

Laboratory Management
PM-01

Risk Management for Patient Safety in Medical Laboratory

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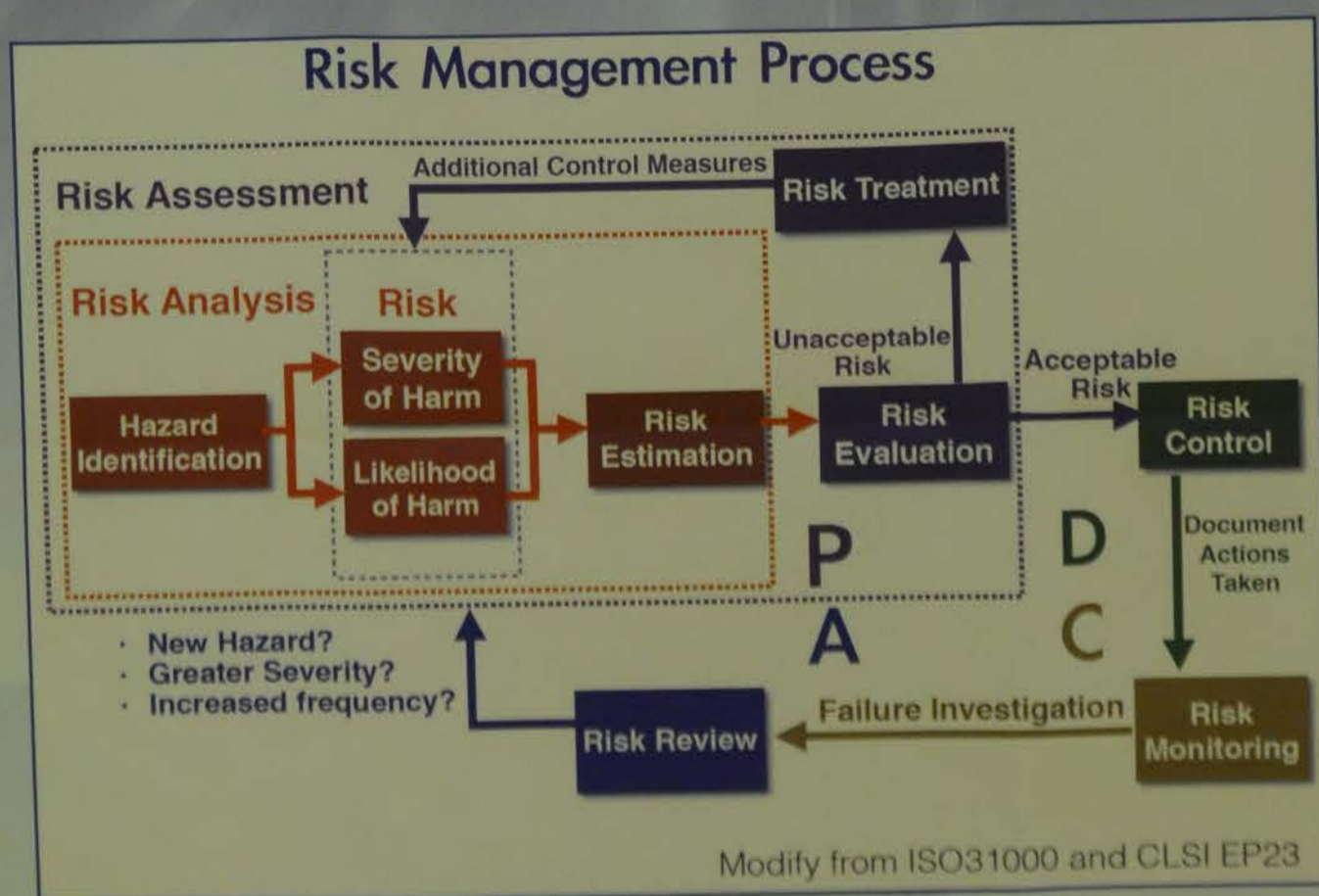
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Failures can occur at any stage of the journey of a specimen through the clinical laboratory, from the initiation of the request to the receipt of the results by the requesting clinician. It is essential that risk control measures are taken to ensure errors are minimised at each stage of the laboratory process. A laboratory error is any defect occurring at any part of the testing processes, from ordering tests to reporting, interpreting, and reacting to results. Although they have been traditionally identified with quality control (QC), the vast majority of these arise from the extra-analytical phases of the total testing process. QC will not tell you about bubbles, clots, hemolysis, anticoagulants or IV fluid contamination, etc.

Therefore, ISO standards strongly advocate that the medical laboratory implement risk management (RM) as a way to ensure quality in their testing processes. It is a requirement of ISO15189 that "The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks.", which means that the laboratory shall carry out RM for patient safety. All activities of a laboratory involve risks to patients that must be managed.

Since risk can occur in any aspects of testing process, the laboratory should conduct a systematic risk identification exercise to register identified risks. Then, evaluate each risk and implement risk control measures for each unacceptable risk to contain risk at acceptable level. Therefore, RM should not be a stand-alone activity or be separate from the testing processes of the laboratory.

However, the level of detail and complexity of the RM system will be dependent on the nature (i.e. size, structure, complexity) of a laboratory and its activities. That is what RM is all about, creating patient safety laboratory services.



Background

To continuously improve and provide more rapid and accurate report is the goal of all laboratories. Our hematology department equipped with multiple analyzers to offer a variety of tests including CBC, HbA1c, PT, aPTT, D-dimer, PCT, NT-proBNP etc. and some of which were still manual data entered. Therefore, we adopted an integrated process re-engineer and implemented test result auto-verification to simplify and streamline the complicated process in the hematology department.

Method

After a total process re-engineering in the hematology department, we sequentially upgraded coagulation analyzer (Sysmex CS2100i), immunoanalyzer (BioMerieux Vidas3), Glycohemoglobin analyzer (ARKRAY HA-8180V) and digital cell morphology system (CellaVision DM96) in December 2014. All testing results were delivered to a single middleware (Sysmex WAM), the same as the currently existing hematology analyzers (Sysmex HST-302N). It provides automatic and manual validation reporting to the laboratory information system (LIS). Consequently, we readjusted the test process, eliminated manual data transcription, and implemented test result auto-verification and real-time auto-release system in June 2015.

Results

Approximately 520 specimens were processed per day in the hematology department. Daily results show the auto-verification passing rate of all test results to be 85% (440 results). It can save about 2.5 hours (0.3FTE) in staff to review the test results per day. The achievement rates of reporting of stat results for emergency department patients within 20 minutes were 98% and within 30 minutes for outpatients were 97%.

Conclusion

Test results auto-verification and auto-release enable laboratory staff to focus on abnormal test results, not only reduce post-analytical process time, but also prevent human errors. A well-designed auto-verification and auto-release system can be an important tool in addressing such crucial issues as medical errors, turn-around time and operational efficiency.

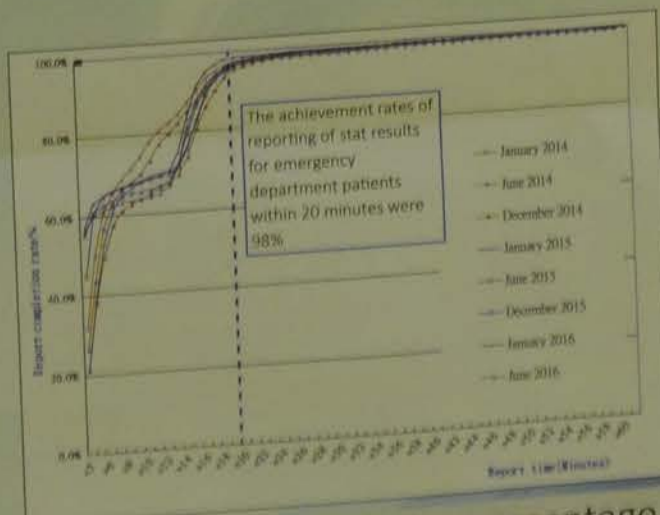


Figure1. The cumulative percentage of reporting time of stat results for ED patients.

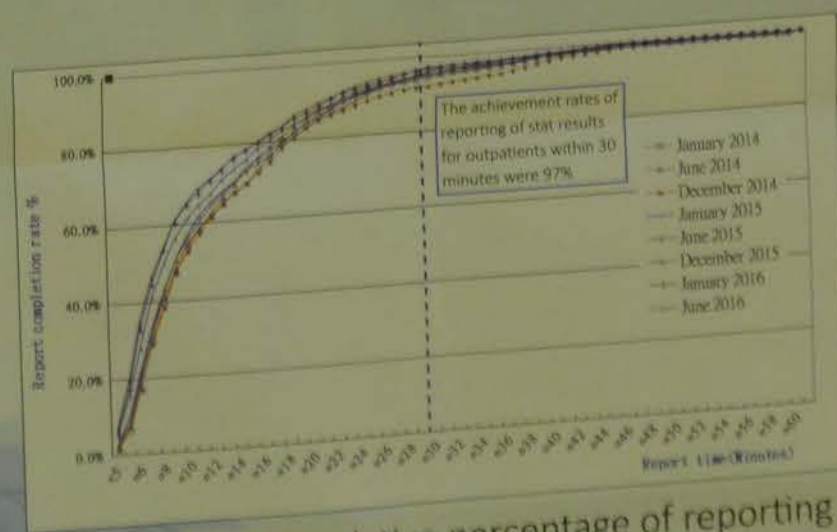
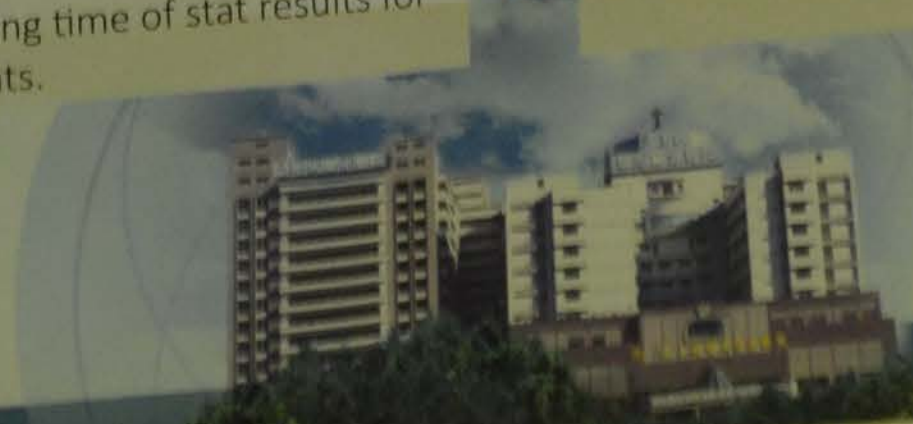


Figure2. The cumulative percentage of reporting time of stat results for outpatients.



Others
PO-2

... for Biomedical Scientists?

... the necessary knowledge, skills and experiences and can play a central role in this new area Multidisciplinary Field.

Challenges for BMS

- Responsibility for:
 - Selection and validation of equipment/device and test
 - Education and training of users
 - Internal and External quality assurance
 - Maintenance
 - Record keeping of quality and patient data
 - Complaint reporting
 - Risk Management
 - Clinical Audit
 - Process
 - Interpretation of data

Conclusion

... patient safety and quality assurance are best ensured by virtue of a multi-disciplinary surveillance system. Biomedical scientists within the ... have the necessary expertise and competence ... like a lead role in ensuring safe and effective ... of POCT and can be a spider in this ... care network.

Laboratory Management
PM-03

**Beyond the microscope:
Assessing the continuing professional
development needs of medical
technologists in the Philippines**

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INTRODUCTION

Medical technologists play a vital role in the delivery of healthcare services through the performance of laboratory tests used in the diagnosis, treatment and management of patients. To ensure the accuracy and reliability of laboratory test results, medical technologists should keep abreast with the latest trends and developments in laboratory medicine (1).

Continuing professional development (CPD) refers to maintenance and enhancement of knowledge, expertise and competence of professionals throughout their careers to a plan formulated with regard to the needs of the professional, the employer, the profession and society (2). There is an increasing interest among professional regulatory agencies in requiring practitioners to demonstrate their engagement with CPD in order to maintain professional competency amid the ever-changing scope of practice and technological advances (3). In the Philippines, Republic Act 10912 was recently enacted into law reviving the conduct of mandatory CPD programs for all professionals as a requirement for the renewal of professional licenses (4).

The development of CPD programs must be based on an empirical assessment of the needs of and planners should focus on addressing shortfalls between existing knowledge or skill and needed competencies (5,6). Further, needs assessment studies should focus on the actual and predicted professional practice requirements, related enabling competence and capabilities, and corresponding learning and change requirements (7). As such, this study assessed the CPD needs, preferred modes of CPD delivery and perceptions regarding CPD among medical technologists in the Philippines.

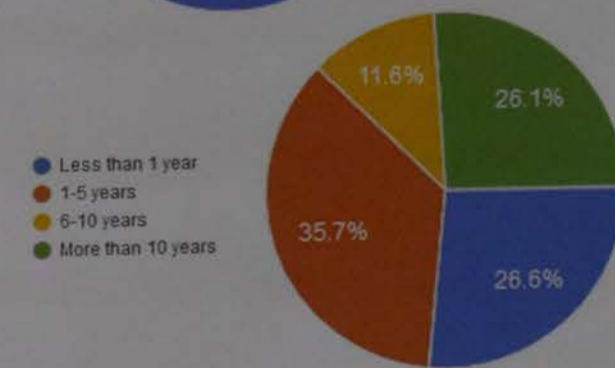
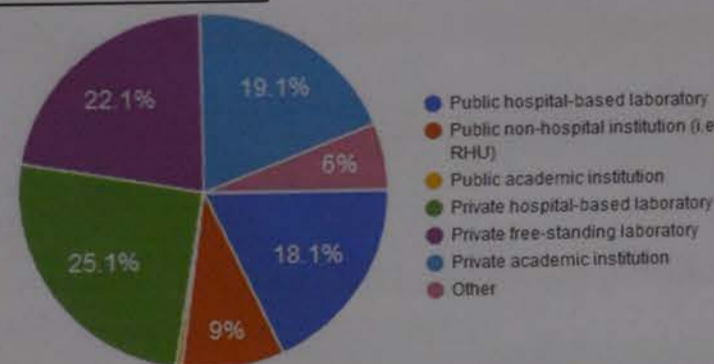
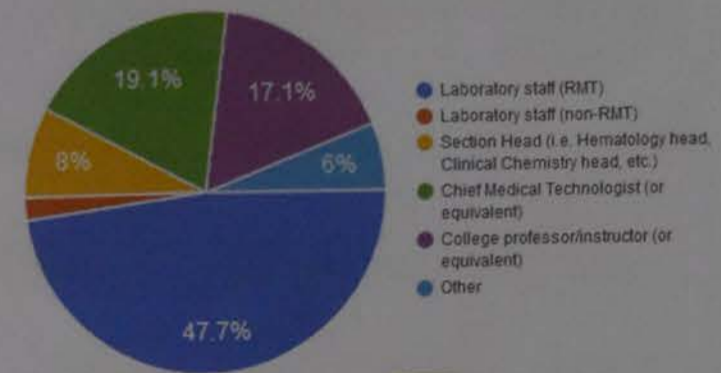
METHODS

A cross-sectional assessment regarding CPD was performed using an online questionnaire (refer to the QR Code link below). Perceived training needs, preferences and perceptions of the respondents were ranked using a 4-point scale and organized into five domains of competency.



DOMAINS

- Quality Management Systems
- Technical Competencies
- Laboratory Management
- Medical Technology Concepts and Practice
- Medical Technology Research



RESULTS

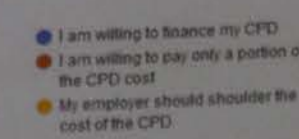
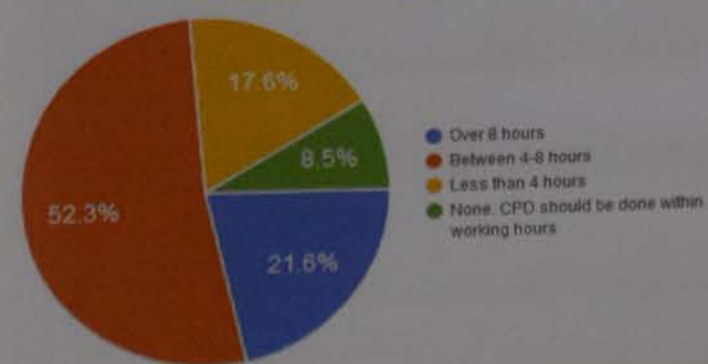
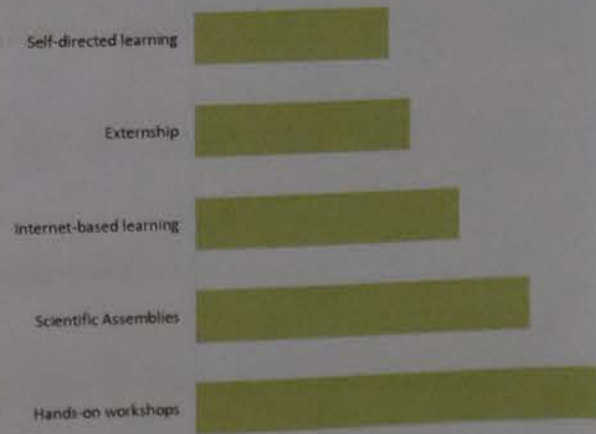


LEADING TOPICS

- Clinical laboratory safety
- Specimen management
- Competency assessment
- Work ethics and professionalism

PERCEIVED BARRIERS

- Cost of CPD programs
- Distance of CPD venue
- Work schedule
- Not enough time for CPD programs
- Personal obligations



CONCLUSION

The most frequently selected topics for training in rank order (mean) according to the identified domains were (a) quality management systems, (b) technical competencies, (c) laboratory management, (d) medical technology concepts and practice, and (e) medical technology research. CPD programs by accredited providers should focus on these areas in developing their plans. The leading topics identified by the respondents were clinical laboratory safety, specimen management, competency assessment, and work ethics and professionalism. The most preferred modes of CPD delivery were hands-on workshops, scientific assemblies, and internet-based (online) learning. Most of the respondents believe that CPD is important in the practice of the profession, are willing to devote 4-8 hours of their own time every month to CPD activities, prefer weekends over weekdays, and are mostly hindered by the cost of the CPD programs and distance of the venue. However, it was noted that there were significant variations on perceived CPD needs of the medical technology professionals when grouped according to cadre-type. This should be explored further in future studies. While this study provide a baseline data for medical technology CPD programs in the Philippines, future trends and technologies should also be considered including the sustainability and effectivity of CPD delivery. CPD providers should focus their attention in addressing the perceived CPD needs of medical technologists and ensure equity in the delivery of CPD programs and activities in the country. As CPD needs will likely vary over time given the dynamism of professional practice in laboratory medicine, this study highlights the need for lifelong learning among medical technology practitioners to maintain relevance and competency in the said field.

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Change Control from a leader's perspective

How can the leader follow ongoing changes in a large decentralized department?

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Introduction

Change Control is used in the laboratory quality management system in a formal process to ensure that changes are introduced in a controlled and coordinated manner. It helps to meet the criteria from both Norwegian authorities and Norwegian accreditation. At the Department of Medical Biochemistry at Aalesund hospital Change Control was first established in 2010 at the Institute of Transfusion Medicine as a claim of the producer of blood products. The department experienced that Change Control was a suitable tool for implementation in the entire department which consists of four laboratories located at four different hospitals.

Method

Change Control ensures that every change in systems or methods will be followed in a controlled and coordinated way. The procedure includes changes in e.g. analytical methods, instrumentation, IT-programs, routines and organization. Prior to all changes a risk assessment will be performed. All changes must be documented in the same template which has to be signed by the laboratory specialist and the laboratory leader.

Examples of questions to be replied to in the form:

Before start:

- What are you going to change?
- Why?
- When?

Give a short overview of the changes.

Perform a risk assessment:

- What kind of risk factors may be involved
- What can be done to avoid the risks
- What can be done to minimize any consequences

After the leaders approval:

Make a plan

Consider who, what and where the changes eventually have implications for

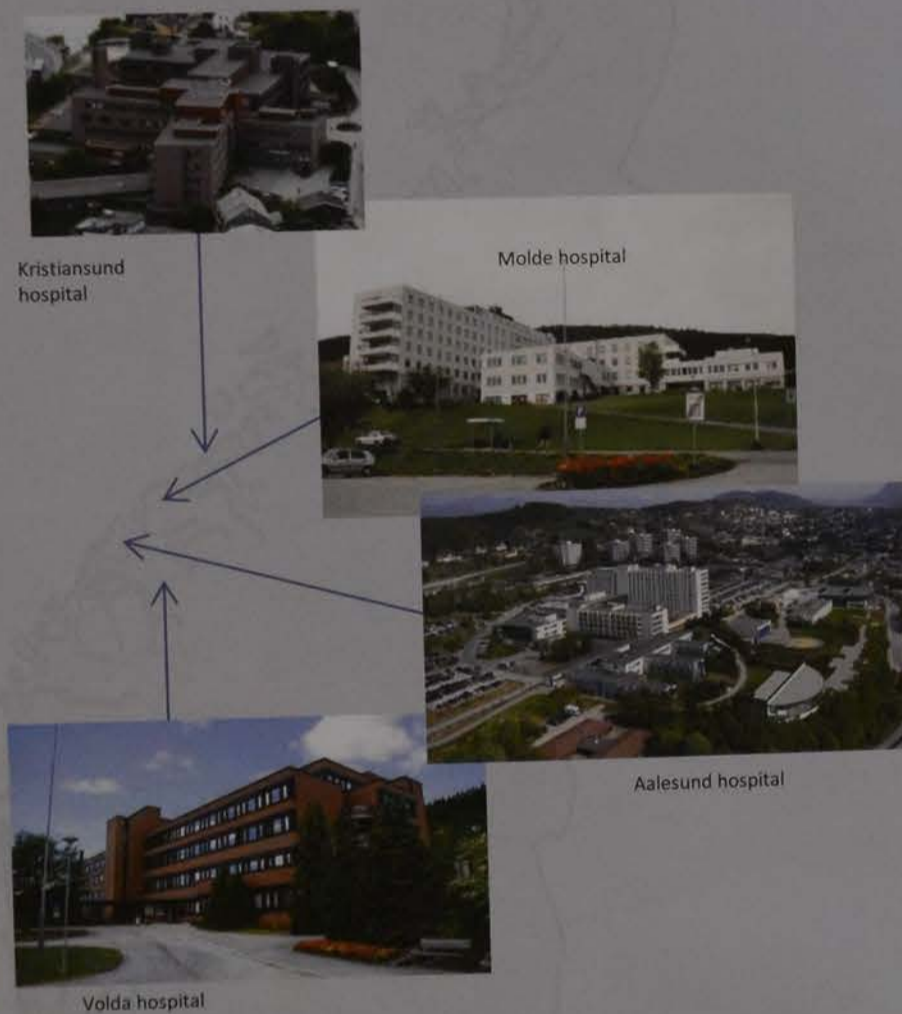
- Environment?
- Locations?
- IT-programs?
- Instrumentations?
- Education?
- New procedures?
- Information?
- Support?
- Other?

