Alexandria Journal of Medicine (2012) **48**, 155–165

Alexandria University Faculty of Medicine

Alexandria Journal of Medicine

www.sciencedirect.com

ORIGINAL ARTICLE

Validation of evidence-based clinical practice guideline: Nursing intervention for newly diagnosed pulmonary tuberculosis patients at community setting

Amel Ibrahim Ahmed *, Sahar Mohamed Soliman, Lamiaa Amin Awad

Community Health Nursing Department, Faculty of Nursing-Mansoura University, Egypt

Received 23 June 2011; accepted 15 August 2011
Available online 31 January 2012

KEYWORDS

Pulmonary tuberculosis;
Nursing intervention;
Clinical guideline;
Chest out-patient clinics

Abstract *Background:* Tuberculosis is a major contributor to disease burden in the developing countries. It is considered the second fatal disease all over the world and the third most important public health problem in Egypt. The direct causes of increasing the burden of tuberculosis are the inconsistent and fragmented health services. The nursing interventions of tuberculosis in community settings require a system of recommendations that ensure the consistency of care.
Objective: The present study aimed at providing a valid evidence-based clinical guideline that assists nurses to intervene consistently to the newly diagnosed patient with pulmonary tuberculosis.
Methods: The intended guideline was developed according to the criteria of the Scottish Intercollegiate Guidelines Network (SIGN) and the American Academy of Neurology. This guideline was developed based on the need for assessments of the intended users (nurses) and the end-point beneficiaries (newly diagnosed patients with pulmonary tuberculosis). The development process of the guideline consisted of seven main steps. The SIGN appraisal tools were used for the critical appraisal phase of the retrieved studies, and the ''Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument'', that was used for appraising the internal validity of the developed guideline.

Abbreviations: SIGN, Scottish Intercollegiate Guidelines Network; AGREE, Appraisal of Guidelines for Research & Evaluation Instrument; CEBPG, Clinical Evidence-Based Practice Guideline

* Corresponding author. Present address: 3 Dr. Aly Ibrahim Ramez Street, Ramel Station, Alexandria, A.R.E., Egypt.
E-mail address: amahmed_1999@yahoo.com (A.I. Ahmed).

Peer review under responsibility of Alexandria University Faculty of Medicine.
doi:10.1016/j.ajme.2011.08.002

ELSEVIER **Production and hosting by Elsevier**

Results: The developed guideline included thirty recommendations categorized into four main themes, which are assessment, nursing diagnosis, nursing care plan and implementation of care plan. The overall assessment of the guideline revealed that two-thirds of academic appraisers strongly recommended the guideline to be used in practice and most of practitioner nurses and practitioner physicians recommended the guideline to be in practice.

Conclusion: The development of this guideline was based on the needs of the targeted users (nurses) and end-point beneficiaries (patients). It was strongly recommended by the appraisers to be used in the outpatients chest clinics. The study recommended that this developed guideline should be disseminated to the policy makers to be approved for application.

1. Introduction

Tuberculosis (TB) is among the top ten causes of death in the world. TB is an important public health problem in the Eastern Mediterranean Region of the World Health Organization. Every year, the disease kills 136,000 people and affects 630,000 in that region.[1]

Tuberculosis is a major contributor to the disease burden in developing countries.[2] It is considered the third most important public health problem in the Egypt.[3] The global plan to stop tuberculosis recommended the sustainability and accessibility of the standardized short-course chemotherapy for all cases of tuberculosis.[4] The directly observed treatment strategy (DOTS) is required to ensure treatment adherence and it helps to reinforce patients' motivation to continue treatment.[5]

The main reasons for the increase of the global burden of TB are the inadequate health services, improper management practices resulting in poor case detection, misdiagnosis, and maltreatment. Demographic changes in world population (increasing changing age structure), and the impact of increasing HIV add to TB burden.[6]

Treatment failure is a serious problem for tuberculosis control program in many countries. In Egypt, it accounts for 3–5% of treatment outcome of new smear positive cases.[7] Treatment failure may occur due to poor compliance of the patient, practitioner errors, and/or irregularity and loss to follow up the treatment. Bearing in minds that treatment failure may be due to the fragmentation and inconsistency of the provided services as well as inadequate provider-patient relations.[8,9]

Nurses play a crucial role in tuberculosis control program. The International Council of Nursing (ICN) believes that nurses are in a position to advocate for strong tuberculosis control programs and to implement the elements of DOTS.[10] Nowadays most tuberculosis treatment is carried out in the community settings. Treatment is best supervised by nurses in regular contact with the patient. The main principle of nursing intervention is the integrated organization of multiple activities to achieve specific outcomes for patients.[11] The nursing intervention requires a system of recommendations that improve performance and support the quality of health services. This system of recommendations can be obtained through developing evidence-based clinical practice guidelines that are defined as "systematically developed statements to assist practitioner and patient decision about appropriate health care for specific clinical circumstances".[12]

Clinical practice guidelines are important tools used by interdisciplinary health care providers to close gaps between current and optimal practices. In addition, guidelines are used to specify and standardize the processes of care for specific patient populations with defined health related conditions, as well as, to operate the implementation of evidence-based practice.[13] Guidelines result from a synthesis of available scientific knowledge as well as expert consensus. The valid evidence-based clinical practice guidelines should integrate the expertise of a multidisciplinary group of clinicians with the perspectives of consumers and the best available research evidence, to make recommendations that support clinical decision-making.[14]

By describing recommended courses of action, guidelines are intended to assist the decision of the practitioner and patient by regarding the most appropriate care process for a specific clinical condition. When used as an integral component of the quality improvement process, guidelines are helpful in the identification and analysis of practice variation and the measurable patient's outcomes. The periodic review, revision, and distribution of guidelines help to keep the practitioner's knowledge base up to date by dissemination of new advances in everyday practice.[15,16]

Regarding tuberculosis clinical guideline, it calls for the attention of the under recognized health problems of tuberculosis patients and discourages the ineffective interventions to reduce the morbidity and mortality rates.[17] The present study has been accomplished to provide a valid evidence-based clinical guideline that assists nurses to intervene consistently to the newly diagnosed patient with pulmonary tuberculosis at community setting.

