ensure the achievement of directional airflow between spaces is the establishment of a minimum 35 l/s flow and/or 2.5 Pa pressure differentials with doors in the closed position.

Artificial ventilation

To reduce the chance of air flow from areas with desired negative pressure such as isolation wards (or bronchoscopy rooms), to the less contaminated areas (i.e. from the isolation wards into the general ward areas) ante chambers may be needed. The ante chamber is to be held at a greater (or neutral) pressure than the isolation wards with interlocking device to doors; one door to be allowed open at one time only). The above process of dilution ventilation and pressure cascading (directional airflow), is indicated in Figure B2 below.

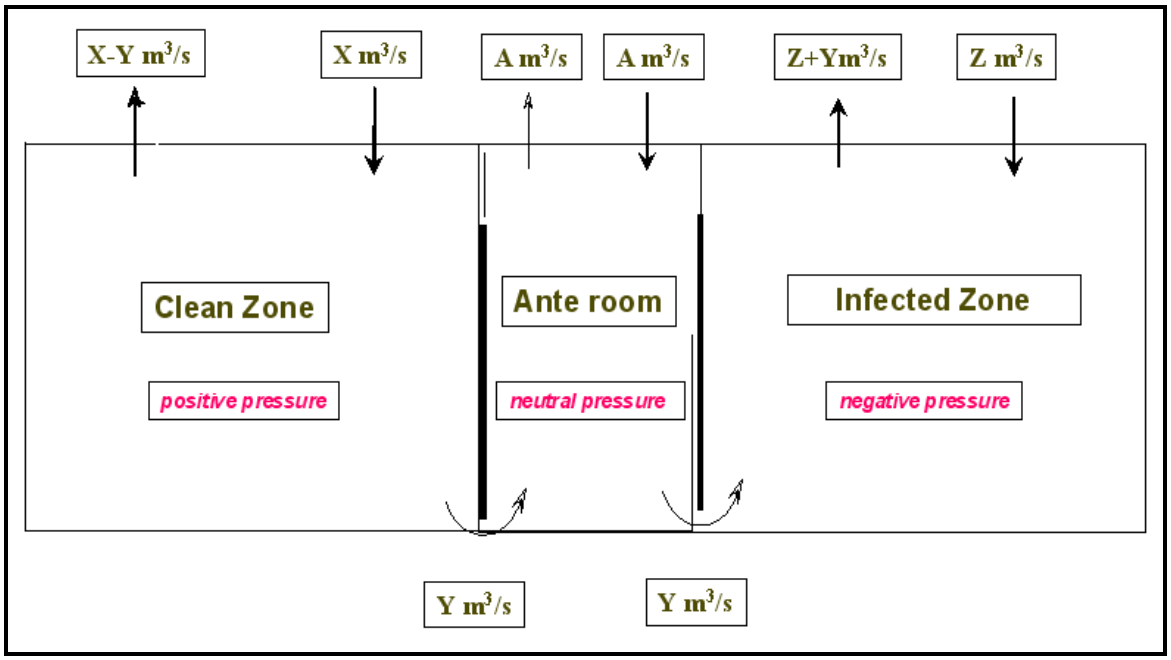

Figure B1: Air supply and exhaust flows to maintain pressure cascading strategy.

- All staff areas such as examination rooms, clerical areas and pharmacy should be maintained at a positive pressure relative to the clinics waiting area whilst ensuring the desired air changes per hour. In the case of the TB Clinic, the above would also apply.

-

Natural ventilation

- Natural ventilation refers to fresh dilution air that enters and leaves a room or other area through openings such as windows or doors[13]. Natural ventilation is controlled when openings are deliberately opened to maintain airflow. Unrestricted openings (that cannot be closed) on opposite ends of a room (opening to the outside of the building), provide the most effective natural ventilation.

- Further it should be noted that for natural ventilation to work effectively, it must be considered from the earliest stages of the facilities design development. When developing the design concept for a naturally ventilated building, three basic steps need to be taken:

1. The desired airflow patterns from inlets to outlets (windows) through the occupied spaces need to be defined. This is closely related to the form and organisation of the building, which in turn depends on the use patterns and even configuration of the site.

2. The principal driving forces, which enable the desired airflow pattern to be achieved, must be identified. Certain strategies tend to be wind-driven; others stack-driven. In a good design, the dominating driving forces are in sympathy with the intended flow rate and distribution.

3. Size and locate the openings (windows) so that the required flow rates can be delivered under all operating regimes.

- The ventilation efficiency of naturally ventilated building is dependent on:
- Wind direction;
- Building geometry;
- Interior obstructions and flow paths;
- Inner and outer temperature (buoyancy); and
- Type and degree of envelope permeability.

-

- Occupants can feel the existence, or lack of air movement in a space. In the absence of ventilation, air will feel stuffy and stale and odours will linger. It should be remembered that the above driving forces may alter during different times of day and may therefore alter any observed patterns of airflow.

[13] The South African National TB Infection Control Guidelines, June 2007.

ANNEXURE C: Risk assessment outcomes and associated classifications

- The following classifications may be used to support the report on the outcomes of the risk assessment. Each of the identified risks to be addressed is classified as follows:

(A) Administrative

- These are risk items that can be addressed by an administrative process.

(T) Transient Environmental

- These are risk items that indicate shortcomings in environmental controls. The manner in which the risk can be addressed however could be via an administrative process. The resolution may be achieved by relocating the procedure to another location where adequate environmental control is achieved, or by ensuring that a protocol is followed, such as an open window policy.

(F) Fundamental Environmental

- These are risks that have been identified due to the absence of required environmental controls. As these desired controls will have financial (and/or will be disruptive to the service provision), the lack of controls identified in this category are fundamental in nature and are therefore critical, needing urgent attention. The resolution to this identified risk will require changes to the service procedure, modifications to the building, and/or installation of ventilation equipment.

-

- The assessment forms, may be utilised to indicate the number of risk issues identified in each of the above three categories for each of the locations assessed that require attention. The report form must reflect each of the number of items identified on these forms in order to provide guidance on suggested resolution to risks identified.

-

-

-

ANNEXURE D: Recommended management strategy form

The following template may be utilised to provide the formal report on the risk assessment of a facility. The report should provide the location where a risk has been identified, the control recommended (namely, administrative, environmental or the use of personal protective equipment.

Situational analysis with recommended management strategy report

FACILITY TYPE:
NAME OF FACILITY:
DISTRICT:
PROVIENCE:
VERSION AND DATE OF TB POLICY IMPLEMENTATION PLAN:
DATE OF ASSESSMENT:

ATTENDEES:

Risks identified needing addressing:	***A***	***Number of items identified:***
	T	***Number of items identified:***
	F	***Number of items identified:***

Location	Risk type			Situational analysis	Recommended Management Strategy
	A	T	F		
				(Risk described, refer to form #)	*(Recommendations, refer to form #))*

Infection Control Assessment lead: ***Name :***_____
Signature :_____
Date :_____

ANNEXURE E: Risk assessment forms

The following risk assessment forms are provided for the risk assessment:

Risk assessment form.	Risk assessment form No.
Hospital data sheet	**RA HOSPITAL D-1**
Site data sheet (Not Applicable for this draft version)	
Facility data sheet (Not Applicable for this draft version)	
Administration Controls	**RA ADM-1 Hospitals**
Environmental Controls	**RA EC-1 Hospitals**
Personal protection equipment	**RA PPE-1 Hospitals**

A form per functional area must be completed. Assessors are to make copies of each form as required.