

○Takuya KANNO, Takaaki KONDO, Chiaki KATO
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Pathophysiological Laboratory Sciences

1. INTRODUCTION

Time-series database construction based on the logic of latent reference intervals (LRIs) has been proposed. The purpose of this study is to apply the LRIs method to a large-sized laboratory database and determine the LRIs for their seasonal variations.

2. SUBJECTS and METHODS

We obtained the outpatient database at the Nagoya University Hospital. A total of 32,1964 ambulant cases aged 40-79 were measured for the following 13 items during Jan 2007-Dec 2011:

Total protein (TP), Albumin (ALB), Total Cholesterol (TC)
Fasting Blood Glucose (FBG), Blood Urea Nitrogen (BUN)
Creatinine (CRE), Uric acid (UA), Aspartate Aminotransferase (AST)
Alanine Aminotransferase (ALT), Lactate Dehydrogenase (LDH)
Alkaline Phosphatase (ALP), γ -Glutamyltransferase (γ -GTP)
Triacylglycerides (TG)

After determining all 13-item LRIs on a monthly basis, we calculated means for consecutive 60 months as the sample representative values to examine seasonal variations. The variation of consecutive values of each item mean was decomposed into three components, seasonal ($S[t]$), trend ($T[t]$), and irregular ($e[t]$) ones on the assumption of additivity.

For the statistical analysis of 12-month seasonality, autocorrelation coefficients were calculated and tested. R (version 3.3.1) commands $stl()$ and $acf()$ were used for the decomposition and autocorrelation calculation.

3. RESULTS and DISCUSSION

TP and FBG in male samples indicated significant autocorrelations, but did not in female samples. Significant autocorrelations were observed in TC in males and younger females. AST also showed high serum levels in winter and low in summer; this seasonal variation was consistently watched over all 4 gender/age subgroups. Furthermore, regarding liver function biomarkers, ALT in older males and ALP in younger males and older females also demonstrated similar results.

Our results are consistent with previous reports. The strong point of our study is the sophistication of sample construction with application of the LSI method. The underlying biological mechanism to generate such seasonal variation is yet to be investigated.

Compute RI ($L_i \sim U_i$) for 13 tests independently of each other as initial values without excluding any results.

Exclude those with abnormal results in other 12 tests disregarding own tests results.

Re-compute RI ($L_i \sim U_i$) after the above exclusion procedure.

Compare the difference between the RI with the previous RI ($L_{i-1} \sim U_{i-1}$)

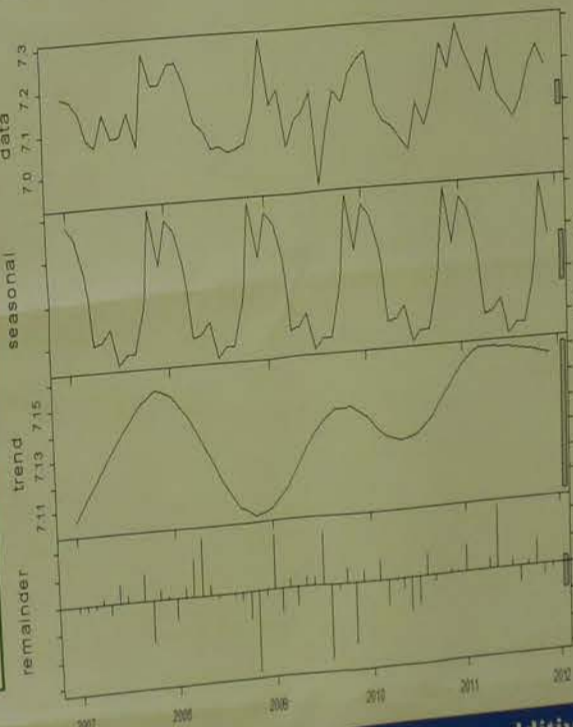
$L_{i-1} = L$ and $U_{i-1} = U$

End

Schematic View of LRIs Method

Reference intervals of total protein in men after each latent abnormal value exclusion (January, 2007)

Extraction step	Sample size	Mean	Min	Max	Range
Base	835	7.1	4.2	9.0	4.8
1	557	7.1	5.6	8.5	2.9
2	341	7.1	5.7	8.2	2.5
3	202	7.2	6.2	8.2	2.0
4	112	7.2	6.3	8.2	1.9
5	80	7.2	6.3	8.2	1.9



Total protein values and its three additive components obtained from a robust STL decomposition among 40-59 y/o male outpatients during January of 2007-December of 2011

Autocorrelation coefficients at lag of 12 months for time-series data of 13 test items by gender and age group (*p < 0.05)

Items	Male		Female	
	40-59 y/o	60-79 y/o	40-59 y/o	60-79 y/o
Total protein (TP)	0.32*	0.34*	0.097	0.14
Albumin (Alb)	0.13	0.062	-0.045	-0.11
Total cholesterol (TC)	0.41*	0.41*	-0.050	0.21
Fasting blood glucose (FBG)	0.30*	0.31*	0.18	0.052
Blood urea nitrogen (BUN)	-0.020	0.033	0.10	0.28
Creatinine (Cre)	0.055	0.18	0.10	0.15
Uric acid (UA)	-0.13	0.16	-0.010	0.48*
Aspartate aminotransferase (AST)	0.36*	0.40*	0.21	0.27*
Alanine aminotransferase (ALT)	0.24	0.39*	0.00020	0.13
Lactate dehydrogenase (LDH)	-0.10	0.021	0.24	0.29*
Alkaline phosphatase (ALP)	0.31*	0.10	0.10	0.18
γ -Glutamyltransferase (γ -GTP)	0.096	0.095	0.10	0.18
Triacylglyceride (TG)	-0.0067	0.023	-0.067	0.039

COI declaration

The presenter has no conflict of interest with any corporate organization relating to this presentation

of the reference range of coagulometry (RO) Japanese

wahara, Kouhei Ohtsuka, Hiroyuki Takahara, Tomoda, Satoshi Fujii
Nagoya University Hospital Medical Laboratory and Blood Chemistry

	INTEM	EXTEM
CT (sec)	145-220	41-82
CFT (sec)	49-102	47-119
A10 (mm)	47-62	45-65
MCF (mm)	51-66	52-70
α (°)	70-80	67-80

Table 2. The reference ranges obtained by means of the results by ROTEM®. The data are calculated reference limits.

	p value	p value
CT	0.061	CT 0.527
CFT	0.199	CFT 0.076
INTEM A10	0.453	EXTEM A10 0.477
MCF	0.850	MCF 0.465
α	0.120	α 0.141

Table 3. The results of gender differences. The gender differences were investigated with t-test (p < 0.05).

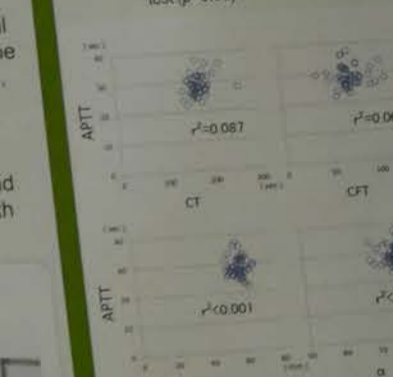


Fig 1. Relation between INTEM parameters and APTT. Coefficient of determination, R-Square, between CT and APTT.



Fig 2. Relation between EXTEM parameters and PT. Coefficient of determination, R-Square, between MCF and PT.

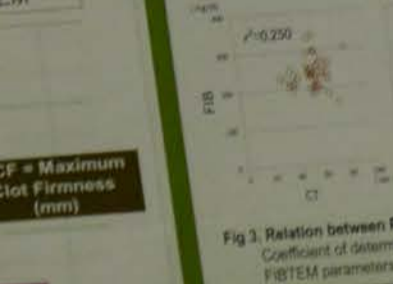


Fig 3. Relation between FIBTEM parameters and FIBTEM parameters. Coefficient of determination, R-Square, between FIB and FIBTEM parameters.

Discussion

We determined the reference ranges of Japanese. The results of this study were compared with the results reported by Lang T¹⁾ and Gami²⁾ material of this study was adult. The results in paediatric age groups³⁾ were similar.

Conclusion

Reference ranges of ROTEM® were determined for the first time in Japanese. These values were utilized to assess the necessity of blood in patients with massive bleeding, and the bleeding and clotting tendency in various populations.

References

- 1) Lang T, et al. Blood Coagul Fibrinolysis 2008; 19: 310
- 2) Gami MT, et al. Anesth Analg 2008; 106: 1000
- 3) Oswald E, et al. Br J Anaesth 2011; 107: 1000

Laboratory Information System
PK-03

Establishment of QMS Everolimus Assay on Abbott Architect e8000 Automatic Chemistry Analyzer

Yu-Hsuan Yang, Ya-Wen Tsai, Li-Ching Wu

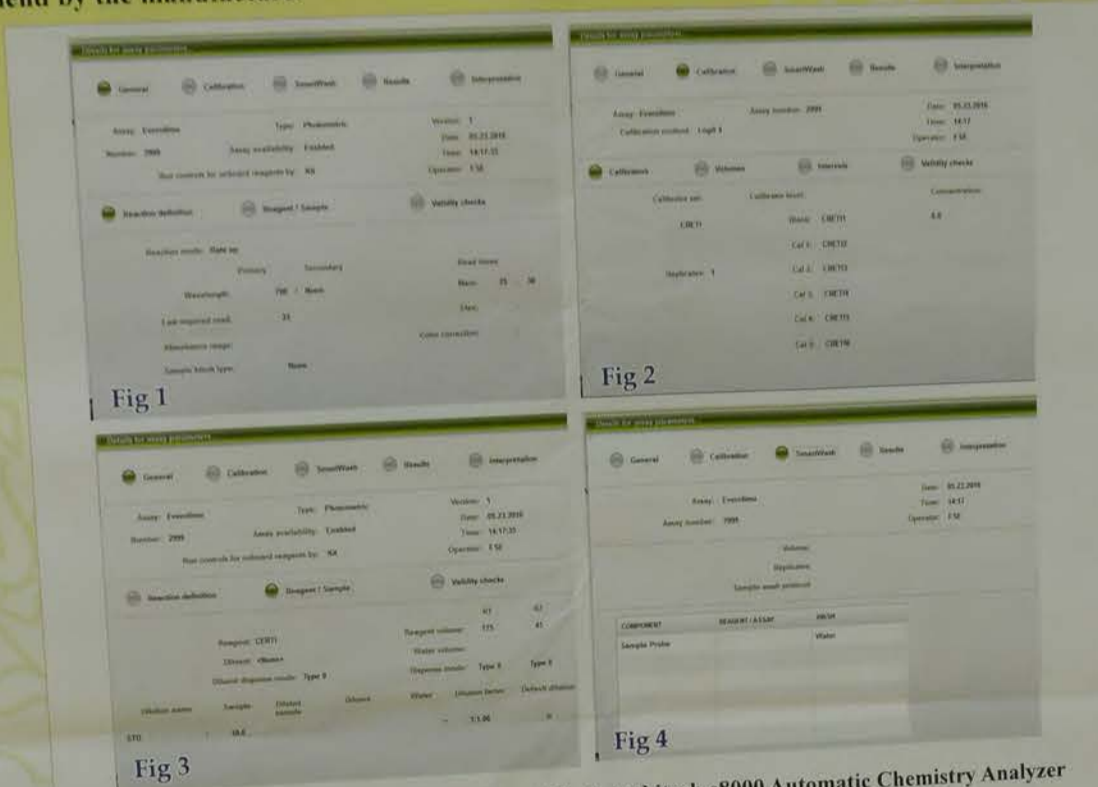
Division of Clinical Pathology, Department of Pathology, Chi Mei Medical Center, Tainan, Taiwan

Background

The Thermo Scientific QMS Everolimus is the newest addition to a full menu of immunosuppressant drug monitoring immunoassays. There are applications for a variety of clinical chemistry analyzers; however, studies on this assay adapted to the Abbott Architect e8000 chemistry analyzer have not been published. This study evaluated the analytical performance of Abbott Architect e8000 clinical chemistry analyzers for Everolimus.

