

treatments. These technologies are particularly valuable in addressing healthcare disparities in resource-constrained settings, including developing countries. This study develops an extended technology adoption framework, building on models from the literature, to explore the factors influencing the adoption of AI chatbots for supporting health treatments. **Methods:** The study surveyed 430 Brazilian adults, utilizing a questionnaire consisting of established scales in health technology research. Constructs included Behavioral Intention, Attitude, Perceived Ease of Use, Empowerment, Perceived Knowledge, and Trust. Respondents had a mean age of 43 years, with 57% identifying as female. A total of 52.5% of the participants reported awareness of AI chatbot applications in healthcare. **Results:** The analysis uncovered significant associations between the constructs, highlighting the critical role of perceived knowledge in shaping perceptions of ease of use (0.726), the influence of trust in chatbot systems on feelings of empowerment in managing health (0.673), and the effect of empowerment on patient attitudes toward adopting AI chatbots (0.792). The model explained 79.2% of the variance in Attitude and 59.3% in Behavioral Intention to use AI chatbots as a tool for health treatment. **Conclusions:** The findings provide actionable insights for healthcare providers and policymakers aiming to promote AI chatbot adoption in medical contexts. Key factors influencing adoption include the dissemination of chatbot technologies within the general population, the availability of alternative healthcare options, and patients' perceptions of their knowledge and confidence in using such tools. Moreover, fostering trust in chatbot systems and emphasizing their role in empowering patients to manage their health is essential for encouraging sustained use. These results contribute to the growing literature on digital health adoption and offer strategic guidance for effectively integrating AI chatbots into healthcare systems.

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CHALLENGES OF PRE-MARKET CLINICAL INVESTIGATIONS OF MEDICAL DEVICES: A MULTI-STAKEHOLDER PERSPECTIVE

Giuditta Callea, PhD¹, Rosanna Tarricone, PhD², CARLO FEDERICI, PhD¹, Helen Banks, MA MED¹, **Maria Luisa Buzelli, MSc¹**, Francesco Benito Malandrini, PharmD¹, Franco Luigi Zurlo, MSc¹, Marta Kerstan, MSc³, Monica Tocchi, PhD⁴, Nicolas Martelli, PharmD, PhD⁵, Tess Martin, PharmD⁵, Ornella Tangila Kayembe, PharmD⁵, Stephane Piat, MSc⁶, Laura Sampietro-Colom, PhD, MD⁷, Andrea Rappagliosi, LLM⁸, Claudia Louati, Master⁹, Yasemin Zeisl, Master⁷, Daniel Beltran, MSc¹⁰, Adrián Valledor, MSc¹⁰, Marta Bragagnolo, Master¹¹, Marit Erna Austeng, MSc¹², Alexandra Herborg Cornelius Poulsson, PhD¹², Kristian Kidholm, PhD¹³, Lise Kvistgaard Jensen, MA¹³, Benedetta Brancadoro, MSc¹⁴, Carmen Furno, MSc¹⁴, Sebastian Kuhn, PhD¹⁵

¹Centre for Research on Health and Social Care Management (CERGAS), SDA Bocconi School of Management, Milan, Lombardy, Italy, Milan, Italy, ²Centre for Research on Health and Social Care Management (CERGAS), SDA Bocconi School of Management, Milan, Lombardy, Italy; Department of Social and Political Science, Bocconi University, Milan, Lombardy, Italy, Milan, Italy, ³DePuy Synthes, Zurich, Switzerland, ⁴Meditrial, New York, NY, USA, ⁵Assistance Publique - Hôpitaux de Paris, Hôpital Européen Georges Pompidou, Pharmacy Department, Paris, France, ⁶CARMAT, Vélizy-Villacoublay, France, ⁷Clinic Barcelona University Hospital, Spain, Barcelona, Spain, ⁸Edwards Lifesciences, Nyon, Switzerland, ⁹European Patient Forum, Brussels, Belgium, ¹⁰Fundació De Recerca Clinic Barcelona - Institut D'investigacions Biomèdiques August Pi i Sunyer, Barcelona, Catalonia, Spain, Barcelona, Spain, ¹¹Global Health Hub, Brussels, Belgium, ¹²Norwegian Institute of Public Health, Oslo, Norway, ¹³Odense University Hospital, Odense, Denmark, ¹⁴Policlinico Universitario Fondazione Agostino Gemelli, Milan, Italy, ¹⁵University of Marburg, Marburg, Germany

