Experience and Challenges of Hematology Laboratory in Korea and Asia

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Samsung Medical Center
Sungkyunkwan University School of Medicine
Seoul, KOREA
I am

• A clinical pathologist & hematopathologist at Samsung Medical Center, Seoul, Korea (1994~)
  – Seoul National University, Medical College & Seoul National Univ. Hospital
  – Visiting: Hematopathology, University of Michigan, Cytogenetics, Mayo Medical Laboratory, Cytogenetics, Baylor College of Medicine

• Former President, Korean Society of Laboratory Hematology (2013~14) and Korean Society of Hematology (2015~16)

• International deputy commissioner for far east civilian lab, Laboratory Accreditation Program, College of American Pathologists (2010~) : CAP inspector since 1999

• Korea councilor, ILSH (2014~2017)
Outline

• Current Hematology Laboratory, Korea
  – @ Samsung Medical Center (SMC)
  – @ Korean Society of Laboratory hematology

• Hematology Laboratory, Asia
  – @ Japan, China, Taiwan, Thailand, Malaysia

• Challenges of Hematology Laboratory, Asia

• Closing
Laboratory Medicine at SMC

- SMC: University affiliated hospital in Seoul, Korea
  ~2,000 beds (700 Cancer Center)
  ~9,000 outpatients/day
- Dept. of Lab Medicine:
  MD: 10 professors, 7 fellows, 10 residents
  MT: ~160

<table>
<thead>
<tr>
<th>Test Items</th>
<th>Test No.</th>
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<tbody>
<tr>
<td>Hematology</td>
<td>314</td>
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<tr>
<td>FCI</td>
<td>119</td>
</tr>
<tr>
<td>Cytogenetics</td>
<td>123</td>
</tr>
<tr>
<td>Molecular G.</td>
<td>794</td>
</tr>
<tr>
<td>Total</td>
<td>2,894</td>
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<table>
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<th>LAB</th>
<th>Test items</th>
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<tr>
<td>Hematology</td>
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<tr>
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<td>Molecular G.</td>
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<td>82,000</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>2,894</strong></td>
<td><strong>30,000,000</strong></td>
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</table>
Hematology Laboratory at SMC

- Laboratory:
  - CBC: ~3,500/day, PT & aPTT: ~1,500/day
  - TLA system with 7 CBC 5-diff. analyzer, 5 coagulation analyzer
  - Morphology review rate: ~15%
  - ~3,500 BM cases/year
  - 2 hematopathologists, 2 fellows, 3 residents, 18 MTs

- Secondary order system by hematopathologists on BM study for FCI, Cytogenetics & Molecular genetic studies etc.

- Integrated hematology service
  - Coagulation/Thrombosis Clinic & Molecular Hematology Clinic by hematopathologists
  - Hematology Monthly Review with Hematologists

- Interpretative reports
  - Bone marrow report with flow cytometry and all genetic test results within 10 days
  - Coagulation profile report
BM & Coagulation Profile Report

DONE MARROW REPORT [BM17-0060]

<DIAGNOSIS>
BM Aspiration and Biopsy, Iliac Crest:
Norepocheloplar Marrow with Increased Blasts (~35%)
* 04110: Acute Myeloid Leukemia with inv(16)(p13.1q22)

<COMMENTS>

Immunophenotype: P1) CD34+ blast cells (17.06% of total events)
= eMPO+CD117+CD13+CD33+CD38+
P2) CD45 moderate/intermediate SSC cells (33.09% of total events)
= eMPO+CD117+CD13+CD14+CD33+CD38+CD45+
= S/G Monocytic population

Chromosome study:
FISH (MDS/AML): NML
FISH (CBFB gene): nuc ish 16q22(CBFBx2)[5 CBFB sep 3 CBFBx1][183/200]
RT-PCR (acute leukemia): POSITIVE, CBFB(16q22.1) and MYPHIL (16p13.11)
c-KIT mutation: Not detected

<REASON FOR REQUEST>
 Acute leukemia requested by Pf. 정철원

<PERIPHERAL BLOOD FINDINGS>
Hb: 10.1 - 11.3 g/dL
WBC: 7.6 - 25510 - 44K - 0.75 %
RBC: Macrocytic and hyperchromic anemia with nRBC(1/100 WBCs)
WBC: Increased in number with blasts(10%), abnormal promonocytes(12%) and monocytosis(12000/μL)
PLT: Moderately decreased in number