Methods

The analysis was performed according to the QMS assay package insert. Analytical performances (imprecision, linearity, limit of detection, and limit of quantification) of this new immunoassay were evaluated. The analyzers were compared with an HITACHI 7600 Analyzers and, which was recommend by the manufacture.

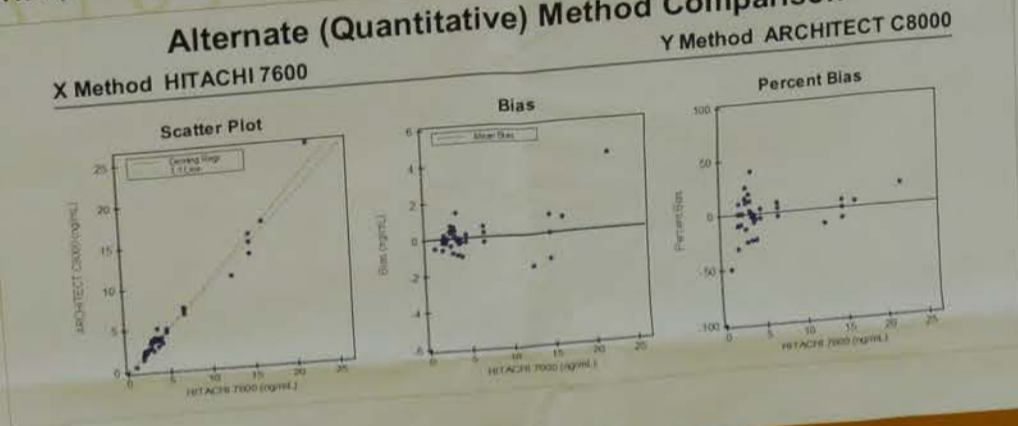


Fig(1-4): Parameters of Everolimus Assay on Abbott Architect e8000 Automatic Chemistry Analyzer

Results

The assay was linear in the range of 0.0-20.0 ng/mL. Limit of detection was 1.5 ng/mL and lower limit of quantitation was 1.3 ng/mL. Within-day and between-day (20 days) coefficients of variation were between 3.1% and 8.76% at mean levels of 3.6, 8.0, and 15.2 ng/mL, respectively. We obtained a Deming regression of $y = 1.091x - 0.452$ ($r = 0.9875$) when comparing with the HITACHI 7600 Analyzers

Alternate (Quantitative) Method Comparison



Conclusion

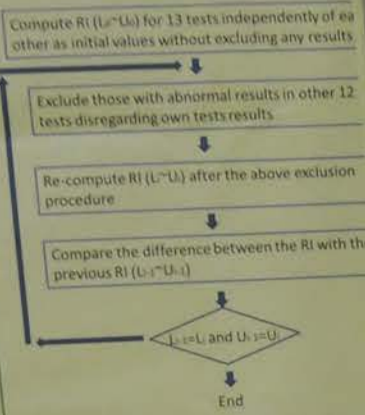
The results demonstrated acceptable performance, validating the use of the QMS Everolimus Assay on the Abbott Architect e8000 analyzer, and will provide an effective monitoring system for patients receiving Everolimus therapy.



ons of Clinical Data Reference Interval

akaaki KONDO, Chiaki KATO
y Graduate School of Medicine
al Laboratory Sciences

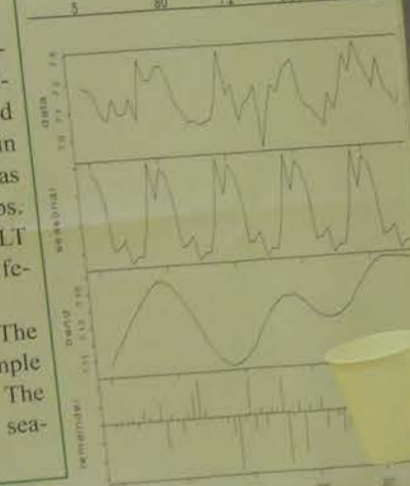
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Schematic View of LRIs Method

Reference intervals of total protein in male after each latent abnormal value exc (January, 2007)

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at lag of 12 months for time-series
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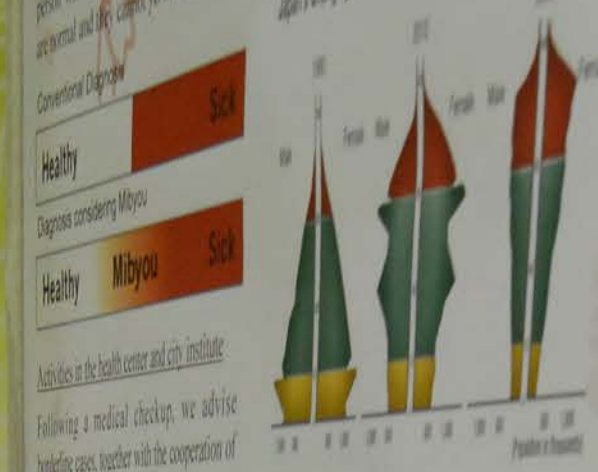
Male	Female
0.59	0.59
0.13	0.13
0.61	0.61
0.90	0.90
-0.020	-0.020
0.068	0.068
-0.13	-0.13
0.38	0.38
0.24	0.24
-0.10	-0.10
0.31	0.31
0.096	0.096
-0.0767	-0.0767

Total protein values and its three add
components obtained from a robust
decomposition among 40-59 y/o
outpatients during January of
December of 2011

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PK-04

Everolimus is the newest addition to a full menu of immunosuppressant drug monitoring immunoassays. There are applications for a variety of clinical chemistry analyzers; however, studies on this assay adapted to the Abbott Architect e8000 chemistry analyzer have not been published. This study evaluated the analytical performance of Abbott Architect e8000 clinical chemistry analyzers for Everolimus.



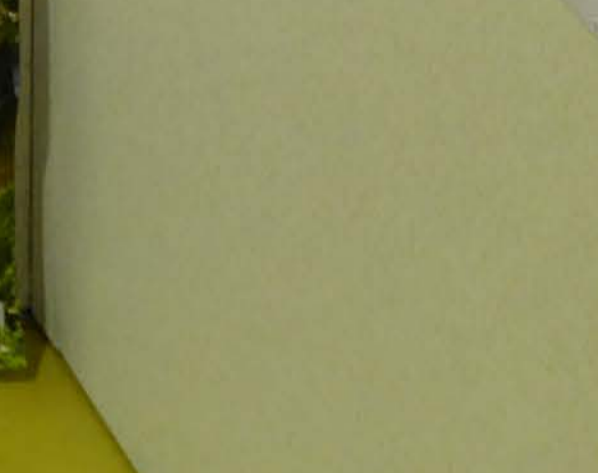
Following a medical checkup, we advise
beneficial cases, together with the cooperation
of the medical team. We researched easier and more
simple measurement methods. We always try to
collect and provide people with the latest
information. Afterwards, we offer them further
training if necessary.

Volunteering for Kumamoto Earthquake victims
Following the disaster in Kumamoto earlier this
year, many stepped forward to offer support.
My medical team and I tested blood pressure
and blood sugar. We tried to listen to them and
gave various advice. Many people were
suffering from stress and high blood pressure.
Listening is a time-tested and often overlooked
form of treatment and essential to mihiyou
medicine for the victims.

Now, we are semi retired, but we still spend
time as biomedical laboratory scientists. We are
endeavoring to obtain licenses as Professional
Mihiyou Instructors. Our aim isn't the
prevention of any particular target disease.
Therefore, we need to continue working on a
wider outlook and better cooperation between
medical professionals.
We are in our 60s. Our parents are
in their 80s and 90s, even over 100.
Longer and healthier lives are so
important for us.



In the 20th Meeting of
Japan Mihiyou System Association



The Contributions of Biomedical Laboratory Scientists Searching for Pre-symptomatic Disease (Mibyou)

Yoko Takaki, Yoshiko Yokota

Yoko Takaki: Member of the Japanese Association of Medical Technologists
Yoshiko Yokota: Former member of the Kawasaki City Institute for Public Health

Mibyou refers to the condition of a person at a stage between being healthy and being sick, specifically two types of conditions; in cases whereby a person does not yet exhibit symptoms, but medical examinations suggest that a person might be at risk of developing a sickness and a person who exhibits symptoms, but test results are normal and they cannot yet be diagnosed sick.

Conventional Diagnosis

Healthy Sick

Diagnosis considering Mibyou

Healthy Mibyou Sick

Activities in the health center and city institute

Following a medical checkup, we advise borderline cases, together with the cooperation of the medical team. We researched easier and more rapid measurement methods. We always try to collect and provide people with the latest information. Afterwards, we offer them further training if necessary.

Activities in the hospital and local events

We collaborated with SAS (Sleep apnea syndrome) and NST (Nutrition Support Team) professionals to discuss ongoing methods of patient care. During local prevention activities, we organized blood inspection complete with explanations and consultations for people while striving to support community health.



Local prevention activities

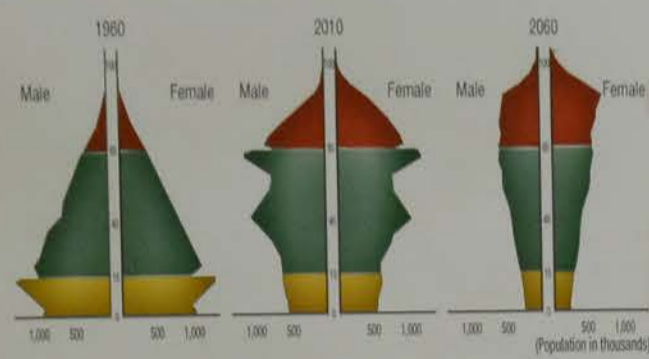


On our ninetieth birthday we call it a 卒寿 (Sotsujiyu). A special celebration of long life. This man is celebrating his with his great granddaughter.

Efforts toward Mibyou medicine

The Japan Mibyou System Association of medical technologists' branch introduced activities to the health care administration in Kanagawa, who aggressively promoted curing Mibyou. We aimed at contributing to longer and healthier lives in the community through local activities.

Japan's Changing Population Pyramid (population by age)



Sources: (For 1960 and 2010) Statistics Bureau (Ministry of Internal Affairs and Communications), Population Census of Japan; (for 2060 projection) National Institute of Population and Social Security Research, Population Projections for Japan (January 2012), based on medium-variant fertility and mortality assumptions.

Volunteering for Kumamoto Earthquake victims

Following the disaster in Kumamoto earlier this year, many stepped forward to offer support. My medical team and I tested blood pressure and blood sugar. We tried to listen to them and gave various advice. Many people were suffering from stress and high blood pressure. Listening is a time-tested and often overlooked form of treatment and essential to mibyou medicine for the victims.

Now, we are semi retired, but we still spend time as biomedical laboratory scientists. We are endeavoring to obtain licenses as Professional Mibyou Instructors. Our aim isn't the prevention of any particular target disease. Therefore, we need to continue working on a wider outlook and better cooperation between medical professionals.

