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 (FBS), Blood Urea Nitrogen (BUN)
- Creatinine (CRE), C-reactive Protein (CRP)
- Alanine Transaminase (ALT), Aspartate Transaminase (AST)
- Alkaline Phosphatase (AP), Gamma-Glutamyl Transferase (GGT)

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 seasonal 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. The version 3.3.1 commands (ARIMA) were used for the decomposition and autocorrelation calculation.

3. RESULTS and DISCUSSION
TP and FBS in male samples indicated significant autoregressions, 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; thus seasonal variation was consistently watched over all 4 gender-age subgroups. Furthermore, regarding liver function biomarkers, ALP 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.
Establishment of QMS Everolimus Assay on Abbott Architect i8000 Automatic Chemistry Analyzer

Xu Huang Yang, Yu Wen, Tai Li-Chung, Wu

Background

The Thermo-Scientific QMS Everolimus is the newest addition to a full menu of immunosuppressive drug monitoring immunoassays. There are applications for a variety of clinical chemistry analyzers, however, studies on this assay adapted to the Abbott Architect i8000 chemistry analyzer have not been published. Therefore, we evaluated the analytical performance of Abbott Architect i8000 clinical chemistry analyzers for Everolimus.

Methods

The analysis was performed according to the QMS assay package insert. Analytical performance (imprecision, linearity, limit of detection, and limit of quantification) of the new immunoassay was evaluated. The analyzers were compared with an Hitachi 7600 Analyzer and, which was recommended by the manufacturer.

Results

The assay was linear in the range of 8.8-24.8 ng/mL. Limit of detection was 0.5 ng/mL, and lower limit of quantification was 1.3 ng/mL. Within-day and between-day CVs showed coefficients of variation were between 3.5% and 8.7% at mean levels of 3.6, 8.8, and 16.2 ng/mL, respectively. We obtained a day-to-day precision of 80% and 68% when compared with the Hitachi 7600 Analyzer.

Alternate (Quantitative) Method Comparison

A Method: ARCHITECT i8000

Conclusion

The results demonstrated acceptable performance validating the use of the QMS Everolimus assays on the Abbott Architect i8000 analyzer, and will provide an effective monitoring system for patients receiving Everolimus therapy.
The Contributions of Biomedical Laboratory Scientists Searching for Pre-symptomatic Disease (Mibyou)
Yoko Takaki, Yoshiko Yokota
Yoko Takaki: Member of the Japan Association of Medical Technologists
Yoshiko Yokota: Member of the Kamagawa City Institute for Public Health

Mibyou refers to the condition of a person in a stage between being healthy and being sick, specifically with respect to conditions in which diseases do not 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.

Conventional Diagnosis

<table>
<thead>
<tr>
<th>Healthy</th>
<th>Sick</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degrees considering Mibyou</td>
<td></td>
</tr>
</tbody>
</table>

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 and evaluated more rapid measurement methods. We always try to collect and provide people with the latest information. At present, we offer them further treatment 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 with explanations and consultations for people while moving to support community health.

Local prevention activities
On our 60th birthday, we call it a "Mibyou Birthday." A special celebration for long life.
This man is celebrating his 90th birthday with his great-granddaughter.

Current status and prospects for BLS (to be reported in clinical operations in Japan)
Experiences with a medical emergency and subsequent clinical impact

Volunteering for Kansuiotsu Earthquake victims
Following the disaster in Kansuiotsu earlier this year, many stepped forward to offer support. My medical team and I tested blood pressure and blood sugar. We tried to lend them to people and give various advice. Many people were suffering from stress and high blood pressure. Testing is a time-span 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 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.

Medical emergency treatment
1. First aid and rapid evacuation
2. Treatment of respiratory and cardiovascular collapse
3. Medical support for traumatic injuries
4. Management of infection and sepsis
5. Management of hypothermia

Medical emergency and subsequent clinical impact
Experiences with a medical emergency and subsequent clinical impact

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

Japan's Changing Population Pyramid (population by age)

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

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Local prevention activities
On our 60th birthday, we call it a "Mibyou Birthday." A special celebration for long life.
This man is celebrating his 90th birthday with his great-granddaughter.
Current status and prospects for BLS to play expanded roles in endoscopic operations in Japan

**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 have received qualifications in endoscopic procedures. However, few BLS are on the regular endoscopy staff at other Japanese institutions and names comprise the main staff.

