Automated Patient Pre-Screening Using a Clinical Trials Patient Matching Algorithm

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1. Background

Effective participant recruitment is key to the success of clinical trials. To optimize recruitment of participants, pre-screening patient electronic health records is essential. Pre-screening has become increasingly burdensome due to the growing breadth of clinical trials and limited staffing resources to dedicate to this endeavor. Current health care information technology systems are typically limited in their ability to support the development of automated information extraction methods, and this is particularly true in oncology, where specific clinical vocabularies are needed to capture semantic meaning and temporal context of clinical findings. In this pilot study, a clinical trials patient matching (CTPM) algorithm was created using artificial intelligence (AI) and natural language processing (NLP) to filter patients based on defined eligibility criteria, extract relevant patient data, and export the data in an easily reviewable format for research staff.

2. Goals

This pilot study aimed to develop and test an CTPM designed to pre-screen GI Oncology patients for an interventional clinical trial, while simultaneously increasing the efficiency of review by research staff.

3. Solutions and Methods

This pilot study consisted of retrospective and prospective use of the CTPM for pre-screening. In the retrospective cohort, patients seen previously in GI Oncology clinics were reviewed to validate the accuracy and efficiency of the CTPM algorithm. In the prospective cohort, patients who had future visits to the GI Oncology department were pre-screened using the CTPM weekly in advance of the participant's scheduled visit.

4. Outcomes

For the retrospective cohort, research staff conducted chart review without use of the CTPM for the randomly selected week of September 14-20, 2020, during which 161 patients visited Yale New Haven Hospital GI Oncology. Six patients were deemed eligible for consent. When the CTPM was applied it successfully excluded 146 patients, narrowing the pool to 15 patients for manual chart review, resulting in 100 percent sensitivity, 94.2 percent specificity, 40 percent precision, and overall accuracy of 94.4 percent. The time for eligibility review per subject with and without the use of the CTPM was tracked, taking an average of 1.82 and 3.11 minutes respectively, showing an improved efficiency of 41 percent.

For the prospective cohort, the week of June 14-20, 2021 was analyzed. Research staff conducted chart review for this week without use of the CTPM during which 193 patients visited GI Oncology with 14 patients deemed eligible for consent. When the CTPM was applied it successfully excluded 156 patients, narrowing the pool to 37 patients for manual chart review, resulting in 100 percent sensitivity, 87.2 percent specificity, 37.8 percent precision, and overall accuracy of 88.08 percent.

5. Lessons Learned and Future Directions

Takeaways from this pilot study included the importance of thoughtful selection of the eligibility criteria used for patient filtering to increase specificity while not compromising sensitivity. Additionally, this pilot provided insight into future applications, such as pre-activation feasibility assessments and

improving pre-screening for rare disease and biomarker driven trials. Scalability testing of the CTPM is ongoing. This expansion includes using the CTPM with additional trials across oncologic specialties and geographic oncology clinic locations within the Yale Cancer Center.