We are in our 60s. Our parents are in their 80s and 90s, even over 100. Longer and healthier lives are so important for us.



In the 22nd Meeting of Japan Mibyou System Association



Current status and prospects for BLS to play expanded roles in endoscopic operations in Japan

Experience with medical teams and international medical support

A Baba, K Imaeda, N Tsunoda, A Iwashita, Y Hasegawa, Yamashita Hospital, Ichinomiya, JAPAN

Medical laboratory staff in Japan is laboratory BLS in Japan. BLS in Japan is involved in endoscopic operations. BLS in Japan is involved in endoscopic operations. BLS in Japan is involved in endoscopic operations.

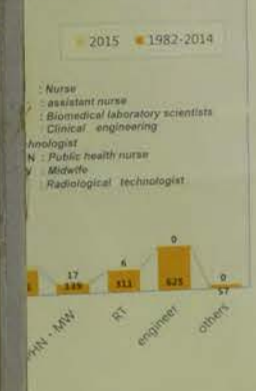
Future prospects

The role of BLS in endoscopic treatment should expand because effort to increase their roles has been recommended in Japan. Therefore, further promotion of medical teams by the Japanese Association of Medical Technologists is important and adding endoscopic treatment to the curriculum for BLS trainees might also be useful.

Breakdown

21 individuals who had become endoscopic operators by 2015 in Japan, and 1,343 were BLS.

Breakdown of endoscopic operations



Medical team at our hospital

Five BLS and 13 nurses comprise the regular endoscopic operations staff. Collaboration among individuals with different specialties has helped to improve our medical service.

Main roles in endoscopic treatment

- (1) Assistance with endoscopic treatment
- (2) Cleaning and sterilization endoscopes
- (3) Reading capsule endoscopy findings
- (4) Maintaining instruments



International support

An international medical support project in Vietnam in 2014. The Methods of Endoscopic Examination, Nagoya University, Professor Goto contributed to a review of our routine procedures.



Quality

Endoscopic treatment and practical training are available at BLS training schools. Procedures for BLS trainees that have increased the number of BLS who aim to staff that performs endoscopic operations.

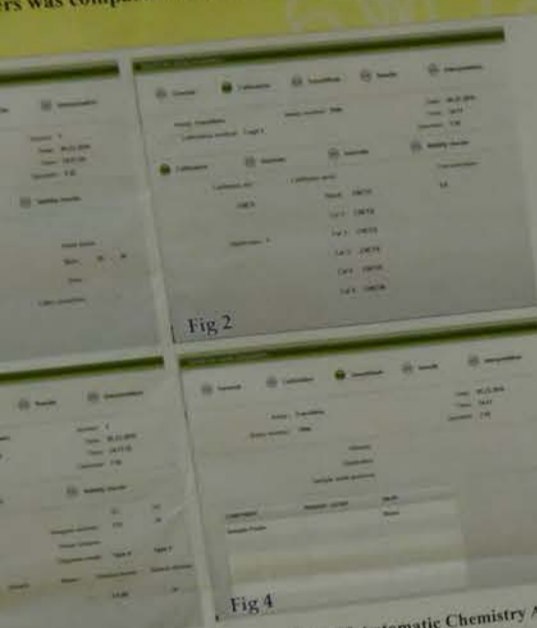
What is doing the endoscopic operations in multidisciplinary collaboration, in many endoscopic medical team is a division of labor system. Medical qualification of BLS staffs, in order to protect each of the qualification in the form of division of labor than endoscopic operations that enables all basically nurses, there is also the opinion that the need for other professions as well as BLS. In addition, there is also the opinion that we can't leave anywhere until the endoscopic operations to the BLS. For BLS, it is important to continue to originate from, such as the Society.

QMS Everolimus Assay Architech c8000 Automatic Chemistry Analyzer

Yang, Ya-Wen Tsai, Li-Ching Wu
Department of Pathology, Chi Mei Medical Center, Tainan, Taiwan

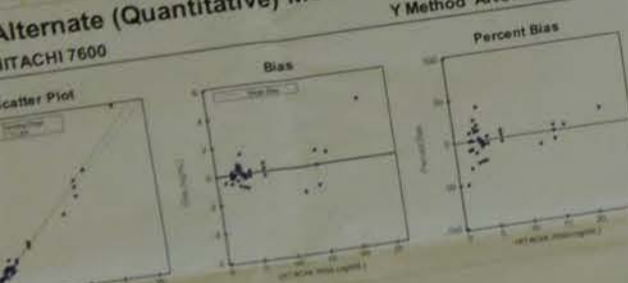
The newest addition to a full menu of immunosuppressant drug assays for a variety of clinical chemistry analyzers; however, studies on the c8000 chemistry analyzer have not been published. This study compared the performance of the c8000 clinical chemistry analyzers for Everolimus.

Linearity, limit of detection, and limit of quantification of this new assay was compared with an HITACHI 7600 Analyzers and, which was



The range of 0.0-20.0 ng/mL. Limit of detection was 1.5 ng/mL, and lower limit of quantification was 3.0 ng/mL. Within-day and between-day (20 days) coefficients of variation were 2.5% and 3.6%, respectively. We obtained a Denning regression of y = 0.98x + 0.1 when comparing with the HITACHI 7600 Analyzers.

Alternate (Quantitative) Method Comparison Y Method ARCHITECT C8000 X Method ARCHITECT C8000



The results demonstrated acceptable performance, validating the use of the QMS Everolimus Assay on the c8000 analyzer, and will provide an effective monitoring system for patients receiving Everolimus.

Laboratory Information System PK-05

The disaster medical care support in which we a medical technologist

Norihiko AMEMIYA¹⁾, Katsue Suzuki-INOUE

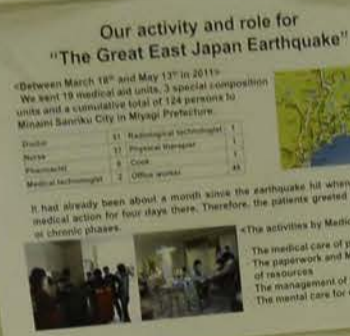
- 1) Department of Clinical Laboratory, University of Yamanashi Hospital
- 2) Department of Clinical Laboratory Medicine, Faculty of Medicine, University of Yamanashi Hospital

Background

"The Great Hanshin/Awaji Earthquake" occurred on January 17th in 1995. It led many domestic medical institutions to concern about medical care at disaster sites. We took medical support action soon after the Yamanashi Prefecture requested us for disaster medical aid.

We took part in the training session for DMAT (Disaster Medical Assistance Team) on March 2012. Therefore, we have come to organize DMATs.

In this session, we are going to share our experience of the training and the actual activities for 5 years after the huge earthquake.



Medical aid team and Medical Technologist

MTs were supposed to mainly provide clinics with the lab testing of blood glucose, prothrombin time and the other exams using POC instruments and Management (M) and (S) by simple test kits, however, we seldom used them.

Many of the evacuee at gymnasiums as an evacuation used them. From this experience, we expect that ultrasonography would be introduced as a medical relief activity in future, providing following-up medical examination for venous thrombosis.

Disaster Medical Assistance Team (DMAT)

DMAT is consisted of doctors, nurses and logistics (5 or 6 members per team) and is the team that has passed professional training. It enables us to have the mobility for taking action within about 48 hours after large scale disasters, or worse casualty incidents happen.

"The Great Hanshin/Awaji Earthquake" occurred on January 17th in 1995. It led many domestic medical institutions to concern about medical care at disaster sites. We took medical support action soon after the Yamanashi Prefecture requested us for disaster medical aid.

Conclusion

DMAT logistics mainly do paperwork on site. However, MT would assume an important role in medical care from now on for substance and chronic patients with ultrasonography. Selection screening and POC instrument management.

For that, it is getting more necessary for medical service workers to get actively involved in multi-disciplinary training, and we hope to get actively involved in disaster medical aid and (S) by simple test kits, however, we seldom used them.

From this experience, we expect that ultrasonography would be introduced as a medical relief activity in future, providing following-up medical examination for venous thrombosis.

Goals and Activities of DMAT

- To secure medical care for disaster victims.
- To provide medical care for disaster victims.
- To provide medical care for disaster victims.
- To provide medical care for disaster victims.
- To provide medical care for disaster victims.
- To provide medical care for disaster victims.

The role and attitude in logistics support

- To secure medical care for disaster victims.
- To provide medical care for disaster victims.
- To provide medical care for disaster victims.
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CASE ①

The rescue operation at the Sasago Tunnel Collapse on December 2nd 2012. At 9:34 am, our DMAT members gathered at the train station to be on standby. Requested by the Yamanashi Prefecture, the first and second party reorganized to units and immediately head to the collapsed site.

CASE ②

The Mt. Ontake Eruption on September 28th and 29th 2014. At the midnight of September 27th, we got the order to send DMAT by the Yamanashi Prefecture to respond to the occurrence of an eruption. We arranged medical supplies, communication equipment and necessary goods, conforming with the transportation for disaster countermeasures. In the early morning, our seven staffs departed at Nagano Prefecture Kisei Hospital as a base and left taking vehicles to the hospital, examining team and staying the head division.

Activity contents by DMAT

In the two disaster relief action, there weren't any necessities for MTs to examine patients as a routine job. Our logistics mainly consisted of collecting information and sending it to Emergency Medical Information System. A secretary seemed to be more favorable to train tasks as coordinator, rather than other medical service staffs, including MTs, pharmacists, radiologists and clinical engineers. At the workplace held by DMAT Executive Office every year, emergency response drills with Japan Self-Defense Forces, JDF and bridge training in with the hospital, the cooperation in the same as those above. Although the present work content will continue to "remain", we expect MTs to take action as a member of medical providers.

Laboratory Information System PK-06

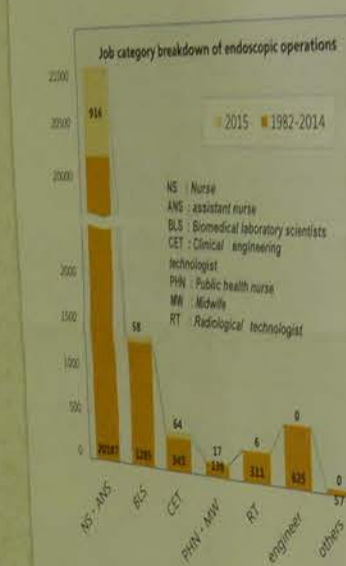
Current status and prospect to play expanded roles in endoscopic operation
Experience with medical teams and international medical support
A. Imai, K. Imai, N. Tomaki, A. Imai, Y. Higashi, I. Masuda, Hospital, Yamanashi University

Background

The main role of biomedical laboratory scientists (BLS) outside Japan is laboratory testing, whereas many BLS in Japan participate in physiological examinations. Five regular BLS are involved in endoscopic treatment at our hospital and two have qualifications in endoscopic procedures. However, few BLS are on the regular endoscopy staff at other Japanese institutions and nurses comprise the main staff.

Job category breakdown

Among 24,010 individuals who had become licensed endoscopic operators by 2015 in Japan, 21,103 were nurses and 1,343 were BLS.



Future prospects

The role of BLS in endoscopic treatment should expand because effort to increase their roles has been recommended in Japan. Therefore, further promotion of Medical Technologists is important and adding endoscopic treatment to the curriculum for BLS trainees might also be useful.

Medical team at our hospital

Five BLS and 13 nurses comprise the regular endoscopic operations staff. Collaboration among individuals with different specialties has helped to improve our medical service.

