Clinical Practice Patterns and Potential Barriers to Generic Drug Use in Special Populations

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BACKGROUND
Clinical practice guidelines (CPGs) and other literature on recommendations and practices of professional medical organizations are used to support clinician decision making. However, these documents may not always be straightforward to implement for special populations such as children, older adults, women, racial/ethnic minorities, and individuals with impaired kidney or liver function. While generic drug substitution is broadly recommended in the medical community, specific organizations’ clinical guidelines may not always agree with this broad recommendation.

OBJECTIVES
• Describe clinical practice guidelines related to drug use in special populations
• Describe potential barriers to generic substitution in special populations
• Identify potential strategies to overcome barriers to generic drug use in special populations

METHODS
We used relevant Medical Subject Headings terms to search the National Guideline Clearinghouse database for Clinical practice guidelines (CPGs) focused on six chronic conditions: Epilepsy; Depressive Disorders; Bipolar Related Disorders; Psychotic Disorders; Anxiety Disorders; Hypothyroidism; and immune-suppressive treatment following solid organ transplantation. We reviewed CPGs in National Guideline Clearinghouse published between 2012 and 2016.

FINDINGS

LIMITATIONS
• Search strategy yielded a small number of relevant medical guidelines related to the conditions of interest
• Main search database contained guidelines published between 2012 and 2016
• A search among medical healthcare organizations yielded fewer relevant clinical recommendations and guidelines than expected; no guideline offered specific recommendation regarding brand to generic substitution.

STRENGTHS
• Expanded CPG search strategy to include clinical recommendations, guidelines, and position statements published directly by medical healthcare organizations
• Established inclusion and exclusion criteria
• Data abstraction performed by multiple reviewers

RECOMMENDATIONS
• Researcher and health professionals (i.e. pharmacists, physicians, pharmaceutical companies etc.) should promote and enforce the need for continuing research so data regarding these special populations can be available and more accessible; these data can encourage pharmaceutical manufacturing and distribution to strictly adhere to the current laws
• Due to lack of evidence, most CPGs could not address the needs of special populations. More research is needed

CONCLUSIONS
Specific recommendations on generic substitution were absent in all the guidelines reviewed. Although several position papers that specifically addressed generic substitution were identifies, these sometimes yielded contradictory information and not all were specifically focused on special populations. Based on the current evidence it is difficult to draw conclusions on practice patterns of and potential barriers to generic substitution in special populations.

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