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Health information technology tools to accelerate gastrointestinal evaluation in patients with iron deficiency anaemia: a cluster randomised controlled trial

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ABSTRACT

Objective System-level safety measures do not exist to ensure that patients with iron deficiency anaemia (IDA) undergo proper diagnostic evaluations. We sought to determine if a set of EHR (electronic health record) tools and an expedited referral workflow increase short-term completion of bidirectional endoscopy in higher risk patients with IDA.

Materials and methods We conducted a pragmatic, cluster-randomised trial randomised by primary care physician (PCP) that included 16 PCPs and 316 patients with IDA. Physicians were randomised to intervention or control groups. Intervention components included a patient registry visible within the EHR, point-of-care alert and expedited diagnostic evaluation workflow for IDA. Outcomes were assessed at 120 days. The primary outcome was completion of bidirectional endoscopy. Secondary outcomes were any endoscopy completed or scheduled, gastroenterology consultation completed, and gastroenterology referral or endoscopy ordered or completed.

Results There were no differences in the primary or secondary outcomes. At 120 days, the primary outcome had occurred for 7 (4%) of the intervention group and 5 (3.5%) of the control group. For the three secondary outcomes, rates were 15 (8.6%), 12 (6.9%) and 39 (22.4%) for the immediate intervention group and 10 (7.0%), 9 (6.3%) and 25 (17.6%) for the control group, respectively, p>0.2. Lack of physician time to use the registry tools was identified as a barrier.

Discussion and conclusion Providing PCPs with lists of patients with IDA and a pathway for expedited evaluation did not increase rates of completing endoscopic evaluation in the short term.

Trial registration number NCT05365308.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ System-level safety measures do not exist to ensure that patients with iron deficiency anaemia (IDA) undergo proper diagnostic evaluation.

WHAT THIS STUDY ADDS

⇒ This study, which evaluated a set of EHR (electronic health record) tools, including a patient registry and an expedited referral workflow to increase short-term completion of bidirectional endoscopy in higher risk patients with IDA, did not increase rates of completing endoscopic evaluation in the short term.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Clinical leaders should not assume that presenting primary care physicians with a list of potentially at-risk patients and an expedited workflow will drive rapid clinical action without additional supports.

⇒ Team-based care is another strategy that could be explored to enhance the completion of diagnostic evaluations for patients with IDA.

INTRODUCTION

Delayed diagnosis of gastrointestinal and other cancers among patients with abnormal signs, symptoms or test findings is a significant quality problem and a leading cause of paid malpractice claims in adult primary care.[1 2] In a large systematic review, shorter time to diagnosis was associated with more favourable outcomes in many cancers, suggesting that efforts to expedite the diagnosis of symptomatic cancer are likely to have benefits for patients in terms of improved survival.[3] Patients with findings concerning for colorectal or upper gastrointestinal cancer may have delayed diagnosis if (1) clinicians do not provide recommendations for an appropriate workup or referral, or (2) the recommended workup does not occur as intended.[4 5] Iron deficiency anaemia (IDA) is a potential early diagnostic sign of gastrointestinal malignancy.[6]

The American Gastroenterological Association (AGA) recommends bidirectional endoscopy as the mainstay for gastrointestinal evaluation, particularly in men and in postmenopausal women for whom no other unequivocal source of iron deficiency has been identified.[6] The global COVID pandemic placed a burden on endoscopy

volumes across the world, resulting in reduced access and delays.[7]

We sought to design and test a set of primary-care-physician-facing clinical decision support tools including a patient registry visible within the EHR (electronic health record), point-of-care alert (Best Practice Advisories in the Epic electronic health record, Epic Systems, Verona, Wisconsin, USA), and an expedited diagnostic evaluation workflow to identify, track and facilitate the care of unevaluated patients with IDA seen in primary care. We conducted a physician cluster randomised trial among primary care physicians (PCPs) recruited from within a single health system who agreed to be randomly assigned to have the tools made available to them at the start of the study, or after a 120-day delay.

