

DEDICATION

to my Family in
Gregana

To my mother

to my sons

to my wife

ACKNOWLEDGEMENTS

This study was carried out from 2005 to 2008 at Khartoum state – Sudan to assess and evaluation of governmental hospitals laboratories I highly appreciate the opportunity given to me at Khartoum state Laboratories and the unit of quality laboratory to finalize my work. My special thanks for support and encouragement are given to Professor Mohammed Osman , Mr Elneel Abdalla., Maged Mohamed ALi the Head of Department of quality. My supervisors Professor Mohammed Abdalrhem to thank for their precious time and good advice.

I wish to thank my co-workers Miss Somia, Sana, Manar, Sara, Nosiba, Naba ,Mai, Mona. And Mr. Murown

Iam lucky to have so many friends. Special thanks for technical assistance, in its many ways are given to Dr. Awadalla Ali Manager of Rokin Elmazia company , Dr Ibrahim Karti and Directors companies of 0

Finally, I want to express my warmest feelings to my family for their tremendous support in such a many ways. Special thanks to My wife Mahassin, and my mother Shamom Elmuk Adlan and for my big family in Greegana vallage in white Nile.

Abstract

This study was carried out in Khartoum state during the period from 2005-2008, aimed to evaluating 38 governmental hospitals laboratories situation and laboratories performance on Quality Indicators With international standards scale & factors affecting the implementation of quality, the laboratories are assessed for compliance against the International Standard, CPA, ISO 17025 and ISO 15189.all the quality management systems operational within the organization and the technical competence of the laboratories to perform the tests are assessed.

Results availability of international standards for total quality management implementation in the laboratories is between 36% -86% the mean 65%, the safe laboratory design and organization 77.5%, laboratory organization 48.5%, document and management system 45.5%, quality of Personnel management 55.5%, the automation used in clinical chemistry laboratories 5%, the errors of laboratories 60% were observed in the preanalytical phase of testing, 37% in the postanalytical phase, and only 3% in the analytical phase, continues assessment for laboratories auditing 26%, 55% of laboratories had calibration system.

The quality control program 67% had internal quality control, 33% had national quality control no laboratories had international quality control , the quality control in this study done for 15 tests most of clinical chemistry tests required in laboratories used normal and pathological control sera the results found CV% For : glucose normal sera 19.1% pathological sera15.5 % acceptable results 74% , CV% urea normal sera 18.9% pathological sera 19.6% acceptable 64.4%, CV% creatinine normal sera 29.65 pathological sera 24.6% acceptable results 67.4%, CV% Sodium normal sera4.4% pathological sera5.1 % acceptable results 88.5 % , CV% potassium normal sera16.6% pathological sera 11.6 % acceptable results 80.5%, CV% Calcium normal sera 10.4% pathological sera13.9 % acceptable results 45%, CV% phosphate normal sera 11% pathological sera13.4 % acceptable results 81%, CV% uric

acid normal sera 27.8% pathological sera 20.1% acceptable results 74%, CV% cholesterol normal sera 20.6% pathological sera 12.4 % acceptable results 91.5%, CV% triglyceride normal sera 21.4% pathological sera 18.1% acceptable results 81.5%, CV% albumin normal sera 13.9% pathological sera 10.6 % acceptable results 92%, CV% total bilirubin normal sera 34.2% pathological sera 22.7 % acceptable results 71%, CV% Alk. ph normal sera 49.1 % pathological sera 41.4% acceptable results 51.5 %, CV% AST normal sera 75.5% pathological sera 50.8% acceptable results 47.5% ,CV% ALT normal sera 82.4 % pathological sera 50.8% acceptable results 42 %, the acceptability of results for all laboratories is 72%, total absolute error 55.56% , inaccuracy (variation) 11.5%, imprecision CV 25.1%.

The evolution of clinical laboratory In vitro diagnostic kits 41 reagents for 8 parameters products by 10 manufactures different companies only 52% of companies had international standards certificate such as TUV, ISO13485, IVD, ISO 9001.

