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Accuracy of self-screening tools for contraindicated use of oral contraceptives: A systematic review

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ABSTRACT

Introduction: Progesterone-only pills have been approved for over-the-counter sale in the United States. The American College of Obstetrics and Gynecology has long supported access to and advises the use of a self-screening tool to identify contraindications if combined oral contraceptives are to be sold without prescription.

Objective: To evaluate whether self-screening tools used by women seeking oral contraceptives are sufficiently accurate to replace in-person screening performed by healthcare professionals to detect relevant contraindications.

Methods: A systematic literature search was conducted using PubMed, Embase, Web of Science, and Scopus on April 16, 2024. Eligible studies were original studies that compared a self-screening tool with in-person screening performed by a healthcare professional. The target condition was defined as the presence of one or more category 3 or 4 contraindications to combined oral contraceptive use according to the World Health Organization's Medical Eligibility Criteria for contraceptive use. The risk of bias was assessed using a modified version of the Newcastle-Ottawa Scale adapted for cross-sectional studies. Due to the heterogeneity in the study populations and tool format, a narrative synthesis was conducted.

Results: Of the 1353 unique records screened, five cross-sectional studies were included, comprising a total of 4,043 participants. The highest sensitivity of a self-screening tool was 83.2% (95% CI, 79.5-85.3) and lowest was 58.8% (95% CI, 51.0-66.3). Two studies presented agreement percentages between self-screening and healthcare professionals for individual contraindications, with all items above 83.6%. A meta-analysis could not be conducted because of the heterogeneity. The overall quality of the included studies was moderate.

Conclusion: Limited but consistent evidence suggests that self-screening tools indicate contraindications to combined oral contraceptive use with moderate to high sensitivity and negative predictive value. These tools may be suitable for triage in situ considering over-the-counter access to combined oral contraceptives, and further validation is warranted.

Keywords: Contraception, Self-assessment, Contraindications, Systematic Review

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INTRODUCTION

The United States and the United Kingdom have recently authorized over-the-counter (OTC) availability of progesterone-only pills (POP) and combined oral contraceptives (COC), respectively [1, 2]. In contrast, many low-income countries already possess legislative or informal OTC access to non-emergency hormonal contraception [3, 4]. The American College of Obstetrics and Gynecology (ACOG) has been a prominent advocate for the OTC availability of POP and COC in the United States [5]. The ACOG emphasizes the general safety of these medications and supports the use of self-screening or pharmacist-aided screening to identify contraindications. In this context, women seeking oral contraceptives could use a self-screening tool as a substitute for consultations with healthcare providers. These tools are designed to function as triage instruments that enable women to determine whether combined oral contraceptives can be safely initiated without clinical consultation.

Self-screening tools are generally based on recommendations of the World Health Organization's Medical Eligibility Criteria for contraceptive use (MEC) [6]. Relevant medical conditions, such as hypertension and diabetes, are grouped into four distinct categories: 1) no restrictions, 2) advantages outweigh theoretical or proven risks, 3) theoretical or proven risks usually outweigh advantages, and 4) unacceptable health risks. The risks outlined in the MEC are linked to the specific estradiol and progesterone contents of a given contraceptive. Consequently, studies assessing the accuracy of self-screening tools often concentrate on COC, as the findings can be transferable to POP.

The accuracy and safety of a self-screening tool might be best described by its sensitivity (i.e,. the ability to truly identify users for whom contraceptive is contraindicated) and negative predictive value (i.e., the likelihood of truly being eligible for contraceptive use upon receiving a negative self-screening result). Although the indications for oral contraception may be clear, women of reproductive age may encounter difficulties in accurately identifying contraindications using a self-screening tool alone.

A previous non-systematic review examining the accuracy of self-screening tools for identifying contraindications to oral contraceptive use has been conducted [7], but most of the evidence included in this review has been authored by the same reviewers [7], and more recent research has since been published. This underscores the necessity for a new, independent systematic review of the evidence.

This systematic review examines the accuracy of self-screening tools employed by women to identify contraindications for oral contraceptive use, assessing whether these tools can substitute for in-person screening conducted by healthcare professionals.

MATERIALS AND METHODS

The systematic review was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses of Diagnostic Test Accuracy Studies (PRISMA-DTA) guidelines [8]. No review protocol was registered prior to conducting this review.

