INTEGRATED NOTIFICATION FOR TUBERCULOSIS

HEALTH TECHNOLOGY ASSESSMENT SECTION (MaHTAS)
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
012/2016
DISCLAIMER
Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has not been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

Please contact: htemalaysia@moh.gov.my, if you would like further information.
DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.
EXECUTIVE SUMMARY

Background
Tuberculosis (TB) is a major global health problem. Worldwide, 9.6 million people are estimated to have fallen ill with TB in 2014. Similar to other developing countries, TB is still a public health problem in Malaysia despite the preventive and control measures taken.

Tuberculosis is an infectious disease for which there is a legal requirement to report the diagnosis to organization. Routine recording and reporting of the numbers of TB cases diagnosed and treated by national TB programmes (NTPs) and monitoring of treatment outcomes was one of the five components of Direct Observed Treatment Short (DOTS) introduced by WHO in 1994. Despite the rapid and worldwide expansion of the DOTS strategy to control TB for the last two decades, case notifications have stagnated since late-2000s, and 3 million TB cases are estimated to remain undiagnosed or not notified each year. In Malaysia, the numbers of TB cases reported in 2015 were 24,220 cases which showed 2% decrease compared to 24,771 cases reported in 2014. However, the number of deaths increased by 5.8% from 1,603 deaths in 2014 to 1,696 deaths in 2015.

Reporting of infectious diseases in Malaysia has been mandated by law since the end of the nineteenth century. Notifiable infectious diseases are specified by regulations made under the Prevention and Control of Infectious Disease Act 1988 whereby to date a total of 26 infectious diseases are required to be notified by law. All laboratory-confirmed cases of TB should be notified by the physician who made the diagnosis to the nearest District Health Office by submission of the notification form within seven days from the diagnosis date. However, there were missed notifications for TB cases leading to inadequate treatment, prevention and control measures.

Besides physician notification, notification by pathology laboratories (integrated notification) has been made mandatory in some countries around the world. If analysis of a sample undertaken at a pathology laboratory indicates that a patient from whom the sample was taken has \textit{M. tuberculosis} infection, the responsible pathologist of that laboratory has a legal obligation to report the diagnosis to the Department of Health.

This technology review was requested by the Director of Disease Control Division, Ministry of Health Malaysia to review the evidence on integrated notification for TB.

Objective/aim
To assess the feasibility, effectiveness, cost-effectiveness and organizational/legislation aspect of integrated notification for TB.
Results and conclusions
A total of 970 titles were identified through the Ovid Interface and PubMed. Six articles related to the effect of integrated notification for tuberculosis were included in this review consisting of three cross sectional studies, one pre and post intervention study, and two policy documents. There was a fair level of retrievable evidence to suggest the effectiveness of integrated notification for TB. Integrated notification from both laboratory and physician was effective in increasing notification, reducing missed cases, reducing delay in notification and treatment. The requirement for integrated notification for TB has been made mandatory in some countries. There was no retrievable evidence on the cost-effectiveness of integrated notification for TB.

Methods
Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EMBASE – 1996 to July 2016, EBM Reviews - Cochrane Central Register of Controlled Trials - July 2016, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to July 2016, EBM Reviews - Health Technology Assessment - 1st Quarter 2015, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2015, AMED – 1985 to February 2015, MANTIS Database – 1980 to July 2016. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 13 July 2016.
1. **BACKGROUND**

   Tuberculosis (TB) is a major global health problem. It causes ill-health among millions of people each year and ranks alongside the human immunodeficiency virus (HIV) as a leading cause of death worldwide. In 2014, there were an estimated 9.6 million new TB cases: 5.4 million among men, 3.2 million among women and 1.0 million among children. There were also 1.5 million TB deaths (1.1 million among HIV-negative people and 0.4 million among HIV-positive people), of which approximately 890,000 were men, 480,000 were women and 140,000 were children. Similar to other developing countries, TB is still a public health problem in Malaysia despite the preventive and control measures taken. The incidence rate of TB in Malaysia has been at around 82 to 85 per 100,000 populations in the last five years. However, the number of new TB cases in the country increased from 15,000 in 2005 to 19,251 in 2011.