2. Material and methods

The intended guideline was developed according to the criteria of the Scottish Intercollegiate Guidelines Network (SIGN) 2008 and the American Academy of Neurology 2004.[18,19]

2.1. Process of guideline development

2.1.1. Determination of needs and scope of the guideline

Pulmonary tuberculosis was chosen as a re-emerging disease in Egypt. Needs and scope of the present Evidence-Based Clinical Practice Guideline (EBCPG) were identified through assessing the current knowledge and performance of the intended users (nurses) and the end point beneficiaries (newly diagnosed patients with tuberculosis). Nurses and patients were involved also to fulfill the requirement of the evidence-based triad.[20]

The needs of the assessment were carried out during the period of four months at the six out-patients' chest clinics all over the Dakahlia governorate. Each out-patient's chest clinic was visited twice/ month with a total eight visits for each clinic. Three tools were developed by the researchers and tested for validity by carrying out a pilot study on five nurses and five patients. Tools were also revised by three community health

nursing experts. Results of the needs assessment were considered all over the development process of the guideline.

2.1.1.1. Assessing knowledge and performance of nurses. All nurses (n = 28) who are working in the six outpatients' chest clinics of Dakahlia governorate during the study, were involved in the study. The distribution of nurses was 15 nurses at El-Mansoura chest clinic, (four nurses) at El-Manzala chest clinic, (two nurses) at Belkas, (3 nurses) at Aga, (two nurses) Dekernes, and (two nurses) at Sherbin.

Knowledge assessment of nurses: A self administered knowledge questionnaire was developed and used to assess nurses' knowledge regarding the nature of tuberculosis, manifestations, and the role of nurses in managing newly diagnosed patients with pulmonary tuberculosis. The total score of knowledge was 47, which covers four items namely: the nature of the tuberculosis, 13 scores (definition of tuberculosis, causative agent, types of tuberculosis, modes of transmission, and manifestations), the treatment strategy 16 scores, (types of treatment, duration, side effect, and Directly Observed Treatment Strategy), and nursing role 18 scores. Open ended questions were used to avoid guessing. Self administered questionnaire sheets were distributed to nurses to assess their knowledge about the management of newly diagnosed patients with pulmonary tuberculosis.

Assessment of nurses' performance: Semi-structured interview sheet for the exploration of nurses' performance included open ended questions about the actual nursing intervention for newly diagnosed pulmonary tuberculosis patients. This sheet includes four main questions about initial patient's assessment, health education, follow-up activities, and documentation. Probing terms were used to obtain answers of the interview questions. Probing terms included demographic information, health history, and barriers of patient's adherence, contacts investigations, treatment side effect, and notification of missed doses, patient's satisfaction, and information confidentiality. An interview was carried out with each nurse for 20–30 min by obtaining information about their actual performance in managing newly diagnosed pulmonary tuberculosis patients.

2.1.1.2. Assessing the needs of newly diagnosed patients with tuberculosis. All newly diagnosed pulmonary patients with tuberculosis (n = 36) were included in the study. They were admitted to the mentioned chest clinics during four months. (*Newly diagnosed patient: A patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than four weeks*).[21]

Semi-structured patients' expectations interview sheet was used to identify the expectations of newly diagnosed patients with pulmonary tuberculosis regarding the role of nurse in the management of disease. This sheet included two questions about interpersonal relationship and the function role of nurses in tuberculosis management. Probing terms such as communication, assessment, treatment administration, and follow up were used to obtain answers of the interview questions. Interviews were carried out with patients throughout the eight visits of each clinic and each patient was interviewed for 10–15 min.

2.1.1.3. Guideline development group. A peer group of work includes three members as follows: three community health nursing specialist, two of them have additional experiences in epidemiology, environmental health, and evidence-based practice. The peer group is appropriate for the local use guideline.[22]

2.1.1.4. Stating clinical search questions. Fifteen clinical search questions were constructed by using the PICO (P = patient, I = intervention, C = comparison, O = outcome) (Box 1). [20]

Box 1 Clinical search questions.

(1) What are the assessment methods of newly diagnosed patient with pulmonary tuberculosis?
(2) What are the risk factors resulting in defaulting in patient with pulmonary tuberculosis?
(3) How do nurses diagnose health needs and problems in newly diagnosed patient with pulmonary tuberculosis?
(4) What are the principles of pulmonary tuberculosis treatment?
(5) What are the best measures to prevent pulmonary tuberculosis among contacts patient with pulmonary tuberculosis?
(6) What are the best measures to control pulmonary tuberculosis?
(7) What is the role of nurse in managing the newly diagnosed pulmonary tuberculosis?
(8) What are the components of educational program for patient with pulmonary tuberculosis and contacts?
(9) Does follow-up of newly diagnosed patient with pulmonary tuberculosis increase the adherence of treatment?
(10) What are the nutritional requirements of patient with pulmonary tuberculosis?
(11) What is the nursing role in implementing the DOTS strategy?
(12) How to increase the adherence of newly diagnosed patient with pulmonary tuberculosis to treatment?
(13) What are the types of nursing records that are used in chest out patients' clinics?
(14) What are the infection control measures to be followed to prevent spreading of tuberculosis infection?
(15) What is the ethical aspect of pulmonary tuberculosis management?

2.1.1.5. Searching for the evidence. A literature search was undertaken to identify potentially relevant evidence to develop the intended evidence-based guideline. The guideline development group reviewed a set of primary and secondary researches and evidence-based guidelines for tuberculosis management. Review of the literature was conducted from electronic bibliographic database. The review of literatures was conducted from 1990 up to 2008 and only English language was utilized during the search. The searched bibliographic database is illustrated in Box 2.