Search strategy

On April 16, 2024, a systematic search was conducted across the databases PubMed, Embase (via Ovid), Web of Science, and Scopus to identify original studies that compared a self-screening tool for contraindicated use of oral contraceptives with an in-person screening performed by a healthcare professional. The search employed a combination of relevant synonyms for the following terms as keywords and/or Medical Subject Headings and/or Emtree Terms: "contraception", "self-screening", "medical eligibility criteria", and "contraindications". The complete search terms are detailed in the Supporting Information Table S1. The search strategy was developed by F.B., E.L., and S.E.C.

Study selection

Eligible studies were required to meet the following criteria: 1) available in English or any Scandinavian language, 2) publication date up to April 16, 2024, 3) classification as an original study, 4) comparison of a self-screening tool with in-person screening conducted by a healthcare professional, 5) use of a screening tool based on WHO category 3-4 conditions, and 6) reporting of an outcome that assesses the accuracy of the self-screening tool, such as sensitivity, negative predictive value,

or agreement between screening tools and healthcare professionals. The target condition was defined as the presence of one or more category 3 or 4 contraindications to combined oral contraceptive use according to the World Health Organization's Medical Eligibility Criteria (MEC) [6]. The study selection process was performed independently by F.B. and S.N using Covidence systematic review software. Any disagreements were resolved through consensus or by involving S.E.C. as a tiebreaker.

Initial screening of records was conducted based on the title and abstract. The second screening involved reviewing the full text. Records that lacked a title or abstract in the review software were identified through searches in the following order: 1) original database, 2) Royal Danish Library (KB.dk), 3) Google Scholar (Scholar.Google.com), and 4) with assistance from a research librarian at Copenhagen University Hospital, North Zeeland. If the full text could not be obtained after these searches, it was excluded from the review and noted as not retrieved.

Data extraction

The index test was defined as any self-administered screening tool designed to identify contraindications for COC use. The reference standard was an in-person clinical assessment conducted by a healthcare professional. The target condition was the presence of category 3 or 4 conditions according to WHO Medical Eligibility Criteria [6]. Data extracted included publication year, study design, study purpose, country, funding source, total number of participants, age of participants, previous use of hormonal contraception among participants, number of participants eligible or contraindicated for the use of POP or COC, criteria used to define contraindicated use in each study, study self-screening tool, sensitivity of the self-screening tool, negative predictive value of the self-screening tool, number of discordant and concordant self-screener/healthcare professional pairings, and agreement percentages for individual self-screening items. If not specified in the study, the sensitivity and negative predictive values of the self-screening tool were calculated based on the data reported in the study. The data extraction was performed manually and independently by F.B. and S.N using online spreadsheet software Google Sheets. Disagreements were resolved by consensus or introduction of S.E.C. as a tiebreaker. No automated extraction tools were used, and the authors were not contacted in cases of missing data.

Quality assessment

The study quality was assessed using the Newcastle-Ottawa Quality Assessment Tool for cohorts, which was modified for applicability to cross-sectional studies concerning self-screening for contraindicated use of COC (Supporting Information Table S2) [9]. Similar replacement categories have been used in other systematic reviews to assess bias in cross-sectional studies [10-12]. Although the QUADAS-2 tool is recommended for diagnostic accuracy studies, the included studies were cross-sectional and often lacked detailed test flow reporting. Therefore, a modified version of the Newcastle-Ottawa Scale was applied, tailored to assess bias in self-screening contexts. Modifications of the quality assessment tool were performed by F.B., S.N. and S.E.C.

Studies were evaluated on a nine-point scale across the following categories: 1) representativeness of the sampling, sample size, and comparability between respondents and non-respondents; 2) examination of potential confounders; and 3) assessment of outcomes, appropriateness of self-screening tools, statistical analysis, and funding sources. Scores ranging from 0-3 points indicated low quality), 4-6 points indicated moderate quality, and 7-9 points indicated high quality.

Analysis

Initially, a meta-analysis was intended, but pooling the data on self-screening tool accuracy was deemed unhelpful in summarizing the evidence. The studies were of varying quality and used different self-screening tools, practical settings, and subpopulations of women, thereby introducing clinical heterogeneity that could skew any pooling of the limited data (Supporting Information Table S3). The findings are presented and analyzed narratively. Variations in the self-screening tool format, target populations, and outcome definitions were explored narratively to describe potential sources of clinical and methodological heterogeneity.