<Bone Marrow Smear>
Particle: adequate
M:E ratio: 9:1
Blasts: 35% of ANC

<table>
<thead>
<tr>
<th>Number</th>
<th>Maturation</th>
<th>Normal</th>
<th>Dysplasia</th>
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<tr>
<td>Erythropliosis</td>
<td>N</td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td>Granulopiosis</td>
<td>N</td>
<td>Normal</td>
<td></td>
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<tr>
<td>Megakaryopiosis</td>
<td>D(slightly)</td>
<td>Normal</td>
<td></td>
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Increased blasts (~35%) and abnormal promonocytes (~15%)

- SPECIAL STAIN
Iron stain: normal storage iron(Grade 2/8).
PAS(+) diffuse, Peroxidase(+), ANBE(-), Lysosome(+)
MPO(-), CD3(-), CD20(+/-), CD79a(+/-), CD23(-), CD117(+20%)
CD34(-30%), CD61(+), megakaryocytes were decreased in number

- BIOPSY SECTION
Cellularity: adequate ~30-80% (overall 60%)
Megakaryocytes: slightly decreased in number
Packed with increased blasts

Reported by W.K.Kwon M.D. / H.J.Kim M.D. / S.H.Kim M.D.
<table>
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<tr>
<th>Case No. BM170534</th>
<th>환자번호: 37502880</th>
<th>성명: 김영수 M/F</th>
<th>검사일: 2017-03-02</th>
<th>담당의사: 정철원</th>
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<tr>
<td><strong>Diagnosis:</strong></td>
<td>Acute Myeloid Leukemia with Maturation</td>
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<td><strong>Immunophenotype:</strong></td>
<td>CD19+ blast cells (9.45% of total events)</td>
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<tr>
<td></td>
<td>CD34+; CD33+; CD4+; CD8+; CD11c-dim+; CD45+</td>
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<td></td>
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<tr>
<td><strong>Chromosome study:</strong></td>
<td>46,XX[20]</td>
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<tr>
<td><strong>FISH(MDS/AML):</strong></td>
<td>WNL</td>
<td></td>
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<tr>
<td><strong>RT-PCR(hemaglobin):</strong></td>
<td>Negative</td>
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<td></td>
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<tr>
<td><strong>FLT3 mutation:</strong></td>
<td>Not detected</td>
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<tr>
<td><strong>CEBPA mutation:</strong></td>
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<tr>
<td><strong>NPM1 mutation:</strong></td>
<td>Detected (0.559)</td>
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<th>Case No. BM170530</th>
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<th>성명: 박영준 M/F</th>
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<th>담당의사: 김석진</th>
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<tbody>
<tr>
<td><strong>Diagnosis:</strong></td>
<td>Chronic Lymphocytic Leukemia / Small Lymphocytic Leukemia</td>
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<tr>
<td><strong>Immunophenotype:</strong></td>
<td>CD19+CD20+ B-cells (47.1% of total events)</td>
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<tr>
<td></td>
<td>CD5+CD10-CD23+CD79b-ZAP70dim+ with lambda restriction</td>
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<tr>
<td><strong>Chromosome study:</strong></td>
<td>46,XY,add(11)(q22)[8/46,XY(12)]</td>
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<tr>
<td><strong>FISH(IGH/CCND1):</strong></td>
<td>Within normal limit</td>
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<th>Case No. BM170537</th>
<th>환자번호: 13494617</th>
<th>성명: 최규현 77/M</th>
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<th>담당의사: 정철원</th>
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<tbody>
<tr>
<td><strong>Diagnosis:</strong></td>
<td>Mantle Cell Lymphoma</td>
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<tr>
<td><strong>Immunophenotype:</strong></td>
<td>CD19+CD20+ B-cells (91.6% of total events)</td>
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<tr>
<td></td>
<td>CD5+CD10-CD23-FCM7dim+CD79b+ with kappa restriction</td>
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<tr>
<td><strong>FISH(IGH/CCND1):</strong></td>
<td>nuc ish 11a13;CCND1x3;14a32;IGHx3iCCND1 con [IGHk2i(179;200)]</td>
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<th>성명: 이규안 79/M</th>
<th>검사일: 2017-03-03</th>
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<tr>
<td><strong>Diagnosis:</strong></td>
<td>Plasma Cell Myeloma (70%)</td>
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<tr>
<td><strong>Immunophenotype:</strong></td>
<td>CD38+CD138+ plasma cells (63.32% of total events)</td>
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<td></td>
<td>CD19+CD56+ with lambda restriction</td>
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<tr>
<td><strong>Chromosome study:</strong></td>
<td>53,XX++;X,der(14)(14:q12p16)dup<a href="1q12q42">1</a>, +5, +6, +9, +11, +13, +15(q10), +19, +21[15]+53,sl.43;X;+3[4]+46,XX(1]</td>
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<tr>
<td><strong>FISH(MMM):</strong></td>
<td>Plasma Cell Myeloma, with 1) monosomy 13q</td>
<td></td>
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<tr>
<td>2) gain of CYS1B signals on 1q21</td>
<td></td>
<td></td>
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<tr>
<td>3) a loss of FGF3 signal on 4p16.3</td>
<td></td>
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<tr>
<td>4) gain of CCND1 signal on 11q13</td>
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<th>성명: DAVYDOVA ELENA 44/F</th>
<th>검사일: 2017-03-29</th>
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<td><strong>Diagnosis:</strong></td>
<td>Primary Myelofibrosis, overt fibrotic stage</td>
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<td><strong>FISH(BCR/ABL1):</strong></td>
<td>WNL</td>
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<tr>
<td><strong>RT-PCR(BCR/ABL1):</strong></td>
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<td><strong>JAK2(V617F):</strong></td>
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<tr>
<td><strong>JAK2(exon12):</strong></td>
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<td><strong>CALR:</strong></td>
<td>Mutation: Detected (0.454)</td>
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</table>
The Health System in Korea

