Received: 16 May 2023 | Accepted: 30 April 2024

DOI: 10.1002/jpn3.12246

JPGN

ORIGINAL ARTICLE

Gastroenterology: Inflammatory Bowel Disease

Standardizing steroid protocols for newly diagnosed inflammatory bowel disease patients: A quality improvement initiative

Nuphar Lendner[1] | **Sharon Perry**[2] | **Thomas J. Sferra**[2] | **Jonathan Moses**[3] | **Denise D. Young**[2]

[1]Pediatrix Gastroenterology of the Rocky Mountains, Denver, Colorado, USA

[2]Division of Pediatric Gastroenterology, Hepatology & Nutrition, UH Rainbow Babies and Children's Hospital, Cleveland, Ohio, USA

[3]Division of Pediatric Gastroenterology, Stanford University School of Medicine, Palo Alto, California, USA

Correspondence

Denise D. Young, 11100 Euclid Ave, Mailstop RBC 6004, Cleveland, OH 44106, USA.
Email: Denise.Young@uhhospitals.org

Funding information

None

Abstract

Objectives: Systemic steroids can be used for induction of inflammatory bowel disease (IBD), but are not recommended as long-term therapy. Steroid weaning requires rigorous monitoring of symptoms, which may be cumbersome and lead to missed opportunities. We aim to describe our local quality improvement (QI) initiative to improve and standardize the steroid weaning process.

Methods: After identifying drivers of steroid weaning, a protocol was developed and implemented for newly diagnosed IBD patients started on steroids and subsequently initiated on anti-TNF-α therapy. Interventions included development of a tapering schedule, and standardizing communication with patients and evaluation of symptoms. The primary aim was to increase the percent of patients called on a weekly basis by 20%; secondary aims were to decrease the median steroid days by 25% and to increase the number of our patients weaned off steroids at 8 weeks from 35% to 75% by 1 year after the initiative.

Results: The median percent of patients called on a weekly basis to assess clinical symptoms and to wean steroids increased to 80% after 1 year. The median number of systemic corticosteroid days decreased from 67.5 to 50.5 days post-protocol implementation with 61.1% patients weaned off by 8 weeks from discharge. Zero patients were admitted for flares with the protocol implementation.

Conclusion: Our experience illustrates that QI methodology can be used successfully to improve and standardize the steroid weaning process, leading to shortened steroid duration and without increased flares and hospitalizations.

KEYWORDS

adalimumab, corticosteroids, Crohn disease, infliximab, ulcerative colitis

1 | INTRODUCTION

Systemic corticosteroids (CS) are often utilized to induce remission in pediatric patients with inflammatory bowel disease (IBD) before transitioning to long-term therapy.[1–3] Rates of remission with CS are not superior to rates of remission using anti-TNF-α alone and are not effective in mucosal healing or preventing disease progression.[1,3–7] Due to their adverse effects, CS are not recommended for long term treatment of IBD. Initiation and completion of CS taper should be done as efficiently and safely as possible, and various weaning schedules have been proposed by ECCO, ACG, and ImproveCareNow Network. However, center and

provider variations, experience, and patient symptoms, can influence rate of steroid discontinuation.[1,8,9]

At our institution, local variability was noted in the methods for follow up communication and CS weaning rate. Some patients received weekly calls from outpatient nurses with tapering instructions while others received a calendar. Some physicians decreased by 5 mg weekly; others decreased by 10 mg weekly. Creating a standardized method to evaluate symptoms of pediatric IBD patients and manage their CS taper would help prevent missed opportunities for weaning and avoid prolonged CS use. We proposed an intervention in which patients would be called weekly to assess symptoms and appropriateness for wean. This would not only decrease unnecessary extended CS courses, but also identify patients in whom a slower wean may be needed.

The primary aim of our quality improvement (QI) initiative was to increase the percent of patients called on a weekly basis by 20%. The secondary aims were to decrease the median steroid days by 25% and increase the number of newly diagnosed IBD patients on anti-TNF-α medications to be weaned off CS by 8 weeks after hospital discharge from 38% to 75%.

What is Known

- Systemic steroids can be used to induce remission in pediatric IBD patients but should not be used for long term therapy due to abundance of adverse effects.
- Steroids should be weaned with initiation of long term therapy for pediatric patients with IBD.

What is New

- Standardization of steroid titration protocols through QI methodology prevented missed opportunities for weaning and unnecessary prolongation of steroid duration.
- Utilization of electronic medical record improves steroid tapering in pediatric IBD.

