


ORIGINAL ARTICLE

Endoscopy and Procedures

Standardized biopsy protocols improve adherence to eosinophilic esophagitis and celiac disease endoscopic biopsy guidelines

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Abstract

Objectives: Optimal detection of eosinophilic esophagitis (EoE) and celiac disease (CeD) requires appropriate sampling of the upper gastrointestinal tract during endoscopy. However, endoscopic biopsy guidelines are poorly followed in clinical practice. A quality improvement (QI) initiative was undertaken to improve adherence to published EoE and CeD biopsy guidelines by creating standardized biopsy protocols.

Methods: A biopsy form with disease-specific biopsy protocols was created and implemented. Endoscopists were initially asked to complete the form pre-procedure to indicate anticipated biopsies. After integration into the electronic health records (EHR), the form was completed by the primary treating clinician at the time endoscopy was requested. Data were collected through chart review of endoscopy and pathology reports. Statistical process control charts were used to analyze these metrics: adherence to biopsy guidelines (outcome measure), biopsy form utilization (process measure), and immediate and delayed procedural complications (balancing measures). Baseline adherence to biopsy guidelines was determined by retrospective chart review of upper endoscopies performed pre-intervention.

Results: Overall adherence to biopsy guidelines improved from an average of 45% to 78.9% with our interventions. Improvement was sustained during the 2-year study period. Adherence to biopsy guidelines improved from an average of 55% to 84% for EoE and from 13.3% to 69.5% for CeD. Decreased variability in biopsy practice was noted over time. The EHR-integrated form led to consistently high utilization (>90%). Both immediate and delayed complications remained zero.

Conclusions: Standardization of endoscopic biopsies using an EHR-integrated pre-procedure checklist leads to improved and sustained adherence to recommended EoE and CeD biopsy guidelines.

KEYWORDS

electronic health records, endoscopy, pediatrics, quality improvement

Abbreviations: CeD, celiac disease; EHR, electronic health record; EoE, eosinophilic esophagitis; GI, gastrointestinal; NASPGHAN, North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition; QI, quality improvement.

[Correction added on 11 April 2025, after the first online publication: Subcategory has been updated.]

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1 | INTRODUCTION

Eosinophilic esophagitis (EoE) and celiac disease (CeD) are diseases commonly diagnosed by endoscopy in the pediatric population. In children, biopsies are routinely obtained from the gastrointestinal (GI) tract during endoscopy.^{1,2} In EoE and CeD, obtaining appropriate biopsies is important in ensuring optimal disease detection.^{3–7} Disease-specific guidelines have been published by gastroenterology societies on the optimal endoscopic biopsies to obtain when evaluating for EoE^{2,8–11} and CeD.^{2,12–15} For EoE, at least a total of four to six biopsies from separate locations in the esophagus (upper and lower portions) are recommended.^{2,8–10} For CeD, a minimum of two biopsies from the duodenal bulb and four biopsies from the distal duodenum are recommended.^{2,12,15} However, multiple studies have shown that these guidelines are poorly followed in real life.^{16–19}

A retrospective pediatric study found that only 8% of all endoscopies followed EoE biopsy recommendations, and only 35% followed CeD biopsy recommendations.¹⁶ A review of our center's baseline endoscopies showed that 55% obtained the recommended EoE biopsies, and 13.3% obtained the recommended CeD biopsies when evaluating these diseases. In children, delay in diagnosis leads to more endoscopies performed over time, increased cumulative exposure to general anesthesia, and negatively affects a child's growth potential and quality of life. In addition, there could be more severe presentation at diagnosis (e.g., fibrostenotic disease in EoE) and potential missed opportunities to improve long-term outcomes (e.g., suboptimal growth, chronic malnutrition, and increased cancer risk in CeD).

A quality improvement (QI) initiative was undertaken to standardize endoscopic biopsies obtained by our pediatric gastroenterologists. We aimed to improve adherence to published EoE and CeD endoscopic biopsy guidelines when evaluating these diseases to a target of above 70% over an 18-month time frame.