METHODS

The study was performed in primary care practices in a large metropolitan city and its northern suburbs, affiliated with a large academic health system. Prior to this trial, we performed a preliminary investigation to estimate how often physicians would judge patients detected by automated review of EHR data would warrant gastroenterological evaluation. We asked three PCPs to review their lists of patients determined to have IDA or iron deficiency without anaemia. These PCPs reviewed their patients' charts and made an assessment of whether additional gastroenterological evaluation was warranted. They judged that 63% of 59 patients required further evaluation (online supplemental table S1). We then conducted a cluster randomised control trial involving 16 PCPs and their 316 patients found to have IDA to evaluate the effects of this strategy compared with usual care between 28 February 2022 and 28 June 2022. Five of the 16 physicians were from with an academic faculty practice and the remaining 11 worked at non-academic practices in urban or suburban locations.

The study was registered in the ClinicalTrials.gov identifier: NCT05365308.

Participants

We approached PCPs at meetings or via email, explained the planned study procedures and included physicians who agreed to participate and be randomised to immediately receiving the intervention procedures or to receive them 120 days later. Formal informed consent was waived for this quality improvement study. Patients of the participating PCPs who met eligibility criteria were included in the study. Men were eligible who were age 18 years or older with a haemoglobin <130 g/L and women were included if age was 40 years or older and haemoglobin was <120 g/L. Both were required to have ferritin below 45 ng/mL and have received the plurality of their health system primary care visits in the prior 18 months from a participating PCP. Patients were excluded if they had completed bidirectional endoscopy in the prior 3 years or if they had three visits with gastroenterologists within the system within the prior 2 years.

Interventions

We created reports of patients meeting the IDA eligibility criteria and made them displayable within the EHR. Physicians were provided a 30-minute training session on how to access and use their reports. Physicians could directly open patients' charts from this report. We also developed a passive clinical decision support alert for office, telehealth and telephone encounters that called attention to the IDA at the point-of-care and were linked to a prioritised referral for endoscopy. The alert was approved for content and use by the health system's Clinical Decision Support Committee and the system's Primary Care Health Clinical Collaborative committee that oversees new changes to primary care. Using an order set linked to this alert, PCPs could directly order upper and/or lower endoscopy within an expedited work queue in the gastroenterology department in their region. If clinicians deemed the patient to be at increased risk from the procedure due to comorbidities, the option for an expedited gastroenterology consultation was provided. Clinicians were also able to acknowledge completion of workup done elsewhere, workup already in progress and if the patient was not medically suitable for further evaluation. Physicians randomised to the immediate intervention group received these interventions at the start of the intervention period and those randomised to the control group received them after 120 days.

Measures

All outcomes were assessed 120 days after the study start date, 28 February 2022. The primary study outcome was the proportion of patients who completed bidirectional endoscopy. Patients who had received either upper or lower endoscopy in the prior 3 years only had to receive the form of endoscopy that was not already performed to meet the primary outcome. Secondary outcomes were (1) any endoscopy completed or scheduled, (2) gastroenterology consultation completed and (3) gastroenterology referral or endoscopy ordered or completed. Post hoc outcomes were colonoscopy performed, colonoscopy ordered, oesophagogastroduodenoscopy performed and oesophagogastroduodenoscopy ordered. We performed an automated, blind assessment of the study outcomes using searches of the discrete data within the electronic health record. Physician authors reviewed patient charts to validate these findings and recorded instances where there was evidence of procedure or referral completion outside of the health system.

Randomisation

Participating PCPs were stratified by the two regions (metropolitan city vs suburbs) and randomly assigned to the two groups. This was done by an analyst blinded to the group assignment until after the randomisation was completed.

