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Healthcare Professionals' Insights Towards Implementing Generic and Biosimilar Medicines' Policies: A Mixed Methods Study Protocol

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Abstract

Introduction

The rising cost of medications presents a global healthcare challenge, necessitating strategies to improve access to affordable treatments. Generic and biosimilars medicines offer substantial savings. Although many health systems have policies to promote their use, adoption remains inconsistent among healthcare providers. This study explores physicians' and pharmacists' knowledge and perspectives towards generics and biosimilars, identifying barriers and facilitators to adoption and informing evidence-base policy strategies.

Methods

Using the Capability, Opportunity, Motivation–Behaviour (COM-B) model and Principal–Agent Theory, this mixed-methods study will assess healthcare providers' knowledge and motivation influencing generics and biosimilars adoption. Phase I will involve a cross-sectional survey of physicians and pharmacists in Abu Dhabi. The primary outcomes will be binary responses to belief in the equivalence of generics and biosimilars. Data will be analysed with descriptive statistics, Chi-square tests, Mann–Whitney U tests. Phase II will comprise semi-structured interviews exploring participants' experiences analysed using thematic analysis.

Discussion

This study will provide valuable insights into how healthcare providers perceive and adopt generics and biosimilars. It will also identify factors influencing prescribing and dispensing behaviours and will offer lessons applicable to other healthcare systems to expand the cost-effective and sustainable use of generics and biosimilars.

Introduction

The increasing cost of medications represents a significant global challenge, impacting healthcare systems, patients, and policymakers alike. To mitigate the financial strain of rising medication costs, many healthcare systems have implemented policies promoting the use of generics and biosimilars. These measures include medications' price controls, mandatory or permissive substitution, and reference pricing (OECD, 2018; OECD, 2020).

Generic medicines are therapeutically equivalent, off-patent alternatives to brand-name drugs and typically cost 20–50% less, generating substantial savings that can reach 90% (Martikainen et al., 2015; Socal et al., 2022; WHO, 2022a). On the other hand, biosimilars are highly similar to approved biologic medicines in terms of safety, efficacy, and structure that can expand access to therapies by reducing biologic drug prices by approximately 27% (Car et al., 2023; Chen et al., 2024; EMA, 2023; Food and Drug Administration, 2024; WHO, 2022b). Despite these advantages many barriers are delaying the adoption of generics and biosimilars as a cost-saving alternatives in the Middle East and North Africa Region (Alqawasmeh et al., 2025; Edgar et al., 2021; Saleh et al., 2017).

Healthcare providers knowledge and attitudes toward generics and biosimilars significantly affect prescribing and dispensing behaviours influencing their uptake. Studies reveal that many physicians and pharmacists lack necessary knowledge about these medications, and are hesitant to actively substitute products (Arnet et al., 2021; Barbier et al., 2021; Cohen et al., 2017). Pharmacists generally exhibit stronger support for generic substitution, whereas physicians tend to show greater scepticism toward both generics and biosimilars (Awada et al., 2023; Chahine et al., 2023).

This variation in perspectives is shaped by several significant barriers, such as insufficient knowledge, inconsistent regulatory frameworks, and cultural resistance. These factors collectively hinder the rapid adoption of cost-effective alternatives. (Alqawasmeh et al., 2025; El-Dahiyat & Kayyali, 2013; Iqbal, 2020). In certain instances, pharmacists may be reluctant to dispense generics because of the lower profit margins associated with these medications compared to branded drugs. This creates an economic disincentive that ultimately diminishes their promotion and accessibility for patients. (El-Jardali et al., 2017) To tackle these challenges, various countries have established different incentive mechanisms at the healthcare provider level. Some have introduced prescription quotas to encourage generic use (Remuzat et al., 2016), others employed profit sharing plans to stimulate biosimilar uptake in particular (Flodmark et al., 2013; Razanskaite et al., 2017).

Patients' trust in generics and biosimilars is also heavily influenced by their physicians' and pharmacists' recommendations, highlighting the critical role of healthcare provider communication Patients' confidence in generics and biosimilars is greatly influenced by the recommendations of their physicians and pharmacists, highlighting the importance of healthcare provider communication (Abduelkarem et al., 2019; Vandenplas et al., 2021). Effective counselling by pharmacists can greatly enhance patients' trust and acceptance of generics and biosimilars, (Rainio et al., 2019) particularly in facilitating the acceptance of biosimilars through legalizing substitutions (Cauchi, 2018; Ling et al., 2025; Thimmaraju et al., 2015).