2 | METHODS

2.1 | Context

This study was conducted at Children's Hospital Los Angeles (CHLA), a tertiary care pediatric hospital, between September 2018 and March 2021. The GI division performs an average of 2000 endoscopies yearly and is a referral center for EoE and CeD pediatric patients in the greater Los Angeles area. Endoscopy may be performed by a different clinician than the primary treating clinician for a given patient. The age of our study cohort ranged from 10 months to 22 years old. There was a significant pause in data collection from March 2020 to July 2020 due to the coronavirus disease (COVID-19) pandemic, during which only emergent endoscopies were performed. This study

What is Known

- Optimal disease detection of eosinophilic esophagitis (EoE) and celiac disease (CeD) requires appropriate biopsies to be obtained during endoscopy.
- EoE and CeD endoscopic biopsy guidelines are poorly followed in real life.
- A delay in diagnosis of EoE and CeD leads to poor long-term health outcomes.

What is New

- An electronic health record (EHR)-based endoscopic biopsy protocol helps standardize practice across endoscopists and improves adherence to EoE and CeD biopsy guidelines.
- Automations and reminders built within the EHR help maintain a high level of utilization of the biopsy protocols.

was reviewed by the Institutional Review Board at CHLA and approved under exempt review status (Study ID: CHLA-20-00147). The SQUIRE 2.0 guidelines were followed for publication (*Revised Standards for Quality Improvement Reporting Excellence—SQUIRE 2.0*; <https://www.squire-statement.org/>).

2.2 | Intervention

We created a standardized endoscopy biopsy checklist (the "GI biopsy form") to be completed pre-procedure. The form lists the recommended biopsies that should be obtained for commonly suspected diseases such as EoE or CeD (Supporting Information S1: Figure 1). Before implementation, an education session was given to our GI clinicians to review current biopsy guidelines and supporting evidence, as well as presentation of baseline data to elucidate the gap in our endoscopic biopsy practice. The form was reviewed with our GI clinicians and the procedure room staff to address any questions or concerns before implementation.

In the first stage of implementation, endoscopists were asked to complete a paper version of the GI biopsy form after reviewing the patient's history and immediately before the start of the procedure. Based on feedback, the form was revised and integrated with our electronic health record (EHR) system (Supporting Information S1: Figure 2) with automation that prompted the form to be completed when the endoscopy request order was placed. As a result, the EHR-based form was completed by the primary treating clinician in the outpatient setting and reviewed by the performing endoscopist as part of the pre-procedure workflow. A