Table 1 Participant characteristics

	Delayed implementation (control)	Immediate implementation (intervention)
Participating primary care physicians	**N=8**	**N=8**
Female, n (%)	5 (62.5)	5 (62.5)
Average years in practice, mean (range)	25.7 (4–38)	21.8 (6–39)
Patients with iron deficiency anaemia	**N=142**	**N=174**
Age, mean (SD) (range)	60.6 (16.5) (40–93)	59.5 (15.6) (33–100)
Female, n (%)	110 (77.5)	149 (85.6)
Ethnicity/race		
Hispanic	20 (11.3)	13 (8.8)
Non-Hispanic white	88 (49.7)	78 (53.1)
Non-Hispanic black	45 (25.4)	26 (17.7)
Asian	11 (6.2)	16 (10.9)
Other/unknown	13 (7.3)	14 (9.5)
Haemoglobin (g/L) mean (range)	108 (67–143)	111 (59–147)
Ferritin (ng/mL), mean (range)	17.6 (2–44.6)	21.4 (2–44)

Statistical analysis plan

To determine the study sample size, we examined historically the rate at which patients meeting these eligibility criteria went on to complete bidirectional endoscopic evaluation over a 120-day period and estimate the intraclass correlation coefficient for this outcome at the PCP level. In the historical control period, the mean completion of the primary outcome per PCP at 120 days was 4.5%. To have at least 80% power to detect an absolute increase in the primary outcome of 15% with an alpha error rate of less than 0.05, we estimated that approximately 8 PCPs per group with an average of 10 eligible patients per PCP would be needed if the intraclass correlation coefficient of this outcome was between 0.01 and 0.05. We analysed the outcomes using generalised logistic regression with physician-level random effects.

After the completion of the intervention period, intervention-group PCPs were asked to complete a brief survey via email that included closed-ended and open-ended questions about the intervention.

RESULTS

Participants

We approached 16 PCPs and 16 agreed to participate. The stratified randomisation produced similar groups (table 1). The flow of participants is shown in figure 1.

Outcomes

Outcomes in the intervention and control groups at 120 days (about 4 months) did not differ (table 2). The primary study outcome of completing bidirectional endoscopy at 120 days occurred for 7 (4.0%) of eligible patients in the intervention group and 5 (3.5%) in the control group. Secondary outcomes also did not differ (table 2). There were numerically more patients in the intervention group with a colonoscopy ordered within the 120-day observation 10.3% vs 4.2% among controls (p=0.054).

During the intervention period, six of the eight intervention-group physicians attended a training session, and five of eight ran their registry report 13 times after being trained. Three of the eight intervention PCPs used the point-of-care alert to acknowledge or order testing for seven patients in the intervention group. One of the eight intervention physicians used the registry report and provided outreach to a patient with abnormal findings, which was asynchronous to a point-of-care encounter. Two advanced gastrointestinal malignancies were found in the intervention group and none in the control group. Five out of eight intervention group physicians completed the post-study survey. Three of the five clinicians had greater than 20 years of clinical experience and the remaining two had 5–10 years of clinical experience. Four of the five (80%) clinicians were dissatisfied by the process used to identify patients with IDA and facilitate GI evaluation. Reasons cited included the lack of another staff member or nurse to review for appropriateness and the lack of time available to review.

DISCUSSION

In this study, providing PCPs several EHR tools including a patient registry and workflow for expedited workup of patients with IDA did not lead to an increase in endoscopy completion in the short term as intended. This study also demonstrated that PCPs rarely used the patient registry following the training session. PCPs who successfully ordered the expedited workup tended to do so using the decision support at the point-of-care. There were numerically more colonoscopies ordered in the intervention group (10 vs 4%), and this difference may have achieved statistical significance with a larger sample size or longer