Due to limited number of studies included in the systematic review, publication bias could not be statistically determined or assessed through a funnel plot. Furthermore, no sensitivity or subgroup analyses were prespecified or conducted because of the small number of included studies and substantial clinical heterogeneity.

RESULTS

TA The search strategy identified 2290 records. Automation tools removed 501 duplicates, and 436 duplicates were manually removed by F.B. The remaining 1353 records were screened based on the title and abstract and 1340 records were excluded. The excluded records were primarily about screening for breast cancer and sexually transmitted infections. Twelve records were retrieved and assessed for their eligibility. One record was not retrieved. Publication journal history shows this to be a recurrent shortform pharmaceutical newsletter and not an original study. The selection process is illustrated in the PRISMA flowchart shown (Figure 1).

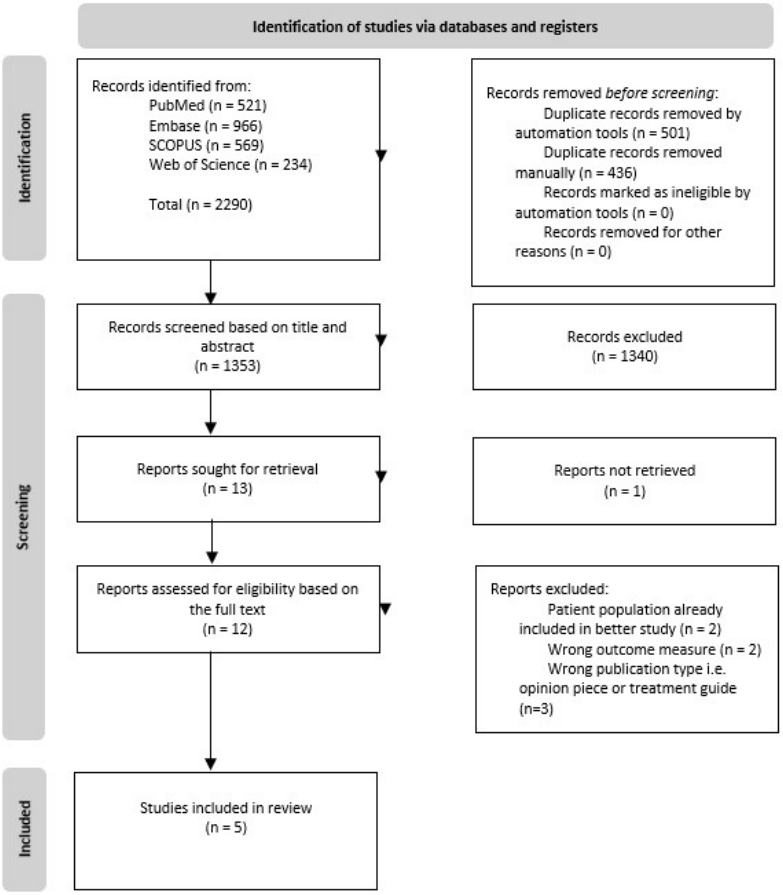

Figure 1: PRISMA flow diagram of study selection process.

Study characteristics

Five studies identified in the search met the eligibility criteria, all with a cross-sectional study design (Table 1) [13-17]. These studies were published from 2005 to 2021 and included study populations from the United States (n=3), the United Kingdom (n=1), and Tanzania (n=1). The sample sizes varied from 328 to 1,651, with a total of 4,043 participants. All studies used a self-screening tool based on WHO category 3-4 conditions that are contraindications for the use of COC. No eligible studies were found regarding self-screening for contraindicated POP use. All studies reported previous use of hormonal contraception, although only four studies examined the relationship between previous use of hormonal contraception and the discordance between self-screening and professional healthcare screening [13, 15-17]. The studies employed sampling from different subpopulations of women attending: 1) a family planning clinic for any reason [13], 2) contraceptive clinic requesting repeat prescription of a combined oral contraceptive [14], 3) shopping mall or flea marked [15], 4) a pharmacy with rights to sell prescription drugs without a doctor's prescription [16], and 5) a general health clinic or subspeciality pediatric care clinic [17]. One additional study nearly met the eligibility criteria, but its comparison of the self-screening results was based on diagnostic codes in the participant's electronic medical journal rather than in-person screening by a healthcare professional [18].