   Tuberculosis is an infectious disease for which there is a legal requirement to report the diagnosis to organization. The International Health Regulations (2005) require all World Health Organization (WHO) Member States to notify TB cases to WHO in order to help with its global surveillance and advisory role. In 1994, WHO introduced a new strategy called Direct Observed Treatment Short (DOTS) course as a method for TB control. Routine recording and reporting of the numbers of TB cases diagnosed and treated by national TB programmes (NTPs) and monitoring of treatment outcomes was one of the five components of DOTS. Despite the rapid and worldwide expansion of the DOTS strategy to control TB for the last two decades, case notifications have stagnated since late-2000s, and three million TB cases were estimated to remain undiagnosed or not notified each year. In Malaysia, the number of TB cases reported in 2015 were 24,220 cases which showed a 2% decrease compared to 24,771 cases reported in 2014. However, the number of deaths increased by 5.8% from 1,603 deaths in 2014 to 1,696 deaths in 2015.

   In countries endemic for TB, TB case finding, treatment, and outcome monitoring are commonly implemented by a vertical organization dedicated to tuberculosis. In Malaysia, reporting of infectious diseases has been mandated by law since the end of the nineteenth century. Notifiable infectious diseases are specified by regulations made under the Prevention and Control of Infectious Disease Act 1988 whereby to date a total of 26 infectious diseases are required to be notified by law. All laboratory-confirmed cases of TB should be notified by the physician who made the diagnosis to the nearest District Health Office by submission of the notification form within seven days from the diagnosis date. However, there
were missed notifications for TB cases leading to inadequate treatment, prevention and control measures.

Besides physician notification, notification by pathology laboratories (integrated notification) has been made mandatory in some countries around the world. If analysis of a sample undertaken at a pathology laboratory indicates that a patient from whom the sample was taken has *M. tuberculosis* infection, the responsible pathologist of that laboratory also has a legal obligation to report the diagnosis to the Department of Health.⁷

Hence, this technology review was requested by the Director of Disease Control Division, Ministry of Health Malaysia to review the evidence on integrated notification for TB.

2. OBJECTIVE / AIM
To assess the feasibility, effectiveness, cost-effectiveness and organizational/legislation aspect of integrated notification for TB.

3. TECHNICAL FEATURES
The term “notification” means that confirmed cases of active TB are notified to the national surveillance system, and then on to WHO.⁸ Notification is a formal process which involves the completion in writing of a standard notification form or automated electronic form by designated health care providers. The notification should include the sputum smear status of the patient.⁹ Among these health care providers are physicians, pharmacists, nurses, infection control officers, medical examiners, morticians, and the administrators of laboratories or other facilities where TB patients receive health care services. All cases of TB are notifiable.¹⁰

Integrated notification is a national infectious disease surveillance system based on mandatory laboratory and physician notification.⁵ Physicians diagnosing cases of TB should notify these cases based on clinical diagnosis with or without laboratory confirmation to the local health department. All bacteriologic and pathologic laboratories that perform diagnostic services on sputum samples are also required to notify the results to physicians and local health department.⁷

4. METHODS
4.1. Searching
Electronic databases were searched through the Ovid interface:
- Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present
- EMBASE – 1996 to July 2016
- EBM Reviews - Cochrane Central Register of Controlled Trials - July 2016
Searches were also run in PubMed. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 13 July 2016.

Appendix 1 showed the detailed search strategies.

4.2. Selection
A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection.

The inclusion and exclusion criteria were:

<table>
<thead>
<tr>
<th>Population</th>
<th>Patient with Tuberculosis</th>
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<tr>
<td>Interventions</td>
<td>Integrated Notification for Tuberculosis</td>
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<td>Comparators</td>
<td>Physician notification alone/laboratory notification alone/no comparator</td>
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<td>Outcomes</td>
<td>i.  Efficacy:</td>
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<td></td>
<td>- Improvement in disease (TB) notification</td>
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<td></td>
<td>- Reduction in delay in patient notification and treatment</td>
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<td></td>
<td>- Reduction in missed cases</td>
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<td></td>
<td>ii. Economic implication (cost, cost-effectiveness)</td>
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<td></td>
<td>iii. Organizational/Legislation</td>
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<td></td>
<td>- Training of staff</td>
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<tr>
<td></td>
<td>- guideline</td>
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<td></td>
<td>- laws/regulation</td>
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<tr>
<td>Study design</td>
<td>Health Technology Assessment (HTA), Systematic Review, Randomised Controlled Trial (RCT), Non randomised controlled trial, Cohort study, pre- and post-intervention study, cross sectional study, case series</td>
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<td></td>
<td>English full text articles</td>
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</table>
Exclusion criteria