Box 2 Searched bibliographic database.

http://www.pubmed.gov	http://ovidsp.tx.ovid.com
Science direct: http://www.sciencedirect.com	Center for Review and Dissemination (CRD) at: www.york.ac.uk/ins/crd/
Wily Blackwell: http://onlinelibrary.wiley.com/	http://search.ebscohost.com/
WHO: www.who.net	CDC: www.cdc.gov
Scottish Intercollegiate Guidelines Network at: http://www.sign.ac.uk/	Cochrane Library, Database of Systematic Reviews: http://www.3.interscience.wiley.com/cgi-bin/mrwhome/106568753/Hom
National Institute for Health and Clinical Excellence (NICE) at: www.nice.org.uk	National Electronic Library for Health at: www.libararyies.nelh.nhs.uk/guidelinesfinder/
National Guideline Clearinghouse at: www.guideline.gov	

The search terms that were used for answering the clinical questions are:

- "Nursing role in tuberculosis management"
- "Assessment of patient with pulmonary tuberculosis "
- "DOTS strategy"
- "Adherence and compliance to pulmonary tuberculosis treatment"
- "Diagnoses of tuberculosis"
- "Health education and pulmonary tuberculosis"

The numbers of obtained documents were 324 studies, the multi-drug resistance and treatment failure studies were excluded. These documents included systematic reviews of randomized trials, cohort studies, cross sectional, case-control studies, expert opinion and guidelines management for newly diagnosed patient with pulmonary tuberculosis. Actually valid and used references were 59 references.

2.1.1.6. Evaluation of evidence and grading recommendations. The retrieved studies were appraised by two members of the development group according to the SIGN system.[18] The SIGN system included three main steps to evaluate evidence and grade the guideline recommendations, namely; study validity rating, determination level of evidence and finally the grade of recommendation.

First step: study validity rating

All primary studies and reviews addressing the relevant topic were appraised by using SIGN checklist that was appropriate to the study design, and then were individually rated for internal validity using the system that is shown in Box 3. [18]

Box 3 Rating of the internal validity description system for studies according to the Scottish Intercollegiate Guideline Network (SIGN) System.

Rating	Description
++	All or most of the criteria have been fulfilled
+	Some of the criteria have been fulfilled
−	Few or no criteria fulfilled

Second step: determination level of evidence:

The study design is assigned by numerical prefix using the system below (Box 4):

Box 4 Numerical prefix assigned to different study designs according to the Scottish Intercollegiate Guideline Network (SIGN) System.

Numerical prefix	Study designs
1	For systematic review or meta analysis or randomized control trials (RCTs)
2	For cohort and case control studies
3	For case report series
4	For expert opinion/logical argument/common sense

Then each study is assigned to a level of evidence by using the system below (Box 5):

Box 5 The level of evidence system according to the Scottish Intercollegiate Guideline Network (SIGN) System.

Level of evidence	Type of Evidence
1++	High quality meta analysis systematic reviews of randomized control trials with a very low risk of bias
1+	Well conducted meta-analysis systematic reviews or randomized control trials with a low risk of bias
1−	Meta-analysis, systematic reviews, or randomized control trials with a high risk of bias
2++	High quality systemic reviewers of case-control or cohort studies with a very low risk of bias and a high probability that the relationship is causal
2+	Well conducted case-control or cohort studies with a low risk of bias and a moderate probability that the relationship is causal
2−	Case-control or cohort studies with a high risk of bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g., case reports, case series
4	Expert opinion

Third step: grade of recommendation

The detailed results of each study were considered in the formulation of each guideline recommendation which was then graded using the following system (Box 6)

Box 6 Grading system of the guideline recommendations according to the Scottish Intercollegiate Guideline Network (SIGN) System.

Grade	Recommendation
A	At least one meta-analysis, systematic review, or RCT rated as 1++. And directly applicable to the target population, or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of result, or extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of result, or extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4, or extrapolated evidence from studies rated as 2+

2.1.1.7. Formulation of guideline drafts. A draft of the intended guideline including pathway of tuberculosis patient in outpatients' chest clinics algorithm was drawn up. The results of the needs of the assessment of the intended users of the guideline (nurses) and end-point beneficiaries (newly diagnosed patient with pulmonary tuberculosis) were considered during stating the guideline recommendation statements. The guideline development group met 16 times over a period of seven month. The guideline was redrafted three times before the final approved format.

2.1.1.8. Guideline revision and evaluation of internal validation. The developed guideline was revised by the ''Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument''.[23] The ''AGREE Instrument'' was adopted and used by the guideline developers to follow a structured and rigorous development methodology and as a self assessment tool to ensure that the guideline is sound.

According to the ''AGREE Instrument'' the number of appraisers to be ranged from 2 to 4 appraisers to ensure the appraisal reliability of the guideline. However; the appraisers group of this guideline, involved academic nursing staff members ($n = 3$) and academic medical staff members ($n = 3$). The academic staff members were specialists in one or more fields of community health, epidemiology, microbiology, and chest diseases. As well as practitioner nurses ($n = 6$) and practitioner physicians ($n = 7$) who are working in out-patient chest clinics were included as appraisers.

The ''AGREE Instrument'' consists of 23 key items organized in six domains. Each domain is intended to capture a separate dimension of the guideline quality as the following:

- Scope and purpose include three items that are concerned with the overall aim of the guideline, the specific clinical questions, and the target patient population.
- Stakeholder involvement includes four items that focus on the extent to which the guideline represents the views of its intended users.
- Rigor of development includes seven items related to the process used to gather and synthesize the evidence and methods to formulate the recommendations and to update them.
- Clarity and presentation include four items dealing with the language and format of the guideline.
- Applicability includes three items pertain to the likely organizational, behavioral and cost implications of applying the guideline.
- Editorial independence includes two items that are concerned with the independence of the recommendations and acknowledgment of possible conflict of interest from the guideline development group.

Each item is rated on a 4-point scale ranging from 4 'strongly agree' to 1 'strongly disagree', with two mid points: 3 'agree' and 2 'disagree'. The scale measures the extent to which an item has been fulfilled. A section for overall assessment is included at the end of the instrument. This contains a series of options 'strongly recommend', 'recommend (with provisos or alterations)', 'would not recommend' and 'unsure'. The overall assessment requires the appraiser to make a judgment as to the quality of the guideline, taking each of the appraisal criteria into account.

