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MITIGATING THE NOCEBO EFFECT IN BIOSIMILAR USE AND SWITCHING: A SYSTEMATIC REVIEW

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BACKGROUND AND OBJECTIVES

Background: In the context of biosimilar use and switching, patients' negative perceptions may trigger a nocebo effect, leading to worsened symptoms and less perceived therapeutic benefit. Considering the crucial role of biosimilars in reducing healthcare costs and expanding access to safe biologics globally, it is essential to develop and implement effective strategies to mitigate the nocebo effect.

Objectives: This systematic literature review aims to: (i) review strategies that have been applied and/or tested for minimizing the nocebo effect in clinical practice, within and outside the context of biosimilar switching, and (ii) propose recommendations for effective mitigation strategies to minimize the nocebo effect in the context of biosimilar switching.

METHODOLOGY

- We screened PubMed and Embase up to April 2023 using search terms related to "nocebo", "biosimilar", "mitigation", "strategy", and "prevention". This was supplemented by snowballing the included studies.
- The quality of the studies was assessed using the Joanna Briggs Institute Critical Appraisal Checklist for Systematic Reviews and Research Syntheses, the Scale for the Assessment of Narrative Review Articles, and the Mixed Methods Appraisal Tool.

RESULTS

Characteristics of the included studies

Of the 1617 identified and screened records, 60 met the inclusion criteria. Among these, 10 (17%) were conducted within the context of biosimilar switching, of which 7 specifically tested strategies to mitigate the nocebo effect. Among the remaining 50 studies conducted outside the biosimilar switching context, 46 tested mitigation strategies.

Key Findings

- Across the included studies, 13 distinct mitigation strategies were identified, which can be employed within the context of biosimilar switching: (i) open non-verbal communication, (ii) positive framing, (iii) empathic communication, (iv) validating communication, (v) shared decision-making, (vi) self-affirmation, (vii) education of patients and healthcare professionals about the nocebo effect, (viii) education of patients and healthcare professionals about biosimilars, (ix) soft-skills training for healthcare professionals, (x) personalized information, (xi) supporting information, (xii) multidisciplinary approach, (xiii) organization of the switch.
- This study presents a comprehensive framework for healthcare providers and patients, employing a combination of multiple mitigation strategies to effectively reduce the nocebo effect, thereby ensuring a successful and smooth transition to biosimilars in clinical practice.

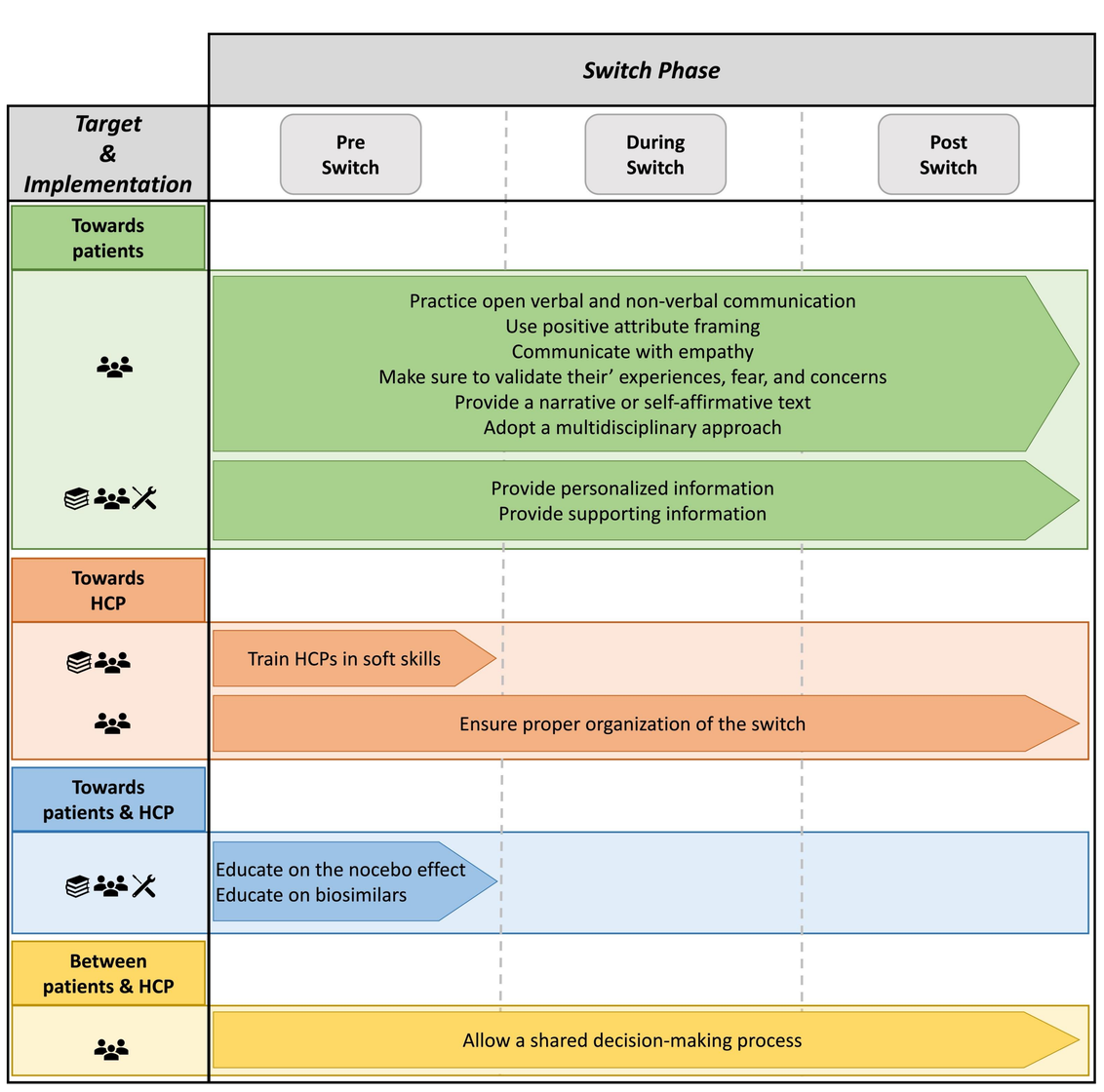

Figure. A comprehensive framework to mitigate the nocebo effect throughout the biosimilar switching process.

CONCLUSION

This review has identified a set of mitigation strategies that have been tested to mitigate the nocebo effect, which can be applied by healthcare professionals in the context of biosimilar switching with the aim of mitigating the occurrence of a nocebo effect. We recommend implementing a combination of mitigation strategies for patients and healthcare professionals to utilize before, during, and after a switch. It should be noted that given the limited number of studies specifically testing nocebo mitigation strategies within the biosimilar switching context to date, drawing definite conclusions about the effect size of each mitigation strategy individually or in combination is not yet possible.

ABBREVIATIONS

Strategies that can be carried out through human interactions between HPCs and patients.

HCP: Healthcare professional

Strategies that can be carried out through educational initiatives.

Strategies that can be carried out through tools including information sheets, educational videos about biosimilars, and so on.

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