



醫學實驗室品質指標 調和

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台灣醫療品質指標計畫(Taiwan Quality Indicator Project, TQIP)

- 早期醫療品質指標資料未經整合，醫療訊息無法共享，財團法人醫院評鑑暨醫療品質策進會利用美國馬里蘭醫療品質指標計畫(MQIP)系統建立醫療品質資料庫。
- 幫助醫院跳過指標定義和軟體設計的階段，直接進入指標資料收集、解讀的過程。**
- 客觀與嚴謹的收集資料將品質量化，以統計資料作為品質計畫的基礎，提供國內醫療院所可進一步**應用的資料與資訊**，達持續改善品質。


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台灣醫療照護品質指標系列

- 2000年:衛生署委託台灣醫務管理學會建構台灣醫療照護品質指標系列(Taiwan Healthcare Indicator Series, THIS)以發展本土之醫療品質指標為目標，參加醫院由近40多家至今已達175家。
- 陳琬雯2010: THIS資料庫符合適用性，希望未來能持續作為各醫療院所發掘改善有效用的工具，進而可幫助提報醫院提高病患照護品質。
- 蘇光烈2012: (1)以加入THIS前後比較，在加入THIS後第3年，其經營效率明顯變差。(2)各權屬別醫院在加入THIS之後，效率平均值均較加入THIS前為低，在加入第2年有明顯差異。(3)加入品質變數能有效提升經營效率。台灣醫療照護品質指標系列實施成效之探討

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醫學實驗室品質指標?

- 99年度品質指標調查統計結果-醫事檢驗學會
 - 急診生化30分鐘時效、急診血液30分鐘時效
 - 生化檢體退收率、血液檢體退收率
 - 報告更改率、危險值成功通報率、血瓶污染率*

訂定依據	家數	訂定依據	家數
同儕經驗	75	自己決定	41
參考文獻	57	醫師建議	23
配合院方政策	69	其他	4

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指標是工具

- 指標數據是間接測量，不直接反映品質
- 指標之間可相互應用及檢視
- 數字的本身並不提供價值的判斷
- 指標的功能在於促成行為的改變
- 指標的最終意義不在數值大小，而在於如何運用增進品質的提昇

醫療品質指標的應用/亞洲大學/楊漢淙/2009.05.30

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TQIP資料收集常見問題

1. 指標太多，費時費力收集數據，又未電腦化，人工作業導致資料漏報。
2. 承辦資料收集人員經常更換，經驗不足。
3. 指標收案人員對指標收集定義不了解。
4. 指標收集對象單位人員配合度不佳。
5. 未將指標收案流程制定標準作業程序。
6. 紀錄記載不夠詳實，影響判定。
7. 資料的產出不夠迅速，不符合資訊上的需求。
8. 需要的資料未儲存，或從未存在。

醫療品質指標的應用/亞洲大學/楊漢淙/2009.05.30

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International Federation of Clinical Chemistry and Laboratory Medicine

Leading the fields of Clinical Chemistry and Laboratory Medicine worldwide

IFCC - Education and Management Division

IFCC - Education and Management Division Working Group: Laboratory Errors and Patient Safety

9.3.8. Laboratory Errors and Patient Safety (WG-LEPS)

The mission of the WGLEPS is to promote and encourage investigations into errors in laboratory medicine, collect data available on this issue and recommend strategies and procedures for improving patient safety.

Terms of references

The Education and Management Division (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) is the main body responsible for the promotion of laboratory errors and patient safety (WG-LEPS) in the field of laboratory medicine. The WG-LEPS was established by the IFCC in 2004, "a focus on addressing errors in laboratory medicine is an important element of the international agenda on patient safety. Theory and accurate laboratory test results are a cornerstone of effective diagnosis and treatment of patients" (Clin Chem Lab Med 2007; 45(5): 887-8).

In the last few years a body of evidence has been collected to demonstrate that many of the errors in laboratory medicine occur in the pre- and post-analytical phases of laboratory testing. Therefore, improving the safety of laboratory testing requires a detailed understanding of the steps involved in the total testing process to identify the hierarchy of risks and challenges to be addressed.

Patient safety is increasingly recognized as a serious problem that requires a globally led approach and the IFCC WG-LEPS should be a tool to improve the knowledge in the field at an international level, and to recommend the development and application of standardized operating protocols.

