Canadian Agency for Drugs and Technologies in Health

RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

TITLE: Home Isolation to Prevent Tuberculosis Transmission: A Review of the Clinical Evidence and Guidelines

DATE: 05 May 2014

CONTEXT AND POLICY ISSUES

Tuberculosis (TB) is a chronic, progressive infection caused by the bacteria *Mycobacterium tuberculosis*. In 70 to 80% of cases it affects the lungs with symptoms such as productive cough, fever, weight loss, and malaise.[1,2] Diagnosis is most often by chest X-ray (CXR) plus sputum smear and culture from three spontaneous morning sputa; positive culture results can return in two to four weeks (including drug susceptibility) but negative results require seven weeks of incubation.[1] Recently, direct polymerase chain reaction testing has been employed.[3] If a positive diagnosis is suspected, the individual is isolated pending further evaluation.[1] A sample diagnosis and management algorithm is included as Appendix 1.

Treatment of active TB in drug-sensitive patients includes two drugs for six months (generally isoniazid and rifampin), plus an additional drug in the first two months (pyrazinamide or ethambutol). Drug treatment extends to nine months with risk factors for relapse, e.g., persistent smear and/or culture positivity after two months of therapy or HIV co-infection.[4] Drug-sensitive TB is considered eradicated or cured when one of the following has occurred:[3]

- Three negative sputum smears and cultures plus two stable CXRs over three months.
- In the absence of cultures, stable CXRs for a minimum of six months and symptoms for six months after treatment completion.

TB is spread via inhaled airborne particles containing *M. tuberculosis* (from breathing, coughing, singing, etc.); it is not spread via touch, contaminated surfaces, or food.[2] Due to droplet spread, isolation is an important element of treatment. Traditionally, isolation was carried out in institutions but, as the isolation period can be lengthy, this places a significant burden on the healthcare system.[5,6] In addition, patients often prefer treatment at home.[4,7] In Canada in the early- to mid-20th century, hospitalization in TB sanatoria or special wards was standard

treatment. In 1953 there were 101 sanatoria and TB units in general hospitals with a total of 19,000 beds. However, by the early 1960s, with the success of drug therapy, only a few TB-dedicated beds were left.[8] For a number of decades, TB has been largely managed in the ambulatory care setting in Canada, although it is frequently diagnosed in hospital. Hospitalization for TB treatment is primarily for patients who are very ill and require hospital-based care and resources.(*Dr. Thomas Wong, Director, Professional Guidelines and Public Health Practice Division, Public Health Agency of Canada, Ottawa, ON: personal communication, 2014 Apr 10*)

TB is a leading infectious cause of morbidity and mortality in adults worldwide, killing about 1.3 million people in 2012, most of them in low- and middle-income countries. Each untreated patient may infect 10 to 15 people per year; however, most of those infected do not develop active disease and rather harbor 'latent disease'.[2] A growing concern is multiple-drug resistant TB (MDR-TB) with the infecting organism being resistant to at least rifampicin and isoniazid. Acquired primarily through direct infection or secondarily through inadequate treatment of drug-susceptible TB, its treatment is lengthy, complex and can cause severe side effects. Worldwide about 5% of patients with TB have MDR-TB,[9] although MDR-TB is rare in Canada with nine cases reported in 2012 (0.6% of total TB cases).[4]

Canada has one of the lowest TB rates in the world although the disease continues to be a public health concern.[10] In Canada in 2012, there were 1,686 reported cases of new active and re-treatment TB with an incidence rate of 4.8 cases per 100,000 population. The dominant age group (17% of the total) was 25 to 34 years. British Columbia, Ontario and Quebec (75% of Canada's population) accounted for 69% of reported cases although the highest incidence rate was in Nunavut at 234 per 100,000 population. Of all reported TB cases in Canada, 64% were foreign-born, 23% were Canadian-born Aboriginal, 10% were Canadian-born non-Aboriginal, and 3% were origin unknown. In Manitoba, Saskatchewan and the territories, most reported cases were Canadian-born Aboriginal peoples. Outcome data in 2012 for 2011 reported cases indicated that 86% had been cured or had completed treatment.[11]