Perform documentation of every change that has been done

- Validation
- Verification

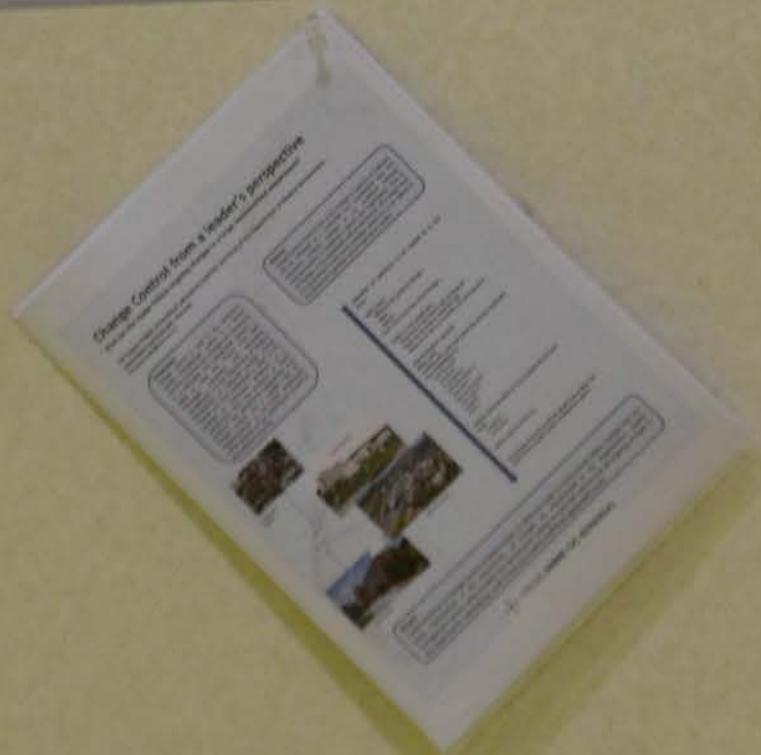
Make a plan for follow up

The change control form will be signed by the leader and saved in the hospitals quality management system.



Results

Implementation of Change Control enables leaders at different levels to continuously follow changes that are being implemented in the laboratories. All changes are documented in the department's quality management system which enables the department's leader to have full control over all ongoing changes in the department's laboratories, even if they are located in different geographic areas.



Laboratory Management
PM-09

Reduction in Hospital-Wide Clinical Laboratory Specimen Identification Errors following Process Interventions: A 10-year Retrospective Observational Study

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Introduction

- Accurate patient identification and specimen labeling at the time of collection are crucial steps in the prevention of medical errors, thereby improving patient safety.
- Common errors related to patient samples occur at the time of collection and often involve mismatched requisition and specimen labels, and unlabeled or mislabeled specimens. Though frequent, we believe that such errors in patient specimen identification (ID) can be almost entirely eliminated. In this retrospective observational study over a 10-year period.

Material and Methods

All patient specimen identification errors that occurred in the outpatient department (OPD), emergency department (ED), and inpatient department (IPD) of a 3,800-bed academic medical center in Taiwan were documented and analyzed retrospectively from 2005 to 2014. To reduce such errors, the following series of strategies were implemented:

1. **Intervention I**: a restrictive specimen acceptance policy for the ED and IPD on 1 April 2006. Relabeling of mislabeled or unlabeled specimens was not allowed, except for in cases of irretrievable specimens.
2. **Intervention II**: a computer-assisted barcode positive patient ID system for the ED on 1 August 2007. Positive patient/specimen identification.



The nurse would use a wireless barcode reader scan their own employee ID badge, then scan the patient wristband barcode, and lastly scan the barcode label on collection tubes to identify the patient. If the patient information of bar-codes not matched, the system will alarm by noise.

3. **Intervention III**: automated sample labeling combined with electronic identification systems introduced to the OPD in June 2009. Two automated tube selecting/label tracking systems (BC-ROBO®787, Techno Medica, Yokohoma, Japan)

Computer-assisted barcode positive patient/specimen identification systems

1. Automatic phlebotomy tube barcode labeling system used in OPD.
2. Scanning the barcode of the patient's collection tubes list and get all the test order information on the screen.
3. Phlebotomist asking patient's name and reading the patient's healthcare insurance cards.
4. Auto-matching the collection tubes ID with healthcare insurance card's ID.
5. Computer matching correct will show "O", if not, will show "X" on the screen.
6. The phlebotomist can perform venipuncture procedure.

4. **Intervention IV**: a computer-assisted barcode positive patient identification system for the IPD in 2010.

Results

Table 1. Comparing patient identification errors between 2005 and 2014.

Sites	January-December, 2005			January-December, 2014			Reduction (%)	P
	Errors	Specimens	Error%	Errors	Specimens	Error%		
ED	423	399,636	0.106	3	444,017	0.0007	99%	<0.001
IPD	556	947,156	0.058	52	1,158,402	0.0045	92%	<0.001
OPD	44	653,553	0.007	3	2,158,819	0.0001	98%	<0.001
Institution	1,023	2,000,345	0.051	58	3,761,238	0.0015	97%	<0.001

Abbreviations: ED, emergency department; IPD, inpatient department; OPD, outpatient department.

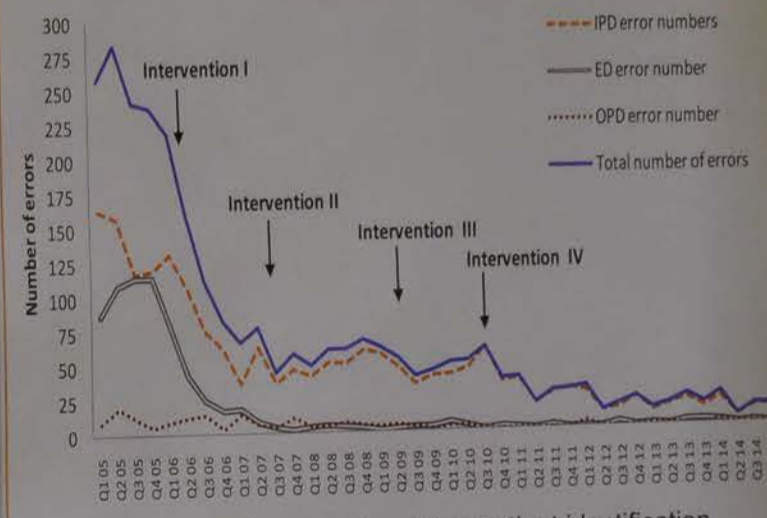


Figure 1. Quarterly errors (y-axis) in patient identification over a 10-year period at LinKou Chang Gung Memorial Hospital. Arrows indicate the start of the four interventions.

Table 2. Specimen identification errors before and after serial interventions

Intervention	Period	Sites	Errors (%)	Specimens	Reduction (%)	P
Pre-intervention I	Apr. 2005-Mar. 2006	ED	415 (0.1034)	401252		
Post-intervention I	Apr. 2006-Mar. 2007	ED	102 (0.0246)	414162	76%	<0.001
Pre-intervention I	Apr. 2005-Mar. 2006	IPD	524 (0.0546)	959930		
Post-intervention I	Apr. 2006-Mar. 2007	IPD	279 (0.0280)	994901	49%	<0.001
Pre-intervention II	Aug. 2006-Jul. 2007	ED	64 (0.0151)	424738		
Post-intervention II	Aug. 2007-Jul. 2008	ED	14 (0.0033)	419905	78%	<0.001
Pre-intervention III	Jun. 2008-May. 2009	OPD	18 (0.0012)	1501198		
Post-intervention III	Jun. 2009-May. 2010	OPD	11 (0.0007)	1601059	43%	0.141
Pre-intervention IV	Sep. 2010-Aug. 2011	IPD	185 (0.0164)	1125755		
Post-intervention IV	Sep. 2010-Aug. 2011	IPD	127 (0.0112)	1135092	32%	<0.001

Of the 2000345 specimens collected in 2005, 1023 (0.0511%) were identified as having patient identification errors, compared with 58 errors (0.0015%) among 3761238 specimens collected in 2014, after serial interventions; this represents a 97% relative reduction. The total number (rate) of institutional identification errors contributed from the ED, IPD, and OPD over a 10-year period were 423 (0.1058%), 556 (0.0587%), and 44 (0.0067%) errors before the interventions, and 3 (0.0007%), 52 (0.0045%) and 3 (0.0001%) after interventions, representing relative 99%, 92% and 98% reductions, respectively.

Conclusion

Accurate patient identification is a challenge of patient safety in different health settings. The data collected in our study indicate that a restrictive specimen acceptance policy, computer-generated positive identification systems, and interdisciplinary cooperation can significantly reduce patient identification errors.

Laboratory Management
PM-10

Using the TPR System to Reduce Accidents and Improve Patient Safety

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Objectives

Patient safety is the foundation of all quality medical services. In order to effectively handle errors and reduce the number of such incidents, Chi Mei Medical Center has established the TPR (Tainan Patient Safety Reporting) system. According to the TPR system, our division reflects on the mistake, analyzes the cause and nature of the mistake, and then develops a precaution and prevention mechanism to keep the mistake from happening again. This allows our division to avoid the same kind of error and to maintain a safe medical environment.

Reporting Incidents and Data Analysis

There were 99 errors in our division in 2015. The majority of these incidents - 55 of them - were about laboratory medicine. The second most common type of mistake involved blood transfusions. There were 41 of these.

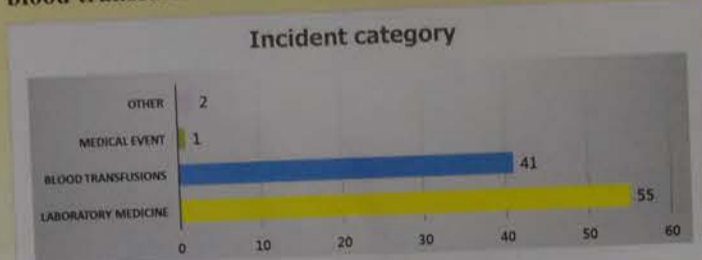


Fig 1. The category of the incidents from TPR system in 2015.

The reporting unit was mainly from the Division of Clinical Pathology (CP), which reported 60 incidents, then OPD with 7 incidents.

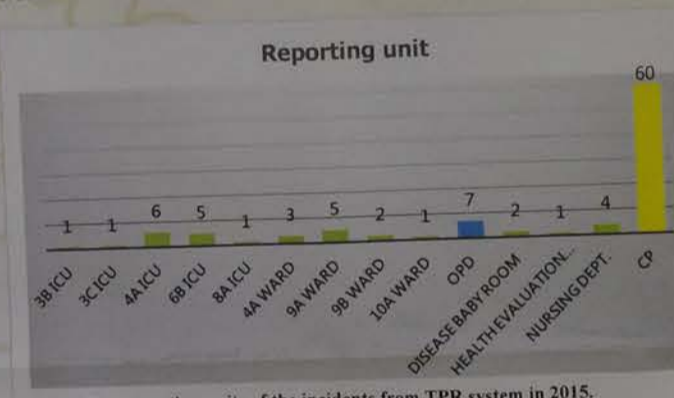


Fig 2. The reporting units of the incidents from TPR system in 2015.

The incident occurred unit was mainly from the Division of Clinical Pathology (CP) with a total of 41 incidents, then ER with 6 incidents.

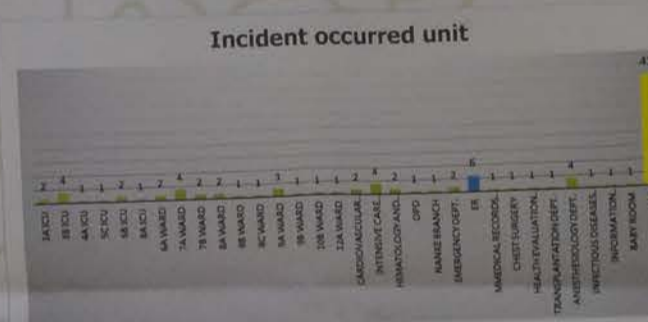


Fig 3. The incident occurred unit from TPR system in 2015.

Most of the mistakes - 65 of them - occurred during working hours between 8:00 and 17:00.

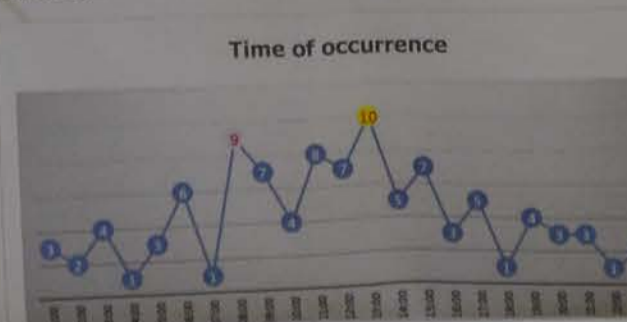


Fig 4. The time of incident from TPR system in 2015.

The Severity Assessment Code (SAC) of 97 incidents is four, ranging from extreme nearly misses to harmless.

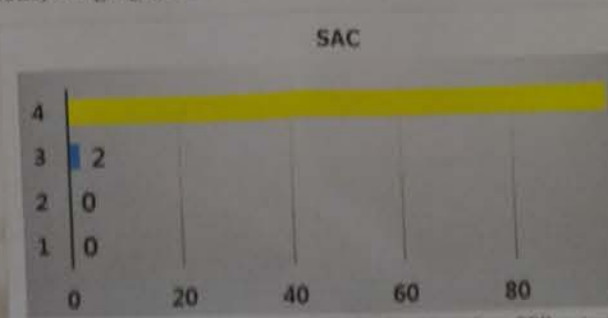


Fig 5. The Severity Assessment Code (SAC) of incidents from TPR system in 2015.

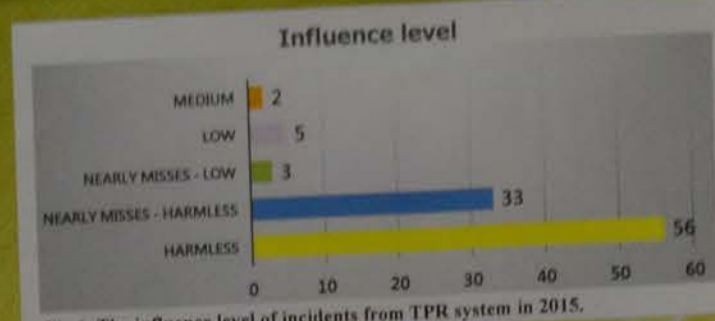


Fig 6. The influence level of incidents from TPR system in 2015.

The majority of stages where errors occurred in sample collection and delivery was 46. There were 31 blood products discarding incidents, and 10 mistakes involving sample analysis and implementation.

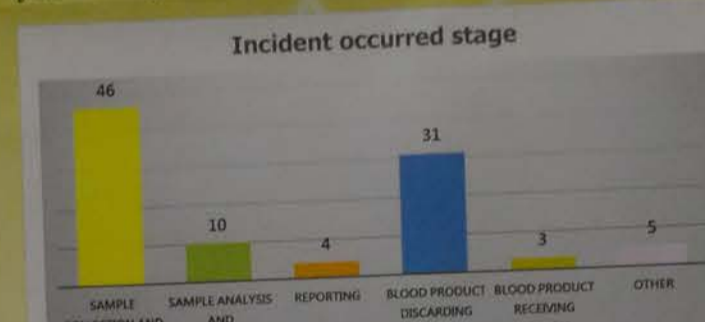


Fig 7. The number of incident occurred stage from TPR system in 2015.

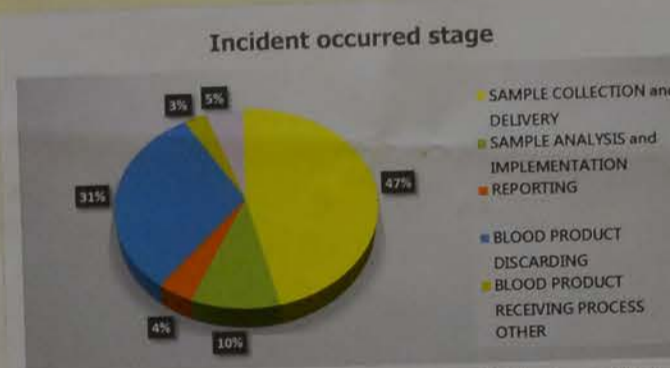


Fig 8. The percentage of incident occurred stage from TPR system in 2015.

Reasons, Results, and Improvements

- Ten incidents were analyzed as system errors and were handled and tracked in a Non-Conformance Report (NCR). Six of the mistakes were resolved by modifying codes from the Laboratory Information System (LIS), and no further problems occurred.
- In the first quarter, five incidents occurred in Specimen Hemolysis. They were caused by operational errors committed by new employees that were using the Specimen Receiving System. The mistakes were resolved by additional hands-on testing, as well as further professional development and training. No such errors occurred in the second through fourth quarters.
- During the first half-year, there were eight incidents caused by clinical identification errors. Samples were mistakenly extracted or sample barcodes were misplaced on blood collection tubes. These errors occurred during peak hours and were partly a result of shortage of labor. Clinical units now make an effort to strengthen patient label accuracy and barcode identification. They also send labor support during peak hours. During the second half-year, the errors decreased by 80%.
- For the first half-year, five incidents happened between 5:00 - 7:00. On-duty medical assistants were re-evaluated. They were also re-trained in standard operating procedures. As a result, the error rate decreased by 60% during the second half of the year.
- Fourteen blood products were discarded due to improper storage. Eight incidents were reported as unnecessary by doctors. Seven were operational errors made by medical employees. In order to resolve these issues, the clinics readjusted the standard operating procedures (SOP) of blood product ticketing. This involved re-examining warning labels, blood product storage procedures, and the tracking of occurring rates of abnormal incidents.

Conclusion

By maintaining statistics of abnormal incidents and by utilizing cause analysis, error occurrence rates will decrease. At the same time, patient safety will increase. This will help reach the goal of a standardized medical environment.

Laboratory Management PM-11

Analysis of Turnaround Time for Inpatient Specimens after organizational integration in a Medical Center in Taiwan

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Introduction

The laboratory turnaround time can be defined differently according to the test type (stat vs routine), analyte, and institution. It is commonly defined as the time from when a test is ordered until the result is reported. The Department of Clinical Pathology in Medical Center in Taiwan defines the laboratory turnaround time (TAT) for outpatients as the time taken from printing a barcode to reporting the test result.

Traditionally, laboratory TAT is determined by the timely progress of 3 phases of testing: preanalytical, analytical, and postanalytical. We designed a new LIS that records TAT data automatically and analyzes the time taken for the 3 phases that comprise the total laboratory TAT for each test.

Laboratory analytical turnaround time (TAT) is regarded a reliable indicator for laboratory effectiveness. The study was to assess laboratory analytical turnaround time in our laboratory and determine the contribution of the different phases after organizational integration.

Method:

The barcode sample see Fig1. TAT is subdivided into preanalytical, analytical, and postanalytical phases based on four checkpoints when reading barcodes, the data are entered automatically into the LIS (Fig 2). The turnaround time (TAT) for all the samples (both routine and emergency) from a medical center for the hospitalized patients were evaluated for one year.

RESULTS

The average TAT for the clinical chemistry samples for before organizational integration and after organizational integration were 3.11 h and 2.22 h for routine inpatient samples. Completion times of the preanalytical, analytical, and postanalytical phases for clinical bio-chemistry for before organizational integration were 52.75±19.58, 81.53±29.09, and 52.09±20.10 min, respectively (Fig3); for after organizational integration were 55.38±16.48, 34.18±12.98, and 43.60±19.34 min, respectively (Fig4).

Conclusion:

For specimens reported between 60 and 90 min, the preanalytical phase was found to need improvement in order to shorten TAT; the main target for improvement was identified as the "waiting time for phlebotomy" step. The TAT demonstrates the need for improvement in the pre- and post-analytical periods. Monitoring the TAT periodically for different phases is beneficial to patient safety.

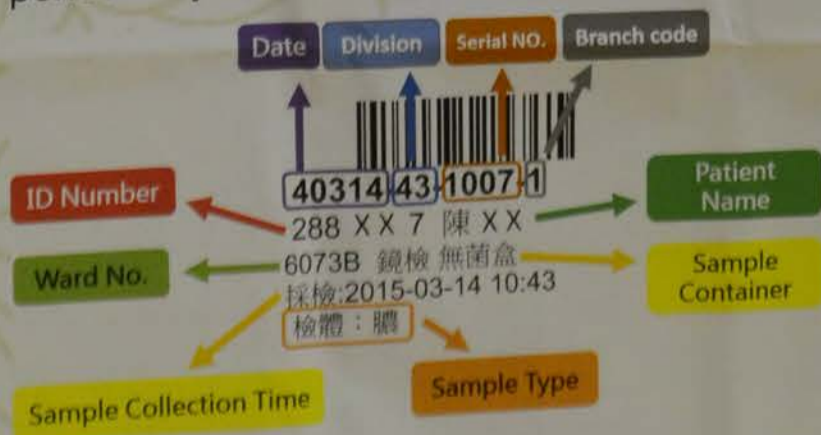


Fig 1 The barcode sample



Fig 2 Sample Tracking System



Fig 3 The average TAT for the clinical chemistry samples for before organizational integration. (mins)

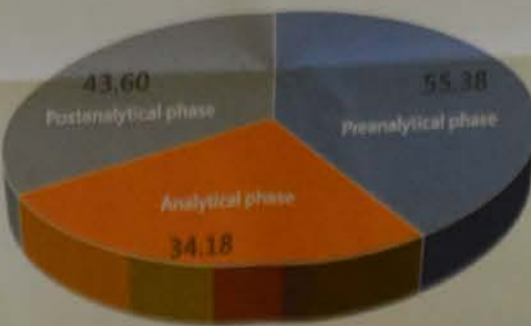


Fig 4 The average TAT for the clinical chemistry samples for after organizational integration. (mins)

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LABORATORY SYSTEM IN MONGOLIA

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Survey goal

Identify areas in which efforts should be directed in order to strengthen the national laboratory system in Mongolia.