<table>
<thead>
<tr>
<th>Study design</th>
<th>Studies conducted in animals, narrative reviews</th>
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<tbody>
<tr>
<td></td>
<td>Non English full text articles</td>
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Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

5. RESULTS AND DISCUSSION

A total of 970 titles were identified through the Ovid interface and PubMed. However, most of the articles focused on the completeness and timeliness of TB reporting. There were six articles included in this review; three cross sectional studies, one pre and post intervention study, and two policy documents. However, there was no retrievable evidence from the scientific databases on cost-effectiveness of this technology. The studies retrieved and included in this review were conducted in Finland, Edinburgh, Thailand, Taiwan, United States, and Australia.

5.1. EFFICACY / EFFECTIVENESS

Kokki M, Holmstrom P, Ruutu P (2005) conducted a cross sectional study in Finland to assess the sensitivity for culture-confirmed tuberculosis of a recently introduced national integrated infectious diseases surveillance system based on mandatory laboratory and physician notification. Notifications were sent to the National Infectious Disease Register (NIDR) via regional registers located in 22 hospital districts. Figure 1 illustrates the flow of information in the surveillance system for infectious disease in Finland. The notifications made by physician and laboratory were linked automatically in the NIDR database using the national personal identity code. The study compared routine laboratory notification to the NIDR for Mycobacterium tuberculosis from January 1, 1995 to December 3, 1996 with data obtained independently from all laboratories offering M. tuberculosis culture and with data from patient records. During the 24 month study period in 1995 to 1996, 991 cases were notified as culture-confirmed to the national surveillance system NIDR. The retrospective, separate collection of culture findings for the reference dataset from each laboratory licensed to implement microbacterial cultures yielded 1054 culture confirmed cases. Linking these two datasets with the national personal identity code identified a total 1059 cases in the study cohort, whereby 984 having been notified to the NIDR as culture verified and 1029 present in the reference dataset (Figure 2). The sensitivity of NIDR for culture positive cases of tuberculosis was 93% (984/1059). The positive predictive value of a case recorded in the NIDR as culture positive case was 99% (984/991). For the culture-confirmed cases in the NIDR (N=984), one or more physician notification forms were found for
876, which give a sensitivity of 89% for physician notification. Hence, the authors concluded that highly sensitive notification system for culture-positive TB can be achieved in an integrated national infectious surveillance system based on laboratory notification.\textsuperscript{5, level II–3}

![Diagram: Flow of information in the surveillance system for infectious disease in Finland, 1995-1996](image)

**Figure 1**: Flow of information in the surveillance system for infectious disease in Finland, 1995-1996

![Diagram: Culture confirmed TB case in the NIDR and reference dataset between 1 January 1995 – 21 December 1996, Finland](image)

**Figure 2**: Culture confirmed TB case in the NIDR and reference dataset between 1 January 1995 – 21 December 1996, Finland

Bradley BL et al. (1988) conducted a cross sectional study in Edinburgh to investigate whether a laboratory notification for positive pathological biopsy specimens would further improve notification process. The authors examined 82 sets of case notes and pathology reports issued from Department of Pathology, University of Edinburgh in which tuberculosis was listed as the primary diagnosis or in the differential diagnosis for the years 1981 – 1984. Cases were checked against the local tuberculosis register for the corresponding years to see whether they had been notified. Pathology reports were coded as follows: (A) a firm pathological diagnosis of TB in which acid fast organisms were present in the sections; (B) strongly suggestive or firm diagnosis of TB made on morphological grounds, though
acid fast bacilli were not seen; (C) cases in which a firm diagnosis of inactive, calcified, or healed TB was made; (D) cases in which TB was mentioned in the differential diagnosis for confirmation or exclusion on clinical grounds. Eleven of 34 patients (32.4%) identified with acid fast bacilli (A) were not notified, and of those in whom acid fast bacilli were not seen but a firm pathological diagnosis was made (B), 15 of 35 patients (42.9%) were not notified. Almost 40% of patients (26/69) with a convincing combined clinical and pathological diagnosis of TB (C) were not notified. Most failures of notification occurred in surgical wards, though physicians also failed to notify positive pathological diagnoses of TB. The study suggests that all positive pathological diagnoses of TB should be notified to the local health board to ensure that notifications reflect the true incidence of disease.\textsuperscript{11, level II-3}