Objectives: To inform the development of a harmonized European Union (EU) Early Feasibility Studies (EFS) Program, at the centre of a Horizon JU IHI project, we collected the perspectives of different stakeholders involved in pre-market clinical investigations (CIs) of medical devices (MDs) on challenges and barriers faced, as well as solutions to improve and promote clinical research in the EU. **Methods:** Online survey for technology developers; open-ended interviews with representatives of EU HTA agencies, notified bodies, clinical sites, scientific associations, national ethics committees, technology developers (including SMEs); focus group with patient advisory group (PAG) of the project and patient associations. **Results:** According to survey respondents, the EU is the preferred location for conducting pre-market CIs. Crucial preference factors refer to trialists' and clinical site teams' competencies, the site's ability to enroll patients, and the time from study submission to first patient enrolled. A main barrier identified by stakeholders involved in CIs is the lack of dialogue between stakeholders, which makes the complexity of the regulatory framework even greater and requirements more difficult to follow. Risk-benefit analysis and device risk assessment were also deemed as major hurdles, together with aspects related to clinical sites (for instance, their experience in pre-market CIs), study design, study endpoints, enrolment targets, the lack of clear templates and guidance. Main obstacles encountered by patients during clinical trials were represented by fragmented information about the study and insufficient time and information to carefully assess the risks and benefits of participating in the study. **Conclusions:** The discussion with all stakeholders clearly shows the multifaceted hurdles faced when bringing medical innovation to market and suggests actions for improvement, such as fostering early collaboration to improve clarity and reduce delays.

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ROLE OF GENERATIVE ARTIFICIAL INTELLIGENCE IN ASSISTING SYSTEMATIC REVIEW PROCESS IN HEALTH RESEARCH: A SYSTEMATIC REVIEW

Muhammed Rashid, MPharm., PhD¹, Cheng Su Yi, MHS², Suwapat Lawin, PharmD Candidate³,

Pongsapat Limhensin, PharmD Candidate³, Suppachai Insuk, PharmD³, Sajesh K. Veetil, PhD⁴, Nai Ming Lai, MBBS⁵, Xiangyang Ye, PhD¹, Nathorn Chaiyakunapruk, PharmD, PhD¹, Teerapon Dhippayom, PharmD, PhD³

¹College of Pharmacy, University of Utah, Pharmacotherapy, Salt Lake City, UT, USA, ²Independent Researcher, Kuala Lumpur, Malaysia, ³Faculty of Pharmaceutical Sciences, Naresuan University, Phitsanulok, Thailand, ⁴School of Pharmacy, IMU University, Pharmacy Practice, Kuala Lumpur, Malaysia, ⁵Faculty of Health and Medical Sciences, Taylor's University, Subang Jaya, Malaysia