Subjects and Methods

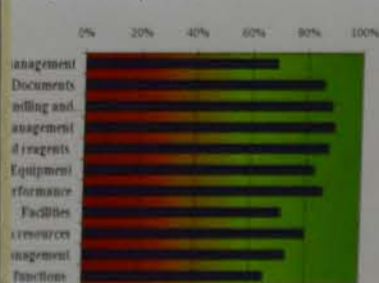
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Table 1. Average scores of various laboratory types

#	Modules	Public labs	Private labs	Big labs	Small labs	Rural labs	Urban labs
1	Organization and management	65%	71%	73%	55%	64%	74%
2	Documents	86%	74%	52%	79%	81%	90%
3	Specimen collection, handling and transport	85%	77%	91%	87%	89%	89%
4	Data and information management	88%	86%	93%	82%	87%	92%
5	Consumables and reagents	88%	86%	94%	80%	77%	84%
6	Equipment	84%	78%	84%	72%	71%	91%
7	Laboratory testing performance	91%	76%	88%	84%	81%	89%
8	Facilities	64%	73%	76%	59%	68%	77%
9	Human resources	74%	87%	88%	57%	72%	64%
10	Biorisk management	79%	80%	93%	62%	70%	76%
11	Public health functions	70%	42%	83%	52%	66%	64%
	Overall average	80%	73%	88%	68%	75%	83%

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Conclusions and Recommendations

1. A national regulatory body needs to be established for the registration of all laboratories and laboratory professional staff.
2. Each laboratory should formally designate an appropriately trained Quality manager.
3. A formal professional development/continuous education system for laboratory professionals should be set-up.
4. Biosafety policy and implementation plan need to be developed.

Laboratory Management PM-12

Improving Patient Safety by Introducing an Effective Intelligence Technology-Based System for Critical Value Notification

Jung-Chin Chen, Le-Hsi Tsal, Yen-Hua Kung, Yen-Chun Lin, Hung-Wen Tsai, Department of Pathology, National Cheng-Kung University Hospital, Tainan, Taiwan.

Background

Approximately 4600 abnormal laboratory results were reported monthly in NCKUH. Although short message system (SMS) sent automatic messages, we needed to switch to a manual process in 5.4% of cases due to communication failure. It is time-consuming and potentially harmful for patients as a result of personal omission, especially for outpatients with life-threatening critical values. Therefore, we introduced a self-designed fail-safe intelligence technology-based critical value notification system (ITNOTIS) in 2015 to improve successful critical value notification rate and clinical intervention.

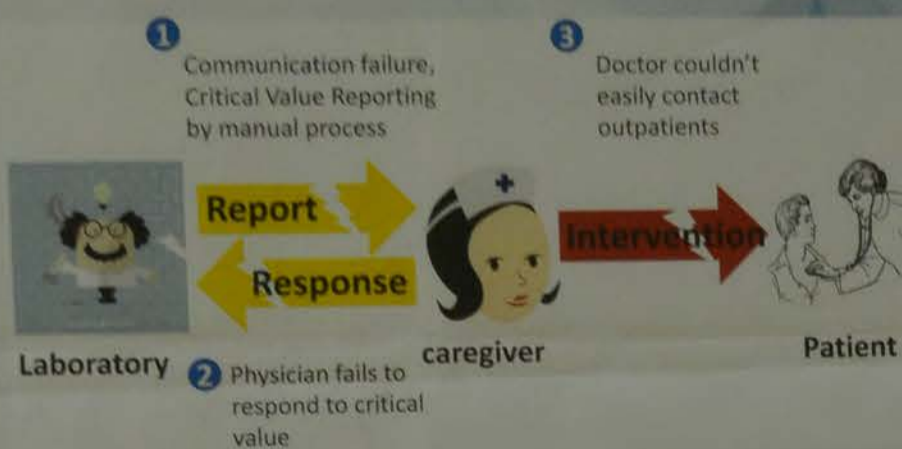


Figure 1. Problems in critical value notification

Method

Our new ITNOTIS system could fix those problems (Figure 1):

1. User-friendly system to replace handwritten steps:

When there is communication failure or no clinical feedback response, the laboratory will be alerted by a pop-up window, which offers the name and phone number of the responsible physician. The laboratory staff could quickly phone the physician and then all the events could be documented electronically (Figure 2).

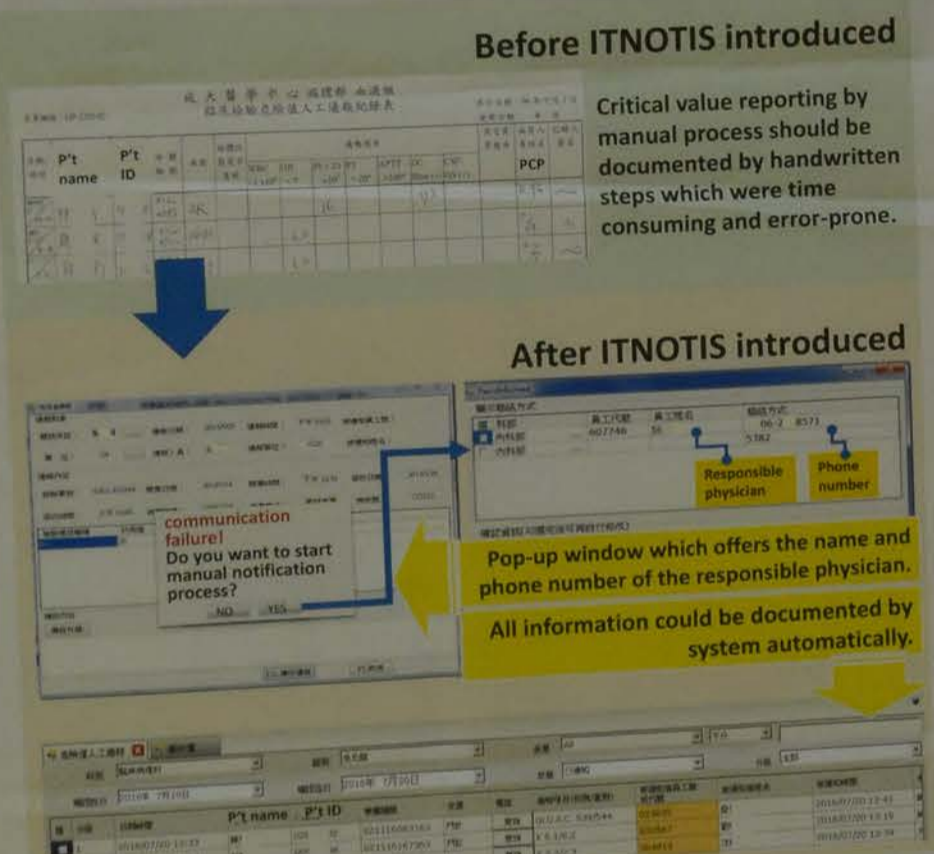


Figure 2. Differences before and after we introduce the ITNOTIS.

2. Back-up process for critical value notification:

If a primary care provider (PCP) fails to respond to a life-threatening critical value within 20 minutes, a back-up process will intervene. Our hospital call-center takes over to repeatedly calling the PCP or inform a second-line duty doctor (Figure 3). The ITNOTIS will automatically direct and record all steps, including follow-up of clinical interventions (Figure 4).

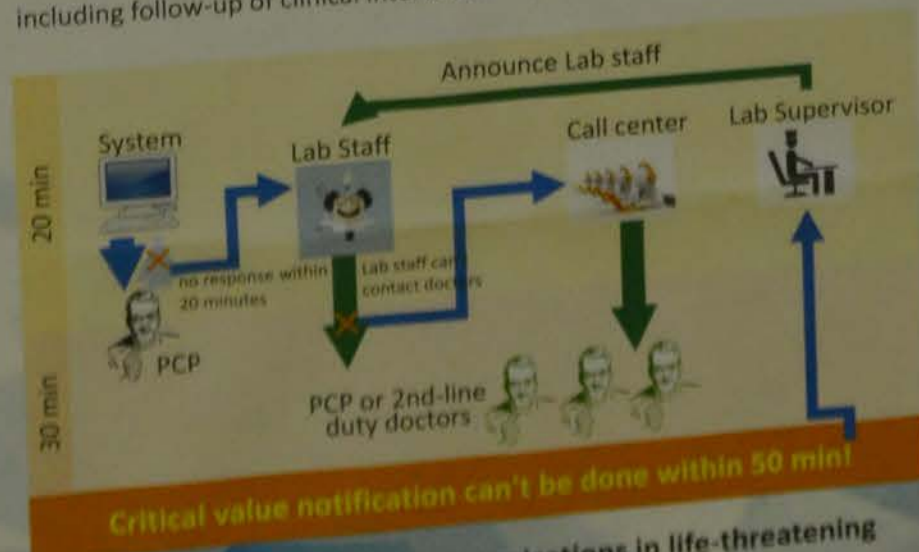


Figure 3. Cross-functional communications in life-threatening critical value notification. Green-blue arrows represent automatic system communication process; green arrows represent manual communication process. PCP, primary care provider.

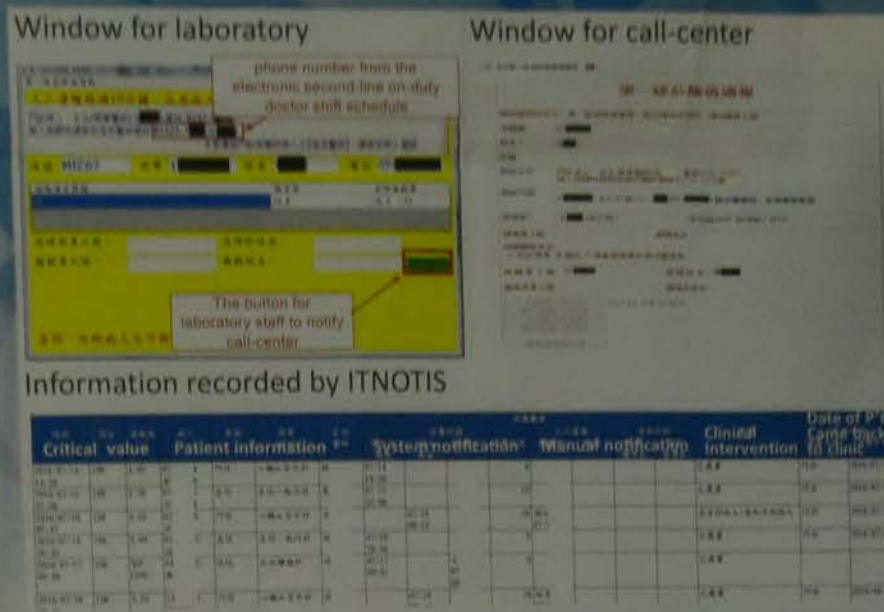


Figure 4. User-friendly interface offers sufficient information.

3. ITNOTIS identifies patient's location automatically, and offers patient's information effectively.

The system can send the outpatient's telephone number to the physician who can easily offer this information to the call-center. Then, the call-center operator will help connect the physician with the patient. If the physician can not contact the patient because of incorrect phone number, he can mark the event in the system. When the patient comes back to hospital, the system will alert an administration staff to correct the phone number.

Result

After introducing ITNOTIS system, we could:

1. Improve the manual notification time (5 min vs 1 min) and rate (92% vs 99%) (Figure 5).

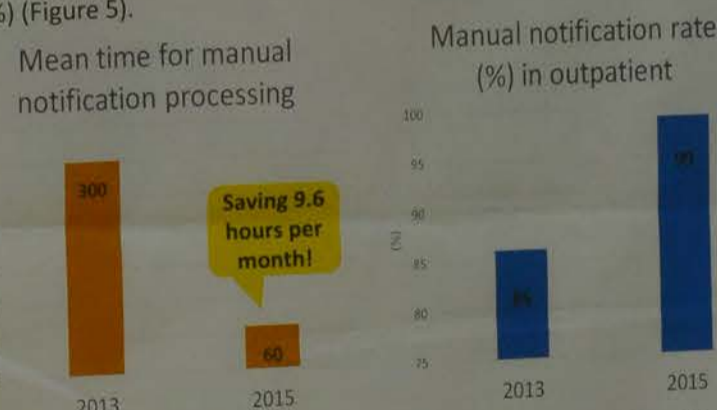


Figure 5. Improvement in manual notification process after ITNOTIS introduced.

2. A large proportion (24.5%) of life-threatening critical value notification was achieved by the back-up system, especially in outpatient (79%) (Table 1). Besides, ITNOTIS shortens the delay of physician's acknowledgement (the mean and median time: 10 and 2 minutes, respectively), especially in outpatients (Median time, from 333 to 26 minutes) and increases the rate of clinical interventions (97% of patients received subsequent treatment).

	Response within 20 minutes	Back-up system	Total number
Outpatient	156(21.0%)	588(79.0%)	744
Emergency	1273(68.5%)	586(31.5%)	1859
Inpatient	2442(96.8%)	80(3.2%)	2522
Total number(%)	3871(75.5%)	1254(24.5%)	5125
Mean acknowledgement time (min)	3	27	10

3. 152 outpatients were called back between April 2015 from March 2016, and 76% of them went back to hospital within 7 days (Figure 6).



Figure 6. Cumulative % of called-back outpatients from 2015/04~2016/03

Conclusion

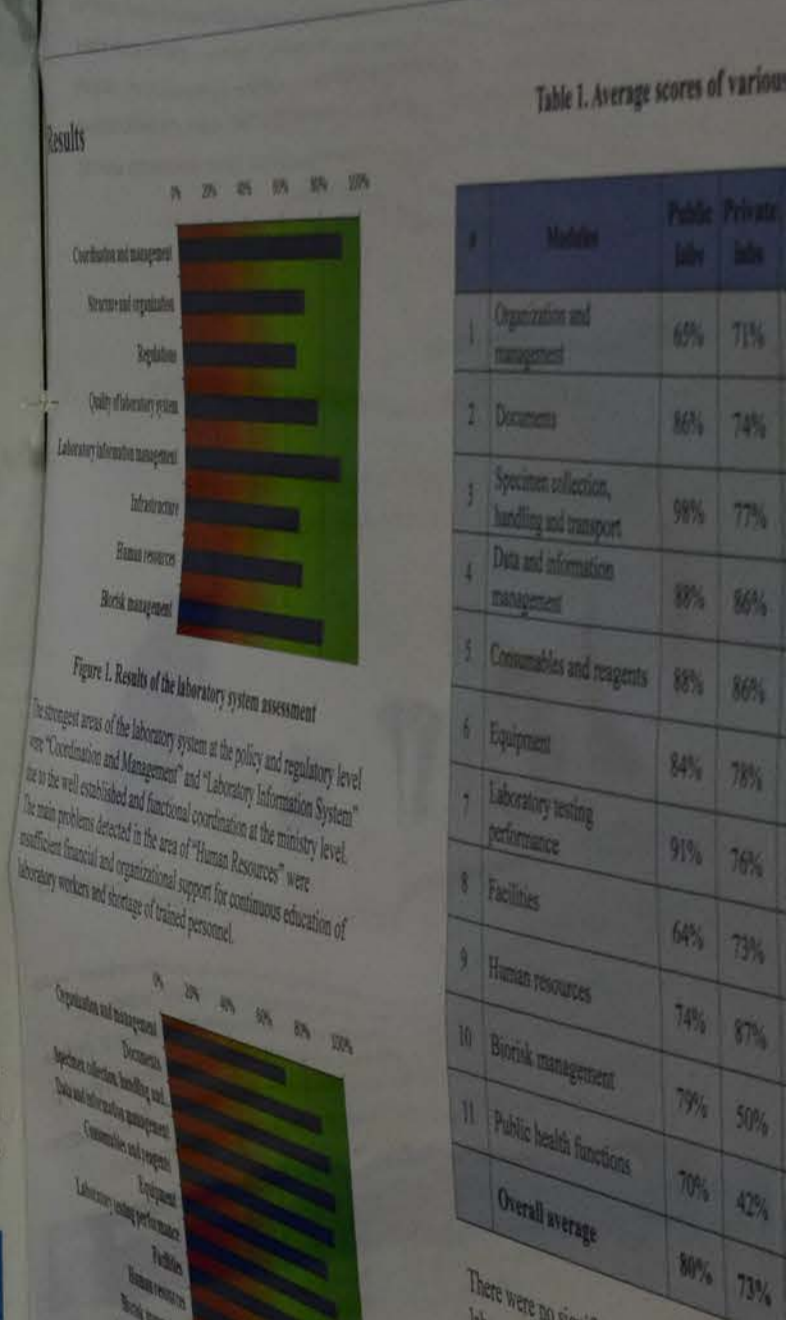
Our fail-safe ITNOTIS system improves the critical value notification by combining automation with manual process, and is more effective than SMS or telephone calling process alone, and has beneficial impact on outpatient care.

Laboratory Management PM-13

LABORATORY SYSTEM IN MONGOLIA
E. Takhjargal, P. Dulmaa, Y. Khudbayar, G. Nural, B. Nagymbold, J. Dulamjav, G. Chuluun, Mongolian Association of Health Laboratories, Mongolia, WHO, France and WHO, Mongolia. Contact e-mail address: rtd@wpro.who.int

Survey goal
Identify areas in which efforts should be directed to improve the national laboratory system in Mongolia.

Subjects and Methods
Two areas of the laboratory system were evaluated at the Ministry of Health level and specific technical laboratory level.
The assessment was conducted using the Laboratory System Assessment (LSA) tool.



There were no significant differences detected between public and private laboratories (75% vs. 83%, p=0.1), public and private laboratories (73% vs. 83%, p=0.1) (Table 6). The overall average scores of public and private laboratories were 80% and 73% respectively. Differences were found in the area of human resources (74% vs. 87%) and public health activities of laboratories (70% vs. 42%).

Conclusions and Recommendations

1. A national regulatory body needs to be established to oversee laboratories and laboratory professional staff.
2. Each laboratory should formally designate a laboratory manager.
3. A formal professional development/continuing education program for laboratory professionals should be set-up.
4. Biosafety policy and implementation plan should be developed.

Laboratory Management PM-13

LABORATORY SYSTEM IN MONGOLIA

T. Enkhjargal¹, P. Dubois², V. Khadkhuu¹, G. Naran¹, D. Regzedmaa¹, J. Dulamjav¹, G. Ghadiok³
¹Mongolian Association of Health Laboratorians, Mongolia, ²IQLS, France and ³WHO, Manila, the Philippines
 Contact e-mail address: enke98@yahoo.com

Introduction

Effective healthcare starts with an accurate diagnosis, and laboratory plays an important role in this. In fact, an estimated 70 – 80% of healthcare decisions affecting diagnosis and treatment involve laboratory investigations. Laboratory services are used not only in disease diagnosis and treatment monitoring but also in health programs for evidence based decisions. Therefore, it is important for a country to assess its laboratory status and identify strengths and gaps of health laboratories.

Survey goal

Identify areas in which efforts should be directed in order to strengthen the national laboratory system in Mongolia.

Subjects and Methods

- Two areas of the laboratory system were evaluated: strategic organization at the Ministry of Health level and specific technical capacities at the laboratory level
- The assessment was conducted using the Laboratory Assessment Tool

Results

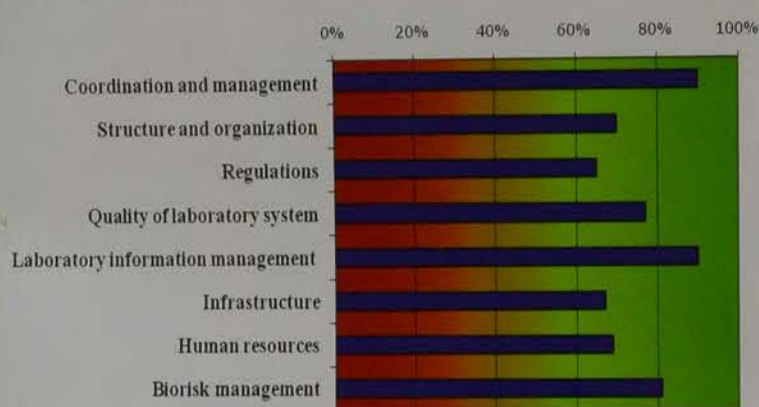


Figure 1. Results of the laboratory system assessment

The strongest areas of the laboratory system at the policy and regulatory level were "Coordination and Management" and "Laboratory Information System" due to the well established and functional coordination at the ministry level. The main problems detected in the area of "Human Resources" were insufficient financial and organizational support for continuous education of laboratory workers and shortage of trained personnel.

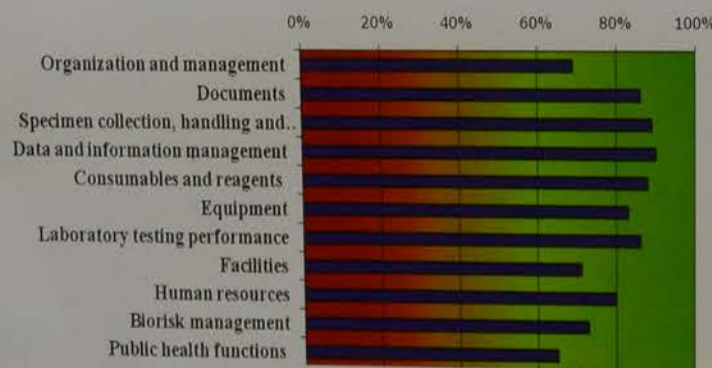


Figure 2. Results of the technical assessment of laboratories

The assessed laboratories were strong in "Data and Information Management", "Specimen Collection and Handling" and "Consumables and Reagents". The testing performance of most laboratories was excellent but the external quality assurance was not available in some test disciplines. Weaker areas were "Facilities", "Public Health Functions" and "Biorisk Management". Although the general safety management of laboratories was very good, the biosafety component was not incorporated in it.

Table 1. Average scores of various laboratory types

#	Modules	Public labs	Private labs	Big labs	Small labs	Rural labs	Urban labs
1	Organization and management	65%	71%	73%	55%	64%	74%
2	Documents	86%	74%	92%	79%	81%	90%
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10	Biorisk management	79%	50%	93%	63%	70%	76%
11	Public health functions	70%	42%	85%	52%	66%	64%
	Overall average	80%	73%	89%	69%	75%	83%

There were no significant differences detected between rural and urban laboratories (75% vs. 83%, $p=0.1$), public and private laboratories (80% vs. 73%, $p=0.4$) (Table 6). The overall average score was higher in bigger laboratories than in smaller ones (89% vs. 69%, $p=0.02<0.05$), and the highest differences were found in the area of human resources (unavailability of trained personnel) and public health activities of laboratories (involvement in the public health network).