Uthaivoravit W et al. (2003) conducted a cross sectional study in Chiang Rai Hospital, Northern Thailand to assess the impact of an enhanced system for notification of TB laboratory results on minimizing delays between hospital admission and treatment initiation and improving the completeness of the TB treatment register. In the enhanced notification system, acid-fast bacilli (AFB) sputum smear results were reported promptly to the Department of Preventive and Social Medicine and to the hospital ward to ensure the immediate registration and prompt treatment of all AFB sputum smear-positive TB patients respectively. Laboratory policy was changed to routine examination 7 days a week to decrease treatment delay on Friday admission. Four hundred and fifty six patients with AFB sputum smear-positive cases recorded from 1994-1999 were studied. Time of admission to hospital, laboratory diagnosis of TB, registration for treatment, and initiation therapy were determined during the implementation of enhancing the laboratory results notification system. The number of unregistered TB patients fell from 44 cases in 1994 to none in 1999. The time elapsed from admission to treatment initiation decreased from a mean of 5.6 days in 1997 (n=162) to 3.1 days in 1999 (n= 136) (P<0.001). This decrease was attributed to a reduction in time between laboratory diagnosis and treatment from 2.7 days in 1997 to 0.6 days in 1999 (P<0.001). The laboratory policy change for Friday admissions resulted in a decrease in 3-day treatment delays. Time from the initiation of anti tuberculosis treatment to date of hospital discharge was as short as 3.3 days. The authors concluded that the study showed that prompt identification, isolation and treatment of TB patients can occur through an enhanced laboratory notification system. Such systems are inexpensive, improve TB care services and may reduce nosocomial transmission of M. tuberculosis.\textsuperscript{12, level II-3}

Chen TC et al. (2011) conducted a pre and post intervention study to investigate the impact of introducing an expedited acid-fast bacilli (AFB) smear laboratory procedure and an automatic, real-time laboratory notification system by short message with mobile phones on delays in prompt isolation of patients with pulmonary TB at hospital in Kaohsiung,
Taiwan. Beginning March 1, 2005, the quality of AFB smear testing was improved by increasing the number of laboratory workers and using barcodes for receiving, labelling and registering specimens. Two experienced technicians were dedicated to performing digestion/decontamination/staining and inoculation in the biosafety level 3 laboratory. Changes in SOP for processing specimens were also implemented. In June 14, 2005, an automated mobile phone SMS to provide real-time notification alerts of critical value and microbiology reports, including positive AFB results and identification of *M tuberculosis* complex from any specimen was implemented. A real-time alert message was sent automatically after an AFB result was keyed into the laboratory information system. All messages were transmitted to the doctors and nurses who cared for patients with positive findings, to the head nurses of the wards, and to the staff of the Department of Infection control. To evaluate the impacts of these improvements, data for all patients with active pulmonary tuberculosis during baseline (January 2004 to February 2005) and intervention (July 2005 to August 2006) phases were analyzed. A total of 96 and 127 patients with AFB-positive TB were reported during the baseline and intervention phases, respectively. There were significant decreases in health care system delays (laboratory delays: reception of sputum to reporting, *P* < 0.001; response delays: reporting to patient isolation, *P* = 0.045; and interval from admission to patient isolation, *P* < 0.001) during the intervention phase. Significantly fewer nurses were exposed to each patient with active pulmonary TB during the intervention phase (*P* = 0.039). The study found that implementation of expedited AFB smear laboratory procedures and an automatic, real-time laboratory mobile notification system significantly decreased delays in the diagnosis and isolation of patients with active TB.\textsuperscript{13, level II-2}

5.2. COST / COST-EFFECTIVENESS

There was no retrievable evidence from the scientific databases on cost-effectiveness of using integrated notification for tuberculosis.

5.3. ORGANIZATIONAL / LEGISLATION

In the United States, a survey of state TB control laws and regulation was conducted by the Centre for Disease Control and Prevention (CDC), United States in 1991. One of the objectives of the National Action Plan was for Advisory Council for the Elimination of Tuberculosis (ACET) and CDC to develop recommendations that address legal issues of TB controls and to publish these recommendations by 1993. The survey indicates that states differ in their approach to the control of TB. Based on the survey, ACET provides recommendation that can be used in revising state TB-control laws. Among the recommendations were:

- Health care providers and allied professionals such as physicians, pharmacists, nurses, infection control officers, medical examiners, morticians and the administrative of laboratories are required to report
confirmed or suspected cases of TB to the appropriate health agency. Appropriate systems should be developed that maximized the reporting of new cases and minimize the reporting of duplicate cases and suspected cases and that protect the confidentiality reports.