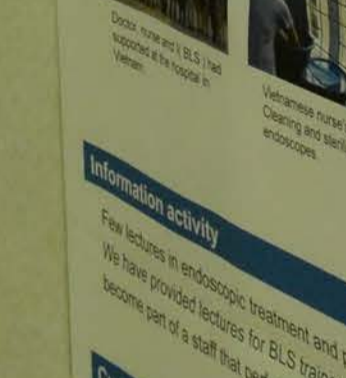
Main roles in endoscopic treatment

- (1) Assistance with endoscopic treatment
- (2) Cleaning and sterilization endoscopes
- (3) Reading capsule endoscopy findings
- (4) Maintaining instruments



International medical support

We participated in an international medical support project in Vietnam in 2014. (Training in Japanese Methods of Endoscopic Examination, Nagoya University, Professor Goto) This experience contributed to a review of our routine procedures.



Information activity

Few lectures in endoscopic treatment and practical training are available at BLS training schools. We have provided lectures for BLS trainees that have increased the number of BLS who become part of a staff that performs endoscopic operations.

Current problems

Although our hospital is doing the endoscopic operations in multidisciplinary cooperation, in Japan, endoscopic medical team is a division of labor system. It is difficult to find endoscopic operations that enable the qualification in the endoscopic operations for nurses and BLS to learn how to physician. The possibility of our BLS is important to continue to improve.

Laboratory Information System
PK-06
Current status and prospects for BLS to play expanded roles in endoscopic operations in Japan
 Experience with medical teams and international medical support
 A Baba, K Imaeda, N Tsunoda, A Iwashita, Y Hasegawa, Yamashita Hospital, Ichinomiya, JAPAN

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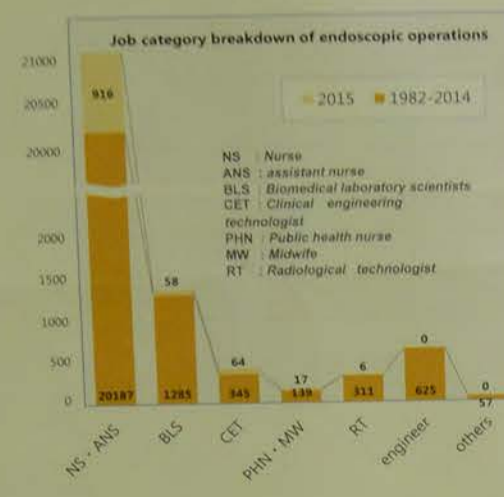
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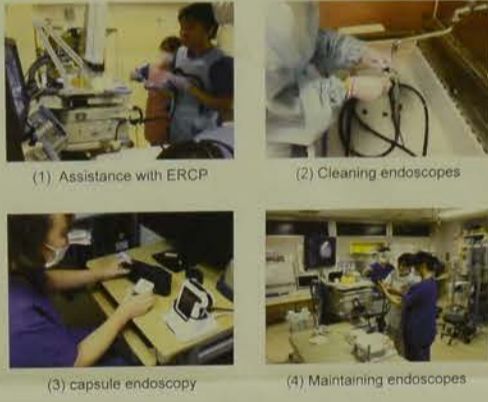


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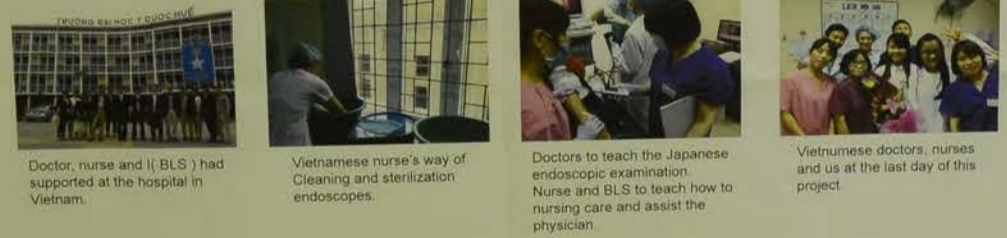
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We participated in an international medical support project in Vietnam in 2014. (Training in Japanese Methods of Endoscopic Examination, Nagoya University, Professor Goto) This experience contributed to a review of our routine procedures.



Information activity

Few lectures in endoscopic treatment and practical training are available at BLS training schools. We have provided lectures for BLS trainees that have increased the number of BLS who aim to become part of a staff that performs endoscopic operations.

Current problems

Although our hospital is doing the endoscopic operations in multidisciplinary collaboration, in many hospitals in Japan, endoscopic medical team is a division of labor system. Medical qualification of multidisciplinary exists, in order to protect each of the qualification in the form of division of labor than cooperate. On the endoscopic operations that enables all basically nurses, there is also a background that it is difficult to feel the need for other professions as well as BLS. In addition, there is also the opinion that do not know how can I leave anywhere until the endoscope operations to the BLS. The possibility of our BLS, it is important to continue to originate from, such as the Society.



Technologists
 for Public Health

Association of
 introduced
 administration in
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 community through

population by age)

2002
 Female Male Female
 Population in thousands

Internal Affairs and Communications, Population
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 and mortality assumptions.

to Earthquake victims

Kumamoto earlier this
 forward to offer support.
 I tested blood pressure
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retired, but we still spend
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In the 22nd Meeting of
 Japan Mibyuu System Association

of long life.

B-2 B-2

Laboratory Information System
PK-07

Commercial Collaboration
between Oita-Oka Hospital and Local Clinics
Facilitating Requests for Outpatient Services from Local Clinics

Yuka Yoshimoto¹, Yutaka Matsugami², Takahiro Kuroeda², Yoshiko Ito¹, Shinobu Goto¹, Yaeko Okada², Yoichi Tatsukawa²
¹Department of Clinical Laboratory, Oita-Oka Hospital, ²Department of Hospital Collaboration

Introduction



Oita-Oka Hospital
 • Hospital beds : 224
 • Diagnostic and treatment departments : 23
 • Community health care support
 • Secondary emergency hospital
 • 7 : 1 nursing standard
 • Collaborating facilities: 208
 → medical facilities : 158
 → care facilities : 50
 • Strong departments : emergency, cardiovascular and plastic surgery

It has been over ten years since Oita-Oka Hospital started collaborating with private clinics. The program began in response to a general demand for access to diagnostic aids and medical imaging equipment from smaller hospitals and clinics in the area. In order to effectively meet the needs of these establishments, our program was designed based on responses to an open-ended survey.

Methods

Surveys were administered to doctors in neighboring hospitals and clinics by the Oita-Oka Hospital Collaboration Committee. Replies from 35 facilities were collected and analyzed. A list of the most in-demand outpatient services was compiled based on that analysis. Medical laboratory technologists then visited hospitals and clinics with the Collaboration Committee directly to explain the list of services being offered and to answer any questions.

Results

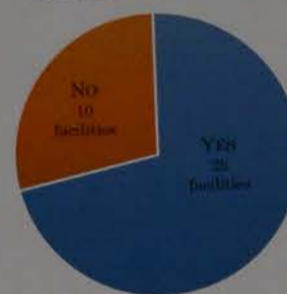
Survey result

1. Would you be interested in requesting blood tests on nights and holidays if available?



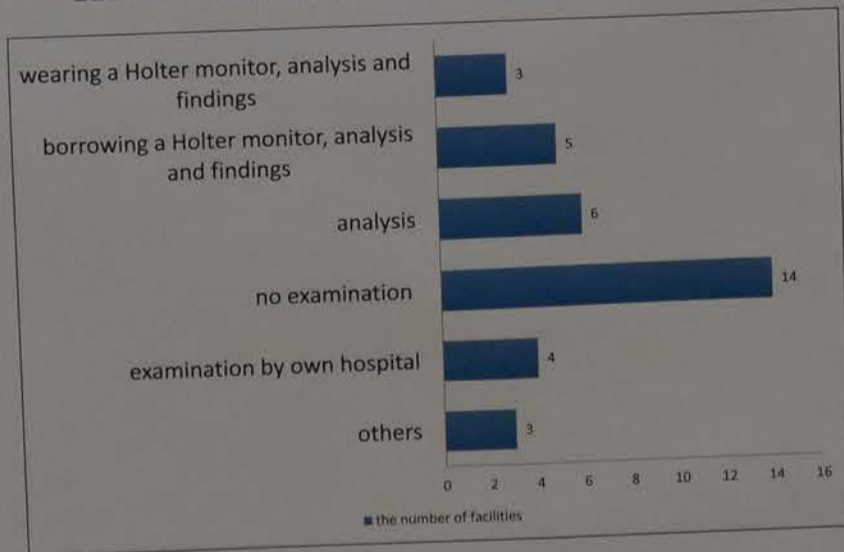
Comments:
 • I want to request them on Saturday and Sunday.
 • I want flow charts or a procedure manual.
 • coagulation tests
 • case-by-case

2. Would you be interested in requesting variety of ultrasound tests if available?

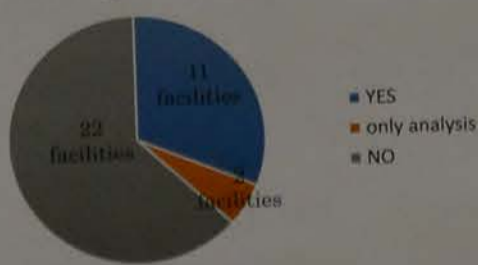


Comments:
 • as the occasion arises
 • heart, deep vein, artery and shunt
 • depends on the hospital department recommendation
 • I want a procedural manual

3-1. Would you tell me about the outsourcing of Holter examinations if applicable.



3-2. Would you request or consider using Holter electrocardiography?



Meet the needs of doctors

1. laboratory tests

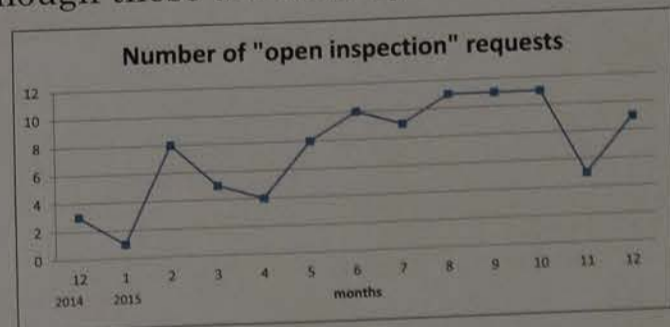
• This began with doctors or medical staff delivering blood samples directly to Oita-Oka Hospital.
 • Doctors using Oita-Oka Hospital's services for the first time were asked which tests they ordered most frequently. A list was made of their responses.

Requests were received from 3 facilities from May to December in 2015.

2. Physiological tests

• These have become 'open inspection' which means the results are given by the ordering doctor.
 • Materials explaining how to order such tests were then distributed to hospitals and clinics.

• EEG, PFT, and NCV tests are also occasionally administered at the request of outside physicians.
 • The number of PSG exams has also increased, although these are done by referral only.



• However, only the number of Holter examinations did not increase!!

Future measures

- Send reports via the internet
- Establish analyzing center and report quickly

Conclusion

The number of requests from local hospitals and clinics has not been very numerous. Being able to meet the needs of doctors and patients and request tests on nights and holidays build trust and confidence in the local community. If this leads to more patient referrals, medical laboratory technologists will be better able to play an active part in supporting community health care.

◆ Hospital and clinics which requested our services.