Conclusions and Recommendations

1. A national regulatory body needs to be established for the registration of all laboratories and laboratory professional staff.
2. Each laboratory should formally designate an appropriately trained Quality manager.
3. A formal professional development/ continuous education system for laboratory professionals should be set-up.
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Background

Effective healthcare starts with an accurate diagnosis, and laboratory plays an important role in this. In fact, an estimated 70 – 80% of healthcare decisions affecting diagnosis and treatment involve laboratory investigations. Laboratory services are used not only in disease diagnosis and treatment monitoring but also in health programs for evidence based decisions. Therefore, it is important for a country to assess its laboratory status and identify strengths and gaps of health laboratories.

Method

Our new (TNOTS) system could fix those problems (Figure 1):

1. User-friendly system to replace handwritten steps:

When there is communication failure or no clinical feedback response, the laboratory will be alerted by a pop-up window, which offers the name and phone number of the responsible physician. The laboratory staff can quickly phone the physician and then all the events could be documented electronically (Figure 2).

Result

After introducing (TNOTS) system in result:

1. Improve the result notification rate from 61.4% to 95.9% (Figure 1)
2. Reduce the manual data entry time from 15 minutes to 5 minutes (Figure 2)
3. Reduce the manual data entry error rate from 10% to 2% (Figure 2)
4. Improve the result notification time from 15 minutes to 5 minutes (Figure 2)
5. Reduce the manual data entry time from 15 minutes to 5 minutes (Figure 2)
6. Reduce the manual data entry error rate from 10% to 2% (Figure 2)

Figure 1. Problems in critical value notification

Figure 2. Differences before and after we introduce the (TNOTS)

2. Back-up process for critical value notification:

If a primary care provider (PCP) fails to respond to a life-threatening critical value within 20 minutes, a back-up process will intervene. Our laboratory doctor (Figure 2) The (TNOTS) will automatically alert and record all steps including follow-up of critical interventions (Figure 4).

Figure 3. Comparison of critical value notification before and after we introduce the (TNOTS)

Figure 4. User-friendly interface offers sufficient information

Figure 5. (TNOTS) identifies patient location automatically and offers patient's information effectively

The system can send the location information to the physician and can reach the information to the patient. The physician can call the patient and the patient can call the physician. The physician can also contact the patient because of some phone number or not. In the event in the system when the patient medical records are not all set, an administrator can correct the error number.

Figure 6. Comparison of critical value notification before and after we introduce the (TNOTS)

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Laboratory Management PM-14

To get all the test results immediately at any time, make a 10,000-bed hospital. Then you can hire many laboratory technicians who can work weekends and at night by taking weekdays off.
Yasushi Kunou, Laboratory Medicine, Nagoya City West Medical Center

[Introduction] Importance of getting test results immediately

A patient comes with a headache at midnight.

A cerebrospinal fluid sample is taken. ⇒ ⇒ ⇒ ⇒ ⇒ ⇒ ⇒ ⇒

(Case 1) Suppose we get the results immediately.

And the herpes simplex virus result is positive.

⇒ The patient needs acyclovir only.

(Case 2) Suppose we cannot get the results immediately.

⇒ The patient needs medications for herpes, bacteria, fungi and TB.

Lumber puncture



[Methods to get test results immediately]

Japan is over populated.

⇒ 10,000 patients are hospitalized within a radius of 20 kilometers in big cities.



Consolidate small hospitals into a 10,000-bed hospital.

⇒ This huge hospital can hire extremely many laboratory technicians.

⇒ Make many of them work weekends and at night.

And let them take weekdays off.

Make them work like people in Las Vegas. ⇒ ⇒ ⇒ ⇒



[Results concerning tests]

There are extremely many technicians in a 10,000-bed hospital.

⇒ They can do all the tests inside the hospital anytime.

⇒ Almost all the test results come immediately anytime.

[Results concerning doctors]

1) Huge hospitals can hire extremely many doctors.

⇒ Make many doctors work on weekends and at night.

And let them take weekdays off.

(Example) A doctor works 4 times a week in the green parts below.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		9am 5pm		9am 5pm	5pm	9am
9am 5pm						

⇒ Specialists always see patients even on weekends and at night.

2) Huge hospitals accept all the ambulances.

⇒ Small hospitals need no technicians at night.

3) Surgeries are done immediately anytime.

4) Patients who work on weekdays can have colonoscopy on weekends.

⇒ More early cancers will be found.

5) The number of doctors in one 10,000-bed hospital is smaller

(Example) One 10,000-bed hospital has 1,000 doctors.

One 500-bed hospital has 100 doctors.

⇒ Twenty 500-bed hospitals have 20 X 100 = 2,000 doctors.

Hence the government saves money.

[Conclusion]

We need huge hospitals.

学会後、廃棄して下さい

Laboratory Management PM-15

The study of radioimmunoassay laboratory management and quality control and effects analysis (HFME) assessment tool to prevent tumor marker laboratory failure mode and effects analysis (HFME)

Ming-Shu Chen¹, Jia-Ling Chen²
¹ Department of Health Care Administration, Oriental Institute of Technology, Far Eastern Memorial Hospital, New Taipei City, Taiwan
² Department of Nuclear Medicine, Far Eastern Memorial Hospital, New Taipei City, Taiwan

BACKGROUND: Healthcare failure mode and effect analysis (HFMEA) is a risk management tool used by accreditation organizations (CAHO), is used to analyze risks, identify failures before they happen and prioritize remedial actions. The purpose of this study was to evaluate the frequency, type, preventability, as well as the impact of errors in a radioimmunoassay (RIA) laboratory of a tertiary care hospital. The study aimed to identify the hazards associated with the process and identify the areas needing improvement.

METHODS: The HFMEA tool and HFMEA program was performed in a radioimmunoassay laboratory between June 2015 and December 2015. The multidisciplinary teams consisted of 3 physicians, 3 laboratory medical technologists and 1 nurse practitioner. The teams were trained to analyze the process of tumor markers reporting, to identify failures and potential effects. Potential probability and severity were classified according to the HFMEA Severity Scale. The study planned to identify the risks and assessed the improvement of medical quality and patient safety.

RESULTS: After analyzing the 23 sub-steps from the 5 main steps (A-E) in the process, 31 failure modes, 40 associated causes and 40 associated effects were identified (as the Table 2). The main reasons were: (1) sample errors, (2) insufficient labeling, (3) outsourcing laboratory errors, and (4) manual data input errors. The improvement actions included: (1) to specify the information of test specimen on the web page, (2) to follow major outliers, (3) to double check sample aliquots, (4) to reduce the outsourcing lab reports error rate, and (5) to double confirm the output of new activities in the revised process significantly reduced the severity scores.

Table 1. The flow chart of tumor marker tests check-up in radioimmunoassay laboratory

Main step A	Main step B	Main step C	Main step D
Orderable	Sampling	Outsourcing	Report input
A-1 Doctor's orders	B-1 Patient identification	C-1 Delivery persons charged	D-1 Manual input report
A-2 Print orders to patient	B-2 Signify order and print barcodes	C-2 Check the specimen	D-2 Confirmation report
A-3 Changes	B-3 Check the blood collection tubes	C-3 Input outsourcing code	
A-4 Input items to LIS	B-4 Paste the barcode stickers	C-4 Outsourcing in testing	
	B-5 Double check specimen and order	C-5 Print the paper report	
	B-6 Secondary signing and specimen centrifugation	C-6 Report to RIA laboratory	
	B-7 Paste the outsourcing barcode stickers on dispensing specimens for the check in		
	B-8 Package the outsourcing specimens and the check in		

Table 2. The Hazard Analysis Matrix and Risk score Index table

No.	Main step	Secondary process	Potential failure modes	Potential causes
B	Sampling	B-4 Paste the barcode stickers	B-4-1 Specimen error (Barcode sticker wrong)	B-4-1-1 Blood sample the wrong bar code
		B-5 Double check specimen and order	B-5-1 Repeating delay (A specimen into B)	B-5-1-1 Insufficient sample names and specimen abnormalities
		B-7 Paste the outsourcing barcode stickers on dispensing specimens for the check in	B-7-1 Repeating delay (A specimen into B)	B-7-1-1 When the M sample did not care names and specimen abnormalities
C	Outsourcing	C-4 Outsourcing in testing	C-4-1 Analysis process error	C-4-1-1 Laboratory abnormalities
		C-5 Print the paper report	C-5-1 Wron report	C-5-1-1 Testing error report
D	Report input	D-1 Manual input report by MT	D-1-1 Wron report	D-1-1-1 Manual key or report attributed to test field
		D-2 Confirmation report	D-2-1 Testing error report	D-2-1-1 Manual input physician: System retrieve data

CONCLUSIONS: HFMEA is an effective tool to identify the risks associated with the process of tumor marker laboratory management and quality control. The study aimed to identify the hazards associated with the process and identify the areas needing improvement.

The study of radioimmunoassay laboratory management and quality control

Healthcare failure mode and effects analysis (HFMEA) as a risk-assessment tool to prevent tumor marker laboratory report errors
Ming-Shu Chen^{*1}, Jia-Ling Chen²

^{*1}. Department of Health Care Administration, Oriental Institute of Technology, New Taipei City, Taiwan
². Department of Nuclear Medicine, Far Eastern Memorial Hospital, New Taipei City, Taiwan

BACKGROUND: Healthcare failure mode and effect analysis (HFMEA), proposed by Joint Commission on Accreditation of Healthcare Organizations (JCAHO), is a proactive tool used to analyze risks, identify failures before they happen and prioritize remedial measures. Aims of this study were to evaluate the frequency, type, preventability, as well as severity of tumor marker report errors in a radioimmunoassay (RIA) laboratory of a tertiary medical center, to examine the hazards associated with the process and identify the areas needing improvement.

METHODS: The RFID tool and HFMEA program was performed in the RIA laboratory between June 2015 and December 2015. The multidisciplinary teams including 3 nuclear physicians, 3 laboratory medical technologists and 1 nurse practitioner and 1 HFMEA staff were trained to analyze the process of tumor markers reporting, to identify possible causes of failures and potential effects. Potential probability and severity were classified using a four-point scale according to the HFMEA Severity Scale. The study planned to reduce the failure risks and assessed the improvement of medical quality and patient safety.

RESULTS:

After analyzing the 23 sub-steps from the 5 main steps (A-E) in the process (as the Table 1), errors were classified into 31 failure modes, 40 associated causes and effects were identified (as the Table 2). The main reasons were: (1) sample errors, (2) insufficient specimen, (3) outsourcing laboratory errors, and (4) manual data input errors. The improvement procedures included: (1) to specify the information of test specimen on the website, (2) to regularly follow major outliers, (3) to double check sample aliquots, (4) to periodically review outsourcing lab reports error rate, and (5) to double confirm the outsourcing reports. The introductions of new activities in the revised process significantly reduced failure rates and severity scores.

Table 1. The flow chart of tumor Marker tests check-up in radioimmunoassay laboratory

Main step A	Main step B	Main step C	Main step D	Main step E
Orderable	Sampling	Outsourcing	Report input	Report confirms
A-1 Doctor's orders A-2 Print orders to patients A-3 Charges A-4 Upload items to LIS	B-1 Patient identification B-2 Signing order and print barcodes B-3 Check the blood collection tubes B-4 Paste the barcode stickers B-5 Double check specimen and order B-6 Secondary signing and specimen centrifugal B-7 Paste the outsourcing barcode stickers and dispensing specimen B-8 Package the outsourcing specimen and the check list	C-1 Delivery persons charged specimen C-2 Check the specimen C-3 Input outsourcing code C-4 Outsourcing in testing C-5 Print the paper report C-6 Report to RIA laboratory	D-1 Manual input report D-2 Confirmation report	E-1 Issued report E-2 Report return E-3 Critical values alarm

Table 2. The Hazard Analysis Matrix and Risk score Index table

No	Main process	Sub No	Secondary process	Potential failure modes	Potential causes of failure mode	RSI ^a	S ^b	O ^c	RN ^d
B	Blood sampling	B-4	Paste the barcode stickers	B-4-1 Specimen error (Barcode stickers wrong)	B-4-1-1 Blood sampling counters posted the wrong bar code stickers	4	1	4	
		B-5	Double check specimen and order by MT	B-5-1 Reporting delay	B-5-1-1 Insufficient specimen volume	2	4	8	
		B-7	Paste the outsourcing barcode stickers and dispensing specimen	B-7-1 Specimen error (A specimen into B tube)	B-7-1-1 When the MT dispensing the sample, did not carefully check the names and specimen ID	4	1	4	
C	Outsourcing	C-4	Outsourcing to analysis and testing	C-4-1 Analysis process error	C-4-1-1 Laboratory quality control abnormalities	4	1	4	
				C-4-2 Error report	C-4-1-2 Reagents abnormalities C-4-1-3 Equipment abnormalities C-4-2-1 Testing process produces an error report	4	1	4	
D	Report input	D-1	Manual input report by MT	D-1-1 Wrong report	D-1-1-1 Manual key in the wrong data or report attributed to incorrect patient	4	1	4	
					D-1-1-2 Manual input report, key wrong test field	4	1	4	
E	Report confirms	E-3	Critical values alarm	E-3-1 Delayed diagnosis and treatment of Dr.	E-3-1-1 The system do not inform the physician; System do not automatically retrieve data	4	1	4	

^a RSI: risk score index; ^b S: severity; ^c O: occurrence; ^d RN: risk number = severity (S) x occurrence (O)

CONCLUSIONS: HFMEA is an effective proactive risk-assessment tool useful to aid in identifying errors of RIA tumor marker reports, and enhancing the laboratory quality.

KEYWORDS: Laboratory Quality Improvement; RFID tool; Tumor Markers; Healthcare Failure Mode and Effects Analysis (HFMEA)



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Using Root Cause Analysis to Improve The Problem of Missing Specimen

Shou-Cheng Lu¹, Yi-Fang Lin¹, Chia-Mei Yeh¹, Kun-Ching Chen¹,
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¹Department of laboratory medicine, ²Department of education,
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Background

Jobs of laboratory specimen for test results has the right owner inseparable impact include: identification of specimen transport, receive, handling, storage, destruction. Therefore our laboratory list some indicators for quality improvement conference like Patient Identification, Specimen Lose, Rejection Rate of Specimens to be instant and accurate.

Method

Find specimen loss reasons can be divided into pump leak, the specimen mistakenly lost, falling to track and unknown reason in total of all we found there were three specimen in 2014 February and March. So for this case analysis and we find four high risk spaces (Picture 1) when transport specimen to basement floor. And we take the measures:

1. Replace transparent acrylic to replace black acrylic to see specimen falling to track we can see it (Picture 2)

2. Specimen labeled clearly informed when the specimen do not exceed this height to avoid overflow. (Picture 3)

3. When transport have inspection must use step to avoid inspection too thick to step

4. Laboratory workers cut specimen transport speed to avoid specimen pop up in transit.



Picture 1. Four high risk specimen falling spaces



Picture 2. Replace acrylic to transparent

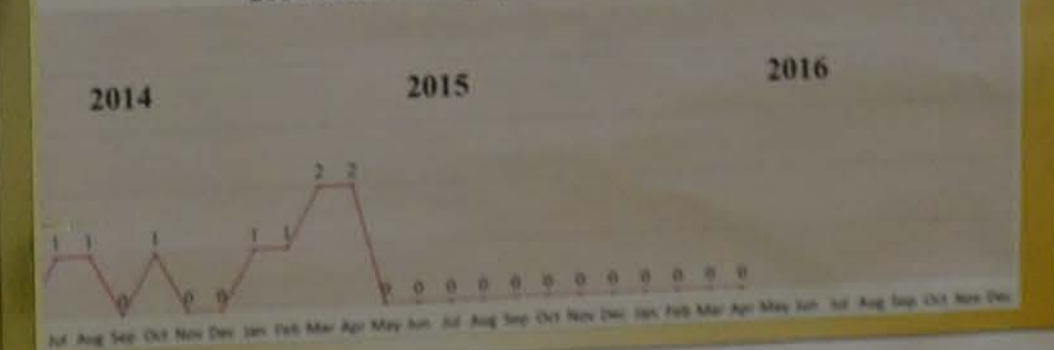


Picture 3. Mark the specimen labeled to avoid specimen overflow

Result

Improvement we have not yet found a case of missing specimen from 2015 April to 2016 April.

2014-2016 Missing Specimen Cases





Comparing different quality control indicators of uncertainty in the clinical biochemistry laboratory

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Background In order to enable clinical doctors to accurately diagnose and treat diseases, the clinical medical technologists at laboratories have to continue to improve quality control ability to ensure the accuracy of test reports and reduce the uncertainty of measurement. Different from the quality control indicators for traditional measurement of uncertainty, this study applied industrial quality control process indicator, Cpk, to clinical biochemical laboratory, and performed the comparison on identification of quality control between it and traditional indicators. This study collected the quality control data of high and low concentrations of daily biochemical test items (including GLU, BUN, CRE, GOT, GPT, NA, K) of a clinical laboratory in a regional teaching school from January to December 2015. After the calculations, this study obtained the quality control process indicator, Cpk, for identification and interpretation. Moreover, this study also performed analysis and comparison between it and traditional indicators. The research results showed that, from January to November, deviation in Cpk indicator of NA, K, and CRE calculated using peer quality control values that could not be identified using multiple traditional indicators were discovered in the laboratory. This study performed ex post facto analysis to further find out the possible reasons for deviation. This study concluded that, compared with traditional quality control indicators, such as CV, bias, and TE, the identification of Cpk indicator was higher. Cpk can help improve the ability to control uncertainty of laboratory measurements. In addition, this indicator can also be used for comparison with peer laboratories.

Methods The biochemical test values analyzed and compared in this study were from a regional teaching hospital in the northern Taiwan. The test items evaluated were 7 common routine biochemical tests in laboratories, including Glucose, GLU, Blood urea nitrogen, BUN, Creatinine, CRE, Glutamate Oxaloacetate Transaminase, GOT, Glutamate Pyruvate Transaminase, GPT, Sodium, Na and Potassium, and K. The biochemical device used for evaluation was Toshiba TBA-2000FR automatic biochemical analyzer. In addition, this study used the reagents of the original manufacturer. The quality control serum was manufactured by Bio-Rad Laboratories, Inc. The quality control serum included low concentration (Level-1) quality control serum (Batch No. 14461) and high concentration (Level-2) quality control serum (Batch No. 14462). This study collected data from January 2015 to December 2016. This study used statistical R software (Version 3.3.1) to calculate Cpk1 and Cpk2, and also obtained the internal monthly quality control values of the examination units in the past. This study calculated the traditional quality control indicators, including: bias, coefficient of variance, CV, analytical total error, TE and total error allowable (TEa).

Results This study found that, compared with the use of new indicator, Cpk2, for monitoring, the use of traditional indicators, such as bias, CV, and TE, by the laboratory to monitor its quality control ability reflected the same quality control values in many aspects. For example, when CV or bias was close to or exceeded reference range values, Cpk2 usually would also exceeded or was close to reference range values. Moreover, except for Cpk1 of NA (Level-2) in February, the Cpk1 of any concentration of other biochemical test items was greater than 1.67 (Table 1), and even the Cpk1 of all of the test items did not meet the standard of 1.33. Therefore, the control identification of the indicator, Cpk1, was lower in quality control, and it could fail to effectively remind laboratory supervisors of the actual issues during examination or in device.

Table 1 Sodium quality control indicators compare

Month	1	2	3	4	5	6	7	8	9	10	11	12
Level-1 indicators												
C _{pk1}	2.10	1.50*	2.59	2.95	2.51	2.63	3.28	3.13	3.35	2.82	3.04	2.52
C _{pk2}	1.22*	1.34	1.86	2.1	1.82	1.94	2.29	2.33	1.83	1.6	1.67	1.81
Bias (%)	-0.4	0.2	0.5	-0.04	0.4	0.2	0.4	0.3	0.05	0.4	0.4	0.6
CV (%)	1.2*	1.4*	0.7	0.8	0.9	0.8	0.8	0.7	0.7	0.8	0.6	0.6
TE (%)	2.80	3.00	1.90	1.64	2.20	1.80	2.00	1.70	1.45	2.00	1.60	1.80
Level-2 indicators												
C _{pk1}	2.50	2.61	1.93	2.60	2.08	1.82	2.19	2.57	1.84	1.87	1.91	2.17
C _{pk2}	1.16*	1.98	1.33	1.57	1.18*	1.03*	1.32*	1.73	0.94*	0.82*	1.11*	1.74
Bias (%)	-0.4	0.3	0.7	0.1	0.3	0.2	0.6	0.6	0.3	0.4	0.8	1.3*
CV (%)	0.9	1.4*	0.9	1	1.2*	0.8	0.8	1.1	1.0	0.8	0.8	0.8
TE (%)	2.20	3.10	2.50	2.10	2.30	2.60	2.20	2.20	2.50	2.40	2.40	2.90

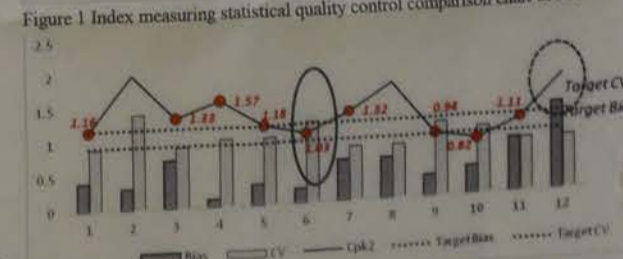
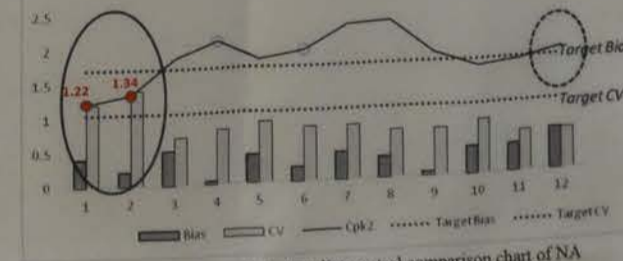
Level-1 indicators reference range target: Target Bias < 1.7% · Target CV < 1.05% · TEa = 3.3% · Reference TEa < 5%
Level-2 indicators reference range target: Target Bias < 0.92% · Target CV < 1.17% · TEa < 4.0% · Reference TEa < 5%

The Cpk2 of NA (Level-1) from January to February and NA (Level-2) in June was generally less than 1.33 (Figure 1 and Figure 2). Moreover, as shown in Figure 2, although the CV of NA (Level-2) in February exceeded the target value and the bias quality control indicator in December was higher than the annual standard reference range value of the laboratory, Cpk2 was normal. In other words, there was no significant deviation in peer laboratories. According to the Cpk2 quality control indicator, this study found that, except for February, August and December, the monthly quality control data of NA (Level-2) usually were lower than those of peer laboratories. Therefore, Cpk2 provided certain reduced quality control ability or unstable information that was originally not discovered in laboratory. As a result, if this study only used traditional indicators to monitor monthly quality control values, it would lead to the misunderstanding that the quality control of NA in December was poorer.