- Confirmed and suspected cases should be reported within two working days of identification of *M. tuberculosis* to the health agency. Reporting should be based on a diagnosis or a presumptive diagnosis. Local health departments should report confirmed and suspected cases to the state TB-control agency within one working day of notification.
- All bacteriological and pathological laboratories that perform diagnostic services are required to report the results to the local health department within one working day of identification.
- Laboratories that perform diagnostic services on specimens from other states should be required to report the results to the state health department TB program from which the specimen was received. Reports should include the patient’s name, address, and physician, and the person or agency referring the positive specimen for laboratory evaluation.

The Government of Western Australia (WA) has enacted a mandatory notification by both diagnosing/treating clinicians and diagnosing pathology laboratories. Medical or nurse practitioner that makes the diagnosis and is in charge of the patient’s management is responsible to notify TB cases to the Department of Health. Notification by pathology laboratories has been mandatory in WA since July 2006. If analysis of sample undertaken at a pathology laboratory indicates that a patient has M. tuberculosis infection, the responsible pathologist of that laboratory has a legal obligation to report the diagnosis to the Department of Health. Both clinicians and laboratories are responsible to notify WA Department of Health by post, fax, telephone, or secure electronic transfer.

5.4. LIMITATIONS
This technology review has several limitations. The selection of studies was done by one reviewer. Although there was no restriction in language during the search but only English full text articles were included in this review.

6. CONCLUSION
There was a fair level of retrievable evidence to suggest the effectiveness of integrated notification for TB. Integrated notification from both laboratory and physician was effective in increasing notification, reducing missed cases, reducing delay in notification and treatment. The requirement for integrated notification for TB has been made mandatory in some countries. There was no retrievable evidence on the cost-effectiveness of integrated notification for TB.
7. REFERENCES


8. APPENDIX

8.1. Appendix 1: LITERATURE SEARCH STRATEGY

<table>
<thead>
<tr>
<th>Ovid MEDLINE® In-process &amp; other Non-Indexed citations and OvidMEDLINE® 1946 to present</th>
</tr>
</thead>
</table>

1. TUBERCULOSIS, PULMONARY/ (71604)
2. (pulmonary adj1 (consumption* or phthis* or tuberculos*)).tw. (30700)
3. tuberculos*, pulmonary.tw. (152)
4. consumption*, pulmonary.tw. (28)
5. phthis*, pulmonary.tw. (7)
6. TUBERCULOSIS/ (98298)
7. koch* disease.tw. (7)
8. ((koch's or koch*) adj disease).tw. (7)
9. tuberculos*.tw. (164864)
10. disease, koch*.tw. (4)
11. MYCOBACTERIUM TUBERCULOSIS/ (42878)
12. (mycobacterium adj (tuberculosis h37rv or tuberculos*)).tw. (36573)
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 (216559)
14. integrated notification.tw. (1)
15. DELIVERY OF HEALTH CARE, INTEGRATED/ (9935)
16. delivery system*, integrated.tw. (6)
17. delivery of health care, integrated.tw. (1)
18. integrated delivery system*.tw. (706)
19. integrated health care systems.tw. (98)
20. system*, integrated delivery.tw. (1)
21. SYSTEMS INTEGRATION/ (8936)
22. integration*, systems.tw. (73)
23. systems integration*.tw. (314)
24. DISEASE NOTIFICATION/ (3936)
25. ((disease or exposure) adj notification*).tw. (188)
26. infectious disease reporting*.tw. (57)
27. notification*, disease.tw. (6)
28. notification*, exposure.tw. (1)
29. reporting*, infectious disease.tw. (0)
30. disease reporting*, infectious.tw. (0)
31. laborator* notification.tw. (25)
32. Clinical Laboratory Information Systems.tw. (13)
33. Complete* notification.tw. (7)
34. Combine* notification.tw. (3)
35. physician notification.tw. (76)
36. LABORATORIES, HOSPITAL/ (4441)
37. hospital laborator*.tw. (2137)
38. laborator*, hospital.tw. (67)
39. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 (23296)
40. 36 or 37 or 38 or 39 (29442)
41. 13 and 40 (811)
42. 13 and 39 (700)
43. limit 42 to (english and humans) (560)