2 | METHODS

2.1 | Context

Our Pediatric Section comprises of nine physicians, two nurse practitioners, and three fellows who care for over 300 pediatric IBD patients. Fellows are supervised in clinic by the same physician each week in fellow's clinic. There is one inpatient nurse, four full time outpatient nurses and one part time outpatient nurse. Each full time nurse covers 2–3 primary providers and the part time outpatient nurse covers the providers whose nurse is not working that day. At the time of our QI project implementation, newly diagnosed IBD patients were typically admitted to the hospital for further treatment and evaluation. Patients were started on intravenous (IV) CS (1 mg/kg with max of 32 mg daily) if other treatments such as exclusive enteral nutrition were not started. Maximum dose of prednisone at discharge was 40 mg once daily. If anti-TNF-α medication was indicated, patients received their first dose before discharge.

2.2 | Key drivers and interventions

A key driver diagram is shown in Figure S1. Key drivers were standardizing the method by which CS were weaned, and establishing reliable symptom assessment and patient follow up. Plan-Do-Study-Act (PDSA) cycles were used to assess our interventions. In November and December 2021 we provided an overview of the initiative and protocol through a series of meetings. We implemented the protocol on January 3, 2022 and conducted the following interventions.

1. *Standardized patient communication through weekly telephone calls and implementation of dot phrases*: The protocol is initiated at discharge when the inpatient nurse notifies the outpatient nurse with information regarding a patient's IBD diagnosis and dose of CS at discharge. The outpatient nurse makes the first telephone call 2 weeks from discharge to assess symptoms and readiness to start CS wean. The call and patient symptoms are documented through the use of dot phrases (Figure S2). Patients continue to receive weekly calls until CS are discontinued. If families were not able to be reached, a voice message was left, and multiple attempts would be made every 1–2 days. Future tasks were made by the nurses to remind them to call patients, and would be set to complete once families were reached.
2. *Standardized evaluation of patient symptoms using a modified version of the short pediatric Crohn's disease activity index (sPCDAI) and the pediatric ulcerative colitis activity index (PUCAI) scores*: A modified version of the sPCDAI and PUCAI scores were used to measure disease activity and guide CS weaning[10,11] (Figure S2). For Crohn's disease, a score of <15 correlated with quiescent symptoms, 15–29 correlated with mild symptoms, and ≥30 correlated with moderate to severe symptoms. For ulcerative colitis, a score of 10 correlated with

quiescent symptoms, a 10–34 correlated with mild symptoms, and ≥35 correlated with moderate to severe symptoms.

3. *Development of a weaning schedule*: We adapted the CS tapering schedule from ECCO/ESPGHAN consensus guidelines.[1] The majority of our providers tapered CS by 10 milligrams (mg) weekly if clinically appropriate, and this was carried over to our new protocol. Once patients were weaned to 5 mg, they were kept at that dose for 1 week before discontinuation. Starting 2 weeks after discharge, the patients received a telephone call from the outpatient nurse to review their symptoms. Based on their clinical symptom assessment, CS were either weaned, kept at the same dose, or increased. There were also instructions to notify the provider if CS dose had to be increased, and if the wean could not be continued for two more weeks in a row (Figure S2). For patients discharged home on 40 mg prednisone daily and able to wean weekly based on clinical symptoms, the expected number of CS days would be approximately 49 days from discharge.

2.3 | Study of interventions

The PI was notified of any newly diagnosed IBD patient admitted to the hospital and started on, or anticipated to start on anti-TNF-α medications, by the inpatient nurse. Weekly chart reviews were conducted to evaluate whether the protocol was followed (initial call at 2 weeks, use of dot phrase, calling weekly), note reasons for protocol deviation, and record dates of initial steroid wean and cessation. On a monthly basis, the process was evaluated to determine whether additional interventions were required.

2.4 | Measures

The primary outcome measure was the median number of CS days in our newly diagnosed IBD patients. Process measures evaluated were the percent of patients contacted at 2 weeks post-discharge and called on a weekly basis thereafter, and use of the dot phrase when assessing clinical symptoms. We also assessed whether patients were discharged home with a calendar with tapering instructions. These measures were chosen as they influenced the key drivers (Figure S1).

2.5 | Analysis

Data analyses and run charts were performed monthly to evaluate the use and effectiveness of the protocol and to drive PDSA cycles.