Canadian populations at risk include people with a history of active TB disease; staff and residents of homeless shelters; urban poor; staff and inmates of correctional facilities; injection drug users; people born in Canada prior to 1966; Aboriginal Canadians; people infected with HIV; and people born or previously residing in countries with a high TB incidence and the health care workers who care for them.[4] In 2009, total TB-related expenditures in Canada were estimated at $75 million, equivalent to $47,000 for each active TB disease case diagnosed in that year.[10]

The purpose of this report is to assess the literature reporting on home (versus hospital) isolation of individuals with active TB including the guidance contained in relevant evidence-based clinical practice guidelines (CPGs).

RESEARCH QUESTIONS

1. What is the clinical effectiveness of home isolation for the prevention of tuberculosis (TB) transmission?
2. What is the comparative clinical effectiveness of home isolation compared with hospital-based isolation for the prevention of TB transmission?
3. What are the evidence-based guidelines regarding home isolation for the prevention of TB transmission?

KEY FINDINGS

Ambulatory care treatment of patients with active TB, including home-based isolation, has been the norm in the developed world for several decades, although initial diagnosis may occur in hospital. A number of conditions for home-based isolation are outlined in very recent and comprehensive guidance from the Public Health Agency of Canada (PHAC), and this management paradigm is broadly supported by guidance issued by a number of health care organizations. Studies of the management of multi-drug resistant-TB from the developing world illustrated the feasibility of home-based isolation and treatment for this very challenging patient population.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 3), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. In addition, bibliographies were hand searched and PubMed related links explored. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and April 4, 2014.

Selection Criteria and Methods

For the clinical review (research questions 1 and 2), publications were selected if they commented on treatment success rates related to the location of isolation of patients with active TB. For the CPG review (research question 3), documents were included if they discussed the management of TB including location of isolation. One reviewer screened the titles and abstracts of the retrieved publications and evaluated the full-text publications for the final article selection. Table 1 summarizes selection criteria. Appendix 2 illustrates document selection flow.

Table 1: Study Selection Criteria

Population	People with active TB infection
Intervention	Home or community isolation
Comparator	Hospital-based isolation or no isolation
Outcomes	Q1: Prevention of TB transmission or infection (surrogate is achievement of TB non-infectiousness) Q2: Comparative clinical effectiveness for home-based versus institution-based care Q3: Guidelines for home isolation, e.g., patient characteristics, air quality factors, duration
Study Designs	Q1 & Q2: HTAs / SRs / MAs, RCTs, non-randomized studies Q3: Clinical guidelines

HTA=health technology assessment; MA=meta-analysis; RCT=randomized controlled trial; SR=systematic review; TB=tuberculosis

Exclusion Criteria

References were excluded if they did not meet the criteria outlined in table 1, if they did not clearly describe details around location of isolation, if they were published prior to 2003 for clinical studies, or if they were duplicate publications of a selected study. CPGs were excluded if they were published prior to 2009 or if the methodology was not clear.

Critical Appraisal of Individual Studies

For the individual studies, attention was paid to study design and size but further assessment was not indicated because, as descriptions of TB treatment programs, the studies were of low quality without further attention paid to rigour. The AMSTAR instrument[12] was used to guide the critical appraisal of the methodological quality of the SR included in this report. For the CPGs, AGREE II[13] was used as a guide with particular attention paid to CPG scope (including specific patient population and intended users); funder and potential conflicts-of-interest of the developers; and aspects of CPG methodology such as scope (included population and CPG target audience), extent and reporting of the literature search, types of included evidence, grading of evidence and recommendations, and funding and conflict-of-interest (COI) information for CPG developers.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search identified 39 citations, none of which met the inclusion criteria. Thirty-two potentially relevant articles were identified through the grey literature, hand searching bibliographies and internet searches. Ultimately, seven citations met the inclusion criteria: four for the clinical review (a systematic review [SR] and three studies) and three for the CPG review. The evidence for each research question is reported separately. Appendix 2 illustrates the document selection flow.