**OTHER DATABASES**

| EBM Reviews - Cochrane Central Register of Controlled Trials | Same MeSH, keywords, limits used as per MEDLINE search |
| EBM Reviews - Cochrane database of systematic reviews |
| EBM Reviews - Health Technology Assessment |
| EBM Reviews – NHS Economic Evaluation Database |

**PubMeD**

Search (((((tuberculosis, pulmonary/[MeSH Terms]) OR tuberculosis/[MeSH Terms]) OR koch* disease>Title/Abstract)) OR tuberculosis*[Title/Abstract]) OR mycobacterium tuberculosis/[MeSH Terms]) AND ((((((((((delivery of health care, integrated/[MeSH Terms]) OR integrated>Title/Abstract)) OR integrated delivery system*[Title/Abstract]) OR integrated health care systems>Title/Abstract)) OR systems integration/[MeSH Terms]) OR integration*[Title/Abstract]) OR systems integration*[Title/Abstract]) OR disease notification/[MeSH Terms]) OR infectious disease reporting*[Title/Abstract]) OR notification*[Title/Abstract]) OR reporting*[Title/Abstract]) OR infectious disease>Title/Abstract)) OR disease reporting>Title/Abstract)) OR laborator*[notification>Title/Abstract]) OR population surveillance/[MeSH Terms]) OR combine* notification>Title/Abstract)) OR complete* notification>Title/Abstract))
8.2. Appendix 2

DESIGNATION OF LEVELS OF EVIDENCE

I  Evidence obtained from at least one properly designed randomized controlled trial.

II-I  Evidence obtained from well-designed controlled trials without randomization.

II-2  Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3  Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III  Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE:  US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)
### Evidence Table: Efficacy/Effectiveness

**Question**: Is integrated notification for tuberculosis effective in reducing missed cases of TB?

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study Type / Methodology</th>
<th>LE</th>
<th>Number of patients and patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up (if applicable)</th>
<th>Outcome measures/ Effect size</th>
<th>General comments</th>
</tr>
</thead>
</table>
**Aim**: To assess the sensitivity for culture-confirmed tuberculosis of a recently introduced national integrated infectious diseases surveillance system based on mandatory laboratory and physician notification.  
**Method**: Since 1994, the clinical microbiology laboratories of Finland have a mandatory duty to notify diagnostic findings to National Infectious Disease Register (NIDR). The data for NIDR are collected using one laboratory notification form and one physician notification form. To evaluate the coverage of NIDR, a comparison was made between all cases notified by laboratories as positive for *M. tuberculosis* by culture | II-3 | 1059 cases of culture confirmed tuberculosis were selected. | Integrated infectious diseases surveillance system | No comparator | - | 1059 culture-positive cases were found, the overall sensitivity of the NIDR was 93% (984/1059). The positive predictive value of a culture positive case in the NIDR to be a true culture-confirmed case was 99%. For the culture-confirmed cases in the NIDR, one or more physician notification forms had been submitted for 89%.  
**Authors conclusion**: A highly sensitive notification system for culture-positive tuberculosis can be achieved in an integrated national infectious disease surveillance system based on laboratory notification. |
**Evidence Table** : Efficacy/Effectiveness  
**Question** : Is integrated notification for tuberculosis effective in reducing missed cases of TB?

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
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<th>Outcome measures/Effect size</th>
<th>General comments</th>
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<tr>
<td>and reference dataset. The NIDR-derived set of cases included all the tuberculosis cases with a laboratory notification on a first specimen positive for <em>M. tuberculosis</em> by culture collected between 1 January 1995 and 31 December 1996. For reference dataset, 18 laboratories that had sent <em>M. tuberculosis</em> notification to the NIDR or licensed to perform clinical microbiology testing for <em>M. tuberculosis</em> contacted to provide data.</td>
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<th>Length of follow up (if applicable)</th>
<th>Outcome measures/ Effect size</th>
<th>General comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Bradley BL, Kerr KM, Leitch AG et al. Notification of tuberculosis: can the pathologist help? BMJ (Clinical research ed). 1988;297(6648):595.</td>
<td>Cross sectional study</td>
<td>II-3</td>
<td>82 sets of patient’s case notes were examined.</td>
<td>Laboratory notification and physician notification</td>
<td>No comparator</td>
<td></td>
<td>Eighty two sets of case notes and pathology reports were examined. Thirty four cases were coded A, 35 B, 5 C, and 8 D. Code A and B - Eleven (32.4%) of patients in whom acid fast bacilli were identified were not notified, and of those in whom acid fast bacilli were not seen but a firm pathological diagnosis was made, 15 (42.9%) were not notified. Code C and D – None of the 13 patients were notified. Almost 40% of patient (26/69) with a convincing combined clinical and pathological diagnosis of TB were not notified.</td>
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</table>
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<td>B) strongly suggestive or firm diagnosis of TB made on morphological grounds, though acid fast bacilli were not seen</td>
<td>LE</td>
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<td>C) cases in which firm diagnosis of inactive, calcified, or healed TB was made</td>
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<td></td>
<td>D) cases in which TB was mentioned in the differential diagnosis for confirmation or exclusion on clinical ground</td>
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### Evidence Table: Efficacy/Effectiveness