The results of evaluation the kits the Uncertainty of glucose diagnostic kits is 9.4% total errors 6.4. Uncertainty of urea diagnostic kits is 6.4% total errors 13.2%, Uncertainty of creatinine diagnostic kits is 13.7% total errors 14.4%, Uncertainty of uric acid diagnostic kits is 9.8% total errors 11.7 %, Uncertainty of calcium diagnostic kits is 7.9% total errors 9.2 %, Uncertainty of cholesterol diagnostic kits is 9.4% total errors 6.4 %, Uncertainty of triglyceride diagnostic kits is 11.8 % total errors 10.3 %, Uncertainty of albumin diagnostic kits is 10.1% total errors 10.8 %.

The total assessment for all diagnostic kits the CV 4.9 % .Variation 7.2%, repeatability 1.34, Uncertainty 9.8% and the absolute total errors 10.3%.

The assessment of control sera use glucose and urea tests, commercial control sera found CV% between 9.1% to 26% uncertainty 18.2% to 42%, stability 4 to 30 days when the prepared sera recommended by WHO CV% between 1.5% to 2.9% uncertainty 3.0% to 58% and stability more than one year.

The results analysis situation of our laboratories in this study on international standards should be need and stimulate the adoption of this standard and promote harmonization of accreditation programs at an international level. Quality assessment process needs to introduce regulation for external quality control, quality auditing, and management of reagents, calibration and quality control material this factors affecting the reliability and accuracy of laboratories results.

بسم الله الرحمن الرحيم

ملخص البحث

أجريت هذه الدراسة في ولاية الخرطوم في الفترة ما بين 2004م إلى 2008م، والهدف من هذه الدراسة تقييم الوضع الحالي لمعامل المستشفيات الحكومية وعددها 38 معمل لمعرفة مدى تطبيق نظام الجودة الشاملة العالمي على هذه المعامل، نظام الأيزو 15189 و 17025 ونظام اعتماد المعامل الطبية البريطانية وكذلك التعرف على الأسباب والمؤثرات على تطبيق الجودة في هذه المعامل وعلى دقة وصحة نتائج إختباراتها.

النتائج المتحصل عليها من هذه الدراسة نسبة تطبيق الجودة الشاملة في المعامل ما بين 36% إلى 86%، وهيئة وسلامة مباني المعامل 77,5%، وتقسيم المعامل إلى تخصصات 48,5%، وجودة النظام الإداري والمستندات 45,5%، وجودة نظام شؤون العاملين 55,5%، والأجهزة الحديثة المستخدمة في معامل الكيمياء السريرية بنسبة 5%، والأخطاء المعملية قبل الفحص وجدت بنسبة 60%، والأخطاء المعملية أثناء الإختبار بنسبة 37%، و 3% فقط من الأخطاء كانت بعد الإختبار.

نظام جودة التحسين المستمر على هذه المعامل وجد أن 26% من المعامل لها نظام مراجعة مستمر، و 55% لها نظام معايرة وقياس للأجهزة والمحاليل المستخدمة. وبرنامج ضبط الجودة الداخلي مطبق بنسبة 67% في المعامل وضبط الجودة القومي 33%، ولاتوجد معامل لها برنامج ضبط جودة خارجي أو عالمي.

برنامج ضبط الجودة الذي أجري على هذه المعامل إستخدم عينة ضبط جودة طبيعية وأخرى غير طبيعية "مرضية" لإجراء 15 إختبار، وهي أكثر الإختبارات الموجودة والمطلوبة في المعامل وكانت النتائج كالآتي:

نسبة معيار التثنت لنتائج السكر في الدم للعينة الطبيعية 19,1% والمرضية 15,5% والنتائج المقبولة 74%، ونسبة معيار التثنت لقياس البولينا في الدم للعينة الطبيعية 18,9% وللعينة المريضة 19,6% والنتائج المقبولة 64,4%، ونسبة معيار