Calculating domain scores:

Domain scores can be calculated by the following formulas:

Maximum possible score
$= 4\,(\text{strongly agree}) \times (\text{number of domain's items}) \times (\text{number of appraisers})$

Minimum possible score
$= 1\,(\text{strongly disagree}) \times (\text{number of domain's items}) \times (\text{number of appraisers})$

The minimum and maximum possible dominos scores of the present guideline were calculated as in the following (Table 1):

Domain scores can be calculated by summing up all the scores of the individual items in a domain and by standardizing the total as a percentage of the maximum possible score for that domain.

[Obtained score − minimum possible score
÷ Maximum possible score − minimum possible score]
× 100.

A Pilot study was conducted on five patients and three nurses to test the validity and clarity of the developed tools number 1, 2 and 3. The developed tools were amended according to the pilot's study results.

2.2. Ethical considerations

- Communication and official approval were obtained from the directorates of each outpatient chest clinic.
- Informed written consents were obtained from nurses and patients to participate in the study.
- The obtained information is considered confidential and kept in closed cabinet for 5 years and accessed only by the research team.

2.3. Statistical analysis

Simple frequency tables and arithmetic means were calculated by SPSS package version 9.00 to illustrate the obtained data.

Table 1 Calculation of the minimum and maximum possible dominos scores of the present guideline according to the ''AGREE Instrument''.

Domains	Scores	Academic nursing staff ($n = 3$)	Academic medical staff ($n = 3$)	Practitioner nurses ($n = 6$)	Practitioner physicians ($n = 7$)
Scope and Purpose (three items)	Maximum	36	36	72	84
	Minimum	9	9	18	21
Stakeholder involvement (four items)	Maximum	48	48	96	112
	Minimum	12	12	24	28
Rigor of development (seven items)	Maximum	84	84	186	196
	Minimum	21	21	42	49
Clarity and presentation (four items)	Maximum	48	48	96	112
	Minimum	12	12	24	28
Applicability (three items)	Maximum	36	36	72	84
	Minimum	9	9	18	21
Editorial independence (two items)	Maximum	24	24	48	56
	Minimum	6	6	12	14

3. Results

Results consisted of three parts; firstly, the results of the needs assessment. Secondly, the guideline's content and recommendations' grading, and finally the guideline revision and evaluation of internal validation.

3.1. Part 1: Needs assessment of the intended users and end point beneficiaries

Table 2 shows that nurses have a good level of knowledge regarding the nature of pulmonary tuberculosis. The etiology, risk factors, and mode of transmission showed mean score of 4.2 ± 1.3. Their level of knowledge about the manifestations and treatment regimen of pulmonary tuberculosis was fair with mean score of 3.7 ± 0.9. On the other hand, their level of knowledge about treatment side effect and nursing role was poor with mean score of 2.6 ± 0.8 and 1.02 ± 0.8, respectively.

Regarding the self reported performance of nurses, Table 3 reveals that nurses perform in different manners throughout the treatment course of pulmonary tuberculosis, according to their personal competence and capabilities. Nurses reported that they do not perform most tasks of nursing role. Most of the nurses were obtaining demographic information, while 17 nurses (60.7%), were assessing the contact. However; follow-up of patients was done by 14 nurses (50.7%) either by obtaining sputum specimen for bacteriology or by observing the change in urine color. Only six nurses (21%) were providing health education about TB and notified the social workers if patients missed the appointments of medication. All nurses recommended that they need a guide to follow in providing nursing intervention to pulmonary tuberculosis patient. They mentioned also that there was no nursing contribution in the plan of tuberculosis management and there were no nursing guidelines or protocols available in the clinical settings.

Table 4 presents the expectations of newly diagnosed patients with pulmonary tuberculosis about nursing intervention. Patients recommended that the role of nurses must be unique and clear. Half of the interviewed patients mentioned the necessity for accurate time of receiving medication, followed by 44.4% who expect nurses to be a link between patient and physician. While, 33.3% of patients expected continuous follow-up from nurses and 22% expressed their needs for a respectful communication manner.

3.2. Part 2: guideline content and recommendations' grading

3.2.1. Assessment

On the basis of experts opinions' evidence (graded level 4)[3] and seven researches (graded level 2++),[24–30] it was concluded that social and environmental factors are considered to be risk factors of tuberculosis infection, as well as lifestyle parameters (smoking, hygiene and nutritional habits) (Recommendation number 1.1.1 Box 7). Furthermore, these evidences and other two level 4 guidelines[31,32] emphasized the importance of assessing these risk factors.

On the basis of one cohort study (graded level 2++)[30] and seven guidelines (graded level 4),[5,10,31–35] the importance of providing a base line data about the manifestation, vital signs, anthropometric measurements, and co-morbid conditions are recommended (Recommendation number 1.1.2 Box 7)

On the basis of four case control studies (graded level 2++)[27,36–38] and one standard of care,[32] in addition to one guideline (graded level 4),[35] they emphasized that knowledge

Table 2 Knowledge's scores of nurses regarding tuberculosis and nursing role.

Items	Total scores	Nurses' scores	Level of knowledge
Nature of the disease	6.00	4.2 ± 1.3	Good >65%
Manifestations	7.00	3.7 ± 0.9	Fair (50–<65%)
Treatment regimen	4.00	2.5 ± 1.1	Fair (50–<65%)
Treatment side effect	12.00	2.6 ± 0.8	Poor (<50%)
Nursing role in managing of tuberculosis patient	18.00	1.02 ± 0.8	Poor (<50%)

Table 3 Distribution of nurses according to the identified tasks performed them in managing newly diagnosed tuberculosis patients at out-patient chest clinics.

Task	Number 28	%
Obtain demographic information	28.00	100.00
Obtain vital signs and baseline weight	0.00	0.00
Obtain past and present health history	00.00	00.00
Identify the patients' knowledge and perception about TB	00.00	0.00
Identify barriers to adherence in taking TB medication	00.00	0.00
Assess the contact for tubercles infection	17.00	60.70
Monitoring and follow up by bacteriology test or change in urine color	14.00	50.7
Observe for side effects or medication reactions	0.00	00.00
Providing education about TB to health care providers	06.00	21.00
Notification system if pt missed appointments of medication	06.00	21.00
Assess patient satisfaction with the services or care	0.00	00.00
Monitor the patient medical records	0.00	00.00
Assure patient confidentiality	0.00	00.00

and believes of the patient regarding tuberculosis affect his compliance to treatment (Recommendation number 1.1.3 Box 7).