The United Arab Emirates (UAE) has a mixed public-private healthcare system that is regulated at both federal and Emirate levels (Alnaqbi et al., 2024). The Emirates Drug Establishment (EDE) is responsible for national drug licensing, registration, and policy oversight (EDE, 2023), while coverage is determined at the individual Emirates level. In Abu Dhabi, the Department of Health (DoH) handles local implementation, insurance coverage, and formulary decisions. Health insurance is mandatory for all residents under Law No. 23 of 2005, with tiered plans primarily administered by the National Health Insurance Company (Daman)(ADG, 2005).

In Abu Dhabi, regulations mandate offering generics to patients (DOH, 2023) and DOH has also published a biosimilar guidance suggesting the prescription of biosimilars for treatment-naïve patients and switching under institutional protocols(DOH, 2024b). However, pharmaceutical spending in the UAE continues

to be high, accounting for approximately 30% of total healthcare expenditures, which is significantly above the averages for OECD countries (AlRuthia et al., 2025; OECD, 2023). Furthermore, limited studies in the UAE indicate that misconceptions about generics and biosimilars persist among healthcare professionals. Only about half of physicians and patients have confidence in or understand generics, with many favouring branded medications (Abduelkarem et al., 2019). Unlike generic medications, biosimilars have not yet been studied extensively in the UAE context. Understanding healthcare providers' familiarity with biosimilars, as well as identifying barriers to their prescription and substitution, is critical as this could hinder their adoption, despite their potential to reduce healthcare costs and improve access to essential medicines (El-Jardali et al., 2017).

This study aims to address healthcare ecosystem gaps by exploring the perceptions of physicians and pharmacists regarding generics and biosimilars in the UAE. It also seeks to identify factors influencing the acceptance of these medications and how healthcare providers' knowledge, experience, and clinical practices shape their attitudes toward generics and biosimilars. By examining these dynamics, this research will provide valuable insights for policymakers, healthcare administrators, and educators, enabling them to design targeted interventions that improve the adoption of generics and biosimilars. Such efforts could enhance patient access to affordable medications, reduce healthcare expenditures, and foster trust in these cost-effective therapeutic options.

While policy directives are in place, their effectiveness ultimately depends on provider behaviour. Addressing healthcare ecosystem gaps via exploring the perceptions of physicians and pharmacists regarding generics and biosimilars in the UAE is therefore very important. It will allow identifying factors influencing the acceptance of these medications and how healthcare providers' knowledge and experience shape their attitudes toward generics and biosimilars. It will also provide critical insights into behavioural, organizational, and systemic barriers to implementing these new standards. By examining these various dynamics, this research will provide valuable insights for policymakers, healthcare administrators, and educators, enabling them to design targeted interventions that improve the adoption of generics and biosimilars. Such efforts could enhance patient access to affordable medications, reduce healthcare expenditures, and foster trust in these cost-effective therapeutic options.

Objectives and research questions

The aim of this study is to identify behavioral, economic, and system level factors that facilitate or hinder the implementation of the new generic medicines' standard and biosimilar guide in Abu Dhabi. We focus on physicians and pharmacists as key stakeholders in medications prescribing and dispensing to investigate how their knowledge, motivations, and systemic constraints influence generics and biosimilar uptake.

The specific research questions are:

- What are the current levels of confidence and knowledge among physicians and pharmacists towards the equivalence of generics and biosimilars compared to original drugs? and how do these differ by profession or demographic factors?
- What barriers do healthcare providers encounter in adopting generics and biosimilars?
- What facilitators support and encourage generic and biosimilar uptake?
- What incentives and interventions do providers propose to strengthen the implementation of generic and biosimilar policies in Abu Dhabi that align financial interests with policy goals?

We hypothesize, based on preliminary literature that healthcare professionals in Abu Dhabi have low levels of acceptance and confidence toward generics and biosimilars.

Theoretical Framework

This study adopts an integrated theoretical approach combining the Capability–Opportunity–Motivation–Behaviour (COM-B) model and Principal–Agent Theory.