Cpk2 also met the standard. This result showed that, laboratory's use of target bias and target CV alone to monitor quality control may cause blind spots. Moreover, this result also verified that Cpk2 can be used for comparison with peer laboratories and can help evaluate the comparison with peers and create the effectiveness of monitoring control.

Conclusion This study suggested that, if future laboratories intend to use statistical quality control indicators as the quality control process ability indicators of certain biochemical test items, they can attempt to use Cpk whose calculation is based on peer laboratories. They are also advised to refer to objective data, such as stability and physiological chances, of different test items and set up internal or reference range values according to their own need for quality control. During the calculation of quality control indicator, because ±3 times of standard deviation of the mean of quality control data of different laboratories with the same machine model and the same batch number were used as the upper limit and lower limit of population specifications, this indicator can be used for comparison with peer laboratories. This indicator can reinforce the ability test only performed once annual in each laboratory or be provided as a quality control reference indicator for examination units failing to perform parallel comparison of internal device of the same machine model in the laboratory to monitor the parallel comparison of laboratory. This study only discussed and analyzed the uncertainty of measurements used in the laboratory. Future studies may further analyze multiple laboratories or more biochemical test items to set up warning thresholds or reference range values with more reference value.

Keywords: Biochemistry; Quality assessment; Uncertainty; Quality Control Indicators



Using Root Cause Analysis to Improve The...
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Background
The management jobs of laboratory specimen for test results has the right owner into the specimen, specimen transport, receive, handling, storage, destruction. Therefore, monitored in quality improvement conference like Patient Identification · Specimen ensure test results instant and accurate.

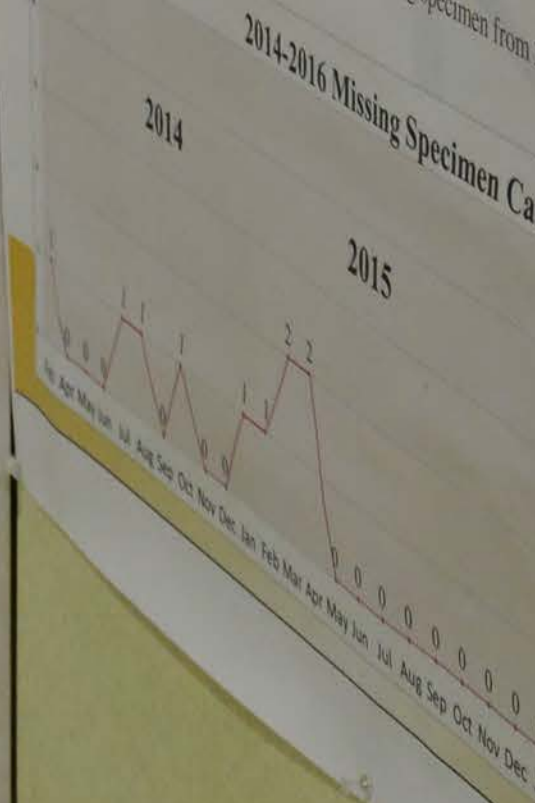
Method

From 2013, we find specimen loss reasons can be divided into the specimen pump leak, the specimen mistakenly lost, the specimen falling to track and unknown reason in total of 10 cases. Especially we found there were three specimen falling to track in 2014 February and March. So for this issue we not cause analysis and we find four high risk specimen falling spaces (Picture 1) when transport specimen from first floor to basement floor. And we talked the following measures:

1. We make transparent acrylic to replace black acrylic so that when specimen falling to track we can see it instantly (Picture 2).
2. We mark the specimen labeled clearly informed when transporting the specimen do not exceed this height to avoid specimen overload (Picture 3).
3. When specimen transport have inspection must use single cartridge to avoid inspection too thick to stop track.
4. Track manufacturers cut specimen transport speed to avoid specimen pop up in transit.

Result

After this improvement, we have not yet found a case of missing specimen from 2014



Laboratory Management
PM-17

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Using Root Cause Analysis to Improve The Problem of Missing Specimen

PM-17

Shou-Cheng Lu¹, Yi-Fang Lin¹, Chia-Mei Yeh¹, Kun-Ching Chen¹,
Hui-Jung Chang¹, Wen-Shyang Hsieh^{1,2}, Wei-Ming Chi¹

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Taipei Medical University-Shuang Ho Hospital, New Taipei City, Taiwan

Background

The management jobs of laboratory specimen for test results has the right owner inseparable impact include: identification of the specimen, specimen transport, receive, handling, storage, destruction. Therefore our laboratory list some indicators monitored in quality improvement conference like Patient Identification, Specimen Lose, Rejection Rate of Specimens to ensure test results instant and accurate.

Method

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Picture 1: Four high risk specimen falling spaces



Picture 2: Replace acrylic to transparent

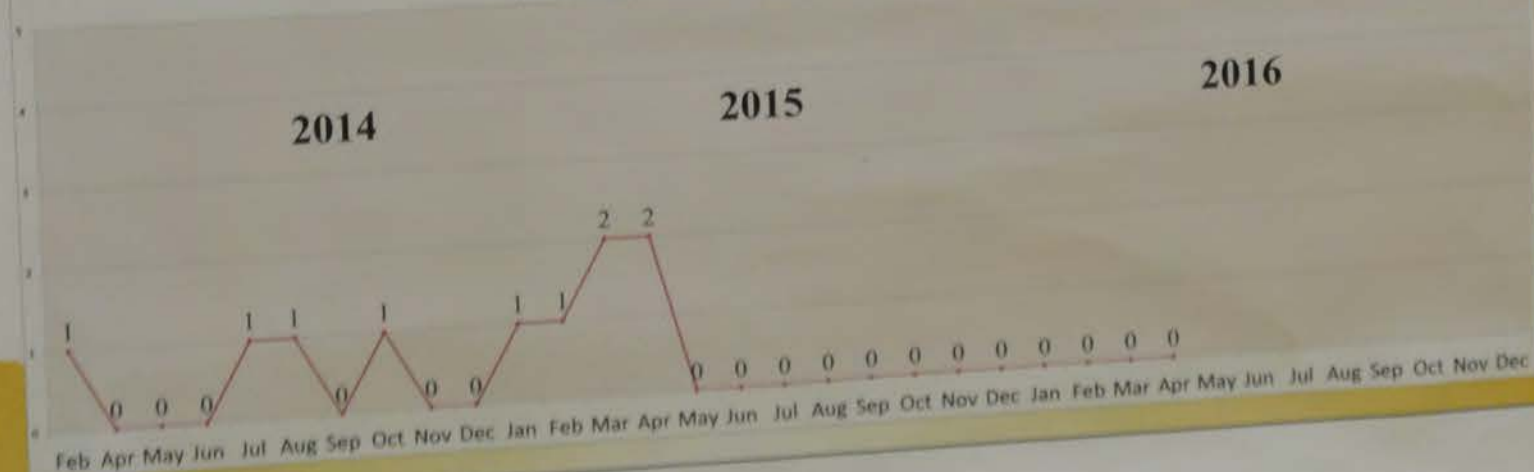


Picture 3: Mark the specimen labeled to avoid specimen overload

Result

After this improvement we have not yet found a case of missing specimen from 2015 April to 2016 April.

2014-2016 Missing Specimen Cases



高雄醫院(委託財團法人高雄醫學大學經營)

Analysis to prevent about transfusion error reporting
Reduce the incidence of abnormal events of blood

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²Kaohsiung Medical University Hospital, Kaohsiung Medical University

outcomes 1

Blood typing flag sticker in the same time

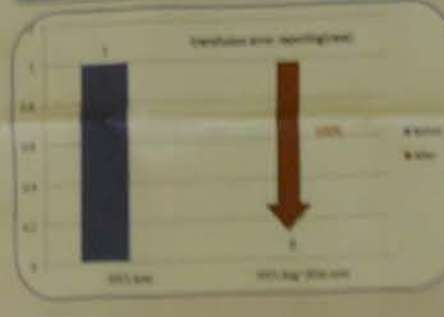


outcomes 2

Training and assessment



Result



For the correct operation of the various transfusion-related inspection, and to familiarize with the correct use of information systems, in terms of clinical staff is quite importance, the project hopes to improve this application RCA practices, identify the root causes blood bank error exception event, and then actual import to standard processes in order to effectively reduce the incidence of abnormal events of Blood Banks.

Laboratory Management PM-18

The establishment of E-document management system

Using management information systems improve organizational performance

Yu-Han Yeh, Cyue-Huei Hua, Yen-Chen Hsein, Yu-Fen Chien
National Taiwan university hospital Yun-Lin branch, the department of laboratory medicine, Taiwan

Proposes

The paperless medical office is a trend in recent years due to heightened senses of awareness about the environment. After ISO 15189 Medical Laboratory Accreditation was performed by case lab, the numerous SOP documents and record forms were produced since 2003. Several problems such as document storage, costs, and waste disposal have to be solved.

Methods

E-document management system was imported by case lab since 2011. In the first stage, all quality control records were integrated into a real-time online quality control system. Quality control (QC) data were automatically sent to system by instrument, and QC performance was compared with different machines and different locations (fig. 1). In the second stage, the knowledge management system was imported and then provided digital QM/QP/SOP documents online. Electronic documents were monitored by Document Control Procedure (fig. 2). In the third stage, a number of ISO records were recorded online, such as instrument maintenance lists and temperature monitoring records. Therefore, maintenance lists can be inspected online and on-time by administrators (fig. 3).

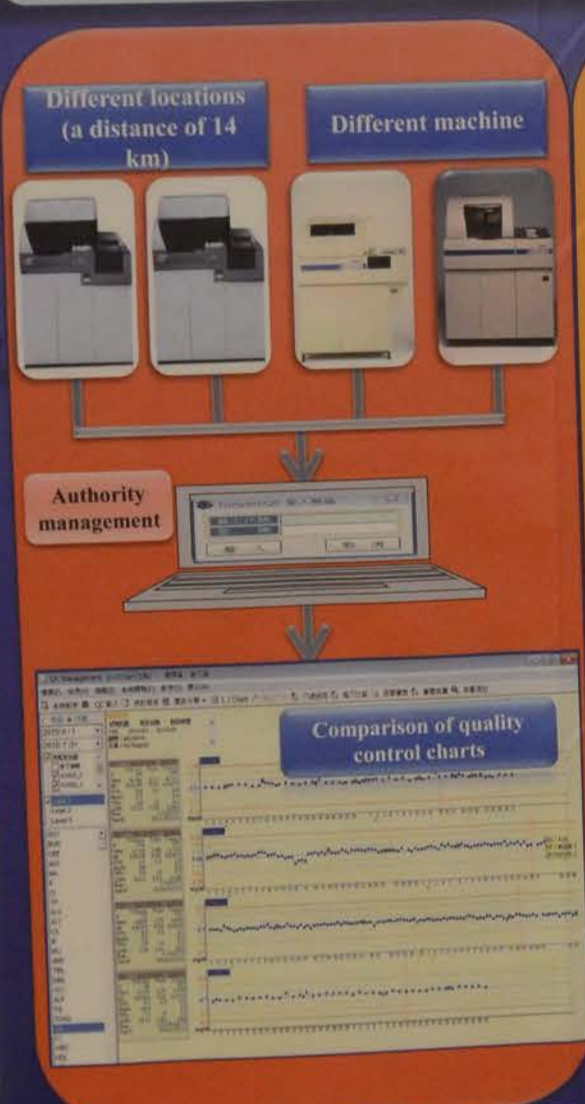


Fig. 1: QC on-line management system

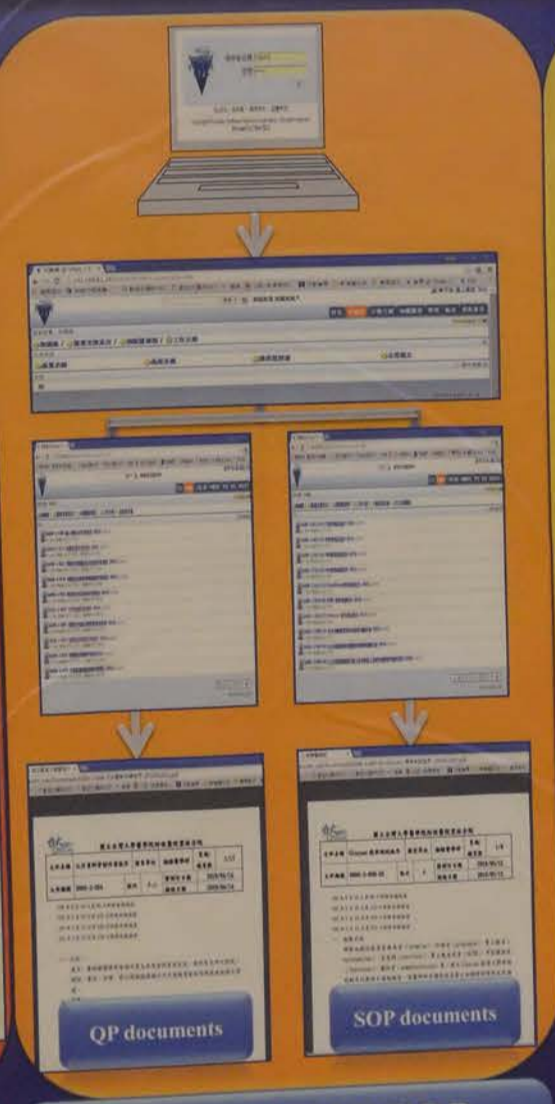


Fig. 2: QM/QP/SOP knowledge management

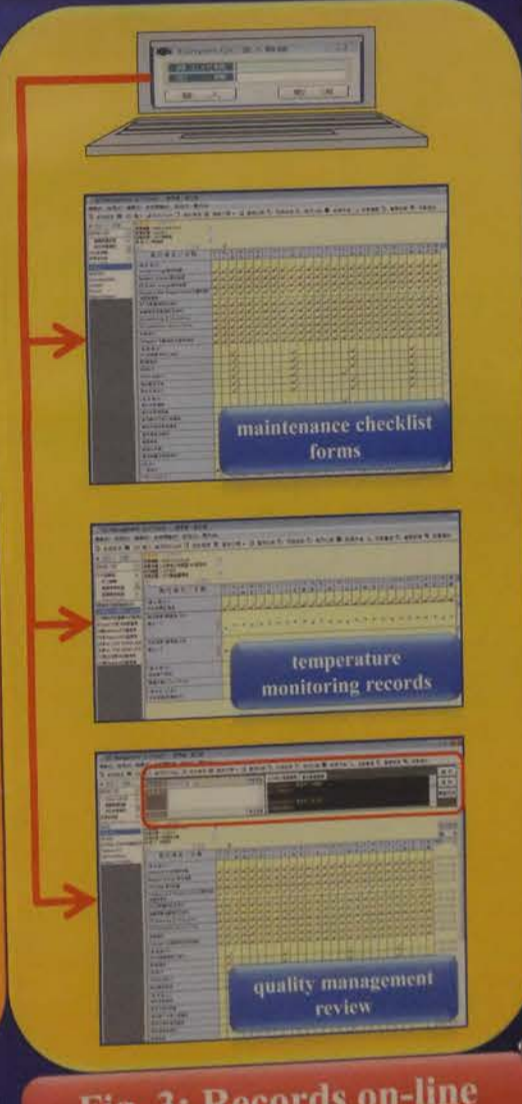


Fig. 3: Records on-line management system

Results and conclusions

After importing E-documents systems, about 34,000 pieces of paper including 1024 SOP documents and 537 records were saved (fig. 4). The advantages of the establishment of E-document management system include reducing the time spent in files transporting, providing on time inspection, reducing the risk of infection during transporting documents, saving files storage space, reducing paper waste disposal. Consequently, using management information systems can improve organizational performance, achieve standardization and enhance quality of laboratory.



Fig. 4: The improvement graph of paper saving

天晟醫院
General Hospital



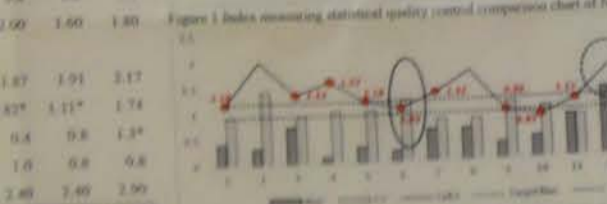
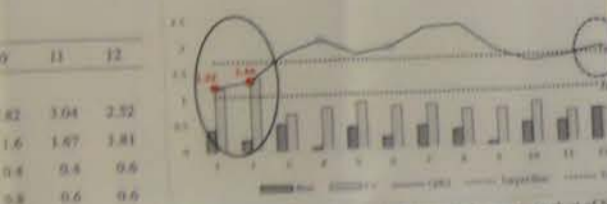
Quality control indicators of
biochemistry laboratory
Chih-Ming Lin^a, Chen-Mao Liao^b
ng Lo^d

n-Chen Medical Hospital^a, Taiwan
oriental Institute of Technology^b, Taiwan
agement, Ming Chuan University^c, Taiwan
n Science, Ming Chuan University^c, Taiwan

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PM-19

Root cause analysis to prevent about transfusion error reporting
To effectively reduce the incidence of abnormal events of blood
banks

Ching-Mei Cheng^a, Chun-Chi Huang^b
^aLaboratory Medicine, Kaohsiung Municipal Hsiangkong Hospital, Taiwan
^bKaohsiung Medical University Hospital, Kaohsiung Medical University

Introduction

2016, 828 Patient (emergency admissions to hospital, medical records showed the blood type of the patient is 'A', but when transfusion therapy performed, nurse found the type of blood product is 'A', and lab report showed is 'O' which one was right?
A transfusion incident involves near miss events' and 'no harm events', though immediate stop because no injury occurred, but that if the 'mistransfusion' actually occurs, may result in patient injury. This case the extent of damage considered 'severe', SMC Level 3, because the case is of considerable educational value, the process root cause analysis (RCA).

Method

Outcomes 1
Blood typing flag sticker in the same time

Outcomes 2
Training and assessment

Result

For the control of transfusion error reporting system

Laboratory Management PM-19



高雄市立小港醫院(委託財團法人高雄醫學大學經營)

Root cause analysis to prevent about transfusion error reporting To effectively reduce the incidence of abnormal events of blood banks

chingmei Cheng^{1,2}, chunchi Huang^{1,2}
¹ Laboratory Medicine, Kaohsiung Municipal Hsiaokang Hospital, Taiwan
² Kaohsiung Medical University Hospital, Kaohsiung Medical University

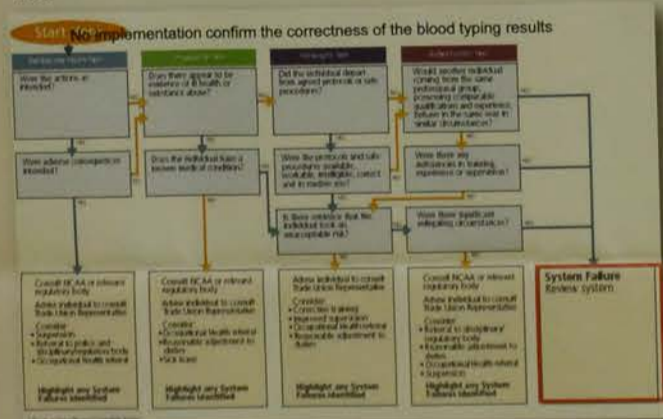
Introduction

2015. 6.29 Patient A emergency admissions to hospital, medical records showed the blood type of the patient is "A", but when transfusion therapy performed, nurse found the type of blood product is "A", and lab report showed is "O" which one was right?

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Method

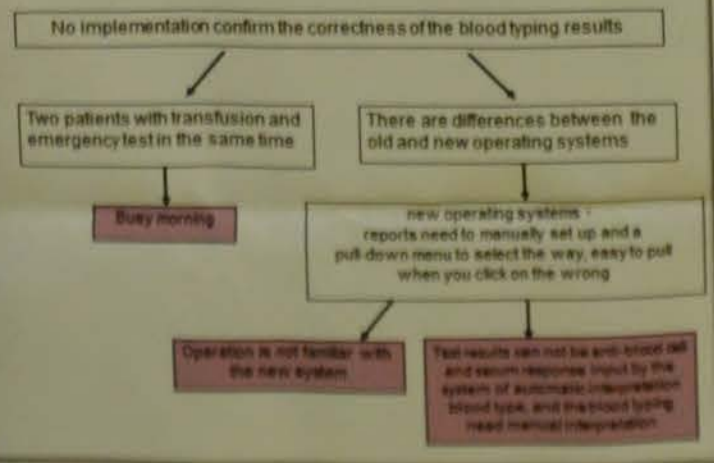
IDT



Tabular timeline

Time	6:30	7:15	7:31	08:30	08:40	08:50	09:00	09:15	09:25	09:30	09:40	08:00
Transfusion order	EM call	Blood typing results input system	nursing station call inquiry blood typing results	Check LIS data	Check LIS data	Check LIS data	Check LIS data	Check LIS data	Check LIS data	Check LIS data	Check LIS data	Check LIS data
Three (A,B,C) blood products transfused on the same patient	Emergency press	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"	patient A blood typing "A" but error is reporting system "O"

Why tree



- Test results can not be auto-interpret and system response input by the system of automatic interpretation blood type, and the blood typing need manual interpretation.
- Operation is not familiar with the new system.
- Blood typing result by the system of automatic interpretation.
- When the establishment of an order print, Blood typing flag sticker print in the time.
- Regular education and training and assessment.

