

HAS' seven year experience with the safety assessment of four esthetic procedures.

**METHODS:**

This is an HAS review of its methods used in four HTAs for the following evaluated techniques: lipolysis; cryolipolysis; esthetic mesotherapy; and, ultraviolet (UV) radiation in tanning devices. The review aimed to describe how these assessments have been undertaken and information sources used, from 2010 to 2017, to appreciate the safety profile of these procedures.

**RESULTS:**

A systematic literature review (SRL) and analysis was performed for all four HTAs. Since findings did not allow for thorough appreciation of safety, additional sources of information were consulted to address evidence gaps. Sources may have included any combination of the following: i) National and international health care authority data and alerts ii) Legal and ethical frameworks iii) Public consultation iv) Expert opinion v) Patient-consumer association opinion vi) Economic analysis

**CONCLUSIONS:**

An adaptation of the HTA methodology was necessary to meet the specific requirements of these assessments. Despite sources accumulated and consulted within the seven year period, quantitative data were found insufficient to fully appreciate the safety profile for any one of the studied esthetic procedures. National regulatory reinforcement on the reporting of adverse events, with implementation of a centralized online tool, is expected to generate and capture reliable data on the frequency and severity of adverse events associated with esthetic procedures. Recent European Union (EU) regulatory requirements on the safety and performance of medical devices include equipment used for esthetic procedures, indicating agreement and alignment on national and EU-level monitoring efforts.

.....

## VP26 A Critical Appraisal Tool For Systematic Mixed Studies Reviews

**AUTHORS:**

Quan Nha Hong ([quan.nha.hong@mail.mcgill.ca](mailto:quan.nha.hong@mail.mcgill.ca)), Pierre Pluye, Sergi Fàbregues, Gillian Bartlett,

Felicity Boardman, Margaret Cargo, Pierre Dagenais, Marie-Pierre Gagnon, Frances Griffiths, Belinda Nicolau, Alicia O’Cathain, Marie-Claude Rousseau, Isabelle Vedel

**INTRODUCTION:**

Systematic mixed studies reviews are a type of systematic review that combine qualitative, quantitative and mixed methods studies. They are gaining in popularity due to their potential for providing in-depth answers to complex clinical problems and practical concerns. However, several challenges are encountered in systematic mixed studies reviews because of the heterogeneity of included study designs. One of these challenges is related to the quality appraisal of included studies. To address this challenge, a critical appraisal tool for assessing the quality of quantitative, qualitative and mixed methods studies was developed in 2007: the Mixed Methods Appraisal Tool (MMAT). The aim of this project was to strengthen the content validity of the MMAT.

**METHODS:**

A new version of the MMAT was developed using the results from a literature review on critical appraisal tools and a modified e-Delphi study with methodological experts (n = 73) to identify the core relevant criteria to include in the MMAT.

**RESULTS:**

The results of this project and the new version of the MMAT will be presented. The MMAT has three main characteristics. First, it can be used for different study designs since it includes criteria for qualitative, quantitative and mixed methods studies. Second, the MMAT focuses on the core relevant methodological criteria and has five criteria per category of study. Third, it includes specific criteria for assessing mixed methods studies.

**CONCLUSIONS:**

Currently, there exists over 500 critical appraisal tools, making the task of selecting the proper tools for use in systematic mixed studies reviews more difficult. The MMAT offers an alternative solution by proposing a unique tool that can appraise the quality of different study designs. Also, by limiting to core criteria, the MMAT can provide a more time efficient assessment.

.....