Current Projects

Improving awareness of laboratory professionals regarding the topic of errors and patient safety

Implementing projects to reduce laboratory errors frequency and types

Implementing projects for error reduction through the design of safer procedures and processes

Cooperating with other scientific organizations (WHO, AACCP, ASCL, etc.) for assuring improvements in the field of patient safety

Organizing meetings and scientific sessions on the topic of laboratory errors and patient safety

Supporting the publications of papers on the topic of laboratory errors and patient safety in scientific journals and monographs

http://217.148.121.44/MqWeb/Page_Presentation.jsf

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Publications

Piabani M, Sciacovelli L, Aita A, Chiozza ML. Harmonization of pre-analytical quality indicators. Biochem Med, 2014;24:105-113.

Piabani M, Sciacovelli L, Aita A, Padon A, Chiozza ML. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Chem Acta, 2013 Sep 5; 430(9):1003-1007. doi: 10.1016/j.cca.2013.07.022. [Epub ahead of print] PMID: 24012863.

Piabani M, Sciacovelli L, Marinova M, Marzocchi J, Chiozza ML. Quality indicators in laboratory medicine: a fundamental tool for quality and patient safety. Clin Biochem, 2013 Sep; 48(5):161-175.

Piabani M, Chiozza ML, Sciacovelli L. Towards harmonization of quality indicators in laboratory medicine. Clin Chem Lab Med, 2012 Jan; 50(1):187-85.


Sciacovelli L, Santolig G, Padon A, Zamboni C, Carraro P, Piabani M. Monitoring quality indicators in laboratory medicine does not automatically result in quality improvement. Clin Chem Lab Med, 2011 Dec; 49(12):483-4.

Piabani M, Sciacovelli L, Lippi G. Quality indicators for laboratory diagnostics: consensus is needed. Ann Clin Biochem, 2011 Sep; 48(9):81-9.

Sciacovelli L, O'Hare M, Skak VA, Caciagli P, Pellegrini C, Da Rin G, Iervasi A, Ghis T, Piabani M. IFCC WG-LEPS: Quality Indicators in Laboratory Medicine: from theory to practice. Preliminary data from the IFCC Working Group Project "Laboratory Errors and Patient Safety". Clin Chem Lab Med, 2011 May; 49(5):823-4.

Sciacovelli L, Piabani M. The IFCC Working Group on laboratory errors and patient safety. Clin Chem Lab Med, 2009 Jun; 47(6):179-85.

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The Model of Quality Indicators (MQI) aims

- objective**, the evaluation of collected data being based on evidence of compliance with specifications and rather than on subjective judgements;
- fair**, precise steps being used for data collection;
- responsive**, being based on the unquestionable identification of "event gets out of control" (noncompliance with specifications) and on the obligation to promptly undertake suitable actions (corrective, preventive, improving);
- transferable**, being easily applicable in different laboratories (context, typology and country).

The Model of Quality Indicators (MQI) will be proposed to, and applied by, all clinical laboratories in order to monitor processes and encourage improvement in performances so as to decrease the error rate in the total testing process.

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Development phases of the Model of Quality Indicators project.

EXPERIMENTAL PHASE Clinica Chimica Acta 404 (2009) 79–85

Step-by-step process:

1. establishing working group
2. identifying Model of Quality Indicators (MQI) for total testing process
3. introducing MQI into routine practice of participating laboratories
4. collecting data using a specifically-designed website
5. assessing and processing data collected
6. achieving consensus on criteria for defining quality specifications
7. defining preliminary desirable quality specifications (SQI) for each indicator
8. applying SQI and assessing data
9. modifying MQI (if necessary)
10. definitively establishing and divulging MQI



Development phases of the Model of Quality Indicators project.

WORKING PHASE


Introducing External Quality Assurance Program to evaluate the performance of clinical laboratories based on MQI.

Steps:

1. collection of laboratories data for each indicator
2. statistical treatment and assessment of the laboratories data in comparison with defined SQI
3. preparation of a report for each participant concerning results evaluation

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Quality indicators selected for the model.

Quality indicators selected for the model:

Code	Quality indicators
Q1-1	Number of requests with clinical question/total number of requests (in percentage)
Q1-2	Number of appropriate tests (with respect to clinical question)/number of requests that report clinical question (in percentage)
Q1-3	Number of requests without physician identification/total number of requests (in percentage)
Q1-4	Number of unintelligible requests/total number of requests (in percentage)
Q1-5	Number of requests with errors concerning patient identification/total number of requests (in percentage)
Q1-6	Number of requests with errors concerning physician identification/total number of requests (in percentage)
Q1-7	Number of requests with errors concerning input of tests (missing/added/misinterpreted)/total number of requests (in percentage)
Q1-8	Number of samples lost or received/total number of samples (in percentage)
Q1-9	Number of samples collected in inappropriate containers/total number of samples (in percentage)
Q1-10	Number of samples hemolyzed (hematology/chemistry)/total number of samples (in percentage)
Q1-11	Number of samples clotted (hematology/chemistry)/total number of samples with anticoagulant (in percentage)
Q1-12	Number of samples with insufficient sample volume/total number of samples (in percentage)
Q1-13	Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant (in percentage)
Q1-14	Number of samples damaged in transport/total number of samples (in percentage)
Q1-15	Number of samples improperly labelled/total number of samples (in percentage)
Q1-16	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-17	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-18	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-19	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-20	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-21	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-22	Number of unacceptable performances in EQA schemes per year/total number of performances in EQA schemes (in percentage)
Q1-23	Average (in percentage) of requests with clinical question/total number of requests (in percentage)
Q1-24	Average (in percentage) of requests with clinical question/total number of requests (in percentage)
Q1-25	Average (in percentage) of requests with clinical question/total number of requests (in percentage)

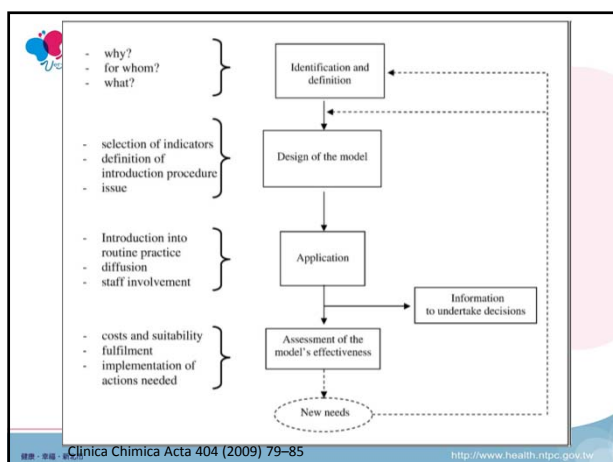
Q1-1 Number of requests with clinical question/total number of requests (in percentage)

Q1-2 Number of appropriate tests (with respect to clinical question)/number of requests that report clinical question (in percentage)

Q1-3 Number of requests without physician identification/total number of requests (in percentage)

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ISO 15189 : 2012

4.14.7 品質指標

實驗室應建立品質指標，以監控與評估檢驗前、檢驗中及檢驗後流程中各關鍵構面的表現。

舉例：不合格樣本的件數、管收及／或接收錯誤的件數、報告修正的件數。

品質指標的監控流程應加以規劃，內容包括建立目標、方法、說明、限制、行動計畫及量測期間。

這些指標應定期加以審查，以確保其持續的合適性。

附註 1：對於非檢驗程序的品質指標監控，例如實驗室安全與環境、設備完備與人員紀錄，以及文件管制系統的有效性等，可提供有價值的管理見解。

附註 2：實驗室須建立品質指標，以系統化監控與評估實驗室對受病人照護之貢獻(見 4.12)。

Source: <http://www.health.ntpc.gov.tw>

Brazilian laboratory indicators program (Clin Chem Lab Med 2012;50:1923–34)

Abstract

Background: This paper describes the evolution, structure, operation and some outcomes of the Brazilian Laboratory Indicators Program created by the Brazilian Society of Clinical Pathology/Laboratory Medicine (Sociedade Brasileira de Patologia Clínica/Medicina Laboratorial, or SBPC/ML), in partnership with ControlLab, a Brazilian Company that provides services for proficiency testing, internal control, calibration, and training indicators for clinical laboratories.

Methods: This web-based program is confidential for all participants. It contains 61 indicators categorized into three groups. Program operation and data analysis methods are described and indicators are reported in box plot format, with grouping varying in accordance with the profiles of the participating laboratories. Three indicators were selected as examples of program effectiveness in 2011: hemolysis, blood re-collection and productivity.

Results: Participants profile, examples of three indicators for the year 2011 (hemolysis, blood re-collection and productivity) and exploratory research conducted in 2012 on the implementation of the program are presented. Data related to laboratories participating in the program from 2006 to 2011 were collected and graphically represented.

Conclusions: The Brazilian Laboratory Indicators Program brings important benefits for participants, contributing to the improvement of existing health systems in Brazil.

Source: <http://www.health.ntpc.gov.tw>

Harmonization of quality indicators in laboratory medicine. A preliminary consensus (Clin Chem Lab Med 2014;52:X–X)

Abstract

Quality indicators (QIs) are fundamental tools for enabling users to quantify the quality of all operational processes by comparing it against a defined criterion. QIs data should be collected over time to identify, correct, and continuously monitor defects and improve performance and patient safety by identifying and implementing effective interventions.