Summary of Study Characteristics

What is the clinical effectiveness of home isolation for the prevention of TB transmission?

Three reports of three observational studies (Table 2) partially fulfilled the inclusion criteria set out in Table 1.[9,14,15] All three reviewed programs implemented in developing nations in South America[14,15] and Africa.[9,14] The primary goal of the studies was to describe MDR-TB treatment programs in situations where care in the home was exclusively or predominantly employed, generally due to high disease burden in the population and very limited hospital infrastructure and funding. No clinical studies described management of drug sensitive TB or management of TB in the developed world, (for example, in Canada).

Table 2: Overview of Included Clinical Studies (all patients had MDR-TB)

Study Location	First Author, Year	Type of Study	Years	Patient Number & Description	Brief Details of Care	Successful Treatment Rate
Peru	Mitnick,[15] 2004	"*DOTS-Plus Program*" description via retrospective chart review	1996-1999	n=75; poor/ family clusters	Treatment was provided in the home by specially trained CHWs under supervision of RNs and MDs. A few patients had initial treatment as out-patients at health centres.	83%
	Furin,[14] 2011	Program description	1996-2011	n=800 (by 2004); poor/ family clusters		89%
Lesotho	Furin,[14] 2011	Program description	2007-2008	n=300; poor, HIV co-infected & mine workers	Initial stabilization at a TB hospital if very ill (e.g. co-infected); continued at home with CHW care; local temporary housing provided if home was remote	71%
Uganda	Horter,[9] 2014	Qualitative report of care experience for patients and stakeholders	2011	n=7; poor and rural	Initial stabilization at a local isolation unit; continued at home with care provided by MSF once a separate sleeping hut was available	NR

KEY: CHW=Community health worker; DOTS=Direct observation of treatment; MD=Medical doctor; MSF=Médecins Sans Frontiers; NR=Not reported; RN=Registered nurse

Detail for the three individual studies:

"DOTS-Plus Program" in Peru[14,15]

In 1996, when the DOTS-Plus Program for MDR-TB was launched by Partners in Health (PIH) (a non-profit organization with headquarters in Boston), treatment of MDR-TB was virtually nonexistent in poor countries due to limited resources and a perceived need for intensive clinical management in referral hospitals.[15] A community-based treatment project included individualized directly observed therapy (DOT) with at least five second-line drugs for 18 to 24 months. Care was provided in the home by a team of specially trained community health workers (CHWs), nurses, and physicians. Treatment was terminated when successful cure was achieved – defined as 12 or more consecutive negative cultures recorded.

Program in Lesotho[14]

Another MDR-TB project sponsored by PIH started in Lesotho (a small African nation; population 2.2 million) in 2007. Prior to this, despite a national TB treatment policy, few patients were diagnosed or treated due to severe community health care worker (CHW) shortages (they existed but were unpaid) and non-functional health centres. TB care was largely provided at district hospitals using facility-based DOTS, and complicated patients were referred to the national hospital. HIV co-infection rates were 70 to 90%. The PIH program started with hospital-based care as many patients were very ill, but in 2010 the program was assumed by the Ministry of Health (MOH) and expanded to the country's 10 health districts. Patients are now initially stabilized in the TB hospital and rapidly discharged home for ongoing care by CHWs. For patients from remote areas, temporary housing is provided. Although treatment success rates were reported, the definition of success was not provided.

Program in Uganda[9]

Médecins Sans Frontières (MSF) has delivered home-based MDR-TB treatment in two rural districts of Uganda since 2009 in collaboration with the local MOH. Initial treatment is delivered in a health centre isolation unit until the patient is clinically stable and can be accommodated at home in a separate sleeping hut. The remainder of the 18 to 24 months of treatment is delivered at home six days per week, directly observed by CHWs employed by MSF. The researchers conducted a qualitative study examining the experience of patients (n=7) and key stakeholders (n=23) to examine experiences of home-based versus hospital-based treatment for MDR-TB. Treatment success rates were not reported (or defined).