The COM-B model (Michie et al., 2011) theorizes that behaviour arises from the interaction of three key components: Capability, Opportunity, and Motivation. Survey items and interview questions will be mapped to COM-B components to ensure comprehensive coverage of determinants. COM-B model will also provide behavioural diagnostic lens to inform both quantitative and qualitative analyses. The study will incorporate Principal–Agent Theory (PAT), rooted in health economics to complement the behavioural lens (Buchanan, 1988; Jensen & Meckling, 1976). Integrating PAT allows the study to explore how macroeconomic and policy structures additionally shape provider behaviour. This conceptual framework connects human behavioural and economic incentives (PAT) to explain how and why providers respond to policy directives.

Methods

The research will use a mixed methodology sequential approach with a quantitative and qualitative component. Initially, the quantitative phase, a cross-sectional survey, with its' observational design, will assess and subsequently determine the opinions and attitudes of healthcare professionals (Kesmodel, 2018) via providing measurable data. The qualitative data will be collected following the quantitative phase to provide deeper insights and contextual understanding of the initial findings.

This sequential approach ensures that the qualitative component complements the quantitative results by clarifying underlying reasons, perspectives, and experiences that explain the observed patterns (Halcomb, 2015). In mixed methodologies, a research paradigm like post-positivism boosts alignment between the two approaches via combining research tools (Krauss, 2005) to investigate health and illness issues scientifically and socially (Grix, 2018). This will also combine strengths of different methods that have no overlapping weaknesses (Creswell & Clark, 2017; Morse, 2016). The quantitative data offers generalizability and identifies patterns, while the qualitative data provides depth and context, explaining the 'why' and 'how' behind the numbers. Moreover,

this approach allows for triangulation, enhancing the validity and reliability of the findings by corroborating evidence across different data (Heale & Forbes, 2013).

A preceding systematic review across the Middle East and North Africa identified the key barriers and facilitators influencing physicians' and pharmacists' adoption of generics and biosimilars in the region (Alqawasmeh et al., 2025). Based on these findings, the survey and interview tools were refined to explore local behavioural, economic, and policy factors shaping prescribing and dispensing practices.

To ensure methodological rigor and transparency, the protocol will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for the cross-sectional survey (Vandenbroucke et al., 2014), the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist for the interview component (Tong et al., 2007), and the Good Reporting of a Mixed Methods Study (GRAMMS) checklist (Lee et al., 2022) for mixed-methods integration and reporting. Adherence to these international reporting standards will ensure clarity and reproducibility in design and analysis procedures.

Phase I: Observational Cross-Sectional Study

Study Design and Participants

Phase I is an observational cross-sectional survey targeting licensed actively practicing physicians and pharmacists in the Emirate of Abu Dhabi. The survey will be administered online (using the Qualtrics platform) and is self-administered via a web link. The full questionnaire is provided in Appendix A. An online healthcare professionals database is available from Abu Dhabi Department of Health website (DOH, 2024a) detailing all licensed healthcare professionals names, license status, facility names, locations and practice types of each healthcare professional. According to the registry, there are approximately 19,650 healthcare providers who meet this criterion.

Sample size

The study will aim to obtain a representative sample of Abu Dhabi's physician and pharmacist populations. We calculated the minimum number of required samples to ensure accurate estimates of key measures using an online sample size calculator (Calculator.net, 2023). Therefore, in order to have a 95% confidence level that the actual value is within ± 5% of the measured/surveyed value, a sample size of 377 participants or more is required for a population of 19,650 healthcare professionals. Moreover, to ensure sufficient power for subgroup comparisons between physicians and pharmacists, a two-proportion chi-square power analysis is performed. To detect moderate differences, at least 100 respondents per professional group (around 200 total) will be needed, assuming a medium effect size (Cohen's $h \approx 0.5$), 80% power, and $\alpha = 0.05$ (Cohen, 1988). Additionally, the sample size calculation methodology was reviewed and confirmed in consultation with a statistician from Lancaster University

Survey Instrument Development

The structured survey instrument was adapted from previously published questionnaires used in similar studies of healthcare professionals' perceptions of generics and biosimilars (Barbier et al., 2021; Binder & Zeitlinger, 2024). The questionnaire was also updated based on results from systematic review in the Middle East and North Africa that informed locally relevant context (Alqawasmeh et al., 2025).