On the basis of one cohort study (graded level) 2++[39] and two guidelines (graded level 4),[31,33] nurse should monitor and follow up the conduction of diagnostic measures namely; chest X-ray, tuberculin skin test, and three sputum specimens test (Recommendation number 1.1.4 Box 7).

On the basis of one expert opinion[3] and four guidelines (graded level 4),[31,32,35,40] the contacts should be assessed for tuberculosis infection within maximum of 15 days (Recommendation number 1.2.1 Box 7).

3.2.2. Nursing diagnosis

On the basis of two guidelines (graded level 4),[10,34] the recognition of health needs and problems of patients is an important base for nursing interventions. Furthermore, clear understanding of patients' situation is a key for objective intervention (Recommendation number 2.1 Box 7).

On the basis of three guidelines (graded level 4),[34,35,40] it is recommended that contact assessment must be an evidence of active case finding (Recommendation number 2.2 Box 3).

3.2.3. Nursing care plan

On the basis of three guidelines (graded level 4)[10,32,34] defining treatment goals and expected outcomes at the beginning of treatment, reduce confusion and misunderstanding. The plan must be realistic and achievable during all stages of treatment (Recommendations number 3.1–3.8 Box 7).

3.2.4. Implementation of care plan

3.2.4.1. Treatment. Based on two systematic reviews (graded level 2++),[41,42] WHO guideline[4] and the National Tuberculosis Program (graded level 4),[34] promoting compliance should be through facilitating treatment access, choosing the most convenient time, place for direct observation treatment and providing other social and medical services (Recommendations number 4.1.1–4.1.4 Box 7).

3.2.4.2. Health education. According to one cohort study (graded level 2++) and three guidelines (graded level 4),[5,10,35] which revealed that health education is an important part of effective control program that has a good cure rate of tuberculosis. The health education should include patient, contacts and care providers. It must address all aspects of disease, treatment regimen, and side effect of medication, healthy behavior, and social relationship. Health education targeted the correction of patient's perception (Recommendations number 4.2.1–4.2.3 Box 7).

3.2.4.3. Follow-up and referral. On the basis of one cross sectional studies,[28] two cohort studies[27,39] (graded level 2++), and five guidelines (graded level 4),[10,31–33,35] they recommended that patient should be followed-up monthly for treatment adherence, medication side effect, and condition progress through sputum test. Also, a cohort study (graded level 2++)[26] revealed that uncontrolled blood sugar interferes the effect of anti-tuberculosis medication (Recommendations number 4.3.1 and 4.3.2 Box 7).

On the basis of two guidelines (graded level4)[34,42] and two systematic reviews (graded level ++2)[43,44] if the patient got disappointed in one visit, the health care worker should conduct a home visit to him for ensuring treatment continuity (Recommendations number 4.3.3 and 4.3.4 Box 7).

3.2.4.4. Documentation and reporting. On the basis of two guidelines (graded level 4)[32,34] which concluded that all patient information regarding progress, intervention, visit schedule, and obstacles should be recorded accurately and clearly in special formats and reported to the assigned health care providers. In addition to one systematic review (graded level 4),[45] emphasized the confidentiality of patient's information as important issue (Recommendations number 4.4.1–4.4.4 Box 7).

Table 4 Distribution of newly diagnosed tuberculosis patients ($n = 36$) according to their expectations about nursing intervention.

Items	Number	%
Accurate timing of medication	18	50
Nurse as link between patient and physician	16	44.4
Continuous follow-up	12	33.3
Proper communication	8	22

3.3. Part 3: guidelines revision and evaluation of internal validation

Tables 4 and 5 present the results of guidelines revision and evaluation of its internal validation according to domains' scores of the ''Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument''.[23] The over all scores of the first three domains (scope and purpose, stackholder involvement, and rigor of

Table 5 Appraisal scores (%) of the guideline according to ''Scottish Intercollegiate Guidelines Network (SIGN) System ''domains by different appraisers.

Agree instrument items	Scores% of domains				Overall score%
	Academic nurses	Academic physicians	Practitioner nurses	Practitioner physicians	
Scope and purpose	77.7	62.9	72.2	73.0	71.5
Stakeholder involvement	66.6	77.7	69.4	53.5	66.8
Rigor of development	76.2	70.1	73.0	66.6	71.5
Clarity and presentation	50.0	66.6	76.4	66.6	64.4
Applicability	67.3	65.3	68.5	61.9	65.8
Editorial independence	90.0	88.0	93.0	91.0	90.5

Table 6 Distribution of appraisers according to their overall assessment of the guideline.

Appraisers	Items			
	Strongly recommended for use in practice		Recommended for use in practice	
	Frequency	%	Frequency	%
Academic nursing staff number = 3	2	66.6	1	33.3
Academic medical staff number = 3	2	66.6	1	33.3
Practitioner nurses number = 6	5	83.3	1	16.6
Practitioner physicians number = 7	5	71.4	2	28.5
Total number of appraisers = 19	14	73.6	5	26.3

development) were (71.5%, 66.8% and 71.5%), respectively, while the score% for the clarity and presentation domain was 64.4%, the applicability domain's score% was 65.8% and the editorial independence's score% was 90.5% Table 5.

As regards to the overall assessment of the guideline, two-thirds of academic nursing and medical staff strongly recommended the guideline to be used in practice and the majority of practitioner nurses as well as three quadrants of practitioner

Box 7 Evidence linked recommendations.

