

## Executive Summary

### A Suggestion on the Assessment Process for Un-assessed Health Technologies

Seok-Hyun Kim, Wonjung Choi, Ryojin Kho, Yeil Joo, Jun-Ho Kim,  
Ho-gun Shin.

National Evidence-based Healthcare Collaborating Agency

#### Background and Purpose

There are health technologies currently used in clinical fields without any regulation or assessment for their safety and effectiveness by proper regulation bodies. Most of them are so called 'Un-listed procedures', and it is hard to evaluate the effectiveness of those technologies since they are judged based on subjective individual standards but the safety assessment was never considered either. For example, The safety of Ocular whitening procedure was continuously issued by clinical experts and Ocular whitening procedure was prohibited by Ministry of Welfare and Health on 2010 based on the assessment report by new Health Technology Committee. Therefore, it is very important to establish assessment process for technologies which are not previously evaluated especially for the safety and evoke issues of the safety of technology itself. In this report, we will check the possible ways to establish assessment process for the technologies of safety issues.

#### Methods and Results

To develop the assessment model for safety of un-evaluated health technologies, we tried to identify any domestically or world widely published articles for assessment of health technologies with safety issues by systematic review, thoroughly reviewed the Ocular whitening procedure case and consultation was done to get significant opinions from experts, who

participated the assessment of Ocular whitening procedure and mainly practice un-evaluated health technologies in clinic. We proposed two schemes. The first one is the assessment model based on issue development by experts' opinion and adopting currently established evaluation process and the other one is based on safety monitoring system and establishing new evaluation process.

The two proposals were examined by 8 clinical panels using Delphi method and AHP. We proposed a modified assessment model according to the result of examination by clinical panel. Proposed model was discussed in the committee composed with clinical experts, members of nHTA committee, and government officers. Based on the results, we proposed a final assessment model.

## Proposing an Assessment Model

The ministry of Health and Welfare should be the responsible one for executing the new assessment for the safety issued technologies and screening of the safety. The assessment process should adopt the process for the current nHTA committee. Once the submission received, nHTA committee decides whether the submission is suitable for the assessment and orders to assemble a separate committee for further assessment of the safety of the technologies. On the consideration of the systematic reviewing is not highly useful in safety examination, following up the patients, case examination, and examination of patient record should be the important methods for the assessment.

## Policy Suggestion

This study was designed to respond correctly and promptly when a specific health technology generates significant safety issues and this kind of studies were never tried before elsewhere. Our past experience of 'Eye Whitening' gave us the necessity of the assessment process for the proper response of regulatory bodies to ease the turmoil generated by the safety

issues. We expect that our report would be the first step to starting the discussion in Korean public health society to generate proper processes to handle safety issues by some problematic health technologies without previous assessment of safety and effectiveness.

**Key Words :**

Unevaluated Health Technology, New Health Technology Assessment Committee, Safety Assessment.