2.6 | Ethical considerations

This QI project was reviewed by the University Hospitals Institutional Review Board and determined to be exempt from human subject research oversight.

3 | RESULTS

3.1 | Baseline data

Retrospective baseline data was collected for pediatric patients diagnosed with IBD and admitted to the inpatient gastroenterology (GI) service from June 1, 2019 to December 31, 2020 and discharged home on systemic CS. During this time frame, our division consisted of seven physicians. All seven physicians saw IBD patients but only five physicians had patients who were admitted to the hospital following diagnosis and started on anti-TNF-α medications. Any patient followed by a pediatric GI fellow was grouped under the supervising Fellows' Clinic physician. The two nurse practitioners did not have any patients who were started on anti-TNF-α medications following IBD diagnosis. There was a total of 26 patients in the baseline cohort (Table 1).

The overall median number of CS days was 67.5 days, with a range of 32 to 111 days. Ten patients (38%) were weaned completely by 8 weeks post-discharge. There was one patient who was CS dependent, but despite this, did not have the longest number of CS. We found that the physicians whose main method of communication were giving family a calendar (physician 1 and 5) had higher median number of steroid days. There was no difference in median CS days depending on provider experience in GI or IBD. Among those receiving weekly phone calls from our outpatient nurses, the median time to wean off

TABLE 1 Demographics of patients at baseline and post-protocol initiation.

	Baseline ($n = 26$)	Post-protocol ($n = 18$)
Sex, *n* (%)		
Male	10 (38%)	10 (56%)
Female	16 (62%)	8 (44%)
IBD diagnosis		
Crohn's disease	17 (65%)	14 (78%)
Ulcerative colitis	8 (31%)	4 (22%)
IBD-U	1 (4%)	0 (0%)
Anti-TNF-α Initiated		
Infliximab	21 (81%)	12 (67%)
Adalimumab	5 (19%)	6 (33%)

of CS was 58.5 days, compared to 76 days for those who were given a calendar (Figure 1).

One patient in the baseline cohort was readmitted during the steroid wean for an IBD flare. This patient had been given a calendar to wean and had continued to wean despite worsening symptoms.

3.2 | Post-protocol data

The QI initiative was implemented in January 2022. In this time period, our division grew to nine physicians. Six of the nine physicians, and one nurse practitioner had patients who were admitted following diagnosis and started on anti-TNF-α therapy. As before, any patient followed by a pediatric GI fellow was grouped under the supervising Fellows' Clinic physician. There were a total of 18 patients in the post-protocol cohort (Table 1).

Our interventions resulted in a change over time, with the median percentage of patients called on a weekly basis increasing from 60% to 80% (Figure 2). We saw an initial compliance with the protocol, with 100% of our patients being called on a weekly basis, but this declined after 2 months. Evaluation of our initiative showed lapses in our process, including some physicians choosing to preemptively override the protocol and wean more slowly for example, by 5 mg weekly rather than 10 mg weekly, for patients with more severe endoscopic disease. In addition, some patients continued to be discharged home with a calendar tapering schedule. Based on these process measures, another educational meeting was held in May 2022 to review the protocol, with emphasis on close symptom monitoring during the weekly telephone calls. We also emailed reminders to the division to eliminate calendar tapering schedules. Following this, there was greater compliance in following the weaning schedule, and there were not any patients discharged home with a calendar.

There was a sustained increase in the percentage of patients called regularly after our educational meeting and email reminders, but we did see another decline the last 2 months as one patient was not called on a weekly basis. The range of number of days to wean off CS was between 12 and 151 days 1 year after protocol initiation, with the median number of CS days decreased by 25.2% to 50.5 days. Eleven patients (61%) were weaned off CS by 8 weeks from discharge. The patients who were on steroids for longer than 8 weeks either started the taper after 2 weeks from discharge, or required an extra week on a previous dose of CS due to symptom severity. The patient with the longest number of CS days was due to CS dependence as they continued to have symptoms during