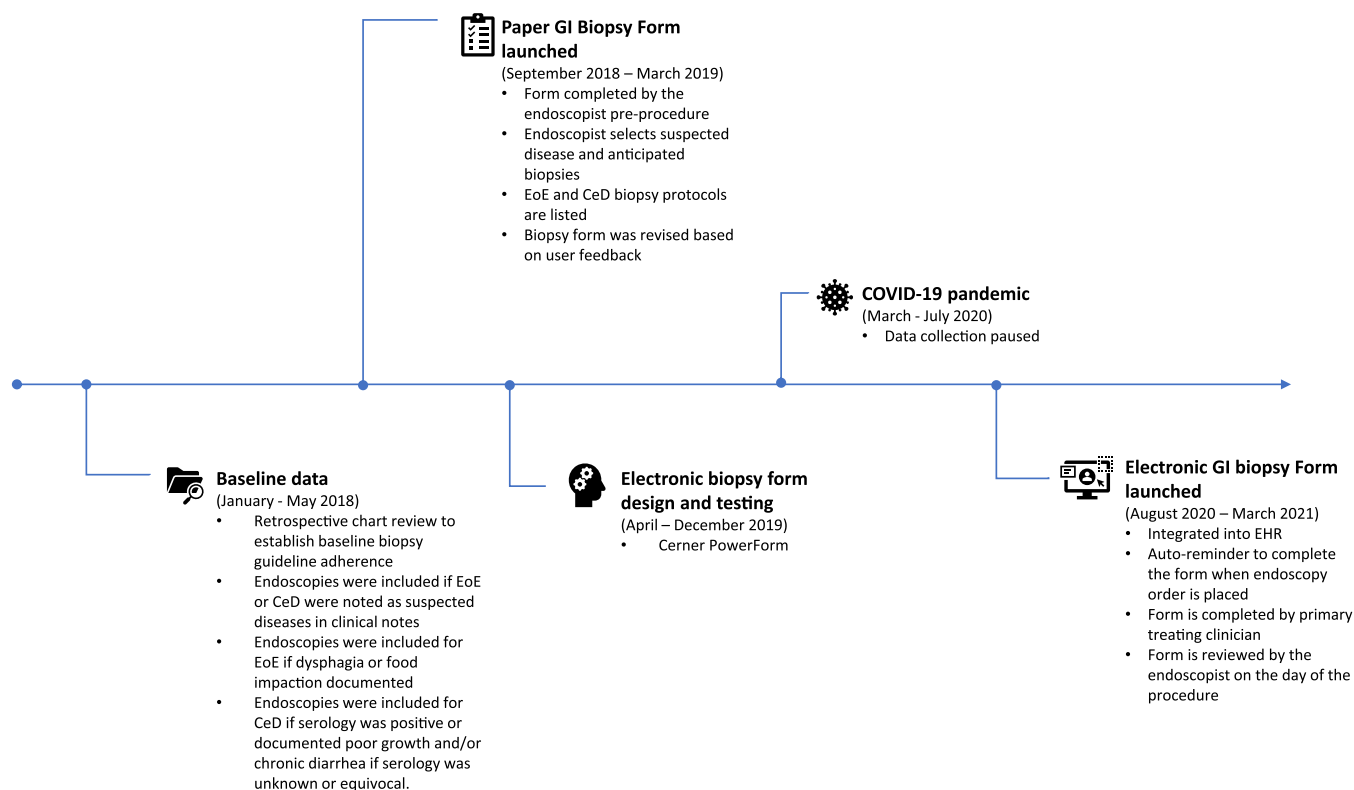


FIGURE 1 Timeline diagram showing the stages of interventions and pertinent events over the project period. CeD, celiac disease; COVID-19, coronavirus disease 2019; EHR, electronic health records; EoE, eosinophilic esophagitis; GI, gastrointestinal.

timeline diagram of the improvement cycles is provided (Figure 1).

2.3 | Study of the intervention

During the study period, the EHR was queried on a weekly basis to identify all qualifying upper endoscopies. Only outpatient elective endoscopies were included. Endoscopies performed for the purpose of control of bleeding, varices surveillance, dilation or other interventional procedures were excluded. Completed GI biopsy forms were collected from the procedure room or reviewed in the EHR to determine utilization. Subsets of endoscopies with EoE or CeD selected as indications were further reviewed with additional information obtained from the medical records, including pathology reports, endoscopy notes, and any documented postprocedure complications. The number and location of biopsies obtained as documented in the pathology report were used to determine guideline adherence.

Baseline data were obtained through retrospective chart review of all upper endoscopies performed in a 5-month period pre-intervention. To ensure a fair comparison, only endoscopies with documented suspicion for EoE and/or CeD in a clinic or endoscopy note, documented positive celiac serology, or clear

documentation of typical symptoms (e.g., for EoE, dysphagia or food impaction; for CeD, poor growth and/or persistent diarrhea if serology was unknown or equivocal) were included, which yielded 71 endoscopies performed for suspected EoE and 33 for suspected CeD.

