Category: Emerging Technology – Completed Project

Real-World Evaluation of AI-Assisted Versus Manual Prescreening for Clinical Trial Eligibility

B. Grones, A. Truxon, M. Dohopolski, A. Rowell

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

1. Background

A 2024 survey of more than 50 cancer centers reported that 52 percent identified limited staffing and high workload as major barriers to clinical trial enrollment (CTE). Recent work has shown that large language models (LLMs) can perform well with little to no decrease in diagnostic performance. One study reported that AI-assisted prescreening reduced the time required to review the same patients for the same trials by 4.5 times versus traditional manual prescreening. Together, these outcomes show that integrating AI into clinical research identification and prescreening workflows may help reduce staff burden while still maintaining similar levels of accuracy.

2. Goals

Few investigations have examined AI-assisted prescreening in prospective, real-world clinical workflows using integrated electronic health record (EHR) systems. This study aims to address that gap by assessing the accuracy and efficiency of an AI-assisted prescreening tool embedded in Epic during prescreening workflows.

3. Solutions and Methods

We compared the effectiveness of AI-assisted prescreening with traditional manual methods spanning four ongoing clinical studies, focusing on accuracy and efficiency. Accuracy was evaluated by comparing manual prescreening outcomes with AI-assisted outcomes using sensitivity, specificity, F1 scores, and the Youden Index. Manual review by a trained staff member served as the gold standard. Efficiency in this context was defined in two ways: (1) time to prescreen a patient and (2) reduction in the prescreening queue size after a defined time interval. Two-sample (independent) t-tests were used to compare mean review times between AI-assisted and manual prescreening groups.

4. Outcomes

The AI prescreening model showed sensitivities of 96-100 percent, specificities of 61-99 percent, and F1 scores of 0.87-0.99 across four studies, indicating agreement with the gold standard. Youden Index values range from 0.60 to 0.98, showcasing the AI-assisted prescreening system's strong discriminative performance.

AI-assisted prescreening significantly reduced average time-to-prescreen in Study 1 (49.8 percent reduction, $p=2.83\times10^{-7}$) and Study 2 (64.0 percent reduction, $p=1.8\times10^{-7}$). No statistically significant difference was observed per patient in Study 3 (p=0.93) or Study 4 (p=0.96). However, total operational workload notably decreased across all trials. Cumulative review time was reduced by 87 percent in Study three, 88 percent in Study one, 95 percent in Study two, and 97 percent in Study four, showing a reduction in the number of patients requiring manual review.

Direct Epic integration enabled real-time review of AI-generated outputs within standard workflows, improving efficiency, and reducing redundant patient reviews.

5. Lessons Learned and Future Directions

AI-assisted prescreening retains diagnostic accuracy while improving operational efficiency in CTE. Integration of the model within Epic demonstrates a strong capacity for translation into other high-volume oncology programs. The adoption of AI-assisted prescreening models has the potential to

streamline clinical trial recruitment, reduce overall staff workload, and improve patient access to research opportunities.

While these results are promising, staff verification remains essential in confirming eligibility determinations and ensuring clinical accuracy, as AI models may still generate false information or "data hallucinations" when interpreting unstructured data.

Future studies should evaluate the downstream effects of this updated workflow on CTE, including approach rates, screening success, enrollment rates, and time-to-accrual. Continued validation over multi-site networks will be critical to generalizing these outcomes.

Figure 1