• Demographic: 60 million, racially homogeneous, rapidly increased aging population
• Disease characteristics: westernized
• Characteristics of hematologic diseases
  – Hemoglobinopathy: rare
  – Lymphoid malignancies
    • Rare CLL, but increasing
    • Rare Hodgkin’s lymphoma, Follicular lymphoma
    • Frequent T/NK lymphomas
    • Increasing Plasma cell myeloma
  – Myeloid Neoplasms

Incident cases of myeloid malignancies in Korea, 2012.
Korean Health system: ‘National Health Insurance Service’

- Health Care Institutions
  - Ask NHIS to pay for health care service costs. (corporation’s share)
  - Ask the corporation to pay for care benefit expense. (corporation’s share)

- The Insured
  - Co-payment
  - Contribution
  - Medical Insurance Card

- NHIS
  - Determine a policy.
  - Manage qualifications.
  - Impose and collect contributions.
  - Pay health care service costs.
  - Announce review results.
  - Health Insurance Review & Assessment Service
    - Announce review results.
    - Evaluation Standards
      - Deliberate on and determine health care service costs.
      - Evaluate the adequacy of health care service costs.

- Ministry of Health and Welfare
  - Health Care Service Costs
  - Benefit Management
  - Health Checkup

Ministry of Health & Welfare
National Evidence-based Healthcare Collaborating Agency (NECA)
National health Insurance Service
Health Insurance Review & Assessment Service
Characteristics of Hematology in Korea

• From President of Korean Society of Hematology, Prof. HJ Kim

• Weakness:
  – under strict national medical insurance system
    • Low medical cost
    • Limited range of application for new test items
  – Most leukemic patients converge on several big hospitals: limited service of special tests on most labs

• Strengths:
  – Full covered medical insurance for all citizens
    • Only 5% patient pay for all cancer patients
  – Collaboration
    • Korean Society of Hematology: 12 working groups
    • Korean Society of Pediatric Hemato-Oncology
    • Korean Society of Laboratory Hematology
    • Korean Society of Blood and Marrow Transplantation
    • Korean Society of Transfusion
Clinical Laboratories in Korea

Dept. of Lab Medicine (CP)
- Chemistry
- Microbiology
- Immunology
- Transfusion
- Genetics
- FCM
- Hematology

Dept. of Pathology (AP)
- Surgical Pathology
- Cytopathology
- Molecular Pathology/EM
- Hematopathology for LN & Others

Clinical Pathologist:
- Board certified: 4 years resident after MD
- 2 years fellowship
- ~40 new CPs/year
- ~1,000 CPs board
- 300~400 active CPs for hematology lab

Medical technologists/technicians
- 3 or 4 years, ~50 colleges
- ~2200 new MTs/year
Hematology Laboratory in Korea

- **Personnel**
  - Lab Director: pathologists (CP) only
  - Certified MT only

- **Hematopathology**
  - BM by CP
  - LN & others by AP

- Recently Digital Cell Morphology System launched

- **Korean Society of Laboratory Hematology (KSLH):**
  - Related Korean Society of Laboratory Medicine
  - Society meetings: two times a year, one day meeting, ~300 attendees
  - Cover all laboratory hematology & hematopathology, related flow cytometry, cytogenetics & molecular genetics
  - Activity: Education, Guideline etc.
  - Morphology Review Board
Challenges of Hematology Laboratory Practice in Korea