Laboratory Information System
PK-08

Use it for Infection Control

Naoki INOUE, Akira YOKOKAWA,
Kazuya SHIRAISHI, Koichi SHIMIZU,
Hana HIYAMIZU

KAWAGUCHI KOGYO GENERAL HOSPITAL

Have you ever thought about if the tourniquets are good hygiene? Absolutely, it depends on the way you use it. In my work place, I have usually used it for every patient without any cleaning. So then, my answer was "always!". I have wanted to make that practice better. At first, I looked for the reports about how hygienic the tourniquets are. Then, World Health Organization (WHO) says that "tourniquets are a potential source of methicillin-resistant Staphylococcus aureus (MRSA), with up to 25% of tourniquets contaminated through lack of hand hygiene on the part of the phlebotomist or reuse of contaminated tourniquets.*1" Also, Centers for Disease Control and Prevention (CDC) says "MRSA is a bacteria that is resistant to many antibiotics. In the community, most MRSA infections are skin infections. In medical facilities, MRSA causes life-threatening bloodstream infections, pneumonia and surgical site infections.*2" After I read those articles, I started to think about it seriously and to make my plan concrete. Next, what I should do is to prevent cross infections by using the tourniquets carefully. Moreover, I was often faced with patients who come back with bleeding due to insufficient hemostasis. I have seen it as a problem for safety and as a risk of infections.

So then, I investigated how contaminated the tourniquets are, culturing the bacteria. There were 10 Cultured samples, which I used a tourniquet for every patient without any cleaning for 2 hours, and wiped it by swab. I sent it to culture. Next, I switch the reusable tourniquets for a single-use type for each patient. And I reuse it to stop patients bleeding with the tourniquet. I counted the patients who came back with bleeding, and compared those patients with a tourniquet to those without one for 5 days.

sample	corony	bacteria	table.1
A	4.0*10 ⁸	S.epidermidis	M.luteus Micrococcrs sp.
B	1.3*10 ³	S.hominis	Pseudomonas sp.
C	1.1*10 ³	M.luteus	gram negative bacilli *
D	6.4*10 ²	S.epidermidis	M.luteus B.subtilis
E	5.1*10 ²	S.hominis	M.luteus Micrococcrs sp.
F	2.9*10 ³	Micrococccus sp.	F.oryzihabitans
G	5.9*10 ²	S.capitis	Pseudomonas sp. P.agglomerans
H	1.7*10 ³	S.hominis	B.subtilis
I	2.2*10 ²	S.warneri	
J	1.4*10 ²	gram negative bacilli *	* not identified

		Table.2				
band-free	day	1	2	3	4	5
	sample	120	109	86	122	84
	bleeding	1	4	1	0	1
with hemostasis-band	day	1	2	3	4	5
	sample	107	89	65	79	71
	bleeding	0	0	0	0	1

From Table.1
Bacterial contamination, including skin indigenous bacteria, were found in all of 10 tourniquets. MRSA was not found in any sample.

From Table.2
The number of patients with bleeding who use a band for stop bleeding was just 1 in over 400. Although, the number of patients with bleeding who stop bleeding by themselves were approximately 1 in 74. Moreover, one in over 400 seem that it happened because of insufficient band tension by phlebotomist. Since then, there are no patients with bleeding, and probability of it keeps going down.



Although there are no MRSA, it does not prove enough hygiene, but indicates tourniquets are poor hygiene, which should not be ignored. To use the single-use type is one of the solutions for preventing the cross infections. Decreasing the ratio of bleeding means decreasing the infection source. I succeeded to decrease the ratio of bleeding. So then, single-use type contributes to decreasing the risk factor. I felt that the potential of the single-use type is higher than expected. Now then, I have used it for infection control.

*1. best practice in phlebotomy 2.1.4, WHO
*2. MRSA infections, CDC
Special thanks language supervisor Rebekah

New trial for the pu...
in Nagoya University
Harumi Kobayashi
Hiroyuki Matsumoto
Department of M...
Department of C...

PK-09

The treatment with anticancer drugs against a cholangiocarcinoma...
pregnancy rate.
Here, we showed that the transition of the oocyte cryopreservation...

Transition of the oocyte cryopreservation

The oocyte cryopreservation of 24 ca...
these periods.
Breast cancer was main as a primary...
The average age at egg collection is...
unmarried rate is 78.9%.
A death after oocyte cryopreservation...
The number of oocyte cryopreservation...

2011 2012 2013 2014 2015
Breast cancer Blood disease total

Ovarian tissue

Case 1
Patient: The 23 years old woman.
Main complaint: Menstrual disorder.
Primary disease: Thyroma.
Background: For fertility preservation, she came our hospital to consultation before she receive postoperative chemotherapy on July 2014. An obstetrician suggested an oocyte cryopreservation and ovarian tissue cryopreservation.
She decided ovarian tissue cryopreservation.

Ovarian tissue
Ova CryoKit Type M

Vitrification Method

Room Temperature
Cryol
Cryol
Cryol

After several minutes, the oocyte should be aspirated from the body...
control of the air in high oxygen (issue) to 1cm x 1cm...
the speed of flow to liquid nitrogen in vitrification...

The transition of the oocyte cryopreservation...
every year by year at our hospital, wh...
The ovarian tissue cryopreservation is eff...
because of the small number...
future, will continue to research each...

Dis

Laboratory Information System
PK-09

New trial for the purpose of the fertility preservation in Nagoya University Hospital.

○Harumi Kobayashi¹, Naomi Furusawa¹, Ryosuke Kikuchi¹, Hiroyuki Matumoto¹, Tadashi Matushita²

¹ Department of Medical Technique, Nagoya University Hospital
² Department of Clinical Laboratory, Nagoya University Hospital

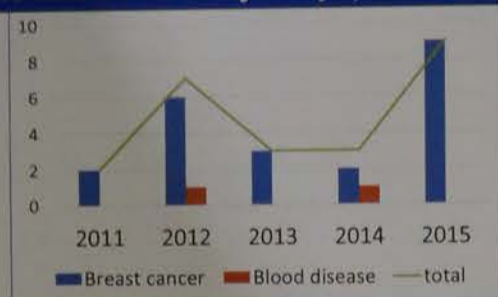
Background

- ◆ The treatment with anticancer drugs against a childbearing age women becomes the decrease of the ovarian function and the reduce of pregnancy rate.
- ◆ Here, we showed that the transition of the oocyte cryopreservation and the ovarian tissue cryopreservation at Nagoya University Hospital.

Transition of the oocyte cryopreservation from 2011 to 2015

- ◆ The oocyte cryopreservation of 24 cases has been carried out during these periods.
- ◆ Breast cancer was main as a primary disease.
- ◆ The average age at egg collection is 35.4 ± 4.2 years old and the unmarried rate is 78.9%.
- ◆ A death after oocyte cryopreservation was the two patients.

The number of oocyte cryopreservation.



Marriage rate.



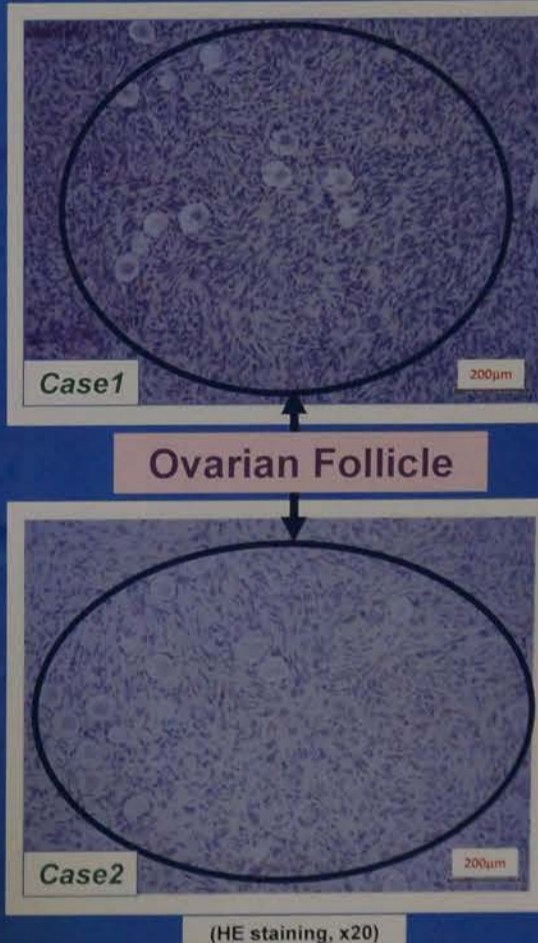
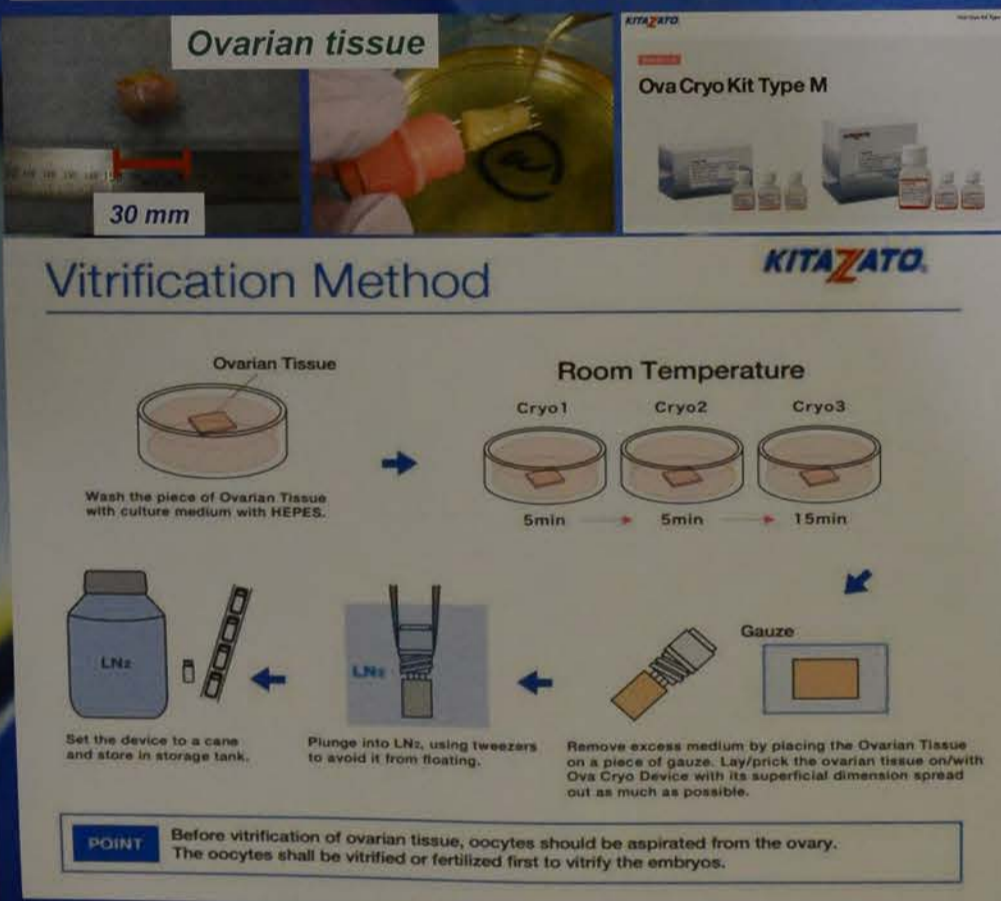
Ovarian tissue cryopreservation

Case 1

- ◆ Patient: The 23 years old woman.
- ◆ Main complaint: Mediastinal shadow.
- ◆ Primary disease : Thymoma.
- ◆ Background: For fertility preservation, she came our hospital to consultation before she receive postoperative chemotherapy on July 2014. An obstetrician suggested an oocyte cryopreservation and an ovarian tissue cryopreservation. She decided ovarian tissue cryopreservation.