2.4 | Measures

Our primary outcome measure was the adherence to EoE and CeD endoscopic biopsy guidelines. An endoscopy fulfills biopsy guidelines if the reported biopsies on the pathology report meet the minimum required for both numbers and location for the suspected disease; for EoE, a total of at least four biopsies from two separate levels of the esophagus (mid/distal or proximal/distal), and for CeD, at least two biopsies from the duodenal bulb and four biopsies from the distal duodenum. Adherence to biopsy guidelines was calculated as the percentage of endoscopies meeting guidelines from the total number of endoscopies performed weekly to evaluate EoE and/or CeD. Endoscopies performed for other indications were excluded. Adherence to biopsy guidelines within each disease was further analyzed to examine any disease-specific trends.

Utilization of the GI biopsy form through our improvement cycles was tracked as a process

measure. Utilization was followed weekly by examining the percentage of completed GI biopsy forms from all upper endoscopies performed, which included indications other than EoE and CeD.

Our balancing measures were immediate complications (within 48 h of the procedure) and delayed complications (within 7 days of the procedure). We monitored this by reviewing any documented adverse events following the endoscopy in the patient's chart.

2.5 | Analysis

Statistical process control (SPC) charts were used to track and analyze changes in both biopsy guideline adherence and utilization of the GI biopsy form through Plan-Do-Study-Act improvement cycles. Data were visualized over time using p-charts. Subgroup analyses within EoE and CeD were performed for guideline adherence. The upper and lower control limits were set at 3 standard deviations. A process change was detected by shifts (8 consecutive points above or below centerline) or trends (6 consecutive points in the same direction) in the data as specified by healthcare improvement data rules for special cause variations.²⁰ QI Macros software was used to create and analyze SPC charts (QI Macros 2018, Lurie Children's Hospital).

3 | RESULTS

3.1 | GI biopsy form utilization (process measure)

Utilization of the GI biopsy form was tracked from initial implementation through improvement cycles. The proportion of completed GI biopsy forms from all qualifying upper endoscopies was followed on a weekly basis. A shift in utilization was noted at Week 17 after implementation of the paper form (4 weeks before launching the EHR-based form) from an average utilization rate of 72.9% to 99% (Figure 2). Utilization was maintained at >90% consistently after implementation of the EHR-based form with reduced variation in usage. A high level of utilization was sustained over 32 weeks through to the end of the study period.

3.2 | Adherence to biopsy guidelines for EoE and CeD (outcome measure)

Our overall biopsy guidelines adherence rate improved from an average of 45.0% to 78.9%, with a process change noted at 4 weeks after implementation of the initial paper GI biopsy form, which was above our target of 70% (Figure 3). EHR integration of the GI biopsy form did not lead to further shift in biopsy guidelines