According to the international standard for medical laboratories accreditation, the laboratory shall establish and periodically review QIs to monitor and evaluate performance throughout critical aspects of pre-, intra-, and post-analytical processes. However, while some interesting programs on indicators in the total testing process have been developed in some countries, there is no consensus for the production of joint recommendations focusing on the adoption of universal QIs and common terminology in the total testing process. A preliminary agreement has been achieved in a Consensus Conference organized in Padua in 2013, after revising the model of quality indicators (MQI) developed by the Working Group on "Laboratory Errors and Patient Safety" of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The consensually accepted list of QIs, which takes into consideration both their importance and applicability, should be tested by all potentially interested clinical laboratories to identify further steps in the harmonization project.

Source: <http://www.health.ntpc.gov.tw>

Harmonization of pre-analytical quality indicators (Biochemia Medica 2014;24(1):105–13)

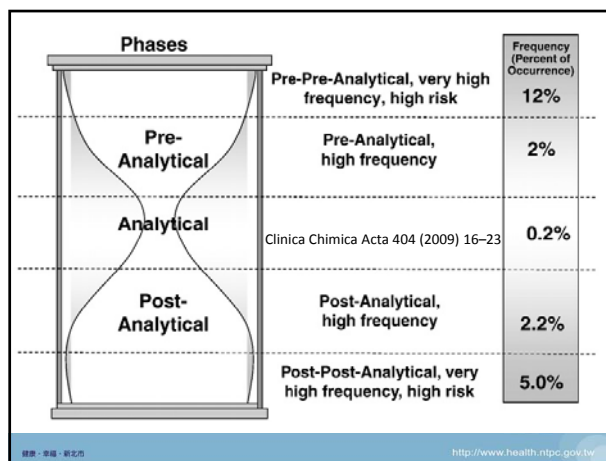
Table 1. Pre-analytical errors grouped in relation to identification and sample problems.

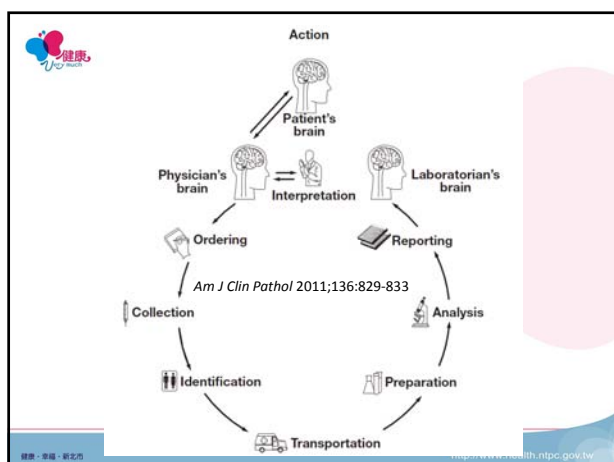
Identification	Sample
Unlabeled samples	Hemolyzed
Mislabeled samples	Clotted
Insufficiently labeled samples	Itineric/epimeric
Samples suspected of being from the wrong patient ("wrong blood in tube")	Incorrect filling level
Irregularities in transfusion labeling requirements (e.g. signature of phlebotomist)	Inadequate quantity
	Lost/not received
	Damaged during transportation and improperly stored

Table 2. Quality indicators of the pre-analytical phase (order of priority: 1 = Mandatory; 2 = Important; 3 = Suggested; 4 = Valuable).

Quality indicator	Priority score
a) Appropriateness of clinical request	
Percentage of "Number of requests without clinical question (outpatients) / Total number of requests (outpatients)"	2
Percentage of "Number of inappropriate requests, with respect to clinical question (outpatients) / Number of requests reporting clinical question (outpatients)"	4
Percentage of "Number of inappropriate requests, with respect to clinical question (inpatients) / Number of requests reporting clinical question (inpatients)"	4
b) Patient identification	
Percentage of "Number of requests with errors concerning patient identification / Total number of requests"	1
Percentage of "Number of requests with errors concerning patient identification, detected before release of results / Total number of requests"	1
Percentage of "Number of requests with errors concerning patient identification, detected after issuing results / Total number of requests"	1
c) Data entry of the request	
Percentage of "Number of outpatients requests with errors concerning physician identification / Total number of outpatients requests"	2

Source: <http://www.health.ntpc.gov.tw>





開放討論：想法

- 收集各實驗室的QI(含定義)
- 組織工作小組參考相關文獻評估現有QI
- 調和現有QI
- 評估QI之可行性與重要性
- 收集資料與分享
- 建議推薦之QI
- 開放討論

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