What is the comparative clinical effectiveness of home isolation compared with hospital-based isolation for the prevention of TB transmission?

One SR[7] including two comparative studies[16,17] was identified. The SR was authored by four WHO employees and included 35 studies of patients with MDR-TB who were treated with drugs (plus surgery in 11 studies) in hospital-based or ambulatory-based settings; the latter could include a hospital admission of less than one month followed by outpatient treatment. The 35 studies from 22 countries were published from 1993 to 2010 covering populations from developing (e.g., Peru and Uzbekistan) and developed nations (e.g., France and the USA). Of

the 35 studies, 27 focused on hospital-based treatment and eight focused on ambulatory-based treatment.

In the SR, a total of 35 described 14,478 patients who were studied over the years 1973 to 2007. Outcomes included cure, treatment completion, treatment failure, death, default and transfer out of the program. A meta-analysis of prospective studies was performed that assessed outcomes of patients treated as in-patients versus out-patients, "in accordance with PRISMA guidelines".

Only two studies directly compared the two treatment settings and these were conducted in Florida[17] and South Africa.[16] In a retrospective chart review, the Florida study[17] compared the state's MDR-TB treatment experience from 1994 to 1997 including 39 patients treated in a special TB hospital for at least part of their treatment, and 31 treated exclusively in the community at local health units, by private physicians, or both. Treatment in hospital was reserved for patients with failure to respond or non-adherence to TB therapy and a concomitant or complex medical condition; 35% were court-committed. Characteristics of the two patient groups showed them to be similar in age, sex, race, country of origin, TB site, CXR findings, and homelessness. However, the groups differed significantly in rates of HIV infection, treatment adequacy, gap between diagnosis and suitable treatment, and number of drugs the TB was resistant to. The hospitalized group fared significantly worse in all these categories.

In a before-after exercise, the South African study[16] prospectively compared 50 patients treated in 2008 for MDR-TB in the community (including a month in hospital) to retrospective chart review of 57 patients treated under the traditional hospital care model from 2001 to 2008. The latter included hospitalizations until sputum cultures were negative. Outpatient treatment was introduced due to the constraints of the centralized hospital-based treatment model, particularly the waiting list for admissions. The before-and-after groups were similar in sex and weight but the outpatient group had a significantly higher rate of HIV co-infection (78% versus 53%; P=0.004).

What are the evidence-based guidelines regarding home isolation for the prevention of TB transmission?

Guidance about TB management has been issued by a number of organizations. Included here are three CPGs that met the inclusion criteria and provided a description of the methodology used (Table 3). All CPGs covered many aspects of TB diagnosis and management and none were focused specifically on the location of treatment or isolation.

Table 3: Summary of Characteristics of Included CPGs (ordered by publication year)

Organization, year	Patient population covered by CPG; target audience for CPG	Literature search described	Extent of included evidence	Grading of evidence & recommendations	Funding; COI
WHO,[18] 2010	Adults with active TB; providers & managers	No	SR for each research question	Yes – used GRADE system	WHO, Global Fund to Fight AIDS, TB & Malaria; no COI
NICE,[19] 2011	Patients with active or latent TB (including children); providers, patients, carers & organizations	Extensive (excluded abstracts & non-English); strategy provided	Critical appraisal and data extraction as per NICE methodology	Yes – system described (evidence level 1-4, recommendations A-D)	NICE; COI declared and available by request
PHAC,[4] 2014	Patients with active or latent TB (including children); PH and clinical professionals	No but provided reference lists	Chapter authors "reviewed all published evidence"	Evidence rated (4 levels); recommendations rated (strong or conditional)	Canadian Thoracic Society, Canadian Lung Association & PHAC; NR

KEY: COI=conflict-of-interest; NICE=National Institute for Health and Clinical Excellence; NR=Not reported; PHAC=Public Health Agency of Canada; SR=systematic review; WHO=World Health Organization

Summary of Critical Appraisal

What is the clinical effectiveness of home isolation for the prevention of TB transmission?