**Future prospects**

The role of BLS in endoscopic treatment should expand because it is becoming more important as their roles have been recognized in Japan. Therefore, further promotion of medical nurses by the Japanese Association of Medical Technologists is important, as doing endoscopic treatment in the curriculum is crucial.

**Job category breakdown**

Among 24,011 individuals who have become licensed endoscopic operators by 2011 in Japan, 621 nurses and 1,364 are BLS.

**Medical team at our hospital**

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

**Roles in endoscopic treatment**

(1) Assisting with endoscopic treatment
(2) Dusting and sterilization of endoscopes
(3) Reusing inanimate endoscopic findings
(4) Maintaining endoscopes

**International medical support**

Eighteen BLS in endoscopic treatment and endoscopic nursing were trained as medical nurses

**Information activity**

Five lectures on endoscopic treatment and endoscopic nursing are available at BLS training schools.

**Current problems**

Although our hospital is doing the endoscopic operations in various sites, we are facing problems. In many hospitals, nurses do not feel endoscopic medical training is a part of their work. It is important that they do not prefer to be a nurse at all. Therefore, this can be an important issue for the endoscopic operators to the BLS.
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 33 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.

**Survey results**

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.
     - 1 wants lab tests or a procedure manual.
     - 1 wants to test case by case.
   - **Outcome:**
     - Most want it available.

2. **Would you be interested in requesting variety of ultrasound tests if available?**
   - **Comments:**
     - 1 receives the requests.
     - 1 wants to check in the hospital department.
     - 1 want a procedural manual.
   - **Outcome:**
     - Most want it available.

3. **1. Would you tell me about the outsourcing of Holter examinations if applicable?**
   - **Results:**
     - Some hospitals receive, analyze, and send results.
     - In some cases, a hospital receives the results.

**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.

**Meet the needs of doctors**

1. **Laboratory tests**
   - **Comments:**
     - 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**
     - Received from 3 facilities from May to December in 2015.

2. **Physiological tests**
   - **Comments:**
     - 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, PPT, 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.

   - **Number of "open inspections" requests**

**Future measures**

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

**Hospital and clinics which requested our services**

---
Have you ever thought about if the tourniquets are good hygiene? Absolutely, it depends on the way you use it. In my workplace, 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 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." 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." 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 came 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.

From Table 1, bacterial contamination, including skin indigenous bacteria, were found in all 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.
New trial for the purpose of the fertility preservation in Nagoya University Hospital

Harumi Kobayashi, Naomi Furusawa, Ryosuke Kikuchi, Hiroyuki Matumoto, Tadashi Matushita

Department of Medical Technique, Nagoya University Hospital
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 reduction of the 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 ± 8.4 years old and the unmarried rate is 78.9%.
- Adolescents after oocyte cryopreservation were the two patients.

**Ovarian tissue cryopreservation**

**Case 1**
- Patient: The 23 years old woman.
- Main complaint: Medullary thyroid cancer.
- Primary disease: Thyroid cancer.
- Background: For fertility preservation, she came out hospital to consultation before she receive postoperative chemotherapy on July 2014. The examination 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 abnormally visual field.
- Primary disease: Glioma of tumor.
- Background: Endoscopic pituitary tumor resection had performed at March 2016. Ovarian function decline had been predicted by the post-operative treatment. Pediatrist suggested about an ovarian tissue cryopreservation to patients and their families.
- Patient and the parents wanted ovarian tissue cryopreservation.

**Discussion**
- The transition of the oocyte cryopreservation for patients with cancer is an increase tendency year by year at our hospital, which is 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.
Background

Although there are no MRSA, it does not prove enough hygiene, but indicates that MRSA could be harmful. It is important to control the nosocomial infections, 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 in decreasing the ratio of bleeding. So, then, the single-use type contributes to decreasing the risk factor. I think that the potential of the single-use type is higher than expected. From now on, I have used it for infection control.