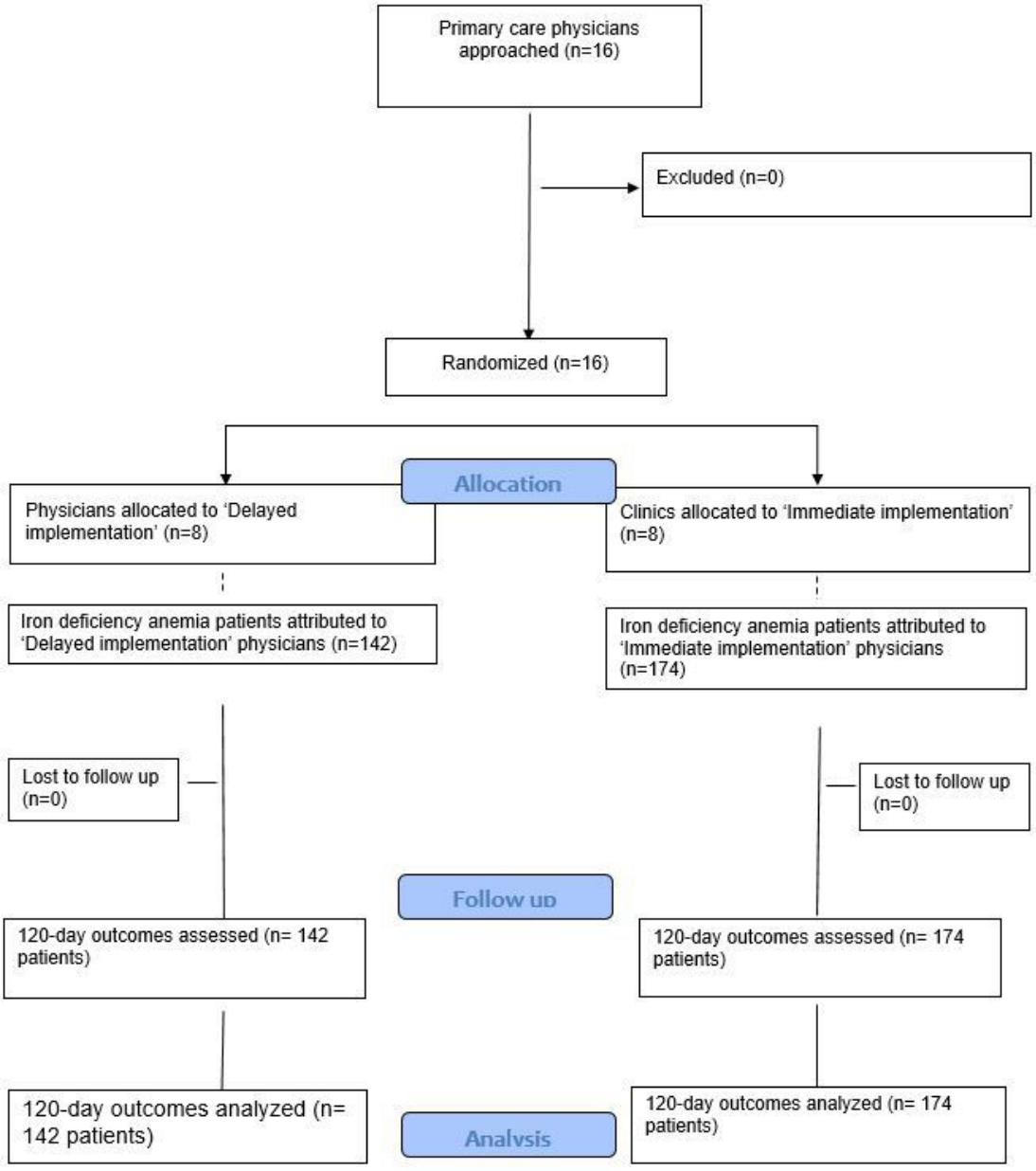

Figure 1 Participant Flow Diagram.

follow-up. Physician survey respondents indicated their dissatisfaction when presented with a new clinical task that was asked of them without the provision of extra time to perform it, or another team member to assist.

Algorithms applied to EHR data have previously been shown to be useful for identifying patients with cancer risk in a large integrated health system based on findings such as prostate-specific antigen elevation, IDA, a positive faecal occult blood test or haematochezia.[8] The effectiveness of clinical decision support aimed at reducing delayed cancer diagnoses has been variable. Active choice ordering, which uses alerts that require clinicians to make a choice to accept or decline a recommended action, has been shown to increase the ordering and completion of colon cancer screening and the ordering of mammography.[9] We are not aware of other studies that took the approach of providing PCPs with lists of their patients with high-risk findings using an EHR registry combined with an expedited work flow.

Three quarters of intervention PCPs willingly participated in the training for this study, and the physician trainer's impression was that they perceived that the tools would be helpful. However, post intervention survey responses revealed that most respondents were dissatisfied with the use of the registry, and that lack of time and lack of additional human resources were cited as reasons for this dissatisfaction.