Case 2

- ◆ Patient: The 13 years old woman.
- ◆ Main complaint: Headache and abnormal visual field.
- ◆ Primary disease : Germ cell tumor.
- ◆ Background: Endoscopic pituitary tumor resection had performed at March 2016. Ovarian function decline had been predicted by the post-operative treatment. Pediatrician suggested about an ovarian tissue cryopreservation to patients and their families. Patient and the parents wanted ovarian tissue cryopreservation.



- ◆ We resected the appendages under a laparoscope and cut cortex of the left or right ovarian tissue to 1cm × 1cm. We stored slices of flaps to liquid nitrogen in vitrification method.

- ◆ We performed histopathological examination, and were able to confirm a lot of ovarian follicles.

Discussion

- ◆ The transition of the oocyte cryopreservation for patients with cancer is an increase tendency year by year at our hospital, which for social background in Japan.
- ◆ The ovarian tissue cryopreservation is effective method for the patients with the time limitation.
- ◆ However, because of the small number of cases, we perform a detailed analysis in the future, will continue to report each time.

Short Time Smoking Cessation Support by Clinical Technologist

Efficacy of semi-structured interviews for inpatients with CKD under educational hospitalization and outpatients

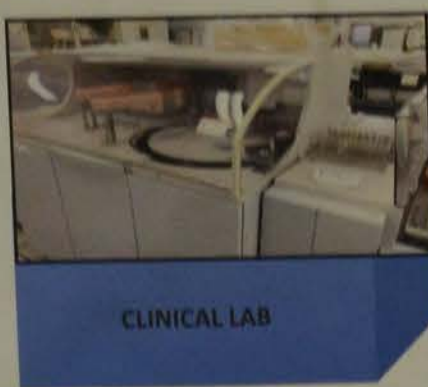
Takashi Yamamoto

Hitachi, Ltd., Hitachi General hospital
Department of Clinical Technology

Yoshihumi Akatsu¹⁾ Nobuko kikuchi¹⁾ Ryo Morikawa MD²⁾
Takashi Nawa MD, PhD³⁾ Atsushi Ueda MD, PhD²⁾

Department of Clinical Technology¹⁾ Department of Nephrology²⁾
Respiratory Medicine³⁾ Metabolism Internal medicine⁴⁾

Background



Former duty: laboratory test

Now: patient-centered team medical care

At a request of the department of nephrology, we are put in charge of clinical explanation for patients of the educational hospitalization by chronic kidney disease (CKD). The increasing opportunities to see various types of patients told us how serious physical problems coming from a lifestyle-related disease are. The evasion of smoking is particularly important to reduce health risks.

Objective

To confirm an effect of the smoking cessation support that a clinical technologist can perform in a short time.

Methods

Target persons: 234 patients who smoke. The patients were grouped into five stages according to Transtheoretical Model claimed by Prochaska.

Approach: Semi-structured interviews using Motivational interviewing (MI), 5A (Ask, Advise, Assess, Assist, Arrange) and 5R (Relevance, Risks, Rewards, Roadblocks, Repetition).

We repeatedly talked to them about smoking cessation during explanation on clinical examination. Smoking cessation support was carried out in less than one minute during blood drawing too.

Period of data collection: From March, 2015 to February, 2016

Statistical evaluation: chi-square test

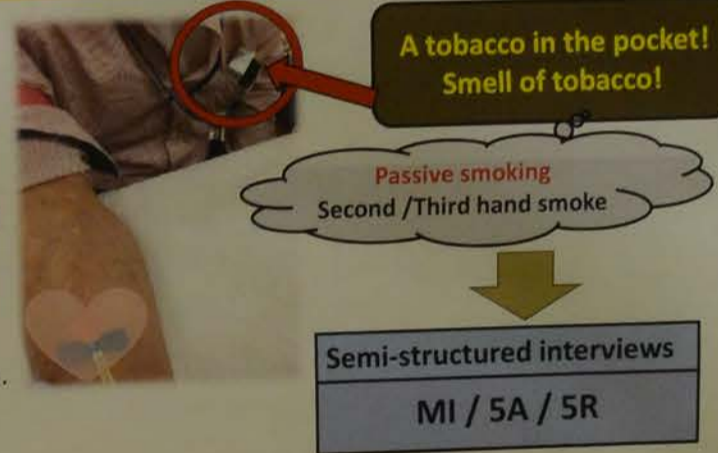


Figure1 Flow of smoking cessation support

Results

Table1 Participants' distribution among five stages according to Transtheoretical Model.

stages	number	%
Precontemplation	105	(45.7%)
Contemplation	81	(35.2%)
Preparation	14	(6.1%)
Action	4	(1.7%)
Maintenance	26	(11.3%)

More than 80% of the participants are not ready to stop smoking.

Table2 Difference of the results by the number of opportunities.

	opportunity	
	once(first time)	multiple
Succeeded	0	6*
Failed	212	16
total	212	22

(*:P < 0.001)

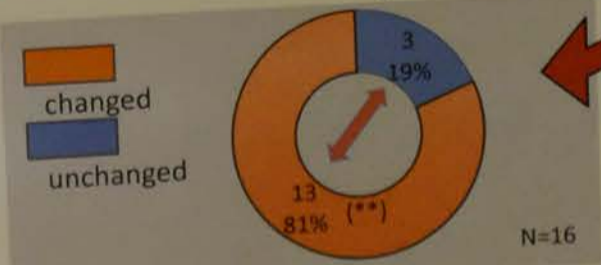
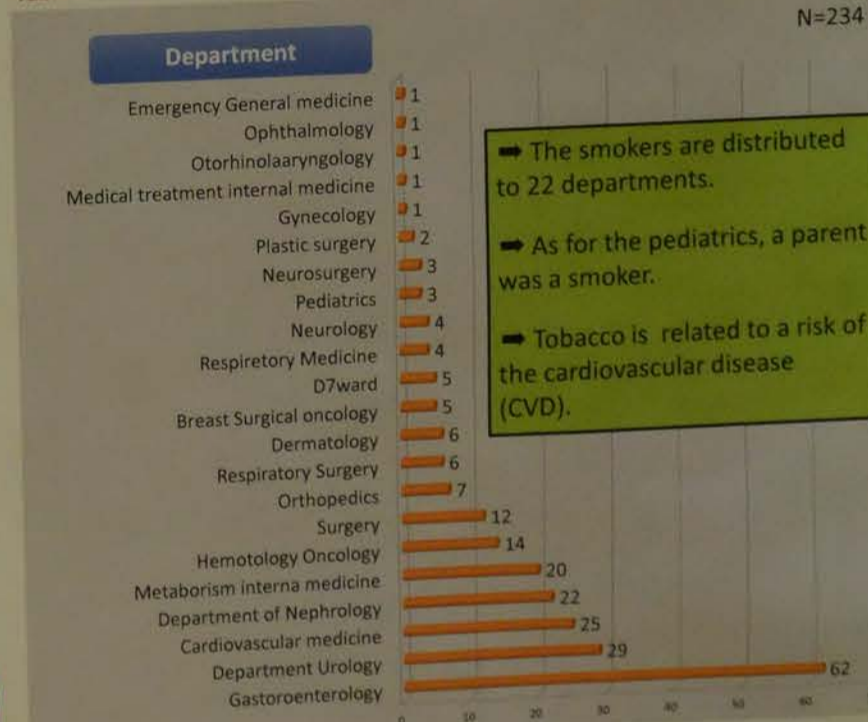


Figure2 Change of the motivation towards smoking cessation.

Table3 Breakdown of the target persons



The smokers are distributed to 22 departments.
As for the pediatrics, a parent was a smoker.
Tobacco is related to a risk of the cardiovascular disease (CVD).

Table2: Continuous smoking cessation support led to successful smoking cessation i.e. to Maintenance stage. 6 led to smoking cessation (*:P < 0.001).

Figure2: Motivation changed positively even among those who failed to stop smoking (**:P < 0.001).

Conclusion

- Even short time supports by clinical technologist work effectively and contribute to both patients' and their families' QOL.
- Clinical technologists can support patients and their families to improve their lifestyle.
- This finding leads us to improve quality and trust of clinical technologists.

Future work

- We aim to...
- 1) develop smoking cessation counseling ability.
 - 2) protect patients and families, children and medical staffs from passive smoking.

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HITACHI
Inspire the Next

Use it for Infection Control

Naoki INOUE, Akira YOKOKAWA,
Kazuya SHIRAIISHI, Koichi SHIMIZU,
Hana HIYAMIZU

KAWAGUCHI KOGYO GENERAL HOSPITAL

band-free	1	2	3	4	5
day	120	109	86	122	84
sample	1	4	1	0	1

Table 2

with hemostasis-band	1	2	3	4	5
day	107	89	65	79	71
sample	0	0	0	0	1

From Table.1

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*1. best practice in phlebotomy 2.1.4, WHO
*2. MRSA infections, CDC
Special thanks language supervisor Rebekah

Laboratory Information System PK-11

TRIPS technology using RFID tags in the phlebotomy room of Kobe University hospital

Takumi Jikimoto, Yasuyuki Sakota, Yuri Ohta, Yuji Nakamachi, Nobuhide Hayashi, Shimpei Kasagi, Jun Saegusa
Kobe University Hospital, Department of clinical laboratory, Japan

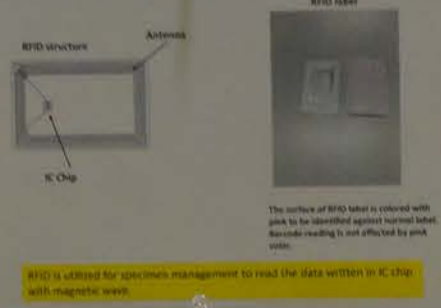
【Abstract】

Radio Frequency Identification (RFID) tags are widely used in our daily life. Recently, Techno Medica corporation has developed RFID patient & specimen identification system, so called TRIPS*. TRIPS* technology is safe, convenient, fast reading, and reduces misidentification. We installed TRIPS in our phlebotomy room in 2014. Here we will show what TRIPS brings us in our phlebotomy room.

【Hospital Brief Overview】 (2014)

- The number of BEDs: 934 (General ward: 888 Psychopathic ward: 46)
- The number of departments: 37
- The number of patients: Average number of outpatients: 2031/day (497,226/year) Average number of inpatients: 840/day
- The number of outpatient blood collection: Average: 461/day (121,624/year)

【RFID Label】



【RFID Features】

- Contactless and data-rewritable
- Simultaneous processing
- Identification with concealment
- Wider read range

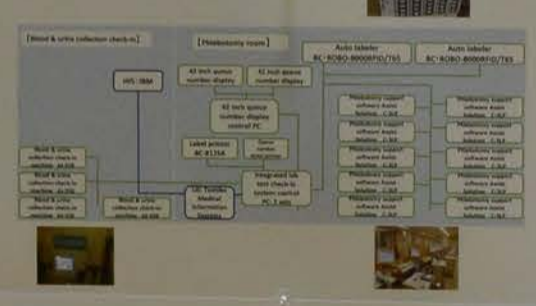
【RFID vs. Barcodes】

	RFID	BCD
Cost of the TAG	High	Low
Print machine of the TAG	Exclusive	Generic
Reader machine of the TAG	Exclusive	Generic
Capacity of the TAG	<64Kbyte	<several decades> byte
Enabled device of the TAG	Many	Few
Endurance of the TAG	High	Low
Rewriting the dates of the TAG	Yes	No

【Instrument】

2 units of BC-ROBO8000RFID to automate selection and labeling of patients' test tube.
TRIPS consists of 2 clients, 1 server, 10 RFID tags reading phlebotomy table.
4 units of automated phlebotomy reception (AI-350) for an automated registration.
1 unit of StatVein that visualizes the vein and helps blood collection.