Among the included studies, one study was of high quality Grossman et al. (2008) [15], three studies were of moderate quality: Shotorbani (2006) [13], Chin-Quee et al. (2013) [16], and Wilkinson (2021) [17], and last study was of low quality Doshi et al. (2008) [14] (Table 2). Notably, one study used a self-screening tool that was considered inferior

Table 1: Characteristics of included studies.

First author, year	Country of population	Age range (y)	No. of participants	Population sample	Prior use of oral contraceptive (%)	Outcome measure
Shotorbani, 2005	USA	[15-45]	399	Women attending family planning clinic for any reason.	71	Agreement between woman/healthcare professional
Doshi, 2008	UK	≥18	328	Women attending contraceptive clinic and requesting repeat COC prescription.	100	Agreement between woman/healthcare professional
Grossman, 2008	USA	[18-49]	1271	Women attending shopping mall or flea marked.	15*	Sensitivity, specificity and negative predictive value of screening tool
Chin-Quee, 2013	Tanzania	[18-49]	1651	Women attending pharmacy (with right to sell certain drugs without doctors' prescription) for any reason.	58	Sensitivity, specificity and negative predictive value of screening tool
Wilkinson, 2021	USA	[14-21]	394	Adolescents or young adults consulting general health clinics or subspeciality pediatric care clinic for any reason.	42**	Multivariate logistic regressions on safe/unsafe discordance adjusted for age etc. (Sensitivity, specificity and negative predictive value of screening tool can be calculated)

*Only current use of hormonal contraceptives stated in article.
**Any hormonal contraceptive, specific figure of oral contraceptive not stated in article.

due to its exclusion of several category 3-4 conditions, Chin-Quee et al. (2013) [16]. The overall quality of this study was moderate. For more information on each study's self-screening tool, see Supporting Information Table S4.

Self-screening for contraindicated use of COC

The sensitivity of the self-screening tools for the contraindicated use of COC was as follows: 1) Grossman et al. (2008) [15], 83.2% (95% CI, 79.5-85.3), 2) Chin-Quee et al. (2013) [16], 69.6% (95% CI, 65.3-73.9), and 3) Wilkinson et al. (2021) [17], 58.8% (95% CI, 51.0-66.3). The negative predictive values of the self-screening tools were as follows: (1) Grossman et al. (2008) [15], 89.1% (95% CI, 87.0-90.8), 2) Chin-Quee et al. (2013) [16], 88.6% (95% CI, 86.8-90.4), and 3) Wilkinson et al. (2021) [17], 64.6% (95% CI, 59.6-69.3).

Two of the included studies, Shotorbani et al. (2006) [13] and Doshi et al. (2008) [14], had incomplete answers for multiple self-screening items. Therefore, they were unable to present data on the sensitivity or negative predictive value of the self-screening tool. Instead, they presented a percentage agreement between self-screening and healthcare professionals on singular items of the self-screening tool. Doshi et al. (2008) [14] found 90% or higher agreement for every self-screening item. Lowest Kappa coefficient on any category 3-4 contraindication was found at the question "Do you have high blood pressure?" of 0.327. A Kappa coefficient represents complete agreement between the self-screener and the healthcare professional. A kappa coefficient of zero represents no more agreement than expected by random chance. Similarly, Shotorbani et al. (2006) [13] found an 83% or higher agreement for every self-screening item. No Kappa coefficient was reported to determine whether the agreement was a chance.

Three studies presented the most common screening items that caused a positive self-screening result. These were "Do you usually get your period every month?" in Shotorbani et al. (2006) [13], "Do you have […] Migraine?" in Doshi et al. (2008) [14] and "You […] may be pregnant" in Chin-Quee et al. (2013) [16].