Methods

Table 1: Patients of smoking cessation support groups according to Transformative Model

<table>
<thead>
<tr>
<th>Stage</th>
<th>Number</th>
<th>%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precontemplation</td>
<td>305</td>
<td>46.7%</td>
<td>650</td>
</tr>
<tr>
<td>Contemplation</td>
<td>91</td>
<td>13.1%</td>
<td>650</td>
</tr>
<tr>
<td>Preparation</td>
<td>54</td>
<td>8.1%</td>
<td>650</td>
</tr>
<tr>
<td>Action</td>
<td>4</td>
<td>0.6%</td>
<td>650</td>
</tr>
<tr>
<td>Maintenance</td>
<td>36</td>
<td>5.5%</td>
<td>650</td>
</tr>
</tbody>
</table>

Figure 1: Change of the motivation towards smoking cessation

Figure 2: Continuous smoking cessation support led to successful smoking cessation i.e. to Maintenance stage, and 6 led to smoking cessation (P<0.001).
TRIPS technology using RFID tags in the phlebotomy room of Kobe University hospital

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

Abstract:
Radio frequency identification (RFID) tags are widely used in our daily life. Research on RFID technology has been studied in many fields, including patient identification and specimen identification systems in clinical laboratories. TRIPS technology is safe, convenient, fast reading, and reduces repetition. We installed TRIPS in our phlebotomy room in 2018, and we will show what TRIPS brings to the clinical laboratory.

[Image of RFID label and features]

RFID features:
1. Contactless and data readable
2. Simultaneous processing
3. Identification with concealment
4. Water-proof range

[Image of RFID system setup and configuration]

Conclusion:
TRIPS technology significantly shortens wait time from 23 to 12 minutes on average in the phlebotomy room. TRIPS also helps to respond promptly for the requisition specimen tracking request and reduces opportunity to lose specimen tubes.
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 analyses 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 following:
1) calculations of RCV
2) evaluation of the delta check using RCV

METHODS

1) Calculation of RCV

The RCV values of 26 chemical test items were calculated according to the following formula:

\[ RCV = 2 \times 10^{-2} \times \left( \frac{CV_l}{100} + \frac{CV_u}{100} \right) \]

Z-score: 2

probability: 99% = 2.58

Within-individual biological variation (CVl) in normal people quoted from Wastagni’s database

Analytical variation (CVu) in laboratory

relative measurement uncertainty estimated by data obtained from internal quality controls (excluding Total bilirubin)

2) Evaluation of the delta check using RCV

RESULTS

Calculations of RCV

<table>
<thead>
<tr>
<th>Item</th>
<th>Reference Value</th>
<th>CVl (%)</th>
<th>CVu (%)</th>
<th>RCV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT</td>
<td>36.2</td>
<td>15.1</td>
<td>3.8</td>
<td>1.7</td>
</tr>
<tr>
<td>AST</td>
<td>36.2</td>
<td>14.0</td>
<td>3.8</td>
<td>1.4</td>
</tr>
<tr>
<td>ALP</td>
<td>270</td>
<td>26.9</td>
<td>3.8</td>
<td>4.2</td>
</tr>
<tr>
<td>CK</td>
<td>0</td>
<td>60.1</td>
<td>3.8</td>
<td>2.3</td>
</tr>
<tr>
<td>LDH</td>
<td>246</td>
<td>22.3</td>
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<tr>
<td>GammaGT</td>
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<td>96.3</td>
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</tr>
<tr>
<td>ALAT</td>
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<td>16.6</td>
<td>3.8</td>
<td>1.3</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>118</td>
<td>72.9</td>
<td>3.8</td>
<td>2.7</td>
</tr>
<tr>
<td>Totalcholesterol</td>
<td>183</td>
<td>70.2</td>
<td>3.8</td>
<td>2.6</td>
</tr>
</tbody>
</table>

CONCLUSION

The delta check method using RCV can simultaneously evaluate variations among multiple analyses and help us grasp the change of test results.

The RCV was suggested in our laboratory.

Supposing it is important to work on the evaluation uncertainty, we thought this would be a good method for evaluation uncertainty.

FUTURE STUDY

In the future, we will get more evidence and verify this method.

TABLE 1

<table>
<thead>
<tr>
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<th>CVu (%)</th>
<th>RCV (%)</th>
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Figure 1: Delta check method using RCV