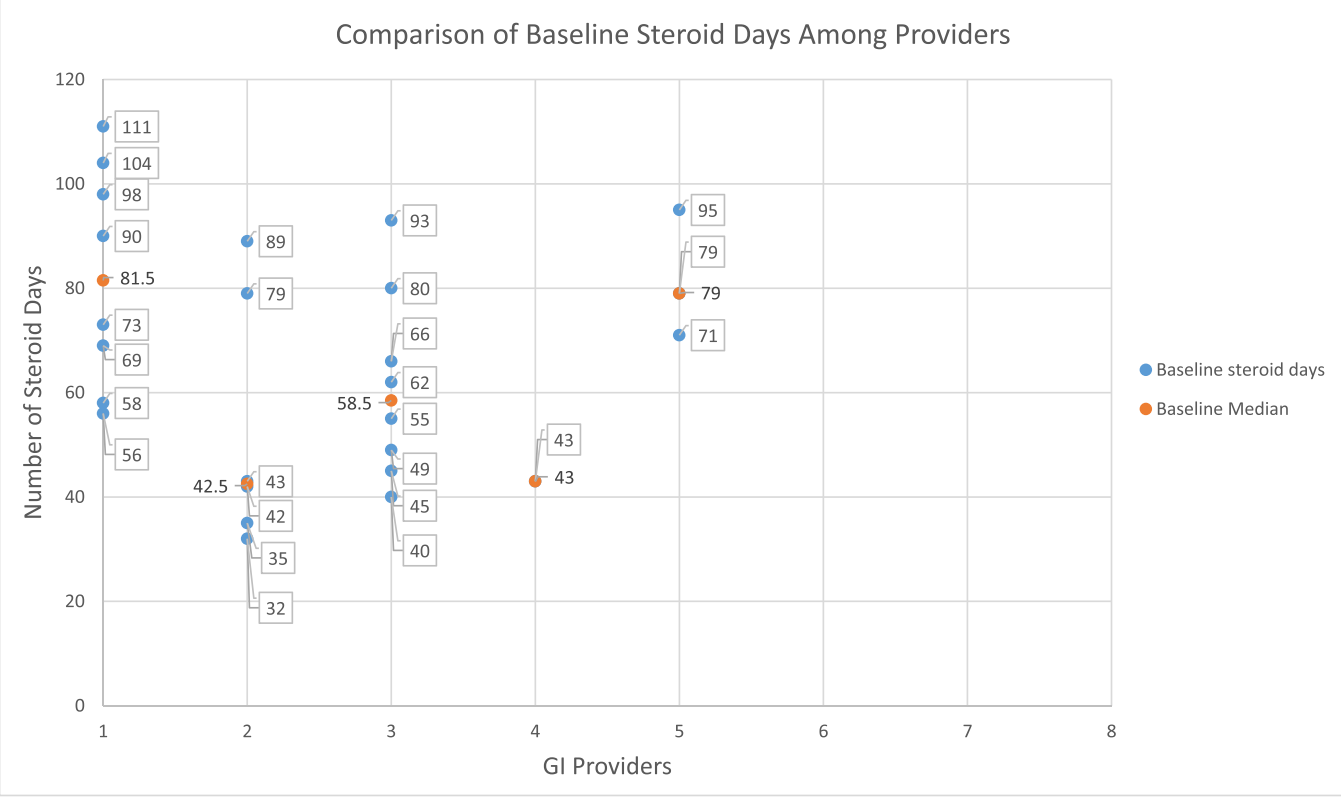

FIGURE 1 Comparison of steroid days among providers at baseline.