Objectives: Generative artificial intelligence (GAI) is widely used in healthcare for various purposes including the systematic review (SR) process. We aim to summarize the evidence on performance metrics of GAI in SR process. **Methods:** PubMed, EMBASE, and ProQuest Dissertations & Theses Global were searched from their inception up to May 2024. Only experimental studies that compared GAI with other GAI or human reviewers at any stage of the SR were included. Modified QUADAS-2 was employed to assess quality of studies that used GAI in study selection process. We summarized the findings of the included studies using a narrative approach. **Results:** A total of 8 out of 3663 records published were included. The included studies used multiple methods of prompt development, evaluation, reliability and model training. Three studies used GAI for study selection alone. One study each used GAI for PICO development, literature search, data extraction, risk of bias assessment, and both study selection and data extraction. GPT-3.5 and GPT-4 demonstrated good accuracy in PICO question formulation. The performance of GAI in the study selection process varied across studies. Though GPT-4 had a better performance in Tit/Abs screening, performance was low in full-text screening and combined Tit/Abs and full-text screening. This variation may be attributed to different prompts used, field of study, and nature of performance assessment. GPT-3.5 has good agreement with human reviewers in extracting simple information, but not with complex information. There was lower agreement between the Cochrane SRs and GPT-4 in performing risk of bias assessment using ROBINS-I. GAI studies focus on selection process had low risk of bias based on modified QUADAS-2. **Conclusions:** GAI can assist in PICO formulation and simple data extraction. Although GAI is revolutionizing healthcare, more practically validated evidence is needed to integrate it into the SR process.

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RTCGM USE IS ASSOCIATED WITH IMPROVED GLYCEMIC CONTROL COMPARED TO ISCGM IN COMMERCIALY INSURED PEOPLE WITH TYPE 2 DIABETES ON SEMAGLUTIDE AND INSULIN

Poorva Nemlekar, MS, Katia Hannah, BS, MPH, PhD, Blake C. Liu, MSc, Greg Norman, PhD

Dexcom, HEOR, Global Access, San Diego, CA, USA

Objectives: Previous research indicates adding glucagon-like peptide-1 receptor agonists (GLP-1 RAs) to an insulin therapy improves glycemic control in people with type 2 diabetes (PwT2D). Additionally, continuous glucose monitoring (CGM) systems, in conjunction with anti-diabetes medications, offer supplementary options to enhance diabetes care. This study evaluated if glycemic outcomes differ between CGM systems (intermittently scanned CGM [isCGM] or real-time CGM [rtCGM]) in PwT2D using insulin (basal and/or bolus) and a GLP-1 RA (semaglutide). **Methods:** Retrospective analysis of de-identified US healthcare claims data from Optum's Clinformatics® database was conducted. CGM-naïve adults (age ≥30 years) with type 2 diabetes using insulin and semaglutide were identified. Index date was first claim for rtCGM (Dexcom G-series) or isCGM (Freestyle Libre, 14-day, Libre 2) between 01/01/2019 through 06/30/2023. Continuous health plan enrollment of 6-months pre- (baseline) and post- (follow-up) index date was required for inclusion. Individuals with evidence of pregnancy were excluded. At least one laboratory HbA1c value was required during baseline and follow-up to calculate the HbA1c change. Multivariate linear regression was used to regress HbA1c change by CGM type controlling for covariates: age, gender, baseline HbA1c, comorbidity, race and region. **Results:** A total of 444 PwT2D taking insulin and semaglutide (rtCGM users, n=205; isCGM users, n=239) with commercial insurance were identified. Participants in both cohorts were approximately 55 years, 29.6-31.7% non-White and 55.1-61.1% male. Overall, a significantly greater HbA1c reduction was observed in the rtCGM cohort compared to the isCGM cohort (difference-in-differences: -0.43%, p=0.042). After adjusting for covariates, rt-CGM use was associated with a -0.31% (p=0.007) greater reduction in HbA1c compared to isCGM use. **Conclusions:** RtCGM use was associated with significantly greater reductions in HbA1c compared to isCGM use. These findings suggest rtCGM use among PwT2D taking both insulin and a GLP-1 RA (semaglutide) can be beneficial and potentially improve glycemic outcomes.

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ECONOMIC IMPACT OF PATTERNED FREQUENCY-MODULATED ORAL STIMULATION IN PRETERM INFANTS

Tobias Muench, MSc¹, Carla Fernandez Barceló, MPH¹, Alex Veloz, MSc², Rhodri Saunders, BSc, MSc, PhD¹