The three included studies provide a limited evidence base with study design of low quality. None completely satisfied the inclusion criteria, i.e., although all studies included patients with active TB who were treated (at least in part) in the home setting; only patients with MDR-TB were included; no studies were comparative for treatment location; and no studies directly measured prevention of disease transmission (rather they mentioned TB cure rates). However, we determined that there was value in reviewing the developing world study experience reporting on MDR-TB, although extrapolation to Canadian populations of patients with drug sensitive TB may be limited.

What is the comparative clinical effectiveness of home isolation compared with hospital-based isolation for the prevention of TB transmission?

The 11-point AMSTAR checklist[12] was used to assess the quality of the SR. Strengths included a comprehensive literature search, inclusion of grey literature, detail about the included studies, assessment of study quality, testing of the heterogeneity of studies combined in the meta-analysis, and assessment of the likelihood of publication bias. However, the AMSTAR tool identified some short-comings as the SR did not identify whether the review was done in duplicate, cite the excluded studies, and report COI for the included studies.

The two individual studies that were separately included were observational with some or all data collected via retrospective chart review. As such they are considered to be of low quality. Both were small (n < 60 in each study group) and one examined patients recruited between 1994 and 1997 and management may have changed since that time. There were differences between the compared patient groups in both clinical study reports: in the Florida study the hospital cohort was sicker and generally more challenging to treat; in the South African study, the outpatient group had a significantly higher rate of HIV co-infection.

What are the evidence-based guidelines regarding home isolation for the prevention of TB transmission?

The AGREE II instrument for guideline quality[13] was used as a general guide with particular attention paid to CPG scope (including specific patient population and intended users); funder and potential conflicts-of-interest of the developers; and aspects of CPG methodology such as scope, extent and reporting of the literature search, types of included evidence, grading of evidence and recommendations, and funding and COI. See Table 4 below for CPG strengths and limitations.

Table 4: Strengths and Limitations of Included CPGs

Organization, Year	Strengths	Limitations
WHO,[18] 2010	• Based on systematic literature review • Used the GRADE system to develop recommendations • Broad consultation and input • Process for updating guideline provided	• Scant detail on the conditions under which home isolation is acceptable
NICE,[19] 2011	• Extensive document produced with rigorous methodology • Clearly defined scope and target audience • Broad consultation and input • Process for updating provided	• Not user friendly for providers, tools for implementation not provided • COI information apparently collected but only available by contacting NICE
PHAC,[4] 2014	• Broad scope, based on review of “all available literature” • Recommendations and levels of evidence provided • Broad consultation and input during development	• Detailed methodology unclear; unclear if systematic methods were used to identify relevant literature • Not user friendly for providers • Recommendations graded but specific links to evidence not provided • No COI information reported

KEY: COI=conflict-of-interest; GRADE=Grading of Recommendations Assessment, Development and Evaluation; NICE=National Institute for Health and Clinical Excellence; PHAC=Public Health Agency of Canada; WHO=World Health Organization

Summary of Findings

What is the clinical effectiveness of home isolation for the prevention of TB transmission?

None of the included clinical studies reported on the clinical effectiveness of home isolation for the prevention of TB transmission; however, there were reports of successful treatment rates using home-based treatment programs:

Peru: The community-based PIH program started in three districts[15] but has now been assumed by the local MOH and covers more than 90% of Peru including treatment of 15,000 patients with a recent treatment success rate of 89%.[14]

Lesotho:[14] The community-based PIH program, now managed by the local MOH, covers more than 90% of Lesotho including treating more than 300 patients with a national TB treatment success rate of 71%.