DISCUSSION

Two self-screening tools have high sensitivity and negative predictive value [15, 16]. One study had a lower sensitivity and negative predictive value [17]. There are no similar practices of patient-led self-screening regarding access to prescription-only drugs. Therefore, a direct comparison to judge the acceptability of the sensitivity and negative predictive value cannot be made. The two studies that reported the accuracy

Table 2: Quality assessment of studies

First author, year	Selection[a, b, c]			Comparability[d]	Outcome[e,g,f,g,h]				Score	
									Total	Quality score
Shotorbani, 2005				**	*	*		*	5	Moderate
Doshi, 2008					*	*			2	Low
Grossman, 2008	*	*		**	*	*	*	*	8	High
Chin-Quee, 2013	*	*		**			*	*	6	Moderate
Wilkinson, 2021		*		*		*	*	*	5	Moderate

*=point given, [a] Representativeness, [b] Sample size justified, [c] Non-respondents, [d] Confounding, [e] Assessment of outcome, [f] Appropriate measure, [g] Statistical test, [h] Funding described

of their self-screening tool in the form of agreement percentage between the self-screener and healthcare professional also generally showed a high level of agreement. These findings suggest that a self-screening tool may be a safe option, but the low number of studies in total warrants caution. Many contraindications for COC are linked to estrogen content [6]. Therefore, POP has fewer contraindications. A study showed that the prevalence of category 3-4 conditions that contraindicate the use of POP is generally low (4.36%) in American women seeking preventative care [19]. Therefore, POP may be a lower-risk alternative when providing OTC access to hormonal contraception.

Another systematic review found that between 5.9-41.9% of women who retrieved prescriptions for hormonal contraception had conditions in their electronic medical journal that contraindicated their use [20]. This discrepancy could be a sign of subpar medical practice or because contraindications were absent at the time of initial prescription. One of the included studies argued that using a standardized questionnaire for renewals may be a safer option than consultation with a primary healthcare provider, Grossman et al. (2008) [15]. By using a systematic approach, in-study healthcare providers may detect far more category 3-4 conditions than they would outside the study setting.

If implemented, OTC access to oral contraceptives may increase continuation rates, lessen unwanted pregnancies, lessen the need for abortion services, and lessen stress on individuals obtaining renewals on oral contraceptives. According to a 2016 survey of 1,385 American women, 29% of the included women reported difficulty in obtaining a prescription or refill [21]. The most frequently cited reasons were: 1) cost of consultation or contraception (14%), 2) challenges in obtaining or attending consultation (13%), and 3) physician requiring a physical exam or Pap smear before providing a prescription. Removing barriers to access may be most effective in healthcare systems where accessibility to medications and healthcare services is lacking [22]. These are often based on multi-payer or direct consumer-payer models of healthcare. However, in healthcare systems where accessibility to services is adequate, moving POP and COC over the counter may not yield convincing benefits.

Many American healthcare providers choose to require routine screening, such as a Pap smear, pelvic exam, or sexually transmitted infection screening, before prescribing contraception [23-25]. Although the services are not specifically required by the ACOG before prescribing oral contraceptives, a smaller study has shown that adherence to routine gynecological screening in women who obtain oral contraception over-the-counter is lower than in their counterparts who obtain prescriptions in-clinic [26, 27]. However, the authors argue that the difference is small and may be of no clinical relevance because many practitioners do not follow clinical guidelines and prescribe these tests with little or no indication.

All self-screening tools in the included studies were based on the WHO guidelines on Medical Eligibility for Contraceptive use [6]. The fifth edition (2015) contains 276 pages. The adaptation of these guidelines into a short form self-screening tool requires simplification of the conditions and language used. Multiple conditions were consolidated into broad questions and nuances in the WHO guidelines were eliminated. For example, all five studies questioned the participant if they had

"diabetes" with no further inquiry in the severity. However, only a history of diabetes >20 years or diabetes complicated by nephropathy, retinopathy, neuropathy, or concurrent vascular disease contraindicates the use of COC.

Three of the included studies used broad questions concerning migraines. Doshi et al. (2008) [14] and Grossman et al. (2008) [15] relied on the participant to interpret what a "migraine" was and did not question if aura was present or not. Chin-Quee et al. (2013) [16] only asked if the participant had "severe headaches". These questioning methods do not differentiate between primary and secondary headache types. Therefore, any headache should be considered a contraindication. By simplifying and consolidating category 3-4 conditions, the studies broaden the definition of contraindicated use, and this may lead to false overidentification of conditions as contraindications. In addition to losing the apparent benefits of contraception, falsely identified women may suffer from unnecessary pathology of their conditions and decreased self-rated health. Though the specific impact on the women may be hard to estimate, low self-rated health has consistently shown to be correlated to increased mortality in both older and younger populations [28, 29]. If implemented, self-screening tools should state that users may still be eligible for hormonal contraception and should consult their primary healthcare provider for conclusive guidance if needed.