The final questionnaire (see Appendix A) is divided into three main sections:

1. Demographics: This section will capture participants' background characteristics such as age, gender, professional role, specialty, years of experience, and primary practice setting (public/private; hospital/clinic/community pharmacy). These data will facilitate subgroup analyses.
2. Perceptions and Knowledge and: this section will be divided into two parts, addressing generics and biosimilars separately, to measure respondents' current confidence towards the equivalence of generics and biosimilars to original drugs. It will also look at their attitudes regarding the quality, efficacy, and safety of generic and biosimilar medicines. Likert-scale and multiple-choice items will be used to address prescribing or dispensing comfort levels, and self-rated knowledge. Objective understanding of generics and biosimilars regulatory aspects and bioequivalence principles will be assessed. Knowledge items will be structured as factual multiple-choice questions with one correct response because we recognize that accurately measuring knowledge through questionnaires can be difficult, due to potential guessing or varied interpretation of questions. The tool will be pilot tested to evaluate clarity and reliability. Correct answers will be aggregated into composite knowledge scores for generics and biosimilars.
3. Incentives and Policy Views: This section will explore awareness of current DOH policies, perceived needs for professional training, and opinions on incentive mechanisms. Respondents will rank potential policy supports, such as DOH-provided education, feedback on prescribing, or recognition and financial incentives and prescribing and dispensing quota.

The questionnaire will undergo pilot testing with a small group of participants to evaluate its content and face validity, as well as to ensure clarity and completion time. After that if deemed necessary, adjustments to the questions will be made. Participants completing the survey will also be invited to indicate their willingness to participate in follow-up interviews for Phase II interview through completing a second mini survey to capture their details using an external anonymous link, maintaining strict confidentiality.

The survey will be conducted in English, the primary language of professional communication among healthcare workers in Abu Dhabi. English use will enhance inclusivity, considering the multinational workforce, and minimize translation-related inconsistencies.

Participant Recruitment and Data collection

The study will employ a non-probability purposive sampling strategy rather than random selection. Data collection for the survey will be conducted in collaboration with healthcare facilities where they will disseminate the survey via their official communication channels; healthcare facilities management, institutions' IRB committees, and affiliated healthcare institutions to ensure broad representation across public and private sectors.

An introductory notification email will be subsequently sent to the facilities three days prior to distributing the survey, outlining the aim of the study and requesting them to forward the survey email invitation to their respective healthcare providers. The introductory page of the survey will include a participant information letter that will explain the purpose of the study, the estimated time required to complete the survey, alongside a section emphasizing the confidentiality of the responses. Participants will also be asked to provide their consent at the beginning of the survey. Reminder emails will be sent till the end of the recruitment period. If the desired sample size for phase I study is not achieved, several strategies can be employed to increase participants recruitment. An extension of the recruitment period by increasing the time frame to allow more time for participants to be recruited will be considered. Also, a possibility to engage professional networks and partner with professional associations in the Abu Dhabi via asking for engagement with medical and pharmacy associations to help distribute the survey to their members. Finally, snowball sampling technique will be also considered to encourage referrals by asking potential participants for referrals to other colleagues (Biernacki & Waldorf, 1981).

Data Analyses

The primary outcomes for phase I study are binary variables measuring whether respondents are convinced of the equivalence of generics and biosimilars compared to original (reference) products. Descriptive statistics will show frequencies and percentages that summarize respondents' demographic and professional characteristics (e.g., profession, years of experience, sector) and overall distributions of "Yes" and "No" responses for each primary outcome. Measures of central tendency (means, medians) will describe composite scores for knowledge and attitudes.

Bivariate analysis will be used to address the second research question, which examines subgroup differences, Chi-square tests will compare responses between physicians and pharmacists and across other demographic factors such as years of experience or practice sector. For continuous or ordinal variables (e.g., knowledge score), Mann–Whitney U tests will be used. Statistical significance will be set at $p < 0.05$ (two-tailed). Moreover, logistic regression analyses will be conducted separately for generics and biosimilars to identify independent predictors of a "Yes" response (i.e., conviction in equivalence). Predictor variables will include profession, years of experience, prior training, practice sector, and knowledge score. This model will test if the acceptance levels are systematically influenced by provider characteristics, while quantifying their relative effects. Results will be reported as odds ratios (ORs) with 95% confidence intervals (CIs).