- From President of KSLH, Dr. JY Han

- Realization (increase) of test charge (fee)
  Thinking on the life-saving role and contribution onto patient survival and critical care, the charge of CBC is inappropriately low-end, compared to other lab tests

- Out of mushrooming guidelines and protocols
  Early adoption and modification to adapt local regulations and policies
  Also considering cost-effectiveness and medical reimbursement

- Hemostasis consultant
  To create new value for laboratory diagnosis and consultation

- Regional (vs Global) networking
  egs. APSTH, Indian Ocean Rim Laboratory Haematology Congress, Cyto Asia 2017

- Education and training
  Students, Residents, Fellowships, Med Tech, Hematologists, etc.
Laboratory Accreditation Program in Korea

• Proficiency testing Program
  – Operated by Korean Association of Quality Assurance for Clinical Laboratory (KAQACL) since 1977 & Korea Institute of Genetic Test Evaluation (KIGTE) since 2005
  – >1400 labs: 800 hospital labs, 350 clinics
  – Hematology
    • 4 trials/year
    • CBC: >1300 labs, Coagulation: PT/aPTT, >500 labs, Blood cell morphology
  – FCM: Stem cells, Lymphocyte subsets, Leukemia/lymphoma phenotyping: 40~55 labs
  – Cytogenetics: ~50 labs
    • Karyotyping, FISH - Constitutional & Neoplastic
  – Molecular Hematology: 20~35 labs
    • RT-PCR for fusion genes: BCR-ABL1, PML-RARA, RUNX1-RUNX1T1, ETV6-RUNX1
    • Mutation studies: JAK2, FLT3-ITD, MPN1, CALR etc.
Laboratory Accreditation Program in Korea

- On site inspection
  - Accredited by Korean Laboratory Medicine Foundation under Korean Society of Laboratory Medicine
  - Inspection by peer
  - Every one or two years
  - Similar to CAP on-site inspection
Summary
Hematology Laboratory at SMC & in Korea

• Strengths & Opportunities
  – Highly qualified personnel: Clinical pathologists, MTs
  – Well organized and cost-effective operation
  – Excellent collaboration with FCI, genetic labs within the same department
  – Leading role in diagnosis of hematologic disorders
  – Clinical application of NGS just started under medical insurance system

• Weaknesses & Threats
  – Tight regulation of medical practice by government
Hematology Laboratory in Asia

- Contact with presidents of Society of Hematology & representatives for laboratory hematology of each country
  - China, Japan, Korea, Malaysia, Taiwan, Thailand
  - Questionnaire about Lab personnel, BM study, PT testing, & Challenges

- Personal experience of CAP international inspection
# Practice of Hematology Laboratory in Asia

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<th></th>
<th>CHINA</th>
<th>JAPAN</th>
<th>KOREA</th>
<th>MALAYSIA</th>
<th>TAIWAN</th>
<th>THAILAND</th>
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<td>no</td>
<td>CP</td>
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<td>Most common director?</td>
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<td>H or MT</td>
<td>CP</td>
<td>CP/MT</td>
<td>CP&gt;H</td>
<td>H/CP/MT</td>
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<td>CP</td>
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<td>CP&gt;H</td>
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<td>CP</td>
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<td>no</td>
<td>yes: national</td>
<td>no, but in progress</td>
<td>no</td>
<td>yes : national</td>
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H : Hematologists  
CP : Clinical pathologists  
HP : hematopathologists  
MT : Med Tech
## BM Study in Asia

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<th>JAPAN</th>
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<td>BM aspiration</td>
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<td>BM biopsy</td>
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<td>1~3d</td>
<td>7d</td>
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<td>7~10d</td>
<td>7~14d</td>
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H : Hematologists  
HP : Hematopathologists/CP  
AP : Pathologists  
MT : Medical Technologists
# National Proficiency Testing in Asia