Serial	Recommendation statements	Grading
1	Assessment	
1.1	Assessing patient health condition	
1.1.1	Obtain essential information about patient's socio-demographic data, surrounding environment and lifestyle	C
1.1.2	Assess the present and past health history	C
1.1.3	Obtain information about patient's knowledge and perception about tuberculosis	C
1.1.4	Ensures that patient complete the required diagnostic measures	B
1.2	Assessing patient's contacts health condition	
1.2.1	Assess the patient's contacts health condition	D
2	Nursing diagnosis	
2.1	Identify the patient's health needs and problems	D
2.2	Identify the contacts' health needs and problems	D
3	Nursing care plan	
3.1	Plan to coordinate the ongoing care and services of clinical visits for specimen collection	D
3.2	Plan to treatment regimen and visit schedule	D
3.3	Plan for identification of treatment obstacles	D
3.4	Plan for patient's motivation to increase adherence to anti-TB medication	D
3.5	Plan for patient's health education	D
3.6	Plan for health education of contacts	D
3.7	Plan to coordinate the ongoing care and services of referral and follow up	D
3.8	Plan for monitoring and evaluation of patient's progress	D
4	Implementation of care plan	
4.1	Treatment	
4.1.1	Implement the schedule of the prescribed treatment	B
4.1.2	Conduct daily visit at the first two months for observed treatment	D
4.1.3	Conduct weekly visit during the complementary four months to receive a day observed dose and take the dose for the rest of the week	D
4.1.4	The nurse should provide motivation and incentives to increase the treatment compliance	D
4.2	Health education	
4.2.1	Implement health educational program for patient	D
4.2.2	Implement health educational program for care provider	D
4.2.3	Implement health educational program for contacts	D
4.3	Follow up and referral	
4.3.1	Monitor the patient health condition monthly	B
4.3.2	Check blood sugar level for patient with co-morbid disease diabetes mellitus	C
4.3.3	Report the social workers about the patient who dropped out an appointment of treatment or follow up	D
4.3.4	Ensure that social workers conduct a home visit for the dropped out patient or conduct it by herself (according to policy)	C
4.4	Documentation and reporting	
4.4.1	Ensure that all patients' data is complete	D
4.4.2	Recording data of each visit and all procedures performed to the patient by using the appropriate format	D
4.4.3	Communicating the patient condition with other relevant health care providers	D
4.4.4	Information of patients and contacts should be considered confidential information	C

physicians recommended the guideline be used in practice (Table 6).

4. Discussion

To accomplish the development of the intended evidence-based clinical guideline, it was important to explore nurses' knowledge and practice in relation: to the management of pulmonary tuberculosis. It was also mandatory to define the views of patients regarding nursing role in their management.[46]

The nurses' level of knowledge and their performance and competence are very important issues to the success of tuberculosis treatment. The nurses' performance affects the patient's adherence to tuberculosis treatment regimen.[47]

The present study revealed a lack of knowledge among nurses regarding the management of pulmonary tuberculosis. Furthermore, most of those nurses did not perform several tasks that are considered the core of nursing role in managing pulmonary tuberculosis. Several studies are in agreement with the present study, as they reported a lack of knowledge regarding the management of pulmonary tuberculosis.[48–50] The involvement of clinical practitioner stakeholders and targeted patients in developing evidence-based guideline enhances their acceptance and application of the guideline's recommendations.[51,52] However; the evidence-based guidelines must consider patients' expectations from the health care system and their preferences regarding the provided interventions.[53]

The present study revealed that patients' expectations for nursing interventions in relation to pulmonary tuberculosis included continuing of care and follow up, adjusting the medication time, as well as linking the contacts with physician. These findings were confirmed by several studies that indicate that patients perceived nursing interventions to facilitate contacting with doctors, follow-up the rest of the treatment, and adjusting medication time.[54–56]

There are many guidelines and standards which[5,10,24,31,32,35,40] provided strong foundation for the present work, but not all of them have an explicit outline on how evidence was identified, interpreted or integrated into the recommendations. The tuberculosis treatment guideline in 2003 published by the Centers for Disease Control and Prevention (CDC) developed its recommendations according to the ''Infectious Diseases Society of America Public Health Service Rating System''. This guideline was compared with guidelines for other groups and it was reviewed by external and internal peer reviewers. CDC guideline 2003 strongly recommended that patient-centered care can be the initial management strategy. This strategy should always include an adherence plan that emphasizes directly observed therapy (DOT).[4] Each patient's management plan should be individualized to incorporate measures that facilitate adherence to the drug regimen. Such measures may include social services support, and coordination of tuberculosis services with those of other providers, this is in agreement with the present guideline's recommendations.

The investigation of contacts of persons with infectious tuberculosis guideline published in 2005 by CDC, also provided supportive foundation to the existing recommendations. However, this document did not provide sufficient methodology describing how the guideline was developed, especially for the searches of electronic database and rating scheme for the strength of evidence, while the working group was well defined. Although the guideline of CDC 2005 mentioned that nurses are one of their intended users, it did not directly mention what they should do, while the present guideline identified the role of nurse clearly and directly.[40]

Other guidelines, namely: WHO 2003, ICN 2004, Federal Bureau of Prisons 2004, NTP 2005, and Tuberculosis Coalition for Technical Assistance 2006, strongly support the recommendations of the present guideline, but none of them stated clear, direct, or applicable statements for nursing interventions.[5,10,31,32,34]

The present guideline demonstrates several strength points. Firstly, it elicits patients' perspectives and considered the actual nursing performance and their level of knowledge during the guideline development process. Secondly, the guideline was evaluated by the intended users (nurses) and their work partners (physicians) who are working in outpatients' chest clinics. Most of them mentioned that the guideline is effective, recommendation stated it clearly, and could be easily implemented by nurses and they are in need for such guideline. Finally, the guideline is attached with supportive tools which will facilitate the nursing interventions. In addition, the guideline formulated within the scope of the WHO guideline for National Program, which will increase its applicability process in the future.[40]

The present guideline is based on different types of studies, which are cohort studies, systematic review, case-control, cross sectional studies, and clinical guidelines. The development of this guideline followed certain process and criteria of guideline development.[14,57–59] All of these references almost have the same criteria and process for a successful guideline development which include proper selection of guideline topic, form of multidisciplinary group of work, developing clinical questions, comprehensively review of literature, rating of articles, and summarizing finding. Moreover, the successful guideline should include writting supported practice recommendations, reviewed and critically appraised by a group of expert reviewers and intended users by using a standardized tool. Finally, the guideline should be distributed to practitioners of its field specialty. Also, this guideline met the appraisal criteria of the ''Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument'' that includes a clear presentation of guideline's scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial independence.[23]

In further phase, the feedback should be obtained from members and practitioners regarding the guideline's effectiveness, and then the degree of guideline adherence and its clinical impact should be evaluated. This further phase is strongly recommended for the present guideline to be implemented in the future.