Uganda: In a study to assess satisfaction with community-based (versus hospital-based) care,[9] researchers noted several key themes emerging through interviews and focus groups: acceptability and preference for home-based treatment, fear of transmission of other infections in hospitals, and development of MDR-TB through poor adherence to and inadequate treatment regimens for drug-sensitive TB. In particular, home-based care was perceived by patients to be safe and conducive to recovery, to facilitate psychosocial support, and to allow more free time and earning potential for patients and caretakers. MSF is a strong advocate for community-based TB treatment as a result of their Ugandan experience with programs covering both drug-sensitive TB and MDR-TB.[20]

What is the comparative clinical effectiveness of home isolation compared with hospital-based isolation for the prevention of TB transmission?

The SR separately examined the hospital-based and ambulatory experiences (Table 5). The pooled treatment success rate for all studies combined was 66.4% (95% Confidence Interval [CI], 61.4 to 71.1%) with no statistical difference between the hospital-based model (66.7%; 95% CI, 61.0 to 72.0%) and the ambulatory model (65.5%; 95% CI, 55.1 to 74.6%).

Table 5: Outcomes for Two Care Settings in the SR (Bassilli et al 2013)[7] *

Outcome	Median / Mean Results across Studies*	
	Hospital Care (27 studies)	Ambulatory Care (8 studies)
Time to treatment initiation	1.5 to 6 months (3 studies)	0.5 to 3 months (3 studies)
Time to sputum smear conversion	2 to 6 months (4 studies)	1.3 to 15 months (4 studies)
Time to sputum culture conversion	2 to 5 months (10 studies)	1 to 3 months (all 8 studies)
Treatment duration greater than 18 months	15 studies (65%)	All 8 studies (100%)
Treatment success rate	Range from 36% to 83%	Range from 38% to 85%

* No statistics were provided

Unfavourable outcomes were compared between groups and although there were trends, no differences were statistically significant (Table 6).

Table 6: Unfavourable Outcomes for Two Care Settings in the SR (Bassilli et al 2013)[7]

Outcome	Rate, Expressed as % (Range)		
	Hospital Care	Ambulatory Care	Pooled
Death	12.9% (10.3-16.0)	7.8% (5.2-11.7)	10.4% (6.3-16.5)
Treatment failure	9.0% (6.5-12.2)	11.4% (6.7-18.8)	9.5% (7.3-12.4)
Default	14.7% (10.2-20.7)	13.3% (7.5-22.6)	14.3% (10.5-19.1)

The SR authors concluded that the ambulatory care model works for treatment of patients with MDR-TB, "*conditional on infection control measures in the home and clinic, clinical condition of the patient, availability of treatment support to facilitate adherence to treatment, and provisions for backup facility to manage patients who need inpatient treatment care*." (pg. 271)

With respect to the two clinical studies that compared treatment settings, the Florida study (1994 to 1997)[17] with significantly different patient groups found that a specialized TB care program, including at least partial inpatient therapy, yielded higher treatment completion rates versus outpatient treatment alone: 79% versus 48%, *P*<0.001. There was no significant difference in the number of days from initiation of appropriate therapy until culture conversion (medians of 39 versus 20 days) although the ranges of required treatment were very large (overall from 1 month to 5 years).

In the South African study,[16] results showed that the median time to initiation of treatment was significantly shorter for the outpatient group (84 versus 107 days; *P*=0.002) as was the time to sputum culture conversion (85 versus 119 days, *P*=0.002). The outpatient group also showed a trend towards shorter time to sputum smear conversion at 59 versus 92 days, *P*=0.055). The favourable outcomes for outpatient treatment led the authors to conclude that community-based treatment can be implemented in their situation and should be employed.

What are the evidence-based guidelines regarding home isolation for the prevention of TB transmission?

The CPGs were reviewed for suggested treatment settings and supporting evidence (Table 7).

Table 7: Summary of CPG Content Related to Home Isolation / Treatment Setting

Organization, Year	Content Related to Treatment Setting
WHO,[18] 2010	*"Community-based care can help to expand access to care but requires a strong reporting system, access to laboratory facilities, and a secure drug supply."* (pg. 76) "*Depending on the local conditions, supervision [of treatment] may be undertaken at a health facility, in the workplace, in the community or at home*." (pg. 77) (No specific grading was provided for the evidence or strength of this recommendation.)