<table>
<thead>
<tr>
<th>Country</th>
<th>National Authority</th>
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</table>
| Japan   | Japan Medical Association/Japan Association of Medical Technologists :~3500 labs  
Japan Registered Clinical Laboratories Association , 1974: ~200 labs  
No authority at the national level |
| Korea   | Korean Association of Quality Assurance for clinical Laboratory(KAQACL), 1977  
Korean Institute of Genetic Testing Evaluation, 2005 |
| Taiwan  | Accreditation by Taiwanese Accreditation Foundation(TAF) or CAP  
Proficiency testing: TSLM-PT, CAP-LAP |
| Thailand| Ministry of Public Health  
Mahidol University  
Thammasat University |
| China   | Not yet |
Laboratory Accreditation Program of CAP in Asia

- >20,000 international labs
- In Asia, 176 labs accredited & PT only 625 labs (2016)

<table>
<thead>
<tr>
<th>Country</th>
<th>CAP Accredited</th>
<th>Pursuing CAP Accreditation</th>
<th>PT Only</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>46</td>
<td>8</td>
<td>84</td>
<td>138</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>7</td>
<td>2</td>
<td>50</td>
<td>59</td>
</tr>
<tr>
<td>India</td>
<td>44</td>
<td>8</td>
<td>30</td>
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<tr>
<td>Japan</td>
<td>17</td>
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<td>147</td>
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<tr>
<td>Korea, South</td>
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<td>46</td>
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<tr>
<td>Malaysia</td>
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<tr>
<td>Singapore</td>
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<td>26</td>
<td>50</td>
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<tr>
<td>Taiwan</td>
<td>22</td>
<td>1</td>
<td>186</td>
<td>209</td>
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<tr>
<td>Thailand</td>
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<td>26</td>
<td>31</td>
</tr>
<tr>
<td>All other Asia</td>
<td>2</td>
<td>1</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>176</td>
<td>22</td>
<td>625</td>
<td>823</td>
</tr>
</tbody>
</table>
CAP in Asia

• My experience :
  • China, Japan, Korea, Taiwan, Thailand, Singapore, HK
  • India, UAE, Saudi Arabia

• Accredited Labs in Asia
  – Big university hospital labs : China, Korea, Singapore, HK, Taiwan
    • >2,000 beds, >5,000 beds
    • TLA-equipped automated, high test volume, complex test items
  – Reference labs : Japan, Korea, China,
  – CRO labs : mainly China, Singapore

• Backbone for national accreditation

• Increased due to widespread international clinical trials
## Challenges of Hematology Laboratory in Asia

<table>
<thead>
<tr>
<th>Country</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>Lack of specialists</td>
</tr>
<tr>
<td>Japan</td>
<td>Standardization problem: morphology, PT/PTT, D-dimer</td>
</tr>
<tr>
<td>Korea</td>
<td>Clinical application of NGS, Tight regulation by government</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Role of laboratory hematologists, Separation lab from clinical hematology, Limited service of special tests, cytogenetics &amp; molecular genetics</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Lack of manpower, Insufficient training, Limited mutation study, Clinical application of NGS</td>
</tr>
<tr>
<td>Thailand</td>
<td>Lack of specialists: coagulation, FCl, Cytogenetics &amp; Molecular genetics, Quality control</td>
</tr>
</tbody>
</table>
Summary, Asia

• Different regulation & different medical environment in each country
  – directorship of hematology lab. : Needs specialists?
  – Medical cost for lab tests

• Quite similar structure of laboratory & organization, Widespread reference labs in Japan

• Common challenges :
  – lack of specialists
  – QA issues
  – New changes : NGS, Liquid biopsy, digital cell morphology system
Opportunity for Asian labs & ISLH

**STRENGTH**
- Only society for pure Laboratory Hematology
- Strong background including instrumental hematology, FCI, Hemostasis etc.

**WEAKNESS**
- Limited scope & participation
  - Clinical hematologists
  - Hematopathologists
  - Geneticists
  - Outside US/Europe

**THREAT**
- Other hematology-related societies
- Genomics

**OPPORTUNITIES: ISLH**
- Networking
- Education
- Expansion
Acknowledgements

• Societies of Hematology & Laboratory Hematology
  – China : Prof. Kaiyan Liu / Prof. Weili Zhao
  – Japan : Prof. Kinuko Mitani / Prof. Kaoru Tohyama
  – Korea : Prof. HJ Kim / Prof. JY Han
  – Malaysia : Dr. Alan Teh Kee Hean / Prof. Dr. N. Veera Sekaran A/l V. Nadarajan
  – Taiwan : Prof. DT Lin / Prof. Wen-Chien Chou
  – Thailand : Prof. Wichai Prayoonwiwat / Dr. Oytip Nathalang

• CAP
  – International Commissioner : Dr. Robert Baisden