5. Conclusion and recommendations

In conclusion, the developed guideline is based on the needs of the intended users (nurses) and end points beneficiaries (patients). Appraisers strongly recommended using this guideline in the out-patients chest clinics.

The study recommended that the developed guideline should be disseminated to the policy makers, to be applied in the outpatients' chest clinics and to be evaluated for its achieved outcomes. Furthermore, supporting training programs would be established for nurses to fulfill the requirements of the guideline implementation and the expectation of patients. These training programs will focus on the implementation plan of the guideline, nursing role in managing pulmonary tuberculosis patient, principles of documentation and communication skills.

References

1. World Health Organization. Global tuberculosis control report 2008: World health statistics fact sheet 2007.
2. World Health Organization. Global tuberculosis control: surveillance, planning, financing. Geneva WHO. Document WHO/CDS/TB/2003; p. 316.
3. Philip C, Madhukar P. Tuberculosis, vulnerability, and access to quality care. *JAMA* 2005;**293**(22):2790–3.
4. World Health Organization. An expanded DOTS framework for effective tuberculosis control. Geneva: WHO; 2002.
5. World Health Organization, Treatment of tuberculosis: guidelines for National Programmes. 3rd ed. Geneva; 2003.
6. Pratt RJ, Grange JM, Williams VG. *Tuberculosis, a foundation for nursing and health care practice*. London: Hodder Arnold; 2005.
7. Al Moamary, Black W, Bessuille E, Elwood K, Vedal S. The significance of the persistent presence of acid-fast bacilli in sputum smears in pulmonary tuberculosis. *Chest* 1999;**116**(3):726–31.
8. Kim SY. Drug-resistant pulmonary tuberculosis in a tertiary referral hospital in Korea. *Korean J Int Med* 1999;**14**(1):27–31.
9. Zwarenstein M, Schoeman JH, Vundule C, Lombard CJ, Tatley M. Randomised controlled trial supervised and directly observed treatment of tuberculosis. *Lancet* 1998;**352**:1340–3.
10. International Council of Nurses. Tuberculosis Guideline for Nurse in the care and control of tuberculosis and Multi-drug resistant tuberculosis. Geneva: ICN; 2004
11. Robert JP, John MG, Williams GV. *Tuberculosis: a foundation for nursing and healthcare practice*. 1st ed. UK: Oxford University Press Inc.; 2005.
12. Lohr KN, editor. *Clinical practice guidelines: directions for new program*. Washington, DC: National Academy Press; 1990.
13. Mead P. Clinical guidelines: promoting clinical effectiveness or a professional minefield. *J Adv Nurs* 2000;**31**:110–6.
14. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay L, Vale L, Whitty P, Eccles MP, Matowe L, Shirran L, et al.. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 2004;**8**(iii–iv):1–72.
15. Brackman RZ, Harris JS. Occupational medicine practice guideline. *Occup Med* 1998;**13**:679–91.
16. Richman R, Lancaster RD. The clinical guideline process within a managed care organization. *Int J Technol Assess Health Care* 2000;**16**:1061–76.
17. Woolf HS, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guideline: potential benefits, limitations and harms of clinical guidelines. *BMJ* 1999;**318**:527–30.
18. Scottish Intercollegiate Guideline Network (SIGN) System. <www.sign.ac.uk>; 2008.
19. Edlund W, Gronseth G, So Y, Franklin G. *Clinical practice guideline process manual*. American Academy of Neurology; 2004.
20. Glasziou P, Del Mar C, Salisbury J. *Evidence-based practice workbook: bridging the gap between health care research and practice*. 2nd ed. Oxford, UK: Blackwell Publishing Ltd.; 2007.
21. Tuberculosis Manual of Prevention and Control. 1st ed. Port-of-Spain Trinidad: The Caribbean Epidemiology Centre (CAREC), P.O. Box 164; 1997.
22. Wil JM, Sanden D, Mettes GD, Plasschaert MJA, Grol PTMR, Verdonschot HE. Development of clinical practice guidelines: evaluation of 2 methods. *J Can Dent Assoc* 2004;**70**(5), 301-1h.
23. The AGREE Collaboration. Appraisal of Guidelines for Research and Evaluation. AGREE Instrument. <http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf>; 2001.
24. Common wealth of Massachusetts Regulations, Standards for Management of Tuberculosis Outside Hospitals. Massachusetts Tuberculosis Nursing Case Management Protocols. Tuberculosis Elimination Achieved through Management October 2001, USA.
25. Hedal E, Dahle UR, Sandven P, Caugant DA, Brattas N, Waaler HT. Risk factors for recent transmission of *Mycobacterium tuberculosis*. *Eur Respir J* 2003;**22**:637–42.
26. Fredrick AD, Kaona MT, Seter S, Leganji S. An assessment of factors contributing to treatment adherence and knowledge of TB transmission among patient on TB treatment. *BMC Public Health* 2004;**4**:68.
27. Lobato NM, Reves RR, Jasmer MR, Grabau CJ, Bock NN, Shang N. Adverse events and treatment completion for latent tuberculosis in Jail Inmates and homeless persons. *Chest* 2005;**127**:1296–303.
28. Cuadras PM, Gutierrez JMP, Sanmartin JLL, Farre MR. Tuberculosis control in the central health region of Catalonia during the period 1986–2000. *Arch Bronconeumal* 2003;**39**(455):63.
29. Morsy AM, Zaher HH, Hassan MH, Shouman A. Predictors of treatment failure among tuberculosis patients under DOTS strategy in Egypt. *East Mediterr Health J* 2003;**9**(4):689–701.
30. Wobeser LW, Yuan L, Naus M, Corey P, Heywood EJ, Holness DL. Expending the epidemiologic profile: risk factors for active tuberculosis in people immigrating to Ontario. *CMAJ* 2000;**163**(7):823–8.
31. Federal Bureau of Prisons. Clinical Practice Guideline: Management of tuberculosis, Bureau. <http://www.bop.gov/news/medresources.jsp>; 2004.
32. Tuberculosis Coalition for Technical Assistance (TBCTA). International Standards for tuberculosis care: Diagnosis, Treatment and Public Health. <http://www.nationaltbcenter/international>; 2006.
33. Neff MAT. CDC and IDSA update recommendation on the treatment of tuberculosis. Am Fam Physician. Treatment of tuberculosis. *MMWR Recomm Rep* 2003;**52**(RR-11):1–77.
34. Ministry of Health and Population, Egypt. National Tuberculosis Program Manual. Cairo: Ministry of Health and Population; 2005.
35. National Institute for Health and clinical Excellence. Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control. Clinical Guideline 33, developed by the National Collaborating Center for Chronic Conditions; 2006.
36. Agboatwalla M, Kazi GN, Shah SK, Tariq M. Gender perspectives on knowledge and practices regarding tuberculosis in urban and rural areas in Pakistan. *East Mediterr Health J* 2003;**9**(4):732–40.
37. Kamel MI, Rashed S, Foda N, Mohie A, Loutfy M. Gender differences in health care utilization and outcome of respiratory tuberculosis in Alexandria. *East Mediterr Health J* 2003;**9**(4):741–56.
38. Bashour H, Mamaree F. Gender differences and tuberculosis in the Syrian Arab Republic: patients' attitudes, compliance and outcomes. *East Mediterr Health J* 2003;**9**(4):757–68.
39. Shukla JS, Warren KD, Woeltje FK, Gruber AC, Fraser JV. Factors associated with the treatment of health-care workers at a Midwestern Teaching Hospital. *Chest* 2002;**122**:1609–14.
40. Centers for Disease Control and Prevention (CDC). Guideline for the investigation of contacts of persons with infectious tuberculosis. Recommendations from the National Tuberculosis Control-