Organization, Year	Content Related to Treatment Setting
NICE,[19] 2011	*"It is important to prevent unnecessary hospitalisation, as this is one of the major cost drivers for TB treatment. Treatment can proceed in the patient's home, considering that the household members will be contacted through contact tracing, and that infectiousness declines rapidly once treatment begins."* (pg. 133) *Recommendation 34: "Unless there is a clear clinical or socioeconomic need, such as homelessness, people with TB at any site of disease should not be admitted to hospital for diagnostic tests or for care.*" (pg. 134) (Recommendation is based on expert opinion / formal consensus [Class D]; under 'evidence' this is labelled a 'good practice point'.)
PHAC,[4] 2014	*"Although frequently diagnosed in hospital, TB is largely managed in the outpatient setting."* (pg. 111) Patients with confirmed TB *"may be discharged to home isolation for the period requiring airborne precautions provided there is clinical improvement, drug-resistant TB is not suspected and there is no contraindication for home isolation"* (pg. 378) (Strong recommendation, based on moderate evidence.)

KEY: NICE=National Institute for Health and Clinical Excellence; PHAC=Public Health Agency of Canada; WHO=World Health Organization

With respect to the particulars of home isolation when treating active respiratory TB (confirmed or suspected), the most detailed guidance was produced by PHAC in early 2014, recommending the following conditions for home isolation:[4]

- "Supervised therapy, if indicated, has been arranged.
- The person does not share a common airspace with non-household members (e.g., rooming house and the household air is not being recirculated to other housing units.
- All household members have been previously exposed to the person. If any household members are tuberculin skin test negative, they should be informed and understand the potential risks.
- No children under the age of 5 or persons with immunocompromising conditions are present in the home (an exception would be if they are receiving prophylaxis or treatment for active TB disease or latent TB infection).
- No visitors should be allowed in the home except for community health workers.
- The person is counselled on and is willing and able to comply with limitations to their movement outside of the home, e.g., does not go to work, school or any other public indoor environment.
- The person should not be allowed to use any form of public transportation (if absolutely necessary, a taxi can be used to attend essential health care appointments provided the person is wearing a mask).
- The person should be allowed to ambulate outdoors since the risk of transmission is negligible provided they are not in very close contact with susceptible individuals for prolonged periods of time." (p. 378)

If conditions have been met, PHAC recommends initiation and maintenance of home isolation until the patient is deemed to be non-infectious, based on: (a) clinical evidence of improvement,

(b) three consecutive negative sputum smears for acid-fast bacteria and (c) evidence of adherence to at least 2 weeks of effective therapy. (Patients with MDR-TB and those with resistance to rifampin are recommended to have three consecutive negative sputum cultures after 6 weeks of incubation prior to discontinuing home isolation.)

Limitations

In seeking specific information and guidance about the treatment setting (home or hospital) for most patients with TB in Canada, a significant limitation was the lack of evidence. The change to primarily outpatient management in Canada occurred decades ago and the basis for the change is not evident. The primary study evidence located for our review was all for MDR-TB and essentially all from developing countries – how well this extrapolates to treatment of drug-sensitive TB in Canada is unclear. However, as the population affected by MDR-TB is a greater challenge to treat, presumably workable systems for MDR-TB could be useful for patient populations with drug-sensitive TB.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Our research questions focused on the effectiveness of isolation at home for patients diagnosed with TB. Historically, it appears that the introduction of effective drug therapy for TB in the 1960s led to a dramatic shift in treatment setting, from prolonged hospitalization in special TB institutions or units to early discharge home or even completely home-based treatment.[8] Current CPGs support this treatment paradigm for most patients. However, home isolation requires careful assessment and maintenance of required specifications plus committed compliance by patients, caregivers and health care providers.[4] Despite its advantages (particularly patient preference and health care savings), home-based isolation and care are not suitable for everyone, particularly patients who cannot ensure maintenance of all the required isolation conditions, are very ill (e.g., with co-morbidities), or have treatment compliance issues.