【Configuration】



【BC-ROBO-8000RFID Features】

- Throughput: 12sec/patient (4 tubes)
- Under batch processing: 300patients/hour
- 30 types of tubes loadable
- Number of tubes loadable in drawer: 100 (Standard drawer) 50 (Small drawer)

【Workflow】

- 10 phlebotomists draw blood from 461 outpatients per day on average in the phlebotomy room. Work flow of the outpatient phlebotomy is as below.
- After registered with the automated phlebotomy reception, patients receive a queue ticket and/or a urine cup. Patients collect their urine and submit them to the urinalysis lab.
- Patient identification is performed based on a queue ticket at the phlebotomy table. For those who is hard to hit veins, we sometimes use StatVein. We also take pictures of successful venipuncture point and save the image (record) into a data base. These methods will enable us to venipuncture next time easier.
- Specimen identification is performed by TRIPS after phlebotomy.

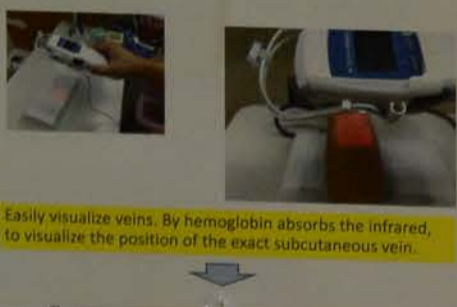
【Blood & urine collection check-in machine】



【Phlebotomy Room Waiting area】

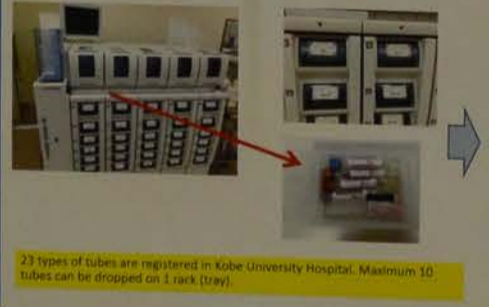


【STAT VEIN Usage】



Easily visualize veins. By hemoglobin absorbs the infrared, to visualize the position of the exact subcutaneous vein.

【Work Flow of Tube labeler-1】



23 types of tubes are registered in Kobe University Hospital. Maximum 10 tubes can be dropped on 1 work (1 day).

【Work Flow of Tube labeler-2】

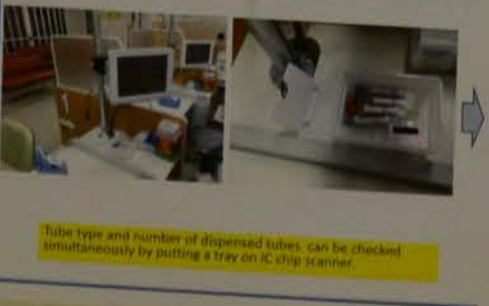


IC chip is stuck in label. RFID technology realizes simultaneous reading, which makes patients identification easier.

【STAT VEIN Usage photos】

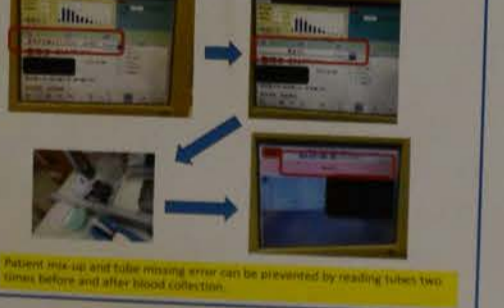


【Work Flow of Tube labeler-3】



Tube type and number of dispensed tubes, can be checked simultaneously by putting a tray on IC chip scanner.

【Work Flow of Tube labeler-4】



Patient mis-up and tube missing error can be prevented by reading tubes two times before and after blood collection.

【STAT VEIN Data Base Usage】



System archives photos of illuminated veins.

【Result】

TRIPS technology significantly shortens wait time (from 23 to 12 minutes on average) in the phlebotomy room.
TRIPS also helps us to response promptly for the inpatient specimen tracking request and reduces opportunity to lose specimen tubes.

【Comparison of Patient Waiting time (Before and After Room Renovation)】

	Before (2013/4)	After (2014/9)
7:00 ~	86 (9)	84 (9)
8:00 ~	89 (11)	93 (12)
9:00 ~	81 (10)	95 (13)
10:00 ~	51 (6)	58 (8)
11:00 ~	41 (5)	38 (5)
12:00 ~	86 (9)	81 (9)
13:00 ~	18 (2)	21 (3)
14:00 ~	8 (1)	10 (1)
15:00 ~	8 (1)	10 (1)
16:00 ~	8 (1)	10 (1)
Total	672 (72)	681 (72)

【Improvement】

- Simplifies patient identification and eliminates errors (specimens are wasted by mistake).
- STAT VEIN enables to collect blood from difficult-to-draw patients.
- Average outpatient waiting time was reduced to 10 minutes, which results in no patient claim about waiting time.
- Archives useful information of individual patient for blood collection.

【Discussion】

Shortening wait time in the phlebotomy room is one of the highest priority tasks in our laboratory.
By utilizing TRIPS technology, we believe that TRIPS can improve the patients' satisfaction.

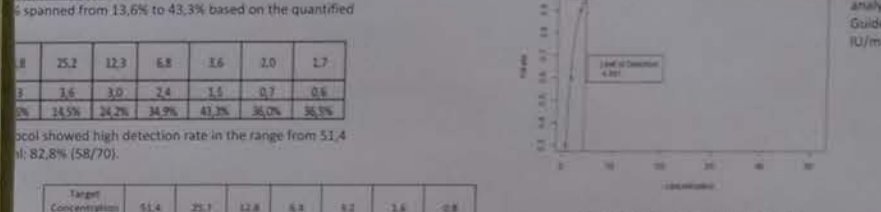
【Conclusion】

Patients requested to reduce waiting time, which was the issue to be improved in department of clinical laboratory.
It was proven renovation of department of clinical laboratory reduced patient waiting time and streamlined clinical laboratory test registration, which made contribution to hospital diagnosis.

Determination of Low HCV Viral Load by RealTime HCV Ultrasensitive Protocol Using Direct Acting Antiviral Agents Therapy

Fabbio Marcuccilli¹, Marco Ciotti¹, Tania Guenci¹, S. Valentina Serafini¹, Carlo Federico Perno^{1,2}
¹Laboratory of Molecular Virology, Polyclinic Tor Vergata Foundation, Viale Oxia 153, 00133 Rome, Italy
²Department of Experimental Medicine and Surgery, University Tor Vergata of Rome

Direct Acting Antiviral Agents (DAAs) have been developed to clear chronic HCV infection. Highly sensitive assays are needed to monitor patients on antiviral therapy. The aim of this study is to assess whether patients with detectable but not quantifiable viremia have more frequently a return to undetectable viral load. We used an ultrasensitive (US) protocol by introducing a modification of the Abbott RealTime HCV assay: larger primers and a modified probe to identify HCV RNA below the validated LOD (Limit of detection) of 12 IU/ml of the standard assay. RNA extraction was performed with the Abbott m2000rt. To evaluate the analytical performances of the US protocol a clinical sample panel was determined by the Abbott RealTime HCV assay was diluted with Basematrix to the target concentrations of 5, 10, 20, 40, 80, 160, 320, 640, 1280, 2560, 5120, 10240, 20480, 40960 IU/ml. To evaluate intra-run variation and the LOD, ten replicates of each dilution were tested in 1 run and to evaluate inter-run variation, ten replicates of each dilution were analyzed in 4 runs.



Target Concentration (IU/ml)	51.4	25.7	12.8	6.4	3.2	1.6	0.8
Mean	25.2	12.3	6.8	3.6	2.0	1.7	
SD	3.6	3.0	2.4	1.6	0.7	0.6	
CV	14.5%	24.2%	34.9%	43.3%	36.0%	36.3%	

Local showed high detection rate in the range from 53.4% to 82.8% (58/70).

Total variation across multiple runs. The CV % across 4 runs per target concentration was respectively, spanned from 18.9% to 82.3% based on the LOD analysis (Guidelines IU/ml).

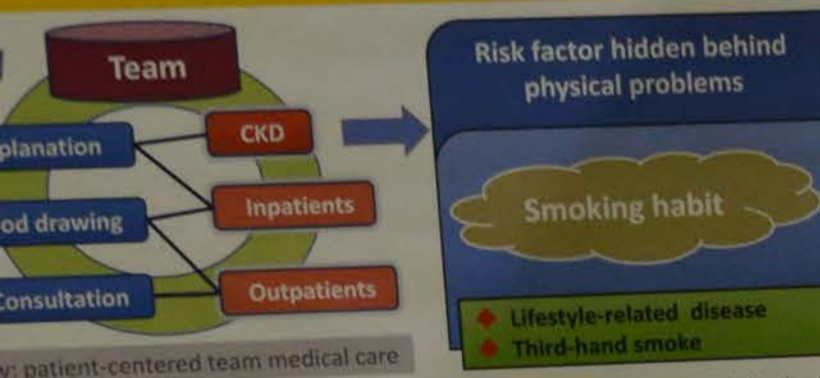
The US protocol of the Abbott RealTime HCV showed high precision, adequate LOD and it thus appropriate for the treatment HCV RNA concentrations for DAA therapies.

Real Time Smoking Cessation Support by Clinical Technologist

Structured interviews for inpatients with CKD under educational hospitalization and outpatients

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we are put in charge of clinical explanation for patients of the educational hospitalization by opportunities to see various types of patients told us how serious physical problems coming from smoking is particularly important to reduce health risks.

Smoking cessation support that a clinical technologist can perform in a short time.

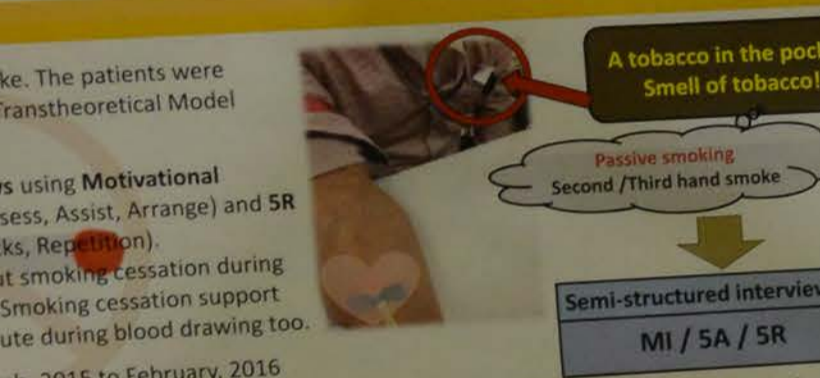


Figure1 Flow of smoking cessation support

Table3 Breakdown of the target persons N=234

Department	Number
Emergency General medicine	1
Ophthalmology	1
Otorhinolaryngology	1
Medical treatment internal medicine	1
Geriatrics	2
Plastic surgery	3
Neurosurgery	3
Pediatrics	3
Neurology	4
Respiratory Medicine	4
OTward	5
Breast Surgical oncology	5
Dermatology	6
Respiratory Surgery	6
Orthopedics	7
Surgery	12
Hematology Oncology	14
Metabolism internal medicine	20
Department of Nephrology	22
Cardiovascular medicine	25
Department Urology	29
Gastroenterology	43

Table2: Continuous smoking cessation support led to successful smoking cessation i.e. to Maintenance stage. 6 led to smoking cessation (*p<0.001).
 Figure2: Motivation changed positively even among those who failed to stop smoking (**p<0.001).

by clinical technologist work effectively and contribute to both patients' and their families' QOL. support patients and their families to improve their lifestyle. improve quality and trust of clinical technologists.

ation counseling ability. families, children and medical staffs from passive smoking. HITACHI Inspire the Next

Laboratory Information System PK-12 Evaluation of Delta Check Method by using Reference Change Value based on Uncertainty

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INTRODUCTION

The delta check method is the most important quality control procedure that compares the two test results and detects whether the difference or ratio between test results exceeds pre-defined checking criteria. The same value, 20%, in all analytes was previously set as the checking criteria in our laboratory. As the checking criteria did not consider biological variation and analytical variation, we could not evaluate changes in the test results objectively. Therefore, we needed to set checking criteria which had more than enough evidence to assess changes in the test results carefully.