lers Association and CDC. MMW Recomm Rep 2005;54 (RR-15):1–47.
41. Volmink J, Garner P. Directly observed therapy for treating tuberculosis. *Cochrane Database Syst Rev* 2006;**19**(2):CD003343, <http://www.ncbi.nlm.nih.gov/pubmed/16625579>.
42. Brewer FT, Heymann SJ. To control and beyond: moving towards eliminating the global tuberculosis threat. *J Epidemiol Community Health* 2004;**58**:822–5.
43. Curran ET, Huffman PN, Pratt RJ. Tuberculosis and infection: a review of the evidence. *Br J Infect Control* 2006;**7**(2):18–23.
44. Mohan A, Nassir H, Niazi A. Does routine home visiting improve the return rate and outcome of DOTS patients who delay treatment? *East Mediterr Health J* 2003;**9**(4):702–8.
45. Verma G, Upshur EG R, Rea E, Benat RS. Critical reflections on evidence, ethics and effectiveness in the management of tuberculosis: public health and global perspective. *BMC Med Ethics* 2004;**5**:2–10.
46. Hyde SP, Falls K, Morris AJ, Schoenwald KS. *Turning knowledge into practice a manual for behavioral health administrators and practitioners about understanding and implementing evidence-based practices*. The American College of Mental Health Administration (ACMHA); 2003, www.tacinc.org or <http://www.acmha.org>.
47. Dick J, Lewin S, Rose E, Zwarenstein M, Walt H. Changing professional practice in tuberculosis care: an educational intervention. *J Adv Nurs* 2004;**48**(5):434–42.
48. Carusa R. Tuberculosis elimination and control: the role of primary care providers. Public Health Update; 2003.
49. Leonor E, Maciel N, Carmen M, Celia R, Zeitoune G, Ferreira I, Fregona G, Dietze R. Prevalence and incidence of mycobacterium tuberculosis infection in nursing students in Vitoria, EspiritoSanto. *Rev Soc Bras Med Trop* 2005;**38**(6):469–72.
50. US Agency for International Development. Expanded Response to Tuberculosis Updated. <http://pdf.usaid.gov/pdf_docs/PDACM409.pdf>; 2009.
51. The Iowa PIC Project. Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services Evidence-Based Practices: An Implementation Guide for Community-Based Substance Abuse Treatment Agencies; 2003.
52. McKinlay E, McLeod D, Dowell A, Marshall C. Clinical practice guidelines' development and use in New Zealand: an evolving process. *NZ Med J* 2004;**117**:1199.
53. Sofaer S, Firminger K. Patient perceptions of the quality of health services. *Annu Rev Public Health* 2005;**26**:513–59.
54. Fortin M, Hudon C, Gallagher F, Ntetu LA, Maltais D, Soubhi H. Nurses joining family doctors in primary care practices: perceptions of patients with multimorbidity. *BMC Fam Pract* 2010;**11**:84, <http://www.biomedcentral.com/1471-2296/11/84>.
55. Mitton C, O'Neil D, Simpson L, Hoppins Y, Harcus S. Nurse-physician collaborative partnership: a rural model for the chronically ill. *Can J Rural Med* 2007;**12**:208–16.
56. Taylor KI, Oberle KM, Crutcher RA, Norton PG. Promoting health in type 2 diabetes: nurse-physician collaboration in primary care. *Biol Res Nurs* 2005;**6**:207–15.
57. Shekelle GP, Woolf HS, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. *BMJ* 1999;**318**:593–6.
58. Richard N, Shekelle PS, Overhage M, Slutsky J, Grimshaw J, Deshpande MA. Standardized reporting of clinical practice guidelines: a proposal from the conference on guideline standardization. *Annu Int Med* 2003;**139**(6):493–500.
59. Eccles M, Clapp Z, Grimshaw J, Higgins PCA, Purves BI, Russell I. Developing valid guidelines: methodological and procedural issues from the North of England evidence based guideline project. *Qual Health Care* 1996;**5**:44–50.