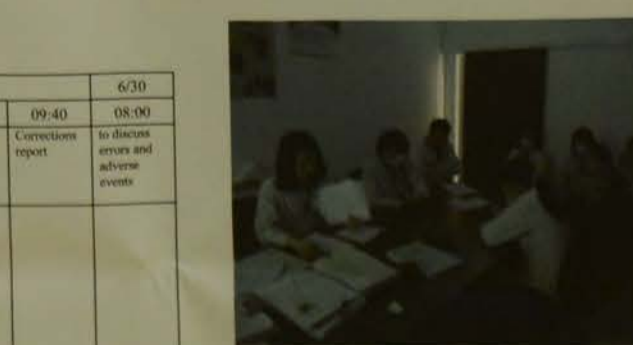
outcomes 1

Blood typing flag sticker in the same time

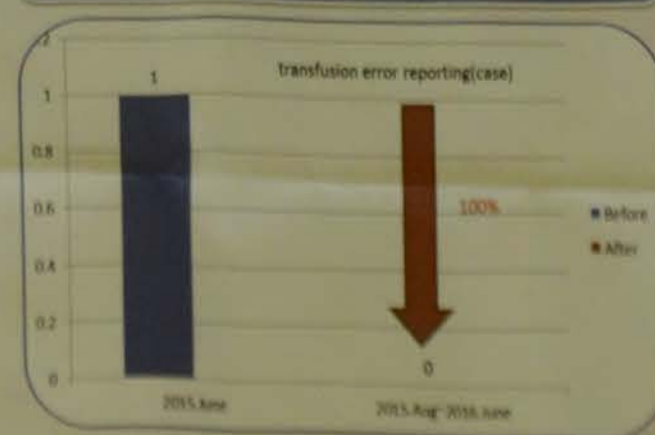


outcomes 2

Training and assessment



Result



For the correct operation of the various transfusion-related inspection, and to familiarize with the correct use of information systems, in terms of clinical staff is quite importance, the project hopes to improve this application RCA practices, identify the root causes blood bank error exception event, and then actual import to standard processes in order to effectively reduce the incidence of abnormal events of Blood Banks.

Laboratory Management -21

Set up and Improve the Management
Clarify the



Department of Pathology & Laboratory Medicine

Introduction

allquot laboratory specimens with barcode which included in hospital, risk from misidentification was eliminated by more and more attention by clinical department. For processes, some can be repeated, such as blood or urine procedure but also impose a greater burden on the health care provider patient from being diagnosed appropriately and treated. It can be a source of potential litigation. Of greater concern are the loss of specimens and timed specimens. The establishment of a system to track and retrieve lost specimens, in order to mitigate the risk.

Materials & Methods

A specimen transport tracking mechanism was established based on error view analysis focused on lost specimen non-compliance process of getting a specimen from clinical unit to the laboratory.

Potential errors / misidentification	Prevention
Released from clinical unit	Each specimen packed in a bag generated which can track. Each bag scanned by the transporter.
Transported to laboratory / transit	Use transport box used to detect possible error (such as missing specimen or mislabeled).
Received by laboratory	Each specimen loaded in a bag and scanned by the transporter.
Received by work station / laboratory delivery	Use specimen collection bag. Each specimen loaded in a bag and scanned by the transporter.
Released from clinical unit, transit or laboratory process	Every 30 minutes, staff for ensuring specimen collection. Every 2 hours, regularly for ensuring specimen collection.
Delayed errors / lost or misplaced specimen	Initiate retrieving action. Notify nursing staff for retrieval.

From 2011 to 2015, 15,149,947 cases investigated from 2011 to 2015. We used the indicators to evaluate the efficacy of specimen transport tracking mechanism. The annual specimen loss rate on a downward trend was implemented from 2011 to 2015 (fully implemented). There were still two lost specimens occurred respectively. The action initiated via specimen transport tracking mechanism were grouped into specimen released error, transit error, and laboratory error, 36%, 52% and 12%, respectively.

Figure 1 Annual Specimen Loss Rate

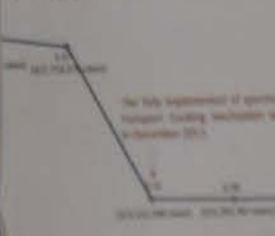


Table 2 Error/person in

Error/person in	Specimen released error	Transit error/Transporter	Laboratory process error/Laboratory staff
36%	52%	12%	

Transit error is always regarded as the proximal cause of an error, which focuses on what steps in the process a check and recovery in order to reduce the risk of future errors. To replace invalid caution labels and revise training, the involvement in processes will be clarified. In addition, staff and laboratory personnel, especially at hand-off of specimens, should be trained. The establishment of a specimen transport tracking mechanism can effectively reduce the risk of error.

Conclusion: The establishment of a specimen transport tracking mechanism can effectively reduce the risk of error. The annual specimen loss rate on a downward trend was implemented from 2011 to 2015 (fully implemented). There were still two lost specimens occurred respectively. The action initiated via specimen transport tracking mechanism were grouped into specimen released error, transit error, and laboratory error, 36%, 52% and 12%, respectively.

Optimization of Blood Culture Reporting Efficiency by Workflow Improvement

Hsiu-Yin Chou¹, Yu-Hsuan Yang¹, Li-Chuan Wang¹, Ya-Wen Tsai¹, Li-Ching Wu¹

¹Department of Clinical Pathology, Chi-Mei Medical Center Young Kang Division, Tainan, Taiwan

Background

Chi Mei Medical Center Chi Mei Medical Center Chi Mei Medical Center Chi Mei Medical Center Chi Mei Medical Center For sepsis diagnosis, blood culture remain the gold standard to confirm the infection. Rapid and accurate test result can save patients from serious septic shock may lead to multiple organ failure with high mortality rate. To provide rapid and accurate preliminary report through workflow improvement, combined with pathogen identification and antibiotic susceptibility test, which can bring benefit to patients with sepsis symptom.

Methods

As start, our preliminary report time was 48.92 hours; where final report took 89.20 hours. From March 2013 to September 2015, we implanted workflow improvement process included increasing blood culture loading frequency, monitoring adequate blood volume collected to ensure optimal recovery, routine education to collectors to control the contamination rate (Pic. 1)(Pic. 2), and the installation of MALDI-TOF for rapid identification to shorten time to report (Pic. 3), resulted in earlier treatment course.

Picture 1. Training course for adequate blood culture collection

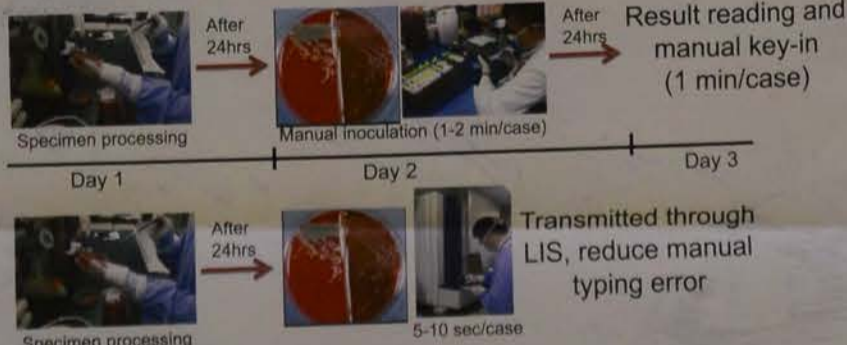


Picture 2. Line drawing on blood culture bottle



Picture 3. Implant Lean Management

Conventional identification



MALDI-TOF MS Identification

Results

The average blood volume increased from 3.9ml to 7.9ml, reach 102.6% growth (Fig. 1); the average time to detection decreased for 4 hours (Fig. 2). The contamination rate decreased from 3.41% to 2.32%, reduced for 31.78%(Fig. 3). The preliminary report time for blood culture shortened from 48.92 hours to 33.65

hours, degree of reduction reached 31.25% (Fig. 4a). The final report time for blood culture shortened from 89.20 hours to 78.83 hours, degree of reduction reached 11.63% (Fig.4b).

Fig 1. Trend to blood volume increment

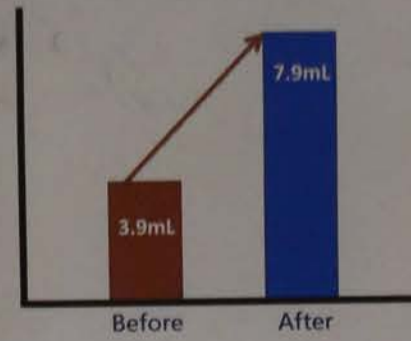


Fig 2. Detection time of positive culture

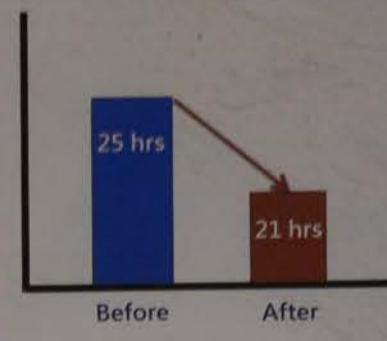


Fig 3. Contamination rate

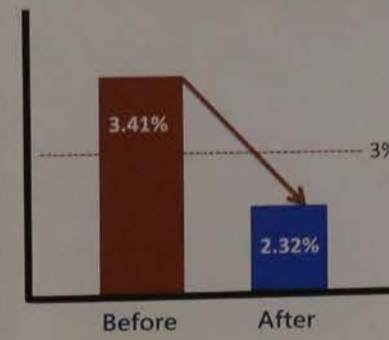


Fig 4. Turnaround Time for Blood Culture

(a) Primary report time



(b) Final report time



Conclusion

Bacteremia or sepsis is the immune response comes from pathogen infection, lead to clinical symptoms like fever and elevated WBC. To diagnose the cause of bacteremia, it is crucial to perform blood culture with good quality collection. Besides, introduce new technology and proceed workflow improvement can significantly reduce the reporting time, hence provide earlier treatment to patients suffer from sepsis.

Department of E-document management

ent information systems improve organizational pe

ch, Cyue-Huei Hua, Yen-Chen Hsein, Yu-Fen Chi
an university hospital Yun-Lin branch, the depart
laboratory medicine, Taiwan

in recent years due to heightened senses of awareness at
laboratory Accreditation was performed by case lab, the numer
ed since 2003. Several problems such as document storage, ce

ported by case lab since 2011. In the first stage, all quality cont
line quality control system. Quality control (QC) data were
nt, and QC performance was compared with different machin
stage, the knowledge management system was imported and th
online. Electronic documents were monitored by Document C
umber of ISO records were recorded online, such as instrumen
toring records. Therefore, maintenance lists can be inspected o

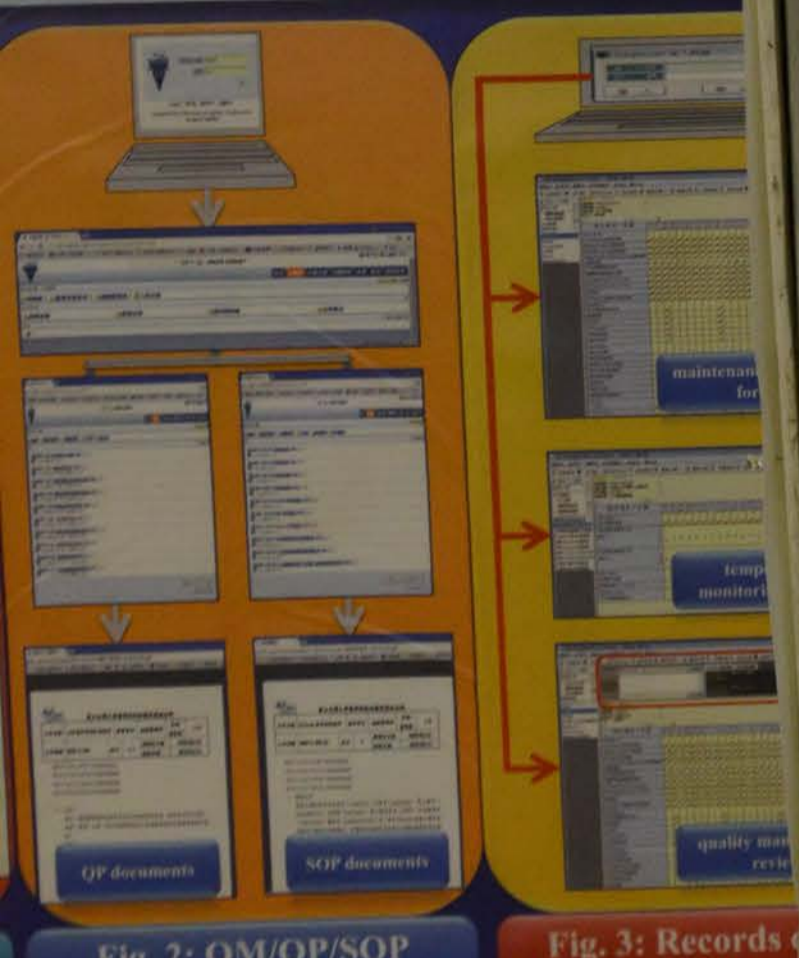


Fig. 2: QM/QP/SOP knowledge management

Fig. 3: Records of management system

ms, about 34,000 pieces
ents and 537 records
of the establishment of
include reducing the time
ing on time inspection,
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organizational
ation and enhance quality

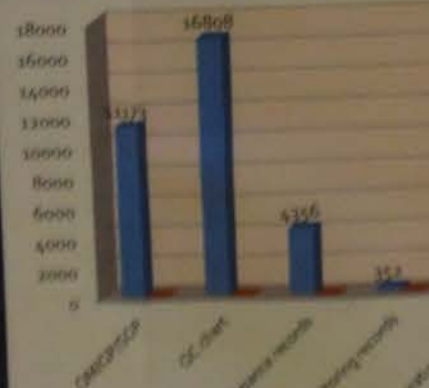


Fig. 4: The improvement of paper saving

After non-stop laboratory specimens with barcode which
implemented in hospital, risk from misidentification was elimi
drawing more and more attention by clinical departme
laboratory processes, some can be repaired, such as label
additional procedure but also cause a greater burden on
It may hinder patient from being diagnosed appropriate
months, or be a source of potential litigation. Of greater concern
in patient specimens and times specimens. The establish
least errors and retrieve lost specimens, in order to mitigate

The optimal transport tracking mechanism was established
cannot not from error view analysis focused on lost specimen
involved process of getting a specimen from clinical unit to

Table 1	Potential errors	Prevention
Misidentification	Barcoding before	
Never released from clinical unit	Each specimen generated which Each bag scanned by transporter.	
Never transported to laboratory / Lost in transit	Use transport box Each bag scanned by transporter.	
Never received by laboratory	Bag and stuffed detect possible missing specimen	
Never received by work station / Lost in laboratory delivery	Use specimen collection bag Each specimen scanned by barcode	
Never released from clinical unit, lost in transit or laboratory process	Every 30 minutes for ensuring specimen Every 2 hours, notify for ensuring specimen	
Detected errors	Initiate retrieving	
Missing or misplaced specimen	Notify nursing station	

A total of 52,047 cases investigated from 2011 to 2015
events as the indicators to evaluate the efficacy of specimen

Figure 1 showed the annual specimen loss rate on a downw
mechanism was implemented from 2011 to 2015 (fully impl
Although there were still two lost specimens occurred resp
near missed were grouped into specimen transport tracking
cause were 26%, 52% and 12%, respectively.

Figure 2 Annual Specimen Loss Rate

Year	Specimen Loss Rate (%)
2011	26%
2012	52%
2013	12%

Table 2
Error/Prevention
Specimen Missing
Transportation
Laboratory

Laboratory Management PM-21

Set up and Improve the Monitoring Mechanism of Specimens Transport Clarify the Key Points of Specimens Loss



Ya-Ching Li; Shu-Wen Lin; Chuan-Po Lee; Hsiu-Chin Fan






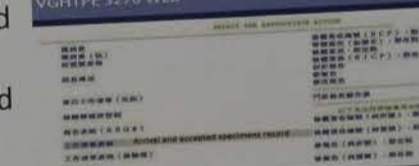
Department of Pathology & Laboratory Medicine, Taipei Veterans General Hospital, Taiwan, R.O.C.

Introduction

After non-aliquot laboratory specimens with barcode which included the patient's ID data and physicians' requisition had been implemented in hospital, risk from misidentification was eliminated to the minimum. In contrast, errors caused by lost specimens are drawing more and more attention by clinical department. For specimen that was lost somewhere between delivery and laboratory processes, some can be repeated, such as blood or urine. Nevertheless doing so may not only put the patient at risk from additional procedure but also impose a greater burden on the health care system through additional cost, time and labor. Moreover it may hinder patient from being diagnosed appropriately and treated timely. Furthermore, lost specimens may increase patient anxiety, or be a source of potential litigation. Of greater concern are for those specimens difficult to collect or cannot recollect, such as pediatric specimens and timed specimens. The establishment of specimen transport tracking mechanism is desired to early detect errors and retrieve lost specimens, in order to mitigate the risks aroused by these incidents.

Materials & Methods

The specimen transport tracking mechanism was established based on the way of corrective actions and preventive actions which comes out from error view analysis focused on lost specimen nonconformity. Table 1 depicts the potential error occurred in steps involved in process of getting a specimen from clinical unit to the laboratory, and its corresponding corrective or preventive actions.

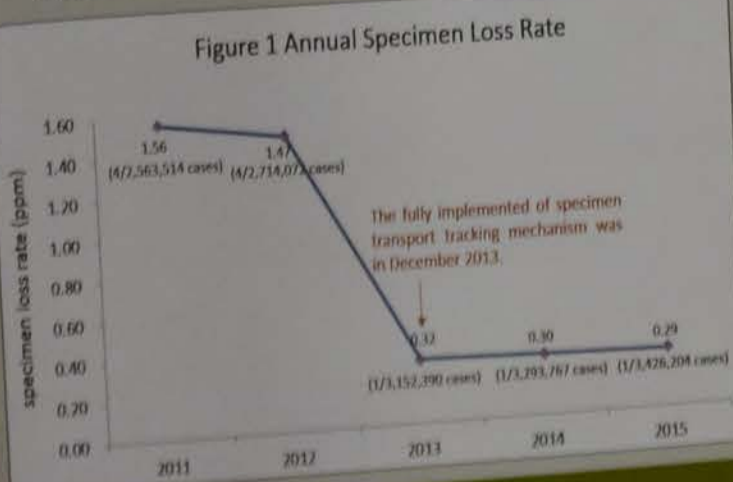
Potential errors	Preventive / Corrective action to avoid or detect errors
Misidentification	Barcoding before specimen collection. 
Never released from clinical unit	Each specimen packed into a bag, and bag barcode generated which can track to every stuffed specimen. Each bag scanned by nurse while taken out by transporter. 
Never transported to laboratory / Lost in transit	Use transport box used for carriage. Each bag scanned on arrival at laboratory reception by transporter. 
Never received by laboratory	Bag and stuffed specimens barcode scanned to detect possible error (unmatched specimen), such as missing specimen or misplaced specimen. 
Never received by work station / Lost in laboratory delivery	Use specimen collection box for carriage. Each specimen loaded in tube rack immediately after barcode scanned. 
Never released from clinical unit, lost in transit or laboratory process	Every 30 minutes, stat specimen receipt list checked for ensuring specimen on track. Every 2 hours, regular specimen receipt list checked for ensuring specimen on track. 
Detected errors / Missing or misplaced specimen	Initiate retrieving action while laboratory process error detected. Notify nursing staff for release and transit errors.

A total of 15,149,947 cases investigated from 2011 to 2015. We used specimens loss rate (PPM) and occurrences of lost specimen events as the indicators to evaluate the efficacy of specimen transport tracking mechanism.

Results

Figure 1 showed the annual specimen loss rate on a downward trend from 1.56 PPM to 0.29 PPM after specimen transport tracking mechanism was implemented from 2011 to 2015 (fully implemented till 2013).

Although there were still two lost specimens occurred respectively in 2014 and 2015, simultaneously 50 specimens were recovered by retrieving action initiated via specimen transport tracking mechanism. The analysis was shown as Table 2. The causes of those 50 near misses were grouped into specimen released error, transit error and laboratory process error, in which the contribution of each cause were 36%, 52% and 12%, respectively.



Error/person involved	Number	Event Description	Correction
Specimen released error/ Nursing staff	18 (36%)	1. Left in nursing station : 11 cases. 2. No specimen collected : 6 cases. 3. ID error : 1 case.	1. Send to laboratory. 2. Draw blood. 3. Recollection.
Transit error/ Transporter	26 (52%)	1. Specimen in transit processing : 18 cases. 2. Specimen left in transport box : 4 cases. 3. Specimen misplaced : 4 cases.	1-3. Send to laboratory immediately.
Laboratory process error/ Laboratory staff	6 (12%)	1. Left in phlebotomy station : 4 cases. 2. Send to other work bench : 1 case. 3. Stuck at pneumatic tube system : 1 case.	1-2. Send to work bench directly. 3. Clean pneumatic tube system to recover the specimen.

Discussion

Human lapses always regarded as the proximal cause of an adverse event. Our tracking mechanism settled up along process mapping, which focuses on what steps in the process a checkpoint can be put into place to early detect occurrences of lost specimen and recovery. In order to reduce the risk of human lapses, the systemic timely reminder is regarded as effective mechanism to replace invalid caution label and revise training. On the other hand, the accountability between each healthcare provider who involves in processes will be clarified. In addition, consistent communication patterns should be established between nursing staff and laboratory personnel, especially at hand-off of specimens and a change of shift.

Conclusion

The specimen transport tracking mechanism can effectively eliminate occurrences of lost specimens through decreasing reliance on human vigilance.

ISO 15189: 2012 implementation checklists for conformity assessment by accreditation bodies: a global study

Dennis Mok CSci MIBMS MNZIMLS

Cleveland Clinic Abu Dhabi, Abu Dhabi, United Arab Emirates

Introduction

Quality management plays a significant role in ensuring the diagnostic serviceability of the medical laboratory (ML) is operating at a technically competent level at all times. Implementation of ISO 15189:2012 requires both laboratory management LM and ML to fulfil specific conformance requirements (CRs) ranging from bench to strategic levels in relation to management system and technical competence. Specifically, Clause 4 of ISO 15189:2012 concentrates on the management system requirements containing 682/1,515 (45%) CRs for both LM and MLs to consider if all areas are related to the areas of operations. In contrast to Clause 5 of ISO 15189:2012 that relates to the implementation of technical competence requirements containing 833/1,515 (55%) CRs for consideration. The implementation of ISO 15189:2012 by the ML represents significant investment of effort and resources in order to competently accomplish all of the relevant CRs and at the same time achieving desired economy, effectiveness and efficiency.

The focus of this study is to quantitatively analyse the extent of CR coverage by ISO 15189:2012 guidance checklists produced by ABs. This research provides information on the usefulness of ISO 15189:2012 guidance checklists supplied by six accreditation bodies (ABs) for organisations who intend to rely on them.

Materials and Methods

Content analysis

Content analysis was used for the identification and location of CRs within Clauses 4 and 5 of ISO 15189:2012. This was supported by a computer-aided qualitative data analysis software, NVivo™ 10 for Windows®.

Evaluability assessment

The '1,515 CRs framework' was used to conduct evaluability assessment on the extent of coverage of CRs by the evaluand checklists.