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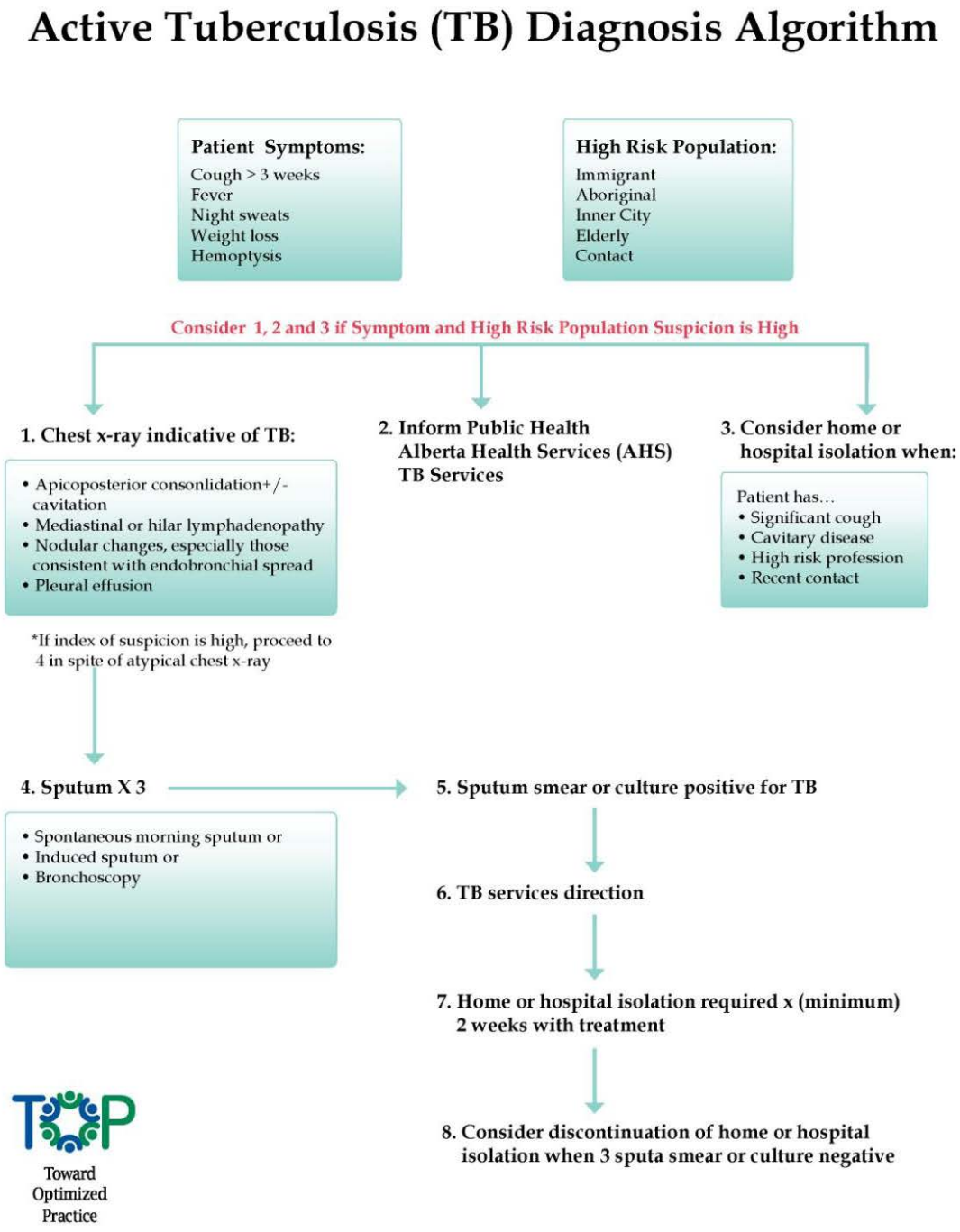
APPENDIX 1: Sample Algorithm for TB Diagnosis and Treatment Setting[1]



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APPENDIX 2: Selection of Included Studies