Laboratory Accreditation Program in Korea

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Korea
Contents

• Healthcare System in Korea

• History of KLAP (Korean Laboratory Accreditation Program)

• KLAP: Present status
  • Inspection
  • Education
  • Research & Developments

• Future of KLAP
Healthcare System in Korea

• Healthcare for ALL
  • Fee for service (traditional reimbursement)
  • National Healthcare Insurance System (incl. lab)

• Healthcare Policy
  • Ministry of Health & Welfare (MOHW)
    • Oversees the national health insurance system
  • National Health Insurance Corporation (NHIC)
  • Health Insurance Review & Assessment Service
    • Conduct reviews
    • Assessment of medical fees
History of KLAP

• KLAP ; *Korean Laboratory Accreditation Program*

• **1998, Ministry of Health & Welfare**
  • Inspection & quality certification program for improving & managing the quality of clinical laboratory tests

• **1999, pilot project launched**
  • Mandatory qualification program for Ref. Lab
  • Organized by KSLM (Korean Society for Laboratory Medicine, formerly known as KSCP)
• 1999, Laboratory Accreditation Committee, KSLM
  • Standing committee
  • Laboratory inspection and its related works
    • Qualification
    • Duties of responsible lab personnel
    • Lab facilities & safeties
    • Quality controls
    • Quality improvements

• Checklists for 11 areas
  • Lab general, Diagnostic Hematology, Clinical Chemistry (General Chemistry, Urinalysis, Special Chemistry), Clinical Microbiology, Transfusion Medicine, Immunoserology, HLA, Molecular Biology, Flowcytometry, Cytogenetics, Limited Lab Service
• 2000,
  • Added - comprehensive laboratory test verification
  • Abolished – limited lab service
• 2004, 13 areas covered
  • POCT, reference lab – pilot program

• 2010, Laboratory Medicine Foundation (LMF, www.lmf.or.kr)
  • Close collaboration with KSLM
  • Joint Certificate for Accreditation
  • Structure of LMF
    • Board Members
      • 18 Board Members
    • Director
    • Business Manager – inspection, education, R&D, treasurer
KLAP : Present Status
Structure of KLAP

Chair, Board Member

Board Member

Director

Inspection
Education
R & D
Treasurer
Goal for KLAP

- Assurance for accurate test results
- Continuous service improvements
  - Efforts to show visible improvements in lab safety & effective test performance
  - Continuous improvements in steps affecting patients’ test results
## CAP vs ISO 15189 vs KLAP

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<td>Conformity Risk assessment</td>
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<td><strong>Assessment Method</strong></td>
<td>Pass/Fail Phase 1 Phase 2</td>
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<td>Unique Scoring system</td>
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<td><strong>Accreditation</strong></td>
<td>2 years Accepted/Deficiency/Recommendations Correction needed before accreditation</td>
<td>3~4 years Deficiency Report</td>
<td>1-year : 80~89% 2-year : ≥90% Fail : &lt;80%</td>
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Unique Scoring System

• Scores: depending on its importance
  • Essential for good lab practice
  • Quality Improvements
  • Focus on . . . . . .

• Mandatory documents & procedures
  • Initial stage: giving high scores
  • If all lab satisfy the conditions, tapering the score to minimum of 1.

• Scores summed up & converted to %
Business Area of KLAP

Chair, Board Member

Board Member

Director

Inspection  Education  R & D  New ??
For Inspection

• Laboratory Accreditation & Inspection
• Comprehensive Verification management
• Accreditation & Inspection for Reference Laboratory Services
• Issuing Certificates for Accreditation
  • Hospital Laboratory
  • Reference Laboratory
Checklist of KLAP

• Lab organizational system
• Proficiency testing
• Quality Assurance Strategy
• Internal Quality Control
• Analytic Process
  • Pre-/Post-analytical
  • Analytical
• Analyzers & instruments
• Inventory
• Lab personnel/environments
Documents needed for inspection

- Certificate for proficiency testing participation
- Problem report for participated proficiency tests
- CQI – structure, proceedings(minutes)
- Guide books for Quality Control
- Technical Manual for tests & procedures
- Lists for lab analyzers and maintenance records
No. of Lab participation & results

No. of Participants   2-Year   1-Year   Self   Withdrawal   Disqualified   Re-inspection
## Results of Accreditation

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For Education

• 1999, 1st education for inspectors
  • Peer-reviewer (Inspector) & examinee
    • Twice a year
    • Changes in checklists
    • Quality improvements

• Education for Residents
  • Once a year
    • At least 2 times throughout whole 4-year residentship

• R&D for quality assurance system for laboratory & new standardized education programs
For Research & Developments

- Checklists updates & revisions
- Funding researches for Laboratory Quality Improvements
- Information System
  - On-line registration for inspectors
  - On-line application for inspections
  - On-line assessments of checklists & summation
Contents of Checklists

- Lab organizational system
- Proficiency testing
- Lab quality assurance strategy
- Internal quality control
- Pre-analytic process
- Analytic process
- Post-analytic process
- Laboratory equipment and instrument
- Inventory
- Lab personnel
- Lab environment
Detailed Questionnaires

- **Common**
  - Qualification of directors
  - Facilities and safeties
    - Space, analyzers, utensils etc
    - Communications (LIS)
    - Medical waste disposal managements
- **Program for Quality improvements & Quality Control**
  - Participation of Proficiency Testing Program
  - Frequency of Internal Quality Control Program & its managements
  - Topics of QI & its reports
• Basic conditions for accredited laboratory
  • Managerial statistics for
    • Key indicators
    • TATs (Turnaround Time) for emergency & routine
  • Temperature /Humidity Monitoring
    • Refrigerators
    • Freezers/Deep freezers
    • Room temperature

• Laboratory Procedures
  • Parallel tests for lot changes
    • Reagents, calibrators
    • Decision criteria
  • Reagent Lot control
  • Analytical Measurement Interval verification
• **Special or field specific**
  • Specific questionnaires for each field
    • Typical analyzers needed to run the tests
    • Temperature monitoring records for PCR etc
    • Separated room for acid-fast bacillus
    • Ocular micrometer
    • Review the effects of complements
    • Parallel tests due to lot changes, ore reagent changes
    • False negative rate for amplification tests

• **POCT**
  • Every POCT analyzer should be controlled
  • QC & maintenance
  • Education program for users

• **Ref. Lab**
  • Specimen transportation – temp., quality indicators..
  • Reception, handling, reporting
  • Data transactions…….
Committee for Checklist Revision

- Development of New Questionnaire & making guidelines for it
- Delete old fashioned, out-dated questionnaires
- Update all the guidelines
- Participate as an Inspector
- Monitor New Questionnaires & scores for adjustments, if needed.
Checklists Revision

• 2000, 1st revision with adoption of complementary lab verification report
• 2001, 2nd revision & applied in year 2002
• 2003, 3rd revision
  • Pilot project for POCT, Ref. Lab
• 2005, 4th revision
  • Pilot project for POCT
  • Ref. Lab – Routine Checklists
• 2007, 5th revision
• 2010, 6th revision
• 2013, 7th revision
  • POCT – Routine checklists
# Checklists (1999)

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Future of KLAP

• Successful implementation of KLAP
  • Voluntary, peer-reviewer

• International Recognition for Accreditation program in Korea (KLAP)

• Establishing guidelines for Standardization
  • Suggest Standard Lab procedures
  • Development of Statistical Programs

• Education for inspectors & participants
  • Development of standardized education programs
Thank you for Your Attention!