Limitations and strengths

Overall, the quality of the included studies was considered moderate. This was due to the study design limitations, which allowed some risk of selection and information bias. Despite the relatively small area of interest, we were able to identify five original studies. Although, one study was deemed to be of low quality, all others were of moderate or high quality. Another strength was the relatively large total number of participants (n=4,043). The limitations of this review were that all included studies relied on convenience samples (clinics or public spaces), therefore, none of the studies reported any characteristics of the non-responders and allowed the risk of selection bias. Another risk of selection bias was that one study tested their self-screening tool on women who had already acquired prescriptions for hormonal contraception in Doshi et al. (2008) [14]. Two of the included studies did not explicitly state whether the medical professionals were blinded to self-screening results before consultation, Chin-Quee et al. (2013) [16] and Wilkinson et al. (2021) [17]. Furthermore, the modification categories used in the quality assessment tool were similar to those used in other systematic reviews [10-12]. However, the specific tools used in this review were not peer reviewed.

Additionally, all studies had a cross-sectional design. Although they constitute a higher level of evidence, randomized controlled trial comparing adverse outcomes of access to oral contraceptives through self-screening and standard medical professional screening may raise ethical concerns. However, alternative longitudinal designs may be both feasible and ethically acceptable. For example, non-randomized cohort studies using a retrospective comparison group unexposed to self-screening and a prospective group exposed to the intervention could be conducted using a trial emulation framework. Such designs would enable stronger inference than cross-sectional studies and may become increasingly relevant if self-screening is implemented in practice. However, true self-screening – defined as unsupervised use of a tool without pharmacist or clinical involvement – has not yet been implemented in any setting. At present, however, analyzing the results of cross-sectional studies remains the most accessible method for assessing the initial safety and accuracy of self-screening tools.

Three of the included studies overrepresented subpopulations of women with characteristics expected to affect the sensitivity and negative predictive value of any self-screening tool, suggesting that these might be higher in a truly random sample of women of reproductive age. These included rural women with a lower socioeconomic status who might have encountered difficulty utilizing a self-screening tool correctly (n=1,651) Chin-Quee et al. (2013) [16]. Similarly, the selection of young women (n=394) with a high prevalence of category 3-4 conditions in Wilkinson et al. (2021) [17] would decrease the negative predictive value of self-screening.

According to WHO guidelines, existing depressive disorders do not contraindicate the initiation of hormonal contraception [6]. However, studies

published after the current WHO guidelines have shown an association between hormonal contraception and depression, suicide attempts, and suicides [30, 31]. Adolescent women were shown to have the highest risk in both studies. Any policy change regarding OTC access to POP or COC should be weighed into this information.

Future studies

To demonstrate the repeatability of the high sensitivity and negative predictive value of a self-screening tool, more comparable studies are needed in new populations of women with diverse socioeconomic backgrounds and medical histories. A large cohort study of Danish women of reproductive age is underway [32]. It aims to map and explore the side effects of hormonal contraception and may provide important data regarding the true prevalence of category 3-4 conditions that are contraindications to POP and COC. This may provide a more precise estimate of any self-screening tool's negative predictive value.

CONCLUSION

This systematic review found that self-screening tools designed to identify contraindications to combined oral contraceptive use demonstrates moderate to high sensitivity and negative predictive value. These findings suggest that self-screening may be a viable strategy to support safe over-the-counter access to combined oral contraceptives. However, the limited number of available studies, their methodological variability, and the absence of validation in broader populations highlight the need for further high-quality research before widespread implementation can be safely recommended.

Conflict of interest: E.L. has served on an advisory board at Astellas Pharma A/S, instructed on behalf of Pfizer Inc., conducted tests for Radiometer Danmark A/S, and participated in meetings with Merck & Co., Inc. and Gedeon Richter Plc. No other authors have any financial or personal relationships that could present a conflict of interest.

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