Results

Selection of evaluand checklists for comparative analysis

A total of six ABs were selected for comparative analysis. These ABs are full members of International Laboratory Accreditation Cooperation.

Evaluability assessment of evaluand checklists from selected accreditation bodies

Evaluand checklists from the six selected ABs were used for the evaluability assessment. The overall results are presented in Table 1.

Table 1. The frequency of conformance requirements by the evaluand checklists.

Australia (AUS)	683 (45%)
Denmark (DNK)	839 (55%)
Finland (FIN)	353 (23%)
International Organization for Standardization (ISO)	1,515 (100%)
Hong Kong (HKG)	1,479 (98%)
Singapore (SGP)	1,409 (93%)
South Africa (ZAF)	368 (24%)

Point distribution analysis of conformance requirements

The CR coverage of each subclause of the six evaluand checklists were plotted onto radar charts for point distribution analysis. The results are presented in Figures 1 to 6.

National Association of Testing Authorities



Figure 1

Hong Kong Accreditation Service



Figure 4

Danish Accreditation Fund

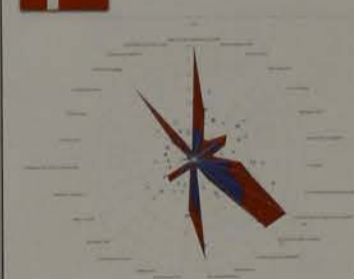


Figure 2

Singapore Accreditation Council

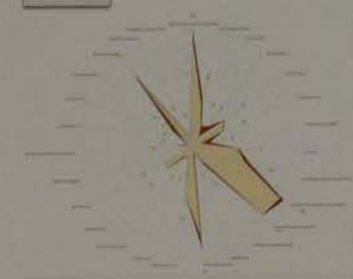


Figure 5

Finnish Accreditation Service

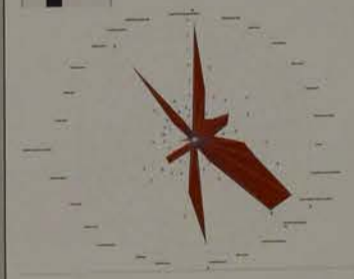


Figure 3

South African National Accreditation System

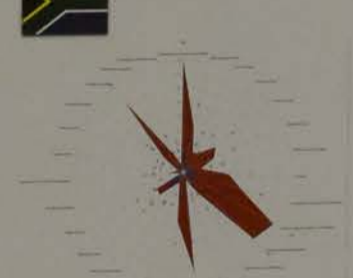


Figure 6

Discussion

The aim of the current study was to determine the extent of ISO 15189:2012 CR coverage provided by the AB guidance checklists. The analytical tool for the evaluability assessment was developed using the concept of 1,515 CRs in ISO 15189:2012. The evaluability assessment identified that CR coverage ranged from 353/1,515 (23%) by the Finnish Accreditation Service to 1,479/1,515 (98%) by the Hong Kong Accreditation Service. The findings of this research provide insights into the CR detection limitations of the recommended guidance checklists by ABs. The evidence suggests that over-reliance on ABs' guidance can have adverse strategic implications for the ML that attempts to address implementation shortfalls. This research has two major practical implications. First, for the sake of transparency, ABs responsible for drafting guidance checklists should consider providing a disclaimer indicating the level of coverage provided. Second, MLs need to be aware that guidance from the relevant AB may need to be supplemented by consideration of further compliance issues with international, national, regional or local regulations or requirements.

References

- Mok, D. & Ang, E. 2016, 'ISO 15189:2012 implementation: an update of related international standards and guidance documents for medical laboratory quality management', *New Zealand Journal of Medical Laboratory Science*, vol. 70, no. 2, pp. 42-66.
- Mok, D., Lim, E., Eckersley, K., Hristov, L. & Kirsch, C. 2013, 'ISO 15189:2012 implementation: an applied guide for medical laboratories', *Australian Journal of Medical Science*, vol. 34, no. 4, pp. 134-73.

Laboratory Management PM-26

Contribution to Integration of Community Care by the Clinical Laboratory Technicians

By Yasuyo Ando, Hiroyuki Ogawa, Nobuyuki Wakasa, Toshie Fukushima
Saitama-Sekishinkai Hospital, Sayama-City, Saitama Pref., Japan



Introduction

The Ministry of Health, Labour and Welfare in Japan is promoting cooperation of medical technology between institutions. The main hospital and their respective out-patient care teams are promoting an integrated community care system that enables a smooth transition from emergency care to long-term out-patient and hospice care. Sekishinkai Hospital, as a main hospital, we are promoting such integration. We have had health care seminars (called Kenkou-juku in Japanese) for local residents on weekdays since November 2012. Over the past three years, we had more than 35,000 total participants, so these seminars were quite successful.

Details about Kenkou-juku :

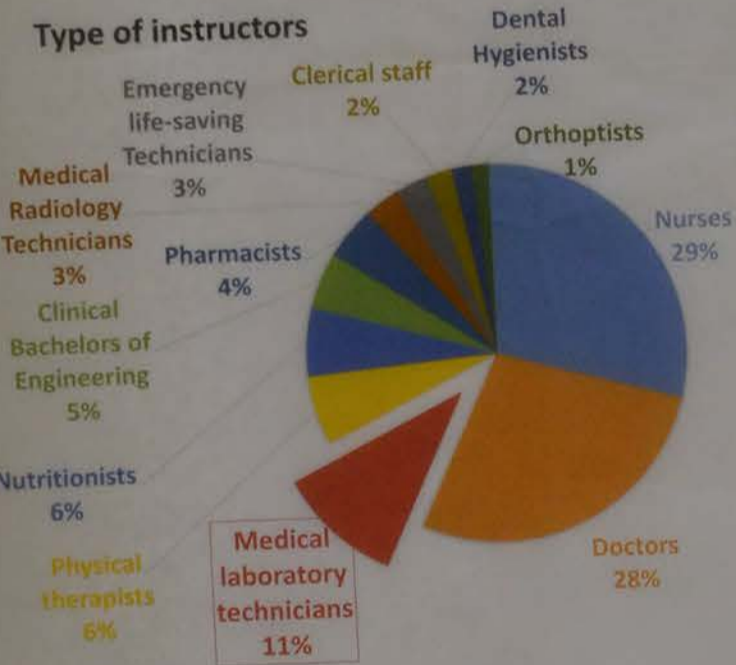
Every weekday there are two back-to-back seminars. Each seminar is run by a different hospital staff member and covers a different topic. They are held at local community centers for free.

Leaflet

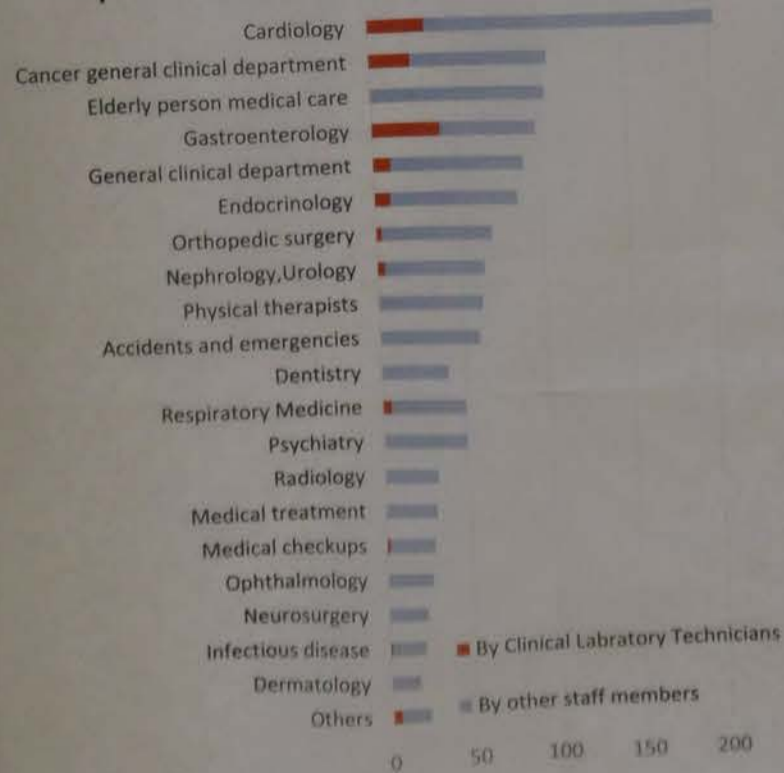


Past Three Years :

Period: November 2012 to November 2015
Total seminars held: 1279, 12 types of instructors



Topics Covered in Seminars



Example Seminars Given by Clinical Laboratory Technicians :

Departments	Classification	Titles
Cardiology	Heart, Vascular	"Risk factors of Arteriosclerosis: bad and good cholesterol explained"
Endocrinology	Diabetes	"Insulin; A hormone from the pancreas."
General internal medicine	Blood	"Understanding anemia, through analysis of blood tests calculation"
Gastroenterology	Gastroenterology	"Do you have stomach discomfort? Perhaps you have acid reflux"
Otorhinolaryngology	Otorhinolaryngology	"Understanding causes of dizziness by ear examination"
Gastroenterology	Medical treatment	"What's the difference between oral and nasal endoscopy?"
Gastroenterology	Preventive medicine	"The ABCs of stomach check up! Inspecting your stomach for signs of cancer"
Cancer general clinical department	Cancer	"How to detect cancer: pathology-cytology tests"
Nephrology	Nephrology	"Understanding renal function from blood tests"
Cancer general clinical department	Cancer	"Breast cancer is not a disease only for women!! Look at breast ultrasonography"
Cardiology	Medical treatment	"What do you understand about of electrocardiography examination?"

Sample Questions from Patients and Answers :

Patient:
This is my checkup data. What range is desirable for good cholesterol?
Clinical Laboratory Technician:
The normal range for good cholesterol range is more than 40 mg/dL. Try to keep bad cholesterol lower than 140 mg/dL and Triglyceride lower than 150mg/dL. Lipid level control and aerobic exercise are effective for arteriosclerosis prevention.
Patient:
How about walking? Walking is effective for raising good cholesterol.
Patient:
This report is my husband's medical checkup. HbA1c was 14% extended normal level, but he told me they were no problem.
Clinical Laboratory Technician:
I did not think so, what should his HbA1c level be?
Patient:
That's too high, the HbA1c normal range is more than 5.4%.
Clinical Laboratory Technician:
I recommend a review of diabetes and nutrition guidance.



Conclusions:

- ✓ We, the Clinical Laboratory Technicians, have run 136 out of 1279 seminars.
- ✓ Many seminars were related to medical care for elderly people. Top three seminars were arteriosclerosis, cancers and elderly persons medical care.
- ✓ However, there were not any planned lectures about elderly person medical care, we provide, therefor it will be necessary to include this in the future.
- ✓ In these workshops, we were able to explain lab data to patients directly and had the opportunity to explain our works.
- ✓ Through learning about the different tests that we do, patients can increase their knowledge of how to receive the most appropriate care, and can make the appropriate connections with their regional health care institutions.
- ✓ Kenkou-juku is an ideal opportunity for us to communicate and connect with local residents personally and individually.

Message for other Clinical Laboratory Technicians

- We have few opportunities to build good relationship with patients, we enjoy interacting with them during Kenkou-jyuku.
- ✓ Let's go out of the laboratory, and engage in positive communication through the clinical interaction.
 - ✓ Let's improve our role in elderly person medical care, such as dementia diagnostic through olfaction examinations.
 - ✓ Let's try to diagnose dementia early through such interactions.

Clinical research support by medical technologists: Challenge to the new field

OHidenobu Koga

ASO Iizuka Hospital
Clinical Research Support Unit / Health Information Management

purpose] realization of medical information and improvement of medical services provided in the medical field. and the adjustment of covariates in observational studies

had transferred to the medical information management and the clinical department of medical information analysis along with the Health Information Management. These are the secondary use and visualization of medical information. The PDCA cycle of desirable CR. We introduce this new initiative for foreign medical technology.

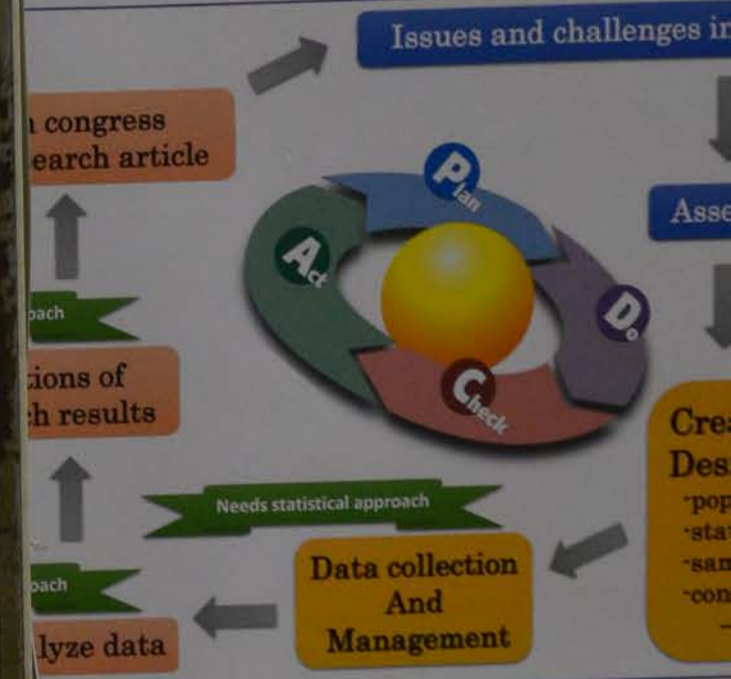


Table Clinical Research

number of order (request) by medical doctor in 2015 (2015/04~2016/03). contents were descriptive and multivariate analysis, design, support of making abstract. appropriate use of statistical methods for comparison between the clinical, patient background) by researchers.



Fig2. The number of orders for clinical research by medical doctor in 2015 (2015/04~2016/03)

to rotate the correct. the quality of CR, it has been required to carry out in cooperation with medical researchers alone. In addition, the role of statistics and statistical personnel is becoming increasingly important. The CR system in many hospitals in Japan. The CR system to become the new active field of clinical laboratory technology. The role of medical staff by medical technologist might to become the

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Laboratory Management PM-27



Trend Research on the Accuracy of Patient Identification at Phlebotomy and Physiological Laboratory Examination

Miki Sunaga MT, Kanako Hattori MT, Junko Yoshino MT, Kyoko Takeda MD, PhD

St. Luke's International Hospital Clinical Laboratory Department

Introduction

St. Luke's International Hospital was accredited by Joint Commission International (JCI) in July 2012. JCI requires medical staffs to confirm a patient's identity by implementing at least two methods. Our laboratory performs it for all patients in their examinations.

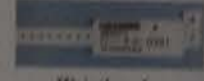
Two confirmation methods

- ① Full name
- ② Date of birth



Please tell us your full name and date of birth!

- To confirm your identity by your full name and date of birth. Please tell us your full name and date of birth before undergoing medical treatment and tests.
- Inpatient: Confirm your name and date of birth by wristband.
- Outpatient: Confirm your name and date of birth by ID card in some cases.



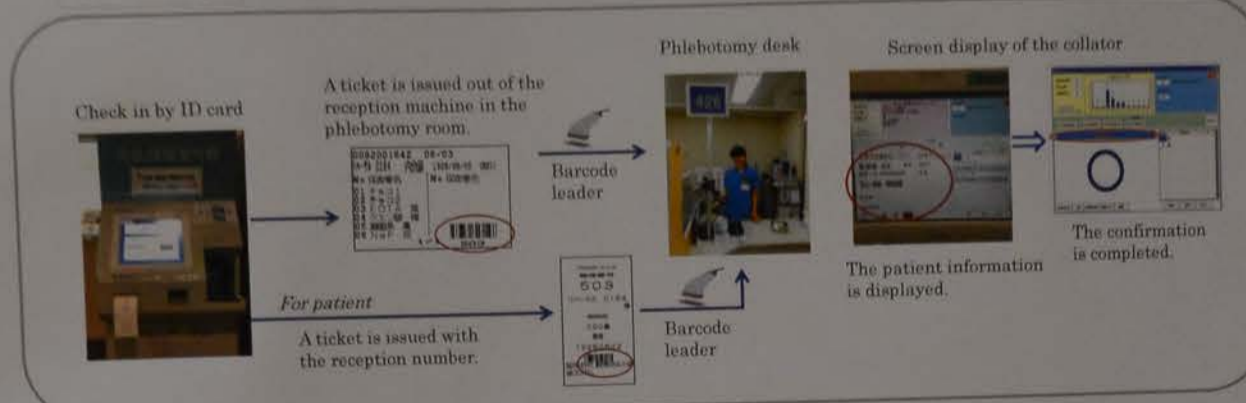
★ We display the poster to get the cooperation of the patient.

Methods

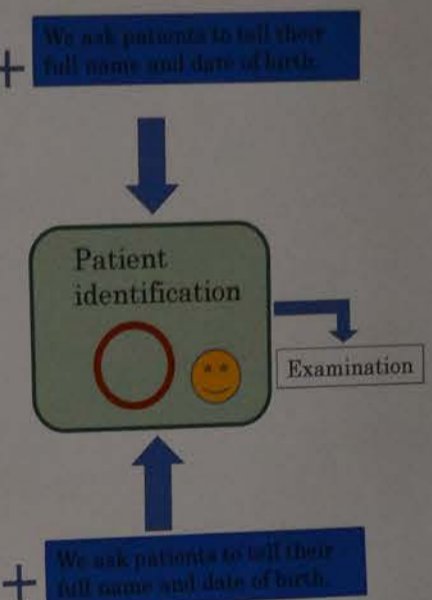
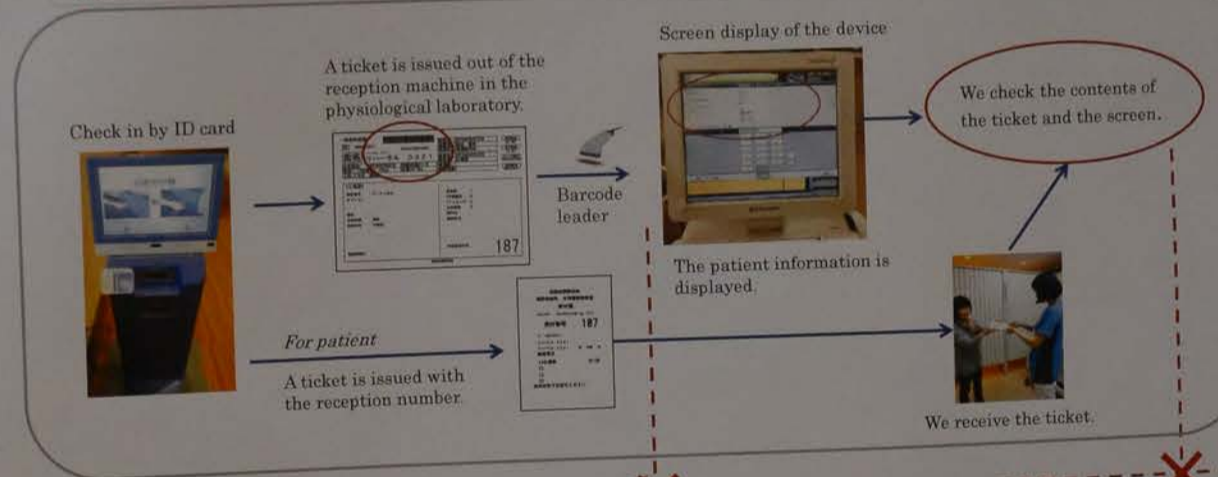
We analyzed the reports on patient misidentification which occurred at phlebotomy and physiological examinations between 2008 and 2015.

Procedures and Patient confirmation

Phlebotomy

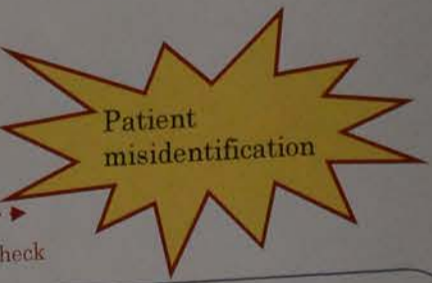


Physiological Laboratory



Without the barcode leader

Without the check



Results

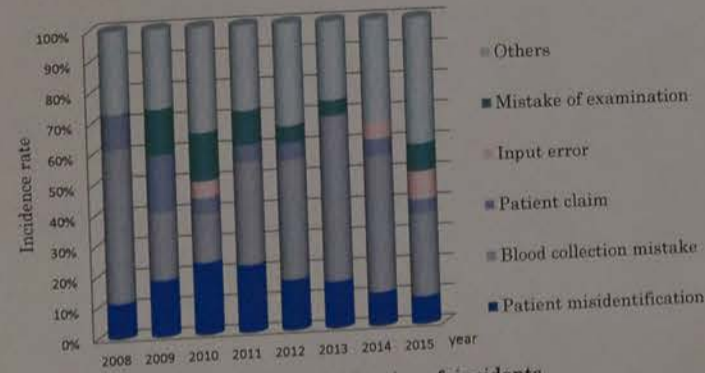


Figure 1 The rate and classification of incidents



Figure 2 The number of cases in screen and patient misidentification

Figure 2 The mistakes occurred when the operator neglected a check of the patient identification on the equipment screen. After the plan had been performed since 2012, there was only one report of misidentification in 2013 and no more patient misidentification since 2014. But there are still cases of screen misidentification.

Discussion and Conclusion

It is well known that human error and computer software error can contribute to patient misidentification in the laboratory. Any individual operation of equipment by medical technologist may cause some mistakes even if there are established systems in place for preventing incidents. However, implementing the plan that asks patients to confirm their full name and their date of birth before any procedure resulted in at least a meaningful reduction of patient misidentification. Therefore it is necessary to establish measures and continue implementing them to avoid serious medical accidents. In addition it is important that both the medical team and the patient cooperate in matters of confirming patient identification.

Introduction & Purpose
 - In recent years, visualization of medical information and improvement have been emphasized in the medical field.
 - Statistical approach and the adjustment of covariates in observational researchers.
 - From July 2014, I had transferred to the medical information management department of medical information analysis along with researchers.
 - Our main businesses are the secondary use and visualization of medical information.
 - Figure 1 shows the PDCA cycle of desirable CR.
 - In this congress, we introduce this new initiative for foreign medical researchers.