Correlation and association analyses using Spearman's rank correlation will assess associations between knowledge, confidence, and satisfaction scores. Effect sizes will be reported to indicate practical significance.

Phase II Qualitative Interviews

Study Design

Phase II will comprise semi-structured interviews, consisting of open-ended questions that allow for the exploration of in-depth responses (Baumbusch, 2010). These interviews will be conducted with physicians and pharmacists to examine their attitudes towards the implementation of generic and biosimilar policies in Abu Dhabi. The use of qualitative research methods that utilize the views of subjects and their experiences allow researchers to understand complex public health issues exploring social and behavioural matters that cannot be discovered through only quantitative methods (Béchet et al., 2016).

Sample Selection and Recruitment

At the end of the Phase I survey, participants will be invited to volunteer for interviews through a separate, unlinked form to ensure confidentiality. Purposive sampling will then be applied to achieve diversity across profession, practice setting, sector, experience, and specialty. Approximately 15 interviews will be conducted, with the final number guided by thematic saturation, defined as the point at which no new insights emerge (Saunders et al., 2018). If any group is under-represented, it will be targeted through follow-up invitations or snowball referrals if necessary.

Interview and Procedure

All interview participants will be required to provide informed consent at the beginning of the interview and after receiving an information sheet explaining the study purpose, confidentiality, and their right to withdraw at any stage. To ensure anonymity, pseudonyms (e.g., "Physician 3," "Pharmacist A") will replace identifying details during transcription and reporting.

Interviews will be conducted at participants' convenience, either in person, by telephone, or through secure online platforms such as Microsoft Teams. Most sessions are expected to occur remotely, lasting approximately 30–45 minutes. With participant permission, all sessions will be audio-recorded and transcribed. The interviewers will follow a semi-structured guide while encouraging open discussion and using probes for clarification.

The interview guide (Appendix B), informed by COM-B model and Principal–Agent Theory will explore experiences with prescribing and dispensing generics and biosimilars, perceptions of related policies, and perceived barriers or facilitators to implementation. The first section of the guide will include questions regarding participants' practice experience, along will the collection of non-identifying demographic information. The second section will include questions

that will focus on assessing the participants' perspectives on the use of generic and biosimilar medicines and what are the facilitators and barriers to the practice. The guide will be pilot tested with two clinicians to refine flow and clarity.

Data Analyses

Interview transcripts will be analysed using thematic analysis following a codebook-driven, post-positivist approach (Braun & Clarke, 2006b). A coding framework informed by the COM-B model and Principal–Agent Theory will guide analysis, while allowing new categories to emerge inductively from the data. This systematic approach will enable the identification of clear themes reflecting patterns in healthcare providers' experiences, perceptions, and behavioural drivers related to generic and biosimilar adoption.

This analysis will follow six steps: data familiarization, initial code generation, theme identification, theme review, theme definition and naming and report production (Braun & Clarke, 2006b). To ensure the quality of the qualitative research, Lincoln and Guba's (1985) four criteria: creditability, transferability, dependability, and confirmability, will be applied (Lincoln & Guba, 1985). Various techniques will be integrated into the research to adhere to these criteria, including an extensive literature review, the use of open-ended questions in interviews, peer review, member checking, tape recording, verbatim transcriptions and sharing findings with participants to validate and enhance accuracy (Lincoln & Guba, 1986).

Integration of Quantitative and Qualitative Data

Findings from both phases will be triangulated during interpretation. Quantitative data will identify patterns of acceptance and their predictors while qualitative data will explain beliefs, barriers, and incentive. This integration will ensure a comprehensive understanding of behavioural, economic and policy factors influencing the adoption of generics and biosimilars in Abu Dhabi.

Data Management and Ethics

For the survey, no personal identifying information (e.g., names, emails, IP addresses) will be collected. For the interview, audio files and transcripts will be stored on encrypted and access-restricted drives. Any potentially identifying content will be removed during transcription. Only the research team will have access to anonymised data for analysis. Moreover, ethical approval will be secured from relevant Abu Dhabi and the University of Lancaster Intuitional Review Board (IRB) committees, and procedures will be compliant with the UAE Personal Data Protection Law (2023), the General Data Protection Regulation (GDPR). The ethical aspects of the research will focus on autonomy, informed consent, confidentiality, and data protection.