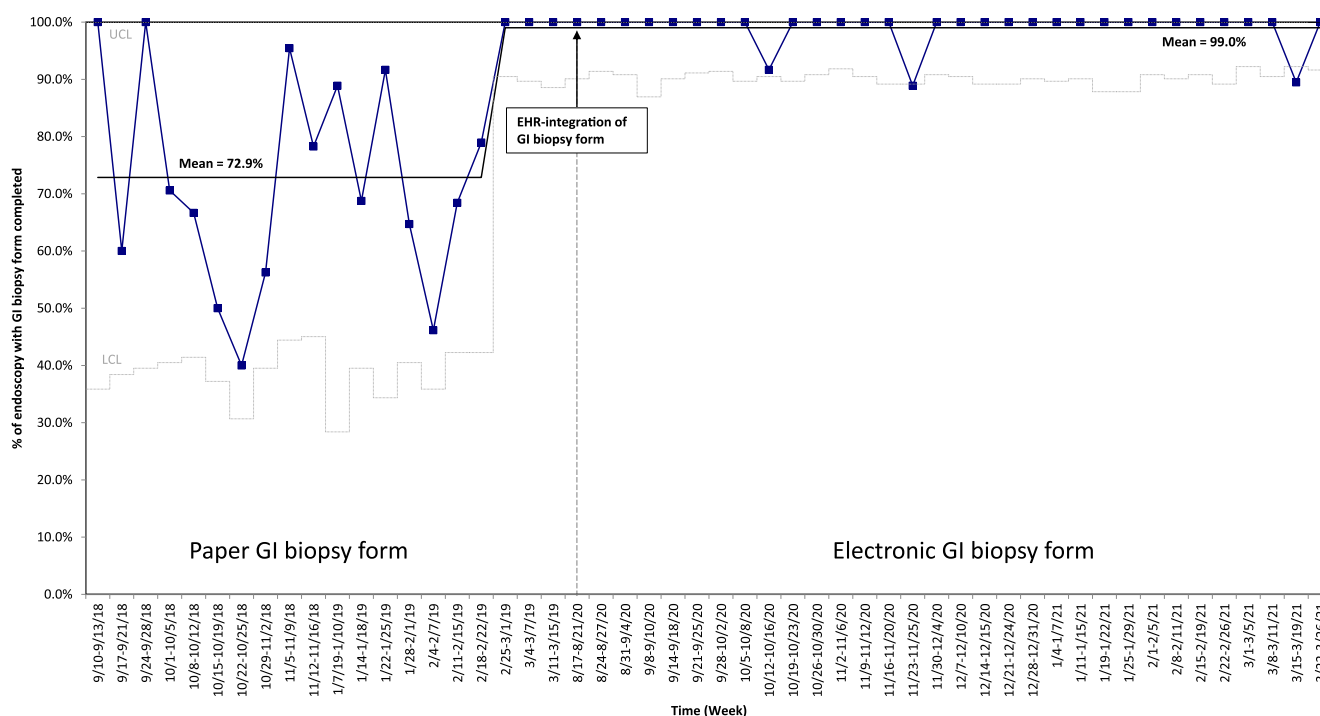


FIGURE 2 P-chart showing utilization of GI biopsy form over time. Each point represents the percentage of completed GI biopsy forms from all upper endoscopies performed per week. The vertical dash line separates the initial implementation of the paper version of the GI biopsy form from the later electronic version embedded in the EHR. The center horizontal black line represents the mean utilization rates through different stages of interventions. The UCL and LCL are represented by the dotted gray lines. EHR, electronic health record; GI, gastrointestinal; LCL, lower control limit; UCL, upper control limit.