AIM

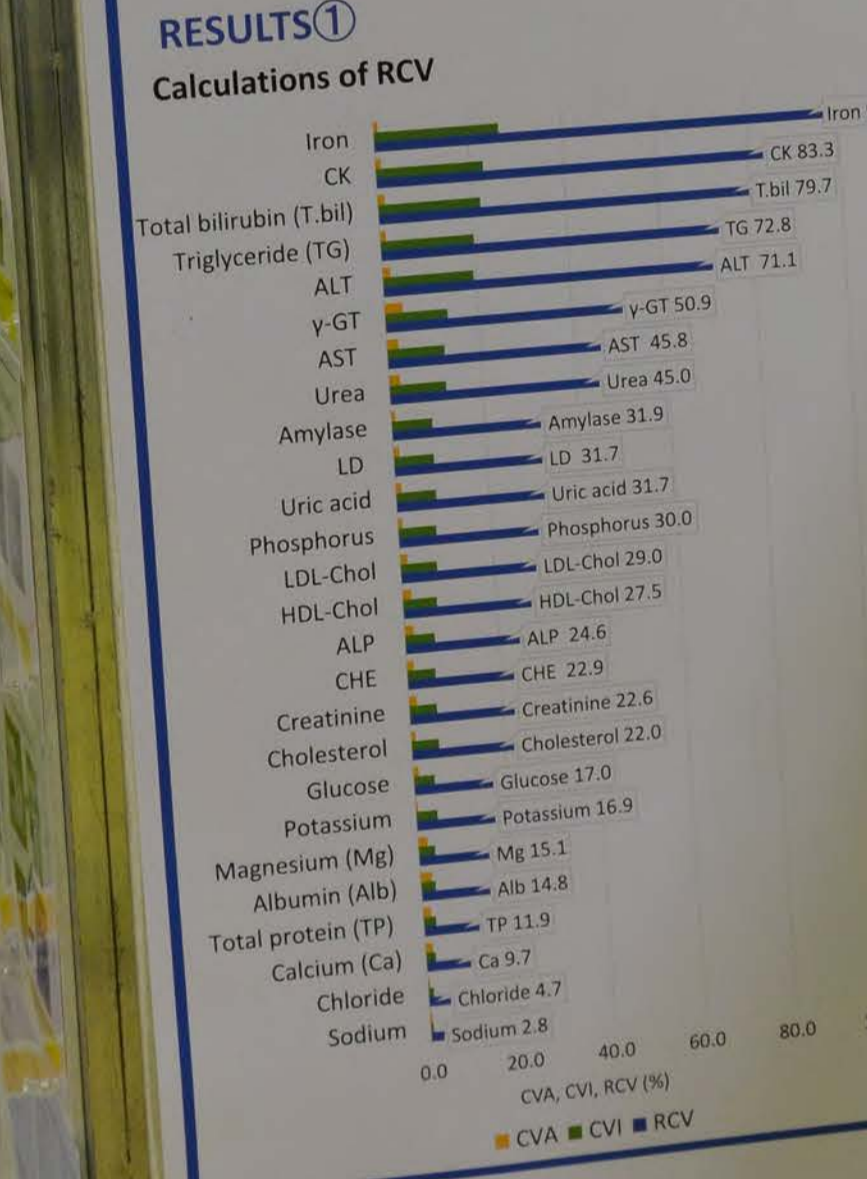
In this study, to evaluate RCV as the new checking criteria in our laboratory, we performed the followings:
 ① calculations of RCV
 ② evaluations of the delta check using RCV

METHODS ①

Calculation of RCV

The RCV values of 26 clinical chemistry test items were calculated according to the following formula:
 $RCV = Z \times 2^{1/2} \times [(CV_I)^2 + (CV_A)^2]^{1/2}$

Z score: Z
 probability 99% = 2.58
Within-individual biological variation: CV_I(%)
 within-individual biological variation in healthy people quoted from Westgard's database
Analytical variation: CV_A(%)
 relative measurement uncertainty estimated by data obtained from internal quality controls (excluding Total bilirubin)



DISCUSSION

- RCV 99% values were from 2.8 to 96.8%.
- ⇒ RCV mainly reflected within-individual biological variation. Compared to before, using RCV enabled us to objectively evaluate changes in test results.
- For patients whose Albumin was checked through the delta check method, high probability of analytes correlated with Albumin (TP, Glucose, Amylase, etc) was also checked. There were conventional correlations found between the main analytes in the ratio of change.
- ⇒ The delta check method using RCV evaluates variation of a single analyte, but simultaneously often identifies other analytes strongly correlated with each other.

Reference Change Value : RCV

$$RCV = Z \times 2^{1/2} \times [(CV_I)^2 + (CV_A)^2]^{1/2}$$

- Difference between two consecutive test results that may indicate a change in the patient health state
- RCV depends on probability(Z), within-individual biological [CV_I] and analytical [CV_A] variation when pre-analytical variation is minimized.
- RCV can be one of judgements to assess variable factors of test results (biological variation, analytical value, etc) objectively.

(Fraser CG, Biological Variation: From Principles to Practice, 2001)

METHODS ②

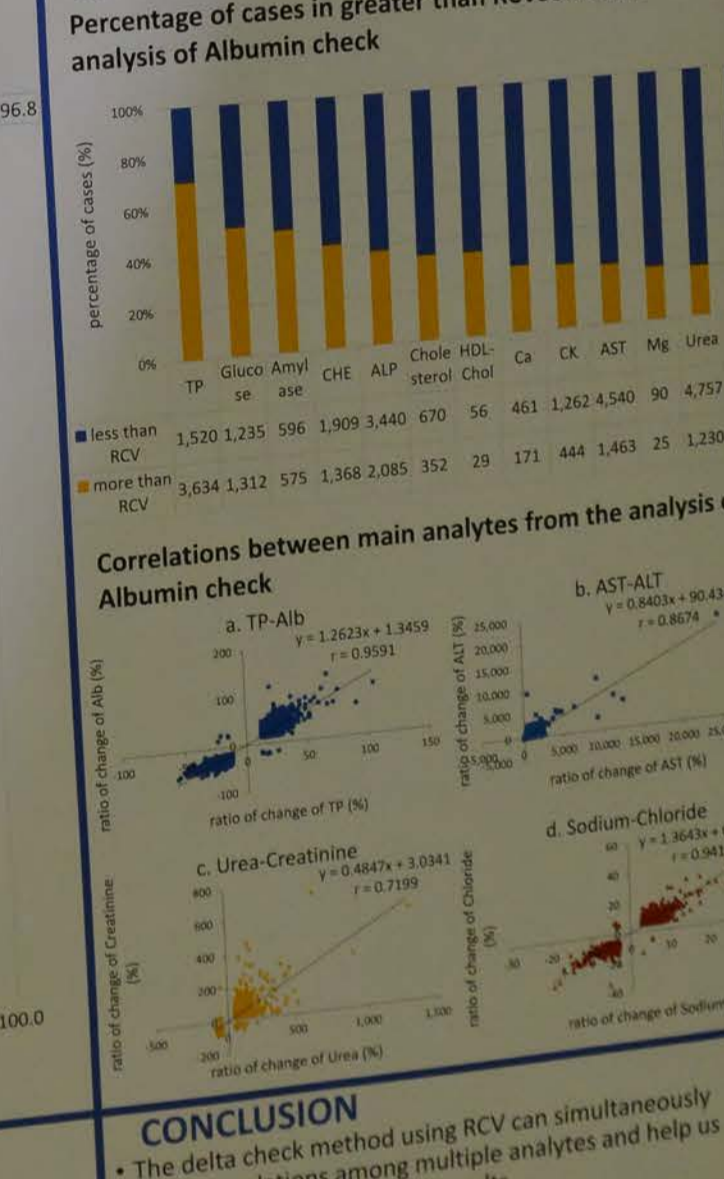
MATERIALS

We collected a total of 53,651 test results for 26 clinical chemistry test items from inpatients and outpatients, and selected out the test results required by each experiment description.

- The RCV values shown in RESULTS ① were set as checking criteria for the delta check method in our laboratory information management system.

In this study, in order to evaluate both the relation between analytes and simultaneously checking components through the delta check method, we examined the followings with patients whose Albumin was checked through the delta check method:

- variations of other analytes
- correlations between main analytes (TP and Alb, AST and ALT, Urea and Creatinine, and Sodium and Chloride)



CONCLUSION

- The delta check method using RCV can simultaneously evaluate relations among multiple analytes and help us interpret the change of test results.
- The RCV was suggested to apply the criteria of judgment in the delta check method in our laboratory.
- Supposing that it is important to apply measurement uncertainty to the assessment of patient's results, measurement uncertainty was used to calculate RCV in this study.

FUTURE STUDY

- In the future, our objective will be to obtain and verify the appropriate z score and calculate RCV in individual patients.

Molecular Diagnosis PL-01

Determination of RealTime HCV Ultra Acting Antiviral

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When drug (Direct Acting Antiviral Agents) have been developed, it is important to measure the concentration of HCV RNA in order to evaluate the effect of the treatment. The aim of this study is to assess whether patients with detectable but not quantifiable HCV RNA can be treated with Direct Acting Antiviral Agents. For this reason, we used an ultrasensitive (LOD: Limit of Detection) of 12 IU/ml of the HCV RNA detection system (Abbott RealTime HCV Ultra) to evaluate the analytical performance of the HCV RNA detection system. The HCV RNA concentration was determined by the Abbott RealTime HCV Ultra assay was diluted with Baseline HCV RNA, respectively. To evaluate the accuracy and the LOD, ten replicates of each dilution were analyzed in 3 runs.

Abbott RealTime HCV Ultra
 The Abbott RealTime HCV Ultra assay is a real-time RT-PCR assay that detects and quantifies HCV RNA in serum or plasma. The assay is highly sensitive and specific, and can detect HCV RNA concentrations as low as 12 IU/ml. The assay is also highly accurate, with a correlation coefficient of 0.99 between the Abbott RealTime HCV Ultra assay and the reference method.

Run	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Mean	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
SD	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10

The real-time RT-PCR assay for HCV RNA detection from Abbott RealTime HCV Ultra (Abbott Molecular, IL, USA).

Conclusion: The US protocol of the Abbott RealTime HCV Ultra showed high precision, and only low on-treatment HCV RNA concentrations for DAA therapies.