Risk will be minimal because as no active interventions will be conducted. Participants will be fully informed that their participation is voluntary. The research questions will concern professional perspectives rather than sensitive personal information. However, procedures will protect autonomy; participants will be able to skip questions or withdraw at any time without penalty; interviews will be scheduled at convenient times and modes; and information sheets will include supportive resources when an unanticipated discomfort arise. Importantly, no monetary incentives will be offered; participation will be framed as a professional contribution to policy improvement.

Discussion

Generic and biosimilars medications have been available for long time in healthcare ecosystems and they present themselves as an important cost containment measure for constrained healthcare systems. Although there are very robust regulations governing their authorizations, the acceptance of generic and biosimilar medications by healthcare professionals is still variable. The purpose of this research is to access the view and perception of physicians and pharmacists of generic and biosimilar medicines in Abu Dhabi, United Arab of Emirates.

This study employs a mixed methods design to examine how physicians and pharmacists in Abu Dhabi perceive and understand generic and biosimilar medicines. The survey will quantify overall acceptance while comparing whether significant differences exist between professional groups. In addition, associations between variables such as gender, profession, experience, prior training, country of graduation, and sector of practice will be analysed to explore potential predictors of belief in therapeutic equivalence. The qualitative phase will contextualize and explain these quantitative findings, providing a deeper understanding of barriers and facilitators to adoption and supporting the development of evidence-informed policy recommendations.

Findings from this study are expected to make three key contributions to both local and international literature. First, they will provide empirical insights into physicians' and pharmacists' perceptions, attitudes, and practices regarding generic and biosimilar medicines within Abu Dhabi's highly insured and multicultural healthcare system, an area where empirical evidence remains scarce. Second, by integrating the COM-B model and Principal–Agent Theory, the study will advance implementation research by linking behavioural determinants with economic and policy incentives, thereby clarifying how organizational workflows, reimbursement mechanisms, and incentive structures influence provider decision-making (Barbier et al., 2021). Third, results will generate actionable evidence to inform education, workflow optimization, motivational supports, and incentive alignment strategies, which will be co-developed with the Department of Health.

Overall, this research will equip policymakers, public health officials, and regulators with robust evidence to enhance the adoption of cost-effective medicines and strengthen the sustainability of pharmaceutical policy in the UAE. Thematic insights will also provide lessons for other health systems globally seeking to expand the use of generics and biosimilars (Braun & Clarke, 2006a; Lincoln & Guba, 1985, 1986). Furthermore, this research will provide transferable insights relevant to international policymakers, and regulators seeking to optimize generic and biosimilar uptake to promote affordability and sustainability in diverse healthcare systems.

Strengths and Limitations

This mixed-methods study integrates quantitative data with qualitative depth to explore behavioural and systemic factors influencing generic and biosimilar adoption in Abu Dhabi. Potential selection bias may occur if digitally active participants are overrepresented, while social desirability and recall bias could affect accuracy of self-reports and might emerge if participants overstate their knowledge or support for generics and biosimilars. These will be mitigated through anonymous data collection and neutral wording. Researcher bias in qualitative interpretation may arise if analysts' prior beliefs influence theme identification, this will be reduced through transparent codebook-based analysis and peer debriefing (Lincoln & Guba, 1985). Although transferability is limited by Abu Dhabi's unique healthcare system and absence of patient data, methodological triangulation, theoretical integration, and diverse provider representation enhance the study's validity and policy relevance to other markets (Saunders et al., 2018).

Declarations

Disclosure of interest

The authors report there are no competing interests to declare.

i. Funding: No sources of financial assistance will be used to conduct the study/analysis described in the manuscript. No funding will be provided.

ii. Conflicts of Interest: None of the authors have any conflict of interest to declare.

iii. Availability of data and material: The data are available upon request from the authors.

iv. Ethics approval: Abu Dhabi Department of Health Ethical Committee Provided.

v. Ethics approval: Lancaster University Provided.

vi. Consent to participate provided.

vii. Consent for publication: not applicable.

viii. Code availability: not applicable.

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