This study has limitations that should be noted. First, this study was done with a small number of PCPs. While the study was adequately powered to detect a 15% increase in the primary outcome over the time period we examined, inclusion of a small number of physicians

Table 2 Study outcomes

	Delayed implementation (control) (N=142)	Immediate implementation (intervention) (N=174)	P value
Primary outcome			
Completion of upper and lower endoscopy at 120 days, n (%)	5 (3.5)	7 (4.0)	1.0
Secondary outcomes			
Any endoscopy completed or scheduled at 120 days, n (%)	10 (7.0)	15 (8.6)	0.68
Gastroenterology consultation completed at 120 days, n (%)	9 (6.3)	12 (6.9)	1.0
Gastroenterology or any endoscopy referral provided or completed at 120 days, n (%)*	25 (17.6)	39 (22.4)	0.29
Additional outcomes			
Colonoscopy completed or scheduled at 120 days, n (%)	5 (3.5)	8 (4.6)	0.78
Colonoscopy ordered at 120 days, n (%)	6 (4.2)	18 (10.3)	0.054
Oesophagogastroduodenoscopy completed or scheduled at 120 days, n (%)	6 (4.2)	8 (4.6)	1.0
Oesophagogastroduodenoscopy ordered at 120 days, n (%)	7 (4.9)	14 (8.1)	0.36

*Specifically, this outcome is indicated by the presence in the EHR of a completed office visit or telehealth visit with a physician, physician assistant or advance practice nurse in the within gastroenterology or the presence of a signed order for a gastroenterology referral or an endoscopy referral.
EHR, electronic health record.

may have limited our ability to determine if the approach taken here may appeal to a subgroup of PCPs. Second, because the duration of the study was short and the use of the registry lists to prompt outreach between office visits was low, 120 days may not have been long enough to see a difference brought about by the point-of-care alerts. Third, this study was conducted in a single health system with a small number of physicians, which may further limit its generalisability. Fourth, while our preliminary investigation suggested that a majority of patients from several other PCPs identified using these methods would warrant further clinical action, we do not have a direct measurement of how many patients included in the trial population would be judged by their physicians to have directly actionable findings.

CONCLUSION

The negative findings of this trial and the unfavourable reception met by adding asynchronous work without additional support or staffing to the PCPs already busy work load suggest that solely providing PCPs with lists of patients with unevaluated IDA and an expedited referral pathway is not sufficient to lead to meaningful improvements in care. Identifying these patients at the point-of-care and providing the capability for ordering an expedited workup seemed promising and may warrant longer term investigation. Team-based care, whereby a clinical team member, such as an advanced practice nurse, is tasked with review and outreach to high-risk patients, is another strategy that could be explored to enhance the completion of diagnostic evaluations for patients with IDA.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The Quality Oversight Committee approved the study as quality improvement, and the Institutional Review Board determined that it was not human subjects research.

Provenance and peer review Not commissioned; externally peer reviewed.

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Supplemental Results for Manuscript titled "Health Information Technology Tools to Accelerate Gastrointestinal Evaluation in Patients with Iron Deficiency Anemia: a Cluster Randomized Controlled Trial"

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Table S1. Results of Chart Reviews by Three Primary Care Physicians of Patients Determined to Have Iron Deficiency without Upper and Lower Endoscopy in the Prior Three Years

Clinician Assessment		**All patients, No. (%)**	**Iron deficiency anemia, No. (%)**	**Iron deficiency without anemia, No. (%)**
Total		59 (100)	33 (100)	26 (100)
Directly actionable		37 (63)	22 (67)	15 (58)
	GI evaluation warranted, not previously referred	21 (36)	12 (36)	9 (35)
	GI evaluation warranted, previously referred but not completed	2 (3)	2 (6)	0 (0)
	Inadequate information in record to determine if GI workup was warranted	14 (24)	8 (24)	6 (23)
Not directly actionable		22 (37)	11 (33)	11 (42)
	Under active GI care	13 (22)	7 (21)	6 (23)
	Workup completed elsewhere	7 (12)	3 (9)	4 (15)
	Workup not indicated based on clinical context	2 (3)	1 (3)	1 (4)