التشتت لقياس الكرياتين في الدم للعينه الطبيعيه 29.65% وللعينه المريضة 24,6% والنتائج المقبولة 67,4%، ومعيار التشتت لقياس الصوديوم في الدم للعينه الطبيعيه 4,4% وللعينه المريضة 5,1% والنتائج المقبولة 88,5%، ومعيار التشتت لقياس البوتاسيم في الدم للعينه الطبيعيه 16,6% وللعينه المريضة 11,6% والنتائج المقبولة 80,5%، ومعيار التشتت لقياس الكالسيوم في الدم للعينه الطبيعيه 10,4% وللعينه المريضة 13,9% والنتائج المقبولة 45%، ومعيار التشتت لقياس الفوسفات في الدم للعينه الطبيعيه 11% وللعينه المريضة 13,4% والنتائج المقبولة 81%، ومعيار التشتت لقياس حمض البوريك في الدم للعينه الطبيعيه 27,8% وللعينه المريضة 20.1% والنتائج المقبولة 74%، ومعيار التشتت لقياس الكولسترول في الدم للعينه الطبيعيه 20,6% وللعينه المريضة 12,4% والنتائج المقبولة 91,5%، ومعيار التشتت لقياس الدهن الثلاثي في الدم للعينه الطبيعيه 21,4% وللعينه المريضة 18,1% والنتائج المقبولة 81,5%، ومعيار التشتت لقياس الزلال في الدم للعينه الطبيعيه 13,9% وللعينه المريضة 10,6% والنتائج المقبولة 92%، ومعيار التشتت لقياس البرولين في الدم للعينه الطبيعيه 34,2% وللعينه المريضة 22,7% والنتائج المقبولة 71%، ومعيار التشتت لقياس إنزيم الفوسفيت القلوي في الدم للعينه الطبيعيه 49,1% وللعينه المريضة 41,4% والنتائج المقبولة 51,5%، ومعيار التشتت لقياس إنزيم أي اس تي للعينه الطبيعيه 75,5% وللعينه المريضة 50,8% والنتائج المقبولة 47,5%، ومعيار التشتت لقياس إنزيم أي ال تي في الدم للعينه الطبيعيه 82,4% وللعينه المريضة 50,8% والنتائج المقبولة 42%.

النتائج المقبولة لكل المعامل 72% والخطأ الكلي المطلق لكل المعامل 55,56% وعدم صحة النتائج أي الخطأ المتكرر 11,5% وعدم الدقة أي الخطأ العشوائي 25,1%.

وتم تقييم وتحليل المحاليل المستخدمة في المعامل للتحقق من نتائجها وجودة انتاجها ومدى مطابقتها للمقياس والمعيار العالمي مثل أيزو 13485 و 9001، وواي في دي

الأمريكية، وتي يو في الألمانية. ووجد أن 52% من الكواشف المستخدمة شركاتها تطبق نظام الجودة العالمي وكانت نتائج تحليل كواشف الكيمياء السريرية كالآتي:

محاليل كاشف الجلوكوز في الدم مدى عدم الثقة "درجة اللايقين" في نتائجه 9,4% والخطأ الكلي 6,4%، ومحاليل كواشف البولينا في الدم مدى عدم الثقة "درجة اللايقين" في نتائجه 6,4% والخطأ الكلي 13,2%، ومحاليل كواشف الكرياتينين مدى عدم الثقة "درجة اللايقين" 13,7% والخطأ الكلي 14,4%، ومحاليل كواشف حمض البوريك في الدم مدى عدم الثقة "درجة اللايقين" 7,9% والخطأ الكلي 9,2%، ومحاليل كواشف الكولسترول في الدم مدى عدم الثقة "اللايقين" 9,4% والخطأ الكلي 6,4% ومحاليل كواشف الدهون الثلاثي في الدم مدى عدم الثقة "درجة اللايقين" 11,8% والخطأ الكلي 10,4%، ومحاليل كواشف الزلالي في الدم مدى عدم الثقة "درجة اللايقين" 10,1% والخطأ الكلي 10,8%.

وكان مقياس التشنت لكل الكواشف المستخدمة 4,9%، ومعامل الاختلاف 7,2%، والتكرارية 1,34، ومدى درجة عدم الثقة لكل الكواشف 9,8%، والخطأ الكلي المطلق 10,3%.