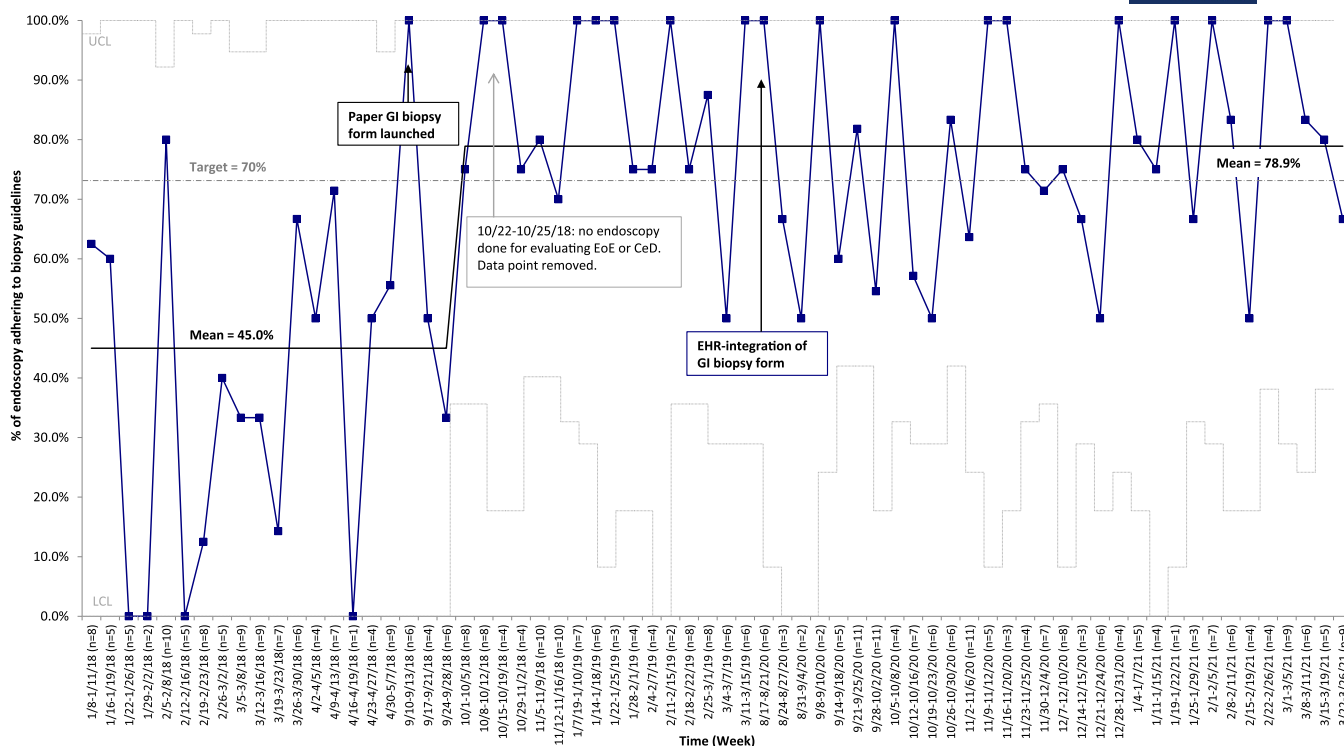


FIGURE 3 P-chart showing overall adherence to biopsy guidelines (EoE and CeD) over time. Each point represents the percentage of endoscopies that met disease-specific biopsy guidelines from all upper endoscopies performed for suspected EoE and/or CeD per week. The center black line represents the mean biopsy guideline adherence through different stages of interventions. A target adherence of 70% is noted by the dashed gray line. A removed data point is annotated with a gray arrow. CeD, celiac disease; EHR, electronic health record; EoE, eosinophilic esophagitis; GI, gastrointestinal; LCL, lower control limit; UCL, upper control limit.

adherence, but the initial improvement in biopsy practice was sustained through the implementation of the EHR-based form for over 32 weeks. There was also reduced variability in biopsy guidelines adherence compared to the pre-intervention period.

Subgroup analysis was performed to examine biopsy guidelines adherence within EoE and CeD. A total of 187 endoscopies were performed for suspected EoE and a total of 104 endoscopies were performed for suspected CeD during the intervention period. Guidelines adherence was reported for every 5 endoscopies performed for each disease indication. An improvement in EoE biopsy guidelines adherence was seen from baseline average of 55% to 84%, and improvement in CeD biopsy guidelines adherence was seen from baseline average of 13.3% to 69.5%. Both centerline shifts were associated closely with the launch of the initial GI biopsy form (Figure 4).

3.3 | Immediate and delayed complications (balancing measures)

Both immediate (within 48 h) and delayed complications (up to 7 days) were followed, and both remained at zero throughout the duration of the study.

4 | DISCUSSION

We improved our existing endoscopic biopsy practices by creating a standardized biopsy form with disease-specific biopsy protocols embedded into the EHR and integrated into our current endoscopy workflow. With these interventions, our endoscopists showed significant improvement in obtaining biopsies following best-practice guidelines when evaluating EoE (55%–84%) and CeD (13.3%–69.5%). An overall improvement in biopsy guideline adherence was seen from baseline of 45% to 78.9% within 4 weeks of implementation of the GI biopsy form and the improvement was sustained throughout the duration of the study. By using automations in the EHR to prompt completion of the form, we were able to achieve a consistently high level of utilization, averaging 99%.