**Question:** Is integrated notification for tuberculosis effective in reducing missed cases of TB?

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<thead>
<tr>
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<th>Length of follow up (if applicable)</th>
<th>Outcome measures/ Effect size</th>
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<tr>
<td>3. Uthaivoravit W, Yanai H, Tappero JW et al. Impact of enhanced notification of tuberculosis laboratory results to minimise treatment delay, Chiang Rai Hospital, Northern Thailand. Int J Tuberc Lung Dis. 2003;7(1):46-5.</td>
<td>Cross sectional study</td>
<td>II-3</td>
<td>456 patients with acid-fast bacilli sputum smear-positive cases were studied.</td>
<td>Enhanced laboratory notification system</td>
<td>No comparator</td>
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<td>The number of unregistered TB patients fell from 44 cases in 1994 to none in 1999. The time elapsed from admission to treatment initiation decreased from a mean of 5.6 days in 1997 (n=162) to 3.1 days in 1999 (n= 136) (P&lt;0.001). This decrease was attributed to a reduction in time between laboratory diagnosis and treatment from 2.7 days in 1997 to 0.6 days in 1999 (P&lt;0.001). The laboratory policy change for Friday admissions resulted in a decrease in 3-day treatment delays. Time from the initiation of antituberculosis treatment to date of hospital discharge was as short as 3.3 days. <strong>Authors conclusion</strong> Prompt identification, isolation and treatment of TB patients occurred through an enhanced laboratory notification system. Such systems are inexpensive, improve TB care services and may reduce nosocomial transmission of M. tuberculosis.</td>
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<td>minutes of receipt of sputum specimens from hospital wards. Identification of an AFB smear positive sputum test result will be informed immediately to hospital ward staff.</td>
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<tr>
<td>4. Chen TC, Lin WR, Lu PL et al.</td>
<td>Pre and post intervention study</td>
<td>II-2</td>
<td>223 patients with positive AFB results were enrolled in this study.</td>
<td>Enhanced laboratory SOP – expedited AFB smear laboratory procedure and an automatic, real-time laboratory notification system by short message with mobile phones</td>
<td>No comparator</td>
<td></td>
<td>A total of 96 and 127 patients with AFB-positive TB were reported during the baseline and intervention phases, respectively. There were significant decreases in health care system delays (ie, laboratory delays: reception of sputum to reporting, ( P &lt; .001 ); response delays: reporting to patient isolation, ( P = .045 ); and interval from admission to patient isolation, ( P &lt; .001 )) during the intervention phase. Significantly fewer nurses were exposed to each patient with active pulmonary TB during the intervention phase (( P = .039 )). Authors conclusion implementation of expedited AFB smear laboratory procedures and an automatic, real-time laboratory mobile notification system significantly decreased delays in the diagnosis and isolation of patients with active TB.</td>
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- including positive AFB results and identification of *M. tuberculosis* complex from any specimen.
- Data for all patients with active pulmonary tuberculosis were analyzed during baseline (January 2004 to February 2005) and intervention (July 2005 to August 2006) phases.
- 4 time intervals during the baseline and intervention phases were recorded and compared to evaluate the effect of the intervention:
  1) Suspicion delay, number of days from reception to ordering sputum for an AFB smear and transporting the specimen to laboratory
  2) Laboratory delay, number of days from reception of specimen in the laboratory to reporting of results
  3) Treatment delay, number of days from return of positive AFB smear results to initiation of treatment
  4) Response delay,
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<td>number of days from return of positive AFB results to isolation of the patient.</td>
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