

Laboratory Medicine in the Era of Disruptive Technology

LMCE 2017 & KSLM 58th Annual Meeting

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Experience of Korean version of CLSI standards

Hee-Jung Chung

Department of Laboratory Medicine, National Cancer Center Hospital, Goyang, South Korea

The background and initiative for the translation of CLSI guidelines by KSLM are desire for quality improvement. There was an increase of necessity for education due to the requiremnet of accreditation of clinical laboratories and expansion of hospial accreditation program. And for this, the importance of CLSI guideline was more emphasized since it is an internationally accepted protocols for clinical laboratory practices. CLSI guidelines translated into Korean was easily accessible by Korean laboratory personnel, and we needed guidelines that were fit for Korean laboratory environment. Since 1999, KSLM established Korean Laboratory Accreditation Program; KLCP. Assessment for Accreditation in Laboratory Excellence occurs in all areas involving laboratory testing. There are a total of 13 areas; 01 Laboratory Management, 07 Comprehensive Report for Laboratory Results, 08 POCT, 09 Referred Test, 10 Diagnostic Hematology, 21 Clinical Chemistry (including Urinalysis), 30 Clinical Microbiology, 40 Transfusion Medicine, 50 7 Diagnostic Immunology, 60 Cytometric Analysis, 70 Histocompatibility Test, 80 Cytogenetic Test, and 90 Molecular Diagnostic Test. Along with Laboratory Accreditation Program, education for auditors and autitees are held twoice annually about revised review checklist and various details regarding quality improvement of laboratories. KLAP began in 1999, and there are 13 areas including laboratory management, clinical chemistry, diagnostic hematology, clinical microbiology. A total of 1,660 checklists which are revised every year by checklist revision committee. As of 2016 year, 291 institutions were accredited. To achieve LAP accreditation, full understanding of CLSI guidelines, which is the standard for Laboratory Practice, is needed.

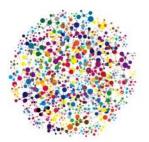
Before the start of translation project, we organized laboratory medicine terminology for the consistency of terminology and formats. Task force team of 16 specialists in each field was organized in April 2009 to publish "Laboratory Medicine Terminology". And after a full year of work, it was finally published in April 2010. A total of 5,685 terms are included in this book: 3,271 have matched English and Korean terms, and 2,414 terms have definitions in addition to terms in both languages, and also commentaries in Korean.

The processes of translation are as follows

- 1. Selection of guidelines
- 2. Recruitment of experts for translation: Open competition
- 3. Workshop & preeducation
- 4. Translation & Review: up to three times
- 5. Editing & Proofreading by committee
- 6. Publication
- 7.

Members of Laboratory Accreditation committee and members of KSLM recommend necessary guidelines. After many times of discussion in committee meeting, 10 guidelines for translations are selected every year. Selected guidelines are reported to Board of Directors of KSLM and receive approval. Recruitment of experts for translation is open to the clinical pathologists who were active members of KSLM. For choosing right translators among the applicants, we set the standards of grading applicants according to research experience in related field, publication record, presentation experience as well as commitment to our organization and participation record of laboratory





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accreditations. Before the start of translation job, workshop was held every year. This is to promote understanding of translation project and responsibilities of participants. After three months of fisrt translation period, primary translation is submitted to the committee. Then, reviewing process is followed. Two knowledgeable reviewers in each area, recommended by subcommittees for each subspecialty, are assigned for the review of each guideline. Reviewing process is similar with that of journal manuscript. Common checklists are given to reviewers which allow filter mistakes systematically. These translation & review set is performed more than 2 times. If the final version of translation is confirmed, editing is done by committee. It was published as a set of book after the publishing work.

KSLM made a first contract with CLSI on July 2009 to translate selected guidelines into Korean. Eight years of translation process was successfully completed producing a total of 80 published guidelines in Korean. Now we are currently working on 9th year of work. Due to the rapid changes in the laboratory environment and the need for standardization of terminology, we are preparing for the publication of a new version of the terminology book for laboratory medicine/clinical pathology. As explained earlier, our project was implemented by systematic and rational methods, and this was possible by active participation of KSLM members as well as by a virtue of huge support from CLSI. These translated guidelines will provide useful information for quality improvement of clinical laboratories in Korea. Furthermore, this work will be the cornerstone of future collaboration between CLSI and KSLM.

Keywords: Standards, CLSI, Guideline, Korean Society of Laboratory Medicine, Laboratory Medicine Foundation