Reasons identified in our root cause analysis for poor biopsy guideline adherence include variable knowledge in EoE and CeD, difficulty recalling or lack of familiarity with various biopsy guidelines, and lack of clearly communicated indication(s) when endoscopy was being performed by a different provider. The GI biopsy form created easily accessible biopsy protocols that were integrated as part of the endoscopy workflow and can be updated as new guidelines are published,

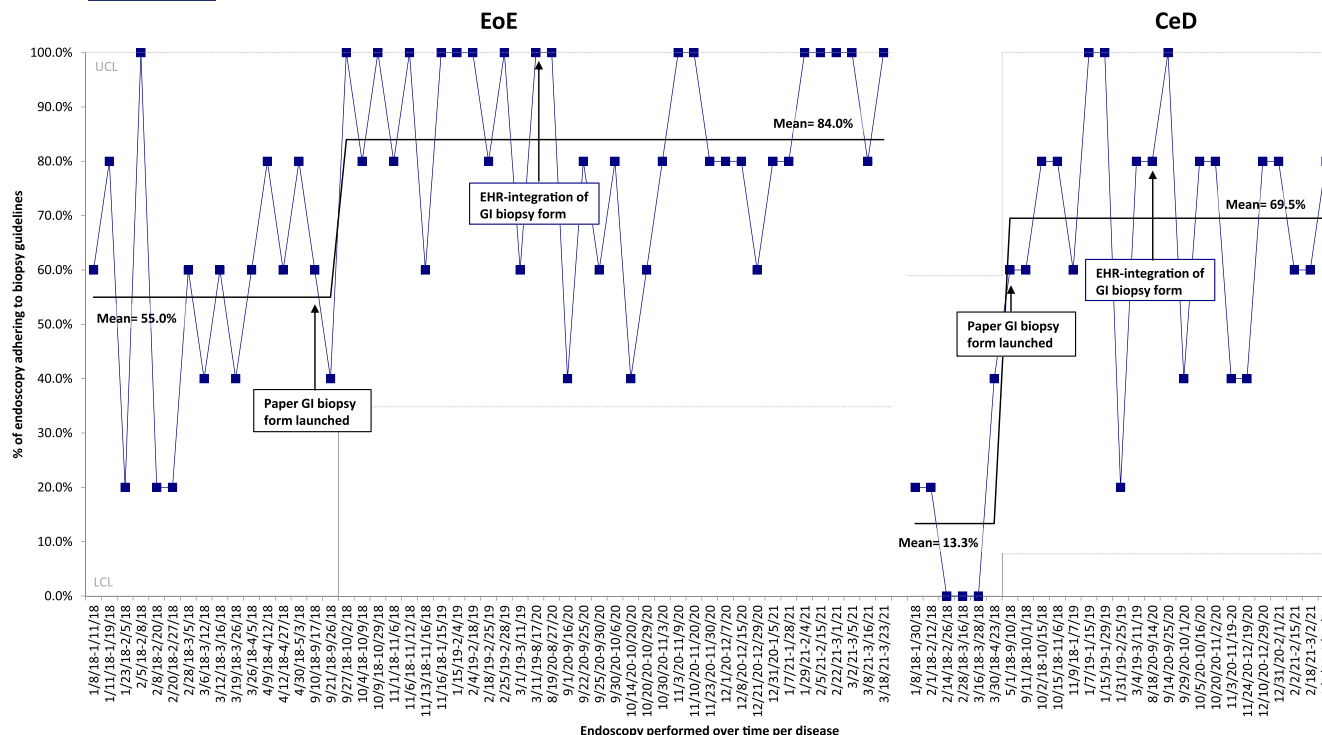


FIGURE 4 P-charts showing biopsy guideline adherence separated by disease. Each point represents the percentage of endoscopies meeting disease-specific biopsy guideline for every five endoscopies performed for the indicated disease. The center black line represents the mean guideline adherence through different interventions. For CeD, the chart was adjusted to reflect where the true process change likely occurred. The data point immediately before process change likely represents common cause variation within a small baseline sample. CeD, celiac disease; EHR, electronic health record; EoE, eosinophilic esophagitis; GI, gastrointestinal; LCL, lower control limit; UCL, upper control limit.