وكذلك تم تقييم عينات ضبط الجودة المنتجة من الشركات التجارية وجد أن معيار التشنت ما بين 9,1% إلى 26%، ومدى درجة عدم الثقة "اللايقين" ما بين 18,2% إلى 42%، ودرجة الثابتية بعد حلها تتراوح ما بين 4 إلى 30 يوم، ونتائج تحليل عينات الجودة المنتجة داخل المعمل موسى عليها من منظمة الصحة العالمية والملائمة لمناخ المناطق الحارة وجد أن معيار التشنت ما بين 1,5% إلى 2,9%، ومدى درجة عدم الثقة "درجة اللايقين" ما بين 3% إلى 5,8% ودرجة الثابتية أكثر من عام.

نتائج تحليل الوضع الراهن للمعامل ومقارنته مع المعايير والمقاييس العالمية يحتاج إلى رعاية وتحفيز وعمل جماعي لوضع برنامج إتماد للمعامل وفق المقياس والمواصفات العالمية وتطبيقها تدريجياً مع برنامج تحسين مستمر ومراجعة ومراقبة المعامل ومعايرة الأجهزة والمحاليل المستخدمة

وبرنامج ضبط جودة داخلي وخارجي مستمر حتى نتحقق من
صحة ودقة كل نتائج المعامل التشخيصية.

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LIST OF ABBREVIATION AND ACRONYMS:-

1. Abbreviation for association, committees, organization and laboratories

ANSI	American National Standards Institute.
BIPM	International Bureau for Weights and Measures.
CAP	College of American Pathologists.
C-AQ	Committee for Analytical Quality.
CCHSA	Canadian Council on Health Services Accreditation.
CCQM	Consultative Committee for Amount of Substance.
CGPM	Conference General des Poids et Mesures.
CIPM	Comite International des Poids et Mesures.
CITAC	Co-Operation on International Traceability in Analytical Chemistry.
EA	European co-operation for Accreditation.
EC	European Community.
EGE-Lab	European Group for the Evaluation of Reagents and Analytical System In Laboratory.
EQALM	European Committee for External Quality Assessment Programmes in Laboratory Medical.
EURACHEM	European Association for Analytical Chemistry.
FDA	U.S Food and Drug Administration.
FINAS	Finnish Accreditation Service.
GHTF	Global Harmonization Task Force.
IEC	International Electrotechnical Commission.
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine.
IRMM	Institute for Reference Materials and Measurements.
ISO	International Organization for Standardization
JCAHO	Joint Commission on Accreditation of Health Organization.
LAP	Laboratory Accreditation Programme.
NATA	National Association of Testing Authorities.
NCCLS	National Committee for Clinical Laboratory Standards.
NIST	National Institute of Standards and Technology (U.S).
OECD	Organization for Economic Co-operation and Development.
PHC	Primary Health Care
SWEDAC	Swedish Accreditation
TAG	Technical Advisory Group.
TC	Technical Committee.
WG	Working Group.

QCRU	Quality Control Reagents Unit
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2. Acronyms

2.1 Acronyms used in equation and calculations

B_A	Analytical bias.
C.I.	Confidence Interval.
CV_A	Analytical coefficient of variation.
CV_G	Inter-individual biological variation.
CV_I	Inter-individual biological variation.
CV_{PRE}	Pre-analytical variation.
FN	False Negative.
FP	False Positive.
RCV	Reference Change Value.
TE_a	Total allowable Error.
TN	True Negative.
TP	True Positive.

2.2 Other acronyms

CLIA	Clinical Laboratory Improvement Amendments.
EN	European Standard.
EQA	External Quality Assessment.
GLP	Good Laboratory Practice.
GUM	Guide to the expression of Uncertainty in Measurement.
ID-GC-MS	Isotope Dilution-Gas Chromatography-Mass Spectrometry.
IMEP	International Measurement Evaluation Programme.
IQC	Internal Quality Control.
IVD	In <i>vitro</i> Diagnostic (medical) Device.
POCT	Point-Of-Care-Testing.
PT	Proficiency Testing.
SI	System International d'Unites.
SMBG	Self Monitoring of Blood Glucose.
ALk.Ph.	Alkaline phosphatase enzymes
AST	Aspartate transaminase enzymes
ALT	Alinine transaminase enzymes

