

chronic health conditions and as an additional element in multi-component intervention programs. However, these conclusions are not definitive due to the low number of studies available for each health condition and their high or unclear risk of bias.

## PP21 Efficacy And Safety Of Aromatherapy: An Overview Of Systematic Reviews

Andrea Duarte-Díaz ([andrea.duartediaz@sescs.es](mailto:andrea.duartediaz@sescs.es)), Amado Rivero-Santana, Lilisbeth Perestelo-Pérez, Yolanda Álvarez-Pérez, Vanesa Ramos-García, Alezandra Torres-Castaño, Analía Abt-Sacks, Ana Toledo-Chávarri, María Padilla-Ruiz, Leticia Rodríguez-Rodríguez, Carlos González-Rodríguez and Pedro Serrano-Aguilar

**Introduction.** Aromatherapy is the field of herbal medicine that uses essential oils distilled from flowers, roots, and herbs and other plant compounds to promote physical and psychological well-being. Essential oils are absorbed into the body in different ways, with the inhaled and topical routes being the most widely used. The aim of this review was to critically evaluate and synthesize the available scientific evidence on the efficacy and safety of aromatherapy for the management of any therapeutic indication. This report was requested by the Spanish Ministries of Health and Science and Innovation.

**Methods.** An overview of systematic reviews (SRs) was performed. The MEDLINE, Embase, CINAHL, and PsycINFO databases were searched for literature published from January 2006 to August 2021. SRs reporting the efficacy and safety of aromatherapy were included. We applied no restrictions in terms of administration route or essential oil used. Two reviewers independently performed screening and selection, data extraction, and quality assessment.

**Results.** We included 74 SRs covering a wide variety of populations and settings. The most reported outcome was anxiety, followed by pain, and the most commonly used essential oil was lavender. Fifteen SRs reported mild adverse events with aromatherapy. Only 11 SRs assessed the certainty of evidence using the GRADE approach. Aromatherapy reduced heart rate and likely reduces anxiety and breathing rate in patients with cardiovascular diseases. Aromatherapy probably also reduces pain in women with primary dysmenorrhea. Additionally, it may reduce blood pressure, acute pain, subjective stress, and the need for antiemetic drugs after surgical procedures. However, the evidence was very uncertain regarding the effect of essential oils on anxiety, pain, and quality of life in patients with cancer, anxiety and pain after a caesarean section, and dental anxiety.

**Conclusions.** Aromatherapy may be useful for managing psychological and physical symptoms in different settings. However, the conclusions of this review are not definitive because of the moderate to high risk of bias in many of the primary studies included in the SRs.

## PP22 A Lifecycle Approach To The Use Of Real-World Evidence In HTA Submissions And Resubmissions: A Decade's Experience

Dima Samaha ([dima.samaha@iqvia.com](mailto:dima.samaha@iqvia.com)), Eliana Tavares, Anke van Engen and Paula Szawara

**Introduction.** Health technology assessment (HTA) bodies worldwide recognize the importance of real-world evidence (RWE) in addressing uncertainties around the effectiveness of new drugs at the time of launch and as part of resubmissions. We assessed the use and acceptability of RWE by analyzing HTA recommendations.

**Methods.** We analyzed 24,841 HTA reports, including original submissions, resubmissions, extensions of original indications, and renewals, published from January 2011 to October 2021 from more than 100 HTA agencies across 37 countries.

**Results.** Our analysis showed that 3,820 (15%) reports mentioned RWE. Between 2011 and 2021 there was an eight-fold increase in the use of RWE, from 4 percent in 2011 to 34 percent in 2021. RWE was most commonly included in HTAs in oncology (26%) and endocrine and metabolic diseases (13%). The main areas supported were effectiveness (40%), safety (38%), and epidemiology (35%). RWE supplemented evidence on survival and quality of life as well as resource utilization, proxy comparators, and utility. Based on an analysis of the 1,474 reports that mentioned RWE, effectiveness was mainly supported by cohort (22%) and observational studies (13%), safety was mainly derived from pharmacovigilance data (9%), and epidemiology data were collected from registries (23%). The top five HTA bodies mentioning RWE in their reports were from France, Germany, Poland, and the United Kingdom (n=2). RWE was most accepted when it supported safety and epidemiological considerations, and to a lesser extent when it was used for effectiveness aspects or understanding management pathways.

**Conclusions.** The inclusion and acceptability of RWE in HTA recommendations varies between HTAs according to their data requirements and assessment methods. While it is not always specified how RWE was considered, there is a clear tendency for its increased use and acceptability, albeit not in all areas. Greater use of and transparency around RWE are likely to continue as multiple RWE initiatives emerge globally.

## PP23 Lost In Translation? The Differences In The Use Of Real-World Evidence Across Key Markets

Christina-Jane Crossman-Barnes, Weiwei Xu ([weiwei.xu@iqvia.com](mailto:weiwei.xu@iqvia.com)) and Ishneet Kaur