reducing the burden on the endoscopist to remember varying biopsy guidelines. Apart from improving biopsy accuracy, we found that the EHR-based biopsy form inadvertently served as a direct and secure route for communicating specific endoscopy needs/concerns between the primary clinician and the endoscopist performing the procedure, improving operational efficiency, and reducing communications external to the EHR which could be difficult to track.

Previous studies examining biopsy practices in EoE and CeD were mostly retrospective studies that examined large cohorts of upper endoscopies with biopsies obtained.^{16,17} However, obtaining all disease-specific biopsies on every endoscopy performed may not be practical and may add unnecessary time and cost to the procedure. We detailed a way for the primary clinician to indicate suspected disease(s) and include specific instructions at the time of endoscopy request, therefore creating a ‘roadmap’ for anticipated biopsies. We believe examining biopsy guideline adherence based on disease suspicion is a more precise measure that better reflects actual practice in endoscopic evaluation of EoE and CeD.

Surprisingly, we did not observe further improvement in adherence to biopsy guidelines with EHR integration of the GI biopsy form. One possibility may

be that with the shift from the endoscopist to the primary clinician completing the EHR-based form, the form may not have been reviewed consistently by the endoscopist. A section was created for the endoscopist to mark if they reviewed the form, but it was not consistently used. We suspect at least a good portion of the EHR forms were still being reviewed by our endoscopists as adherence did not drift back down toward the pre-intervention level. Regardless, finding a more reliable way to monitor how the form is being reviewed in the procedure room and adding automated reminders may help further improve our adherence to biopsy guidelines. We also observed a slight decrease in adherence in the immediate period after the implementation of the EHR-based form. We suspect this reflects the natural learning period with any new EHR-based changes.

A few limitations were noted in our study. The study coincided with the onset of the COVID-19 pandemic, which led to the suspension of elective endoscopy and a significant pause in data collection. While elective endoscopy resumed in June of 2020, and we were able to launch the EHR-based biopsy form by August 2020, the impact of the pandemic was profound, and there were fundamental changes in clinical operations that likely affected our data post-EHR integration.

Additionally, to maintain consistency in the operational definitions of our metrics, we used the strictest criteria to identify suspected CeD, leading to a very small CeD baseline cohort due to variation in the documentation.

Future analysis would focus on examining the rate of disease detection with our interventions to see if the improved adherence to published guidelines leads to actual improvement in disease detection for EoE and CeD. As the confirmed diagnosis of EoE and CeD remains a rare event in the overall number of pediatric endoscopies being performed, we did not have a large enough sample at the current stage of this study to perform a sufficiently powered comparative analysis. Future QI efforts would also include expansion to other disease processes that are diagnosed by endoscopy and biopsies, such as helicobacter pylori gastritis and inflammatory bowel disease. Currently, there are fewer concrete biopsy guidelines surrounding these other disease processes, and therefore, we have opted to focus on EoE and CeD. Finally, future studies may consider addition of cost-benefit analysis to understand the potential cost of missed disease and repeated endoscopies resulting from suboptimal endoscopic biopsies.

5 | CONCLUSIONS

Standardized EHR-based endoscopic biopsy protocols are an effective tool to help endoscopists follow best-practice guidelines in obtaining biopsies during routine upper endoscopies performed to evaluate EoE and CeD. In group settings where endoscopy may be performed by different providers, it helps to succinctly communicate specific indications and needs for a particular patient, and to standardize care across providers who may have different levels of disease-specific expertise. Future studies may expand to include other diseases, and additional cost-benefit analysis may be helpful to understand the potential cost of missed disease and unnecessarily repeated endoscopies.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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