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TOOL FOR QUALITY CONTROL OF TUBERCULOSIS SPUTUM SMEAR EXAMINATION IN PERIPHERAL LABORATORIES.

Key words : tuberculosis, tool, sputum smear examination, quality control, laboratory

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บทคัดย่อ

สถานการณ์ : ห้องปฏิบัติการเวชศาสตร์ชันสูตรในโรงพยาบาลชุมชนและในศูนย์วัณโรคเขต จังหวัดขอนแก่น ประเทศไทย

วัตถุประสงค์ : เพื่อพัฒนาเครื่องมือสำหรับการควบคุมคุณภาพการตรวจเสมหะเพื่อหาเชื้อวัณโรคในห้องปฏิบัติการเวชศาสตร์ชันสูตรส่วนท้องถิ่น

วิธีการ : ใช้วิธีการของการวิจัยระบบสาธารณสุข (Health systems research) เริ่มต้นด้วยการวิจัยเพื่อวิเคราะห์ระบบที่เป็นอยู่ในขณะนั้น แล้วออกแบบเครื่องมือ และตามด้วยการวิเคราะห์การใช้เครื่องมือในระบบปกติของการควบคุมโรค

ผล : ได้ระบบของการควบคุมคุณภาพของห้องปฏิบัติการเวชศาสตร์ชันสูตร ซึ่งประกอบด้วยการตรวจซ้ำกลุ่มตัวอย่างของสไลด์ โดยใช้วิธีการสุ่มตัวอย่างแบบ Lot quality assurance sampling และมีการประเมินตัวชี้วัด 2 ประการ ได้แก่ สัดส่วนของสไลด์ที่เตรียมไม่ดี และสัดส่วนของสไลด์ที่อ่านผลไม่ถูกต้อง อนึ่งมีการพรรณนาปัญหาอุปสรรคของการใช้เครื่องมือเอาไว้ด้วย

สรุป : เครื่องมือสำหรับควบคุมคุณภาพการตรวจเสมหะเพื่อหาเชื้อวัณโรคของห้องปฏิบัติการเวชศาสตร์ชันสูตรส่วนท้องถิ่น ได้ถูกพัฒนาขึ้นมาและมีการทดลองใช้และพบว่าเป็นประโยชน์ในการปรับปรุงคุณภาพของห้องปฏิบัติการเวชศาสตร์วันสูตรส่วนท้องถิ่น ในจังหวัดขอนแก่น ประเทศไทย

Abstract:

Setting: District hospital laboratories and a reference Zonal Tuberculosis Control Centre Laboratory in Khon Kaen Province, Thailand.

Objective: To develop a peripheral laboratory quality control tool of tuberculosis sputum smear examination

Methods: Health systems research. First exploratory research and tool design, later analysis of tool application in the routine control programme.

Results: A system of laboratory quality control consisting of re-examination of a sample of slides, using the lot quality assurance sampling technique was created. Two indicators are measured: the proportion poorly prepared slides and the proportion incorrectly read slides. Difficulties in applying the tool are described.

Conclusion: A tool for quality control of tuberculosis sputum smear examination in peripheral laboratories has been developed and tested, and found useful to improve the quality of peripheral laboratories in Khon Kaen, Thailand.

Key words : tuberculosis, tool, sputum smear examination, quality control, laboratory

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INTRODUCTION

The microscopic examination of sputum smears is an important step in the diagnosis of tuberculosis patients (1,2,3,4,5). Most tuberculosis control programmes in developing countries have a network of peripheral laboratories where sputum smears are examined by local laboratory technicians. A system of quality control of these peripheral laboratories needs to be in operation to ensure their reliability (3).

A quality control system can consist of regularly testing the laboratory technicians with already prepared slides (4,6). Such test is directed only to reading (and staining) capability (3,7). It is, however, advisable to also check the technique of sputum collection, smearing and staining under working conditions because poorly prepared slides cannot be examined well and can give rise to false results (8). A quality control tool that includes slide preparation quality and slide reading has been developed by the MURLEP Project (9) and is described below.

The MURLEP project is a multidisciplinary health systems research project carried out by university researchers in co-operation with health service staff in Khon Kaen province, Thailand, aiming at the development of tools for tuberculosis control programme managers to easily assess the quality of the programme and to identify appropriate interventions to improve performance.

METHODS

In Khon Kaen province there are 19 district hospitals, each with a laboratory. The laboratory of the Zonal Tuberculosis Control Centre (TBZC) serves as the reference laboratory. After exploration of the methods and conditions in some district hospital laboratories (DHL), the quality control method was designed and tested out in 3 DHLs. After several revisions the tool was applied by supervisors during their routine supervision visits to 13 district hospitals while a researcher observed the application. Feasibility and ease of use were discussed with all staff involved and the tool adapted to its present format.

RESULTS

Format and description of the tool

The system of quality control consists of the following parts:

1 The supervisor provides the peripheral laboratories with slide boxes and instructed to keep the positive and negative slides of the last three months separately.

2 The supervisor during the supervision visit checks these slides for completeness by counting the slide results in the laboratory register and comparing this number with the number of slides kept.

3 The supervisor randomly selects , from the boxes, 11 positive and 11 negative slides from the lot kept by the laboratory technicians.

4 The supervisor fills out the two worksheets (see figure 1). He enters on the worksheet for the reference laboratory only the identification of the 22 slides (positive and negative slides mixed) , but on the peripheral laboratory form also the slide reading results.

5 The supervisor brings the slides together with the reference laboratory form to the reference laboratory, where the laboratory technician assesses the slides for quality of preparation and reading and completes the form.