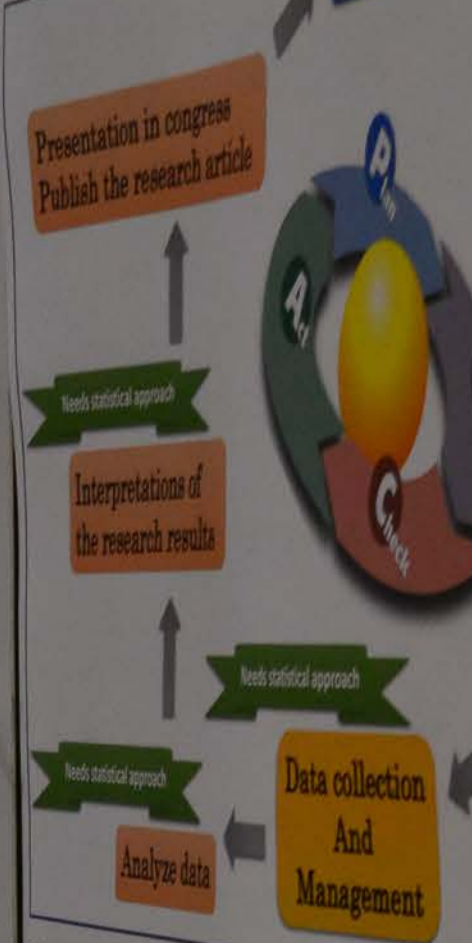


Fig.1. PDCA cycle of desirable Clinical Research
 [Result]
 - Figure 2 shows the number of order (request) by medical occupation in 2015 (2015/04~2016/03).
 - The detail request contents were descriptive and inferential statistics, multivariate analysis, and survival analysis, CR design, support of making slide and congress abstract.
 - It seemed that appropriate use of statistical hypothesis test and the comparison between the different groups (especially, patient background) were difficult for many researchers.
 [Discussion]
 - In CR, researchers have to rotate the correct PDCA cycle of CR.
 - In order to improve the quality of CR, it has been required to carry out the start of the CR than do researchers alone.
 - Under such circumstances, the role of statistics and statistical performance is not well equipped CR system in many hospitals in Japan.
 - CR support seemed to become the new active field of clinical laboratory.
 - CR support for all medical staff by medical technologist might to be a good idea.
 [Contact us]
 Miki Sunaga MD, PhD (msunaga@stluc.com)

Fig.2. The number of cases in screen and patient misidentification in 2015

Laboratory Management PM-28

Clinical research support by medical technologist Challenge to the new field

OHidenobu Koga

ASO Iizuka Hospital
Clinical Research Support Unit / Health Information Management

[Introduction & Purpose]

- In recent years, visualization of medical information and improvement of quality of clinical research (CR) have been emphasized in the medical field.
- Statistical approach and the adjustment of covariates in observational studies are difficult for many researchers.
- From July 2014, I had transferred to the medical information management and CR support unit and launched the department of medical information analysis along with the Health information manager.
- Our main businesses are the secondary use and visualization of medical information and CR support.
- **Figure 1** shows the PDCA cycle of desirable CR.
- In this congress, we introduce this new initiative for foreign medical technologist.

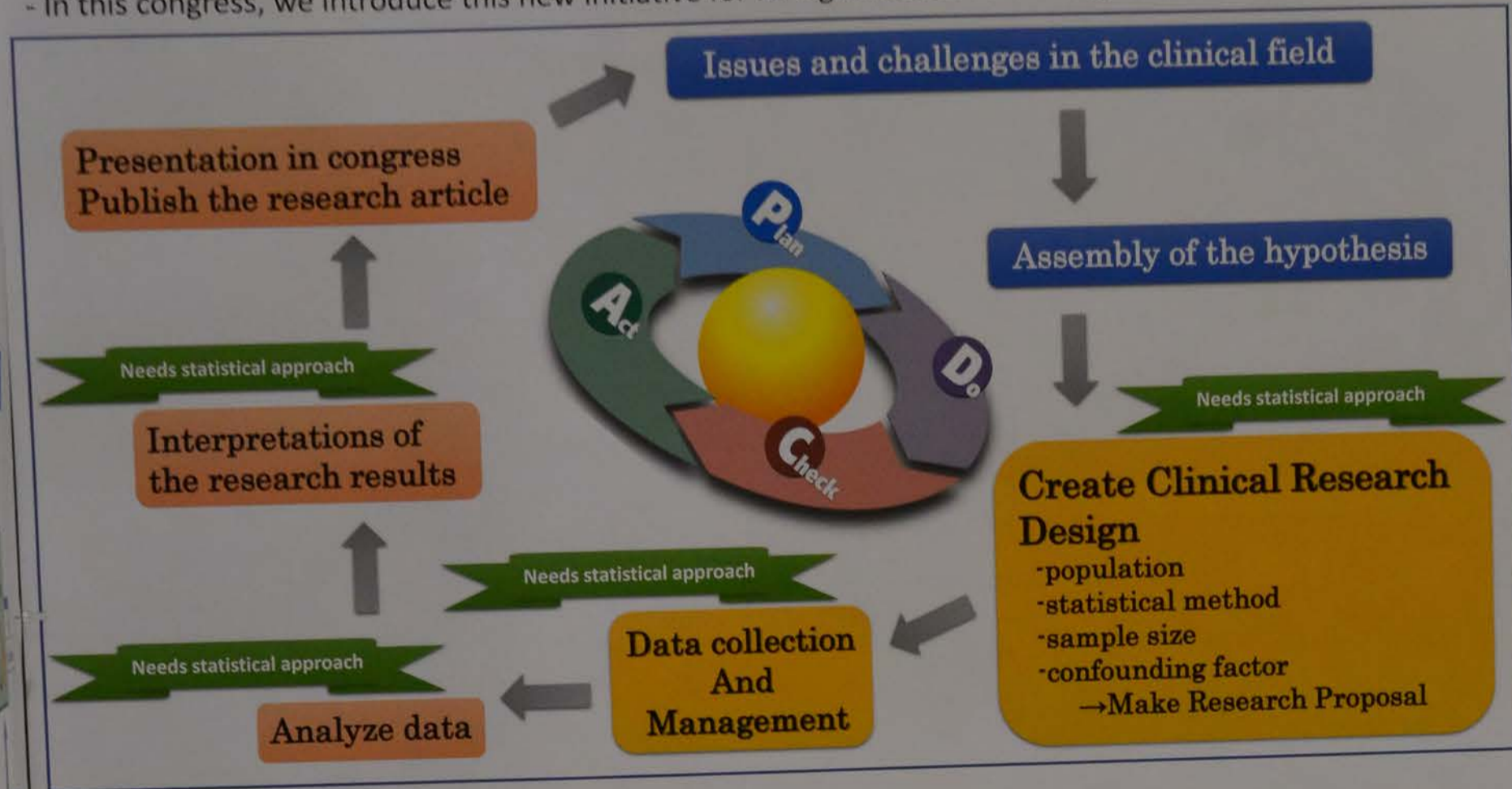


Fig1. PDCA cycle of desirable Clinical Research

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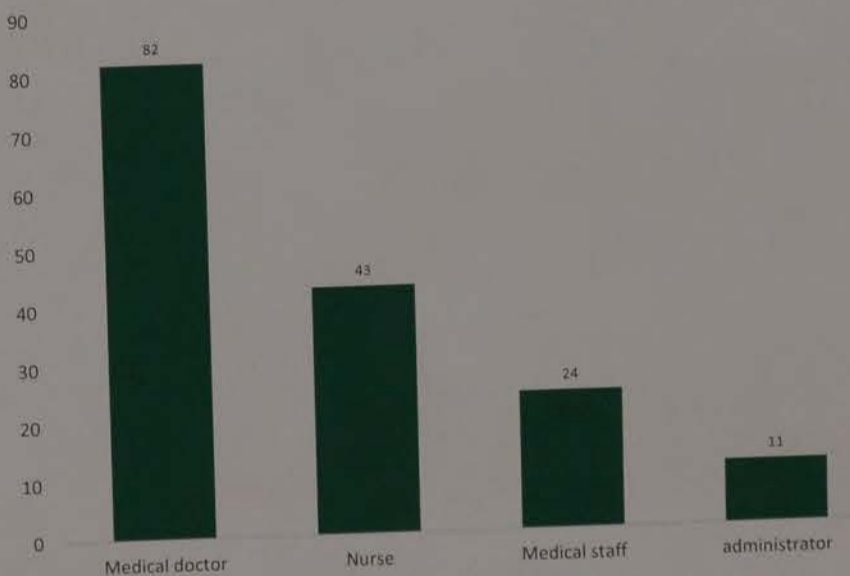


Fig2. The number of order (request) by medical occupation in 2015 (2015/04~2016/03)

[Discussion]

- In CR, researchers have to rotate the correct PDCA cycle of CR.
- In order to improve the quality of CR, it has been required to carry out in cooperation from the stage of the start of the CR than do researchers alone.
- Under such circumstances, the role of statistics and statistical personnel is particularly important.
- However, it is not well equipped CR system in many hospitals in Japan.
- CR support seemed to become the new active field of clinical laboratory technicians.
- CR support for all medical staff by medical technologist might to become the new active field of medical technologist.

[Contact us]

HIDENOBU KOGA (hkogah1@aih-net.com)

ASO IIZUKA HOSPITAL

tion 01
Transforming Biomedical Science Through
Peter Hu, Ph.D., HCSS

IAACLS
National Accrediting Agency for Clinical Laboratory Sciences
naaccls.org

Statement:
Healthcare through Better Graduates
Improving clinical laboratory science services locally through better graduates
A diversified community of clinical laboratory science professionals
Improving excellence and improving clinical laboratory science through established criteria and sharing of best practices
Opportunities for global laboratory practice and collaboration

BENEFITS OF ACCREDITATION: Why Choose NAACLS?
A process of external peer review in which an agency grants public recognition to a program that meets or exceeds national standards of educational quality. Participation in the accreditation process is voluntary since accreditation is not required for licensure or certification. Although a voluntary process, it is valuable. The benefits include, but are not limited to, the following:
- External peer review process that includes a Self-Study Review and Site Visit, identifies for the public and standards of educational quality.
- Improvement of educational programs by involving faculty and staff in ongoing self-evaluation and peer review.
- Better understanding of the goals of professional education.
- Reasonable assurance that practitioners meet minimum educational standards upon entry into the profession.
- Improved programs in achieving their unique objectives.

Laboratory Management PM-29

Report on the management of CPAP using the communication modem

Ritsuko miyachi
Saga Central Hospital

Introduction

Continuous Positive Airway Pressure (CPAP) User for Sleep Apnea Syndrome (SAS) needs regularly visits to hospital. This time we had succeeded in streaming works by the management of CPAP using the communication modem (MCC). We report the survey results for CCM to investigate the effectiveness.

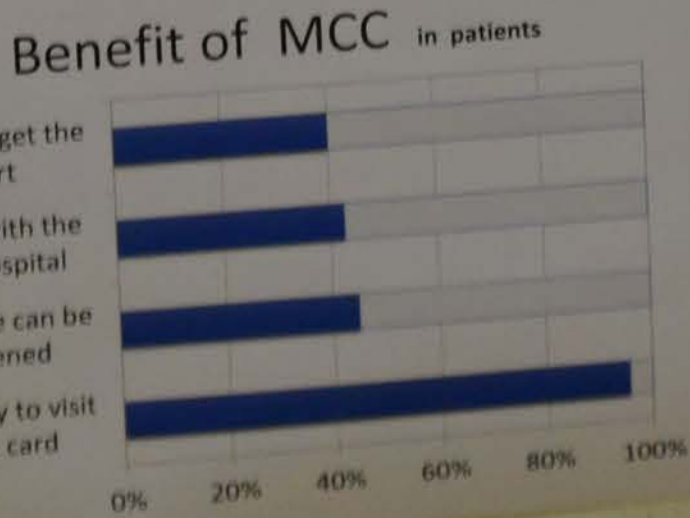
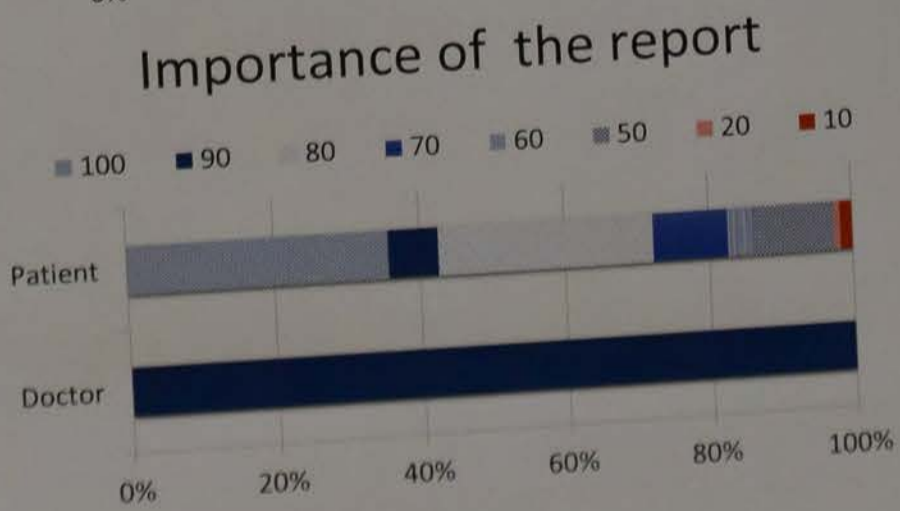
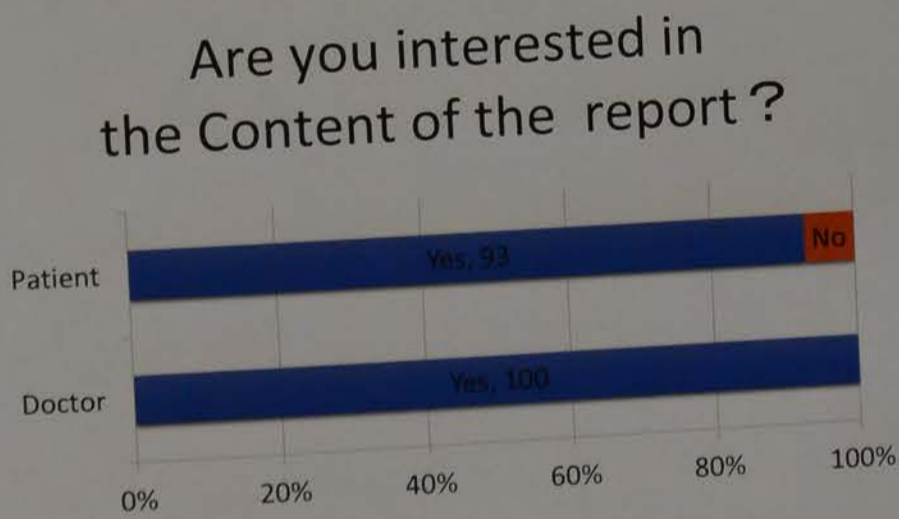
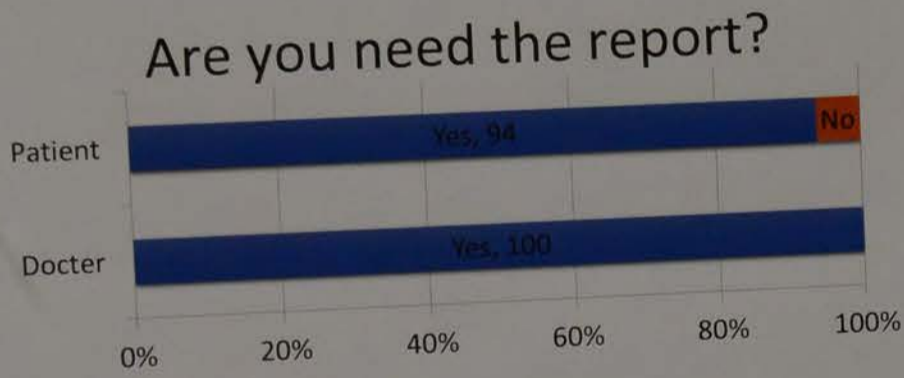


Methods

Target is patients who obtained the consent CPAP user and using more than 2 month and November 2015 of the examine. The survey asks multiple-choice questions and yes no questions. We carried out to the waiting time of patients and doctors.

Result

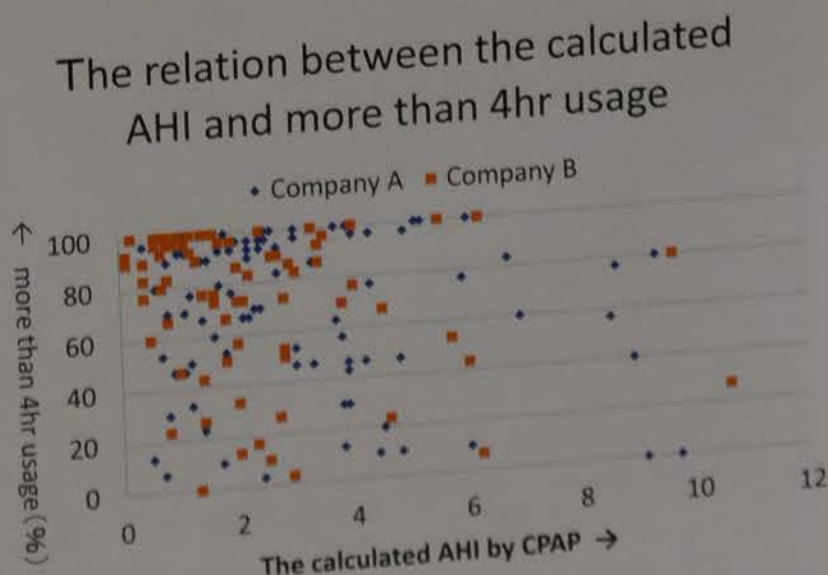
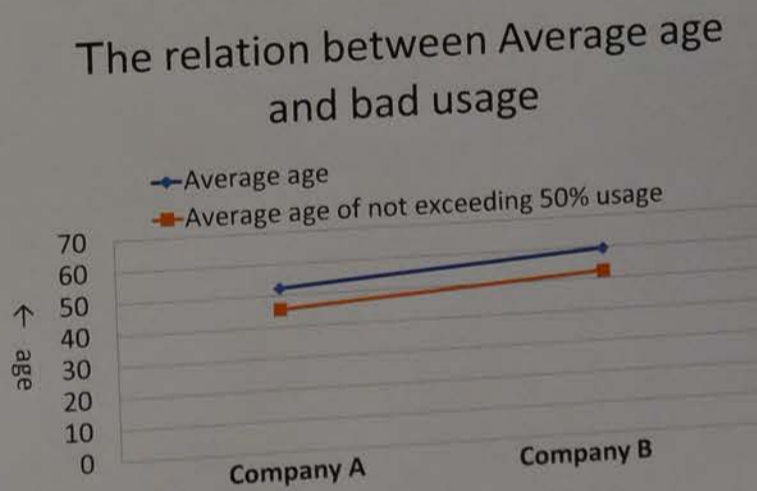
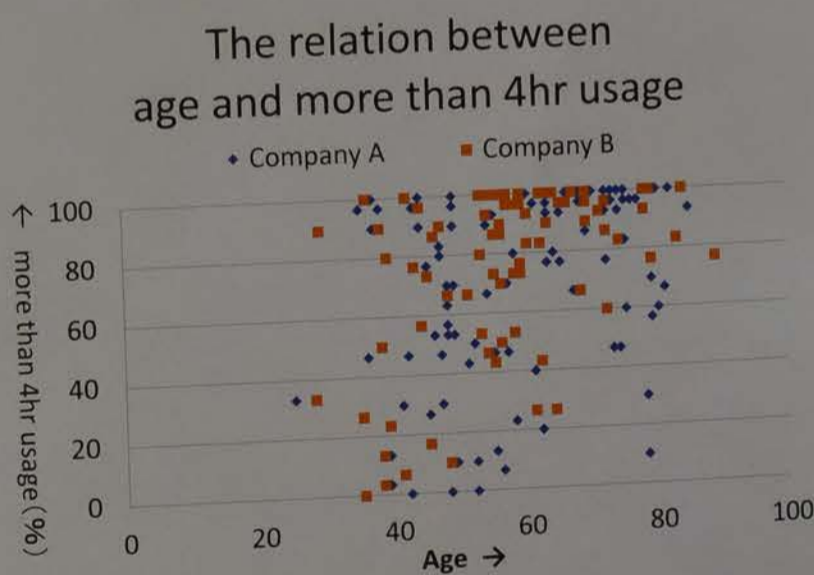
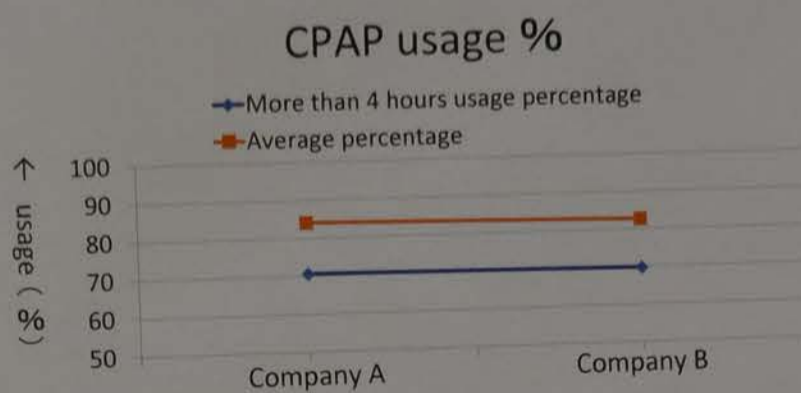
It is 123 people to using CPAP more than 2 month among 231people Patients Outpatients of CPAP. (male 94people, average age 57.0-years-old : female 21people, average age 60.5-years-old)



The report was found to be very important for the patients and doctors. And therefore making a report is indispensable to the examination to the laboratory.

<Benefit for Laboratory>

- ① We can make the report in a planned way. (The best effect)
 - ② We can respond quickly about bad usage. (There is possibility to gain trust by patients)
 - ③ It's can get easily to aggregate data. Statistical data of fixed interval as follows.
- Two companies to provide MMC, 3/2016
Company A= 101 people
Company B= 77 people



As stated above we can make a relationship of total win by MCC. I think that medical technologists should be a person who understands well the patient's sleep and we can be a good supporter in the team medical by the advantage of MCC.

Education PN-01



Value Statement:
Better Healthcare through Better Graduates
Maximizing clinical laboratory science services locally through competent program graduates
Linking a diversified community of clinical laboratory educator peers
Stimulating excellence and improving clinical laboratory science education through established criteria and sharing of best practices
Forging opportunities for global laboratory practice and career development

Accreditation is a process of external peer review in which an agency grants public recognition to a program of study or an institution that meets established standards. Programs that participate in the NAACLS programmatic accreditation process culminate in a public listing of the institution's name in the NAACLS directory of accredited programs.

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