6 The supervisor fills out the peripheral laboratory results and completes the column on comparison of reading. If 0 or 1 slide is poorly prepared or incorrectly read he concludes, at the bottom of the form, that performance is acceptable. Otherwise he concludes that performance is not acceptable. (For explanation of these criteria see the section "discussion".)

7 During the next visit to the health unit he discusses the results with the laboratory technicians and agrees on solutions for improvement. (E.g. to refresh the stain regularly, to improve smearing technique, to take a short refresher course at the reference laboratory.)

Experience from the application of the system

Three problems during the application could have introduced a bias:

* Did the laboratory technicians keep all the slides?

Four of the 13 peripheral laboratories had not kept slides at all because of communication problems. Four had kept few slides because they had heard the instruction late. Five had kept all slides. No intentional selection of slides seemed to be made by the laboratory technician.

* Was the sampling of the slides done randomly?

In 3 laboratories all slides had to be sampled because only few were kept. The supervisor had no problems in making a random selection.

* Was the reference laboratory technician blinded to the peripheral laboratory results?

No problems in the blinding were discovered.

The supervisors stated that the application of the tool itself was not difficult. The reference laboratory technician was enthusiastic and wanted to continue the system in the routine programme.

DISCUSSION

We decided that two indicators for the quality of peripheral laboratory needed to be measured: the proportion of poorly prepared slides and the proportion of incorrectly read slides. The reason for the latter is rather obvious, the reason for the first was shown by the earlier study (8): poorly prepared slides can cause false results but because the reference laboratory technician cannot read these slides well either, no higher disagreement was found in this group of slides. So the proportion incorrectly read slides alone does not sufficiently indicate peripheral laboratory quality. In consultation with the health service managers we decided that performance

is acceptable when both proportions were equal or less than 20%. If performance becomes better, a stricter level can be adopted.

The second decision we made was to use the method of lot quality assurance sampling which has been advocated by the World Health Organisation (10) and also by several authors (11,12,13,14,15). In this method a sample of slides is taken out of a bigger lot and the whole lot is rejected if more than a certain number of the sampled slides appears to be below standard. The method is based on 95% confidence intervals around a proportion such that the higher confidence level is within the pre-set maximum. Without understanding this background the method is still easy to carry out by the supervisors.

In most laboratories more than 200 slides are kept in 3 months time. If in 22 slides, that are sampled from this lot, 0-1 slide is poorly prepared or if 0-1 slide is incorrectly read, the lot can be accepted. The proportion 1/22 (4.5%) of poorly prepared or read slides has a 95% confidence interval (CI) from 0% to 20%, just within the pre-set acceptable level of performance. If the lot of slides is less than 200 the 95% CI is even narrower.

A third decision we made concerned the sampling of positive and negative slides. Slide results are graded 'negative' (no AFB seen in 100 oil immersion fields), doubtful, +1, +2 and +3 according to the number of AFB seen per field. To make comparison easy we divided the slides in 'negative' and 'positive' slides only. Doubtful slides are excluded. Under routine conditions in the DHL there usually are 10 to 20 times as many negative than positive slides. A positive sputum slide usually means that the patient will be treated for tuberculosis. Since a false positive slide result has therefore serious implications (16,17), we felt that these slides need extra attention by the reference laboratory. We decided to oversample the positive slides and to take 11 positive and 11 negative slides. If there were less than 11 positive slides kept by the laboratory technician, negative slides took their places.

It has been advocated to select the sample of slides from the treatment register (3). We disagree with this method because it excludes the largest group of slides, namely from tuberculosis suspects. Therefore a selection should be made of all slides taken.

Not all slides were kept by the laboratory technicians, mainly because of communication problems. If these are solved they still may forget to keep slides or may dispose the poorly prepared ones. It is therefore important that the supervisor checks the lot of slides for completeness, as is indicated in the instruction.

To start a new system always has some difficulties in the beginning. Good preparation is necessary in which all parties involved agree to the new system. In Khon Kaen province too many other duties and an outbreak of dengue haemorrhagic fever hampered good preparation by the supervisors. It is expected that with some time the system will run well.

Motivation to use the system well is increased when the heads of the health facilities and the tuberculosis programme manager agree with the system and ask for the results.

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Figure 1

Peripheral laboratory / Reference laboratory (delete one)

TUBERCULOSIS CONTROL

WORKSHEET FOR TUBERCULOSIS LABORATORY QUALITY CONTROL WITH THE METHOD OF SPUTUM SMEAR RE-EXAMINATION
(instructions on reverse side)

District Hospital: ..... Date of Report: __ / __ / __
Supervisors: .....
Reference laboratory technician: ..... Date of re-examination: __ / __ / __
Number of slides examined in the last 3 months: ___
Number of slides kept in the last 3 months: ___ ; pos.slides ___ ; neg. slides ___

Peripheral slide no. from TB lab. register	Date of slide staining	Reference laboratory assessment					Periph. laborat. reading + / -	Comparison of reading result	
		GOOD: sputum and smearing and staining	POOR preparation of slides			reading result + / -		correct	not correct
			sputum	smearing	staining				

Conclusion on performance:
1. The proportion of poorly prepared slides ( ) is acceptable ( ) needs improvement
2. The proportion of not correctly read slides ( ) is acceptable ( ) needs improvement

Codes for columns 'Reference laboratory assessment':
1.sputum: G: good sputum S: saliva
2.smearing G: good smearing TN: too thin TK: too thick NE: not egally O: other
3.staining G: good staining R: red background C: crystalization O:other
General comments from Reference laboratory technician:

_____

_____