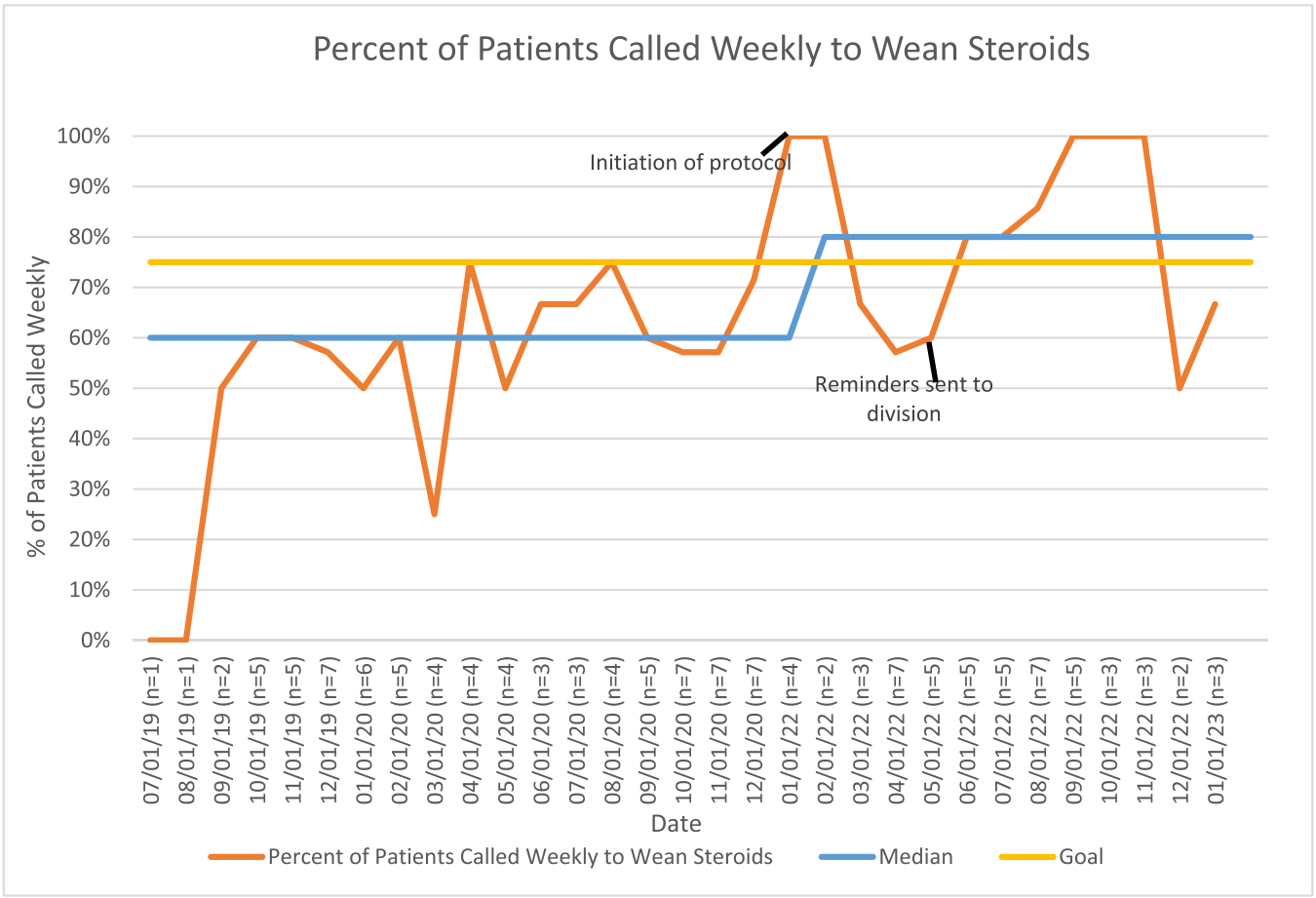

FIGURE 2 Percent of patients called weekly to wean steroids pre- and post-protocol initiation.

the steroid taper. These patients contributed to an increase in median CS days at 1 year compared to baseline from Providers 2 and 4. However, despite these individual patient circumstances, overall there was less variability and a narrower range of days in which steroids were weaned (Figure 3). We did not see an increase in the number of hospital admissions for IBD flares with implementation of the protocol. Our CS-free remission rate remained stable at 88.8% after the QI initiative.

4 | DISCUSSION

Systemic CS are often used to induce remission in newly diagnosed IBD patients, but have a significant side effect profile that makes it less favorable when compared to newer biologic therapies that work effectively to both induce and maintain remission.[2–7] Recent population based studies show varying trends of CS prescription for IBD patients.[12–15] At our institution, inconsistencies were noted in CS weaning methods of newly diagnosed IBD patients started on biologic therapy, resulting in variability in length of CS course, and resulted in missed opportunities to wean. Thus, a QI initiative was started, with a primary aim of increasing use of weekly telephone calls, and secondary aims of decreasing the median number of CS days and increasing the number of patients weaned off CS by 8 weeks from discharge.

In the 12 months after initiation of the CS tapering protocol, we achieved our primary aim, with use of weekly telephone calls increasing from a median of 60% to 80%. The median number of CS days also decreased by 25.2%. We increased the number of patients from 38% to 61.1% who were weaned off CS by 8 weeks from discharge. This was shy of our secondary aim goal of 75%. On further review, it was noted that patients who were on CS for longer than 8 weeks had mild symptoms as defined by the sPCDAI or PUCAI for a longer period of time, and were thus transitioned to a slower CS wean as outlined per protocol. Thus, this was not a failure of the QI initiative, but rather revealed a balance measure involving select patients. We established 8 weeks as a goal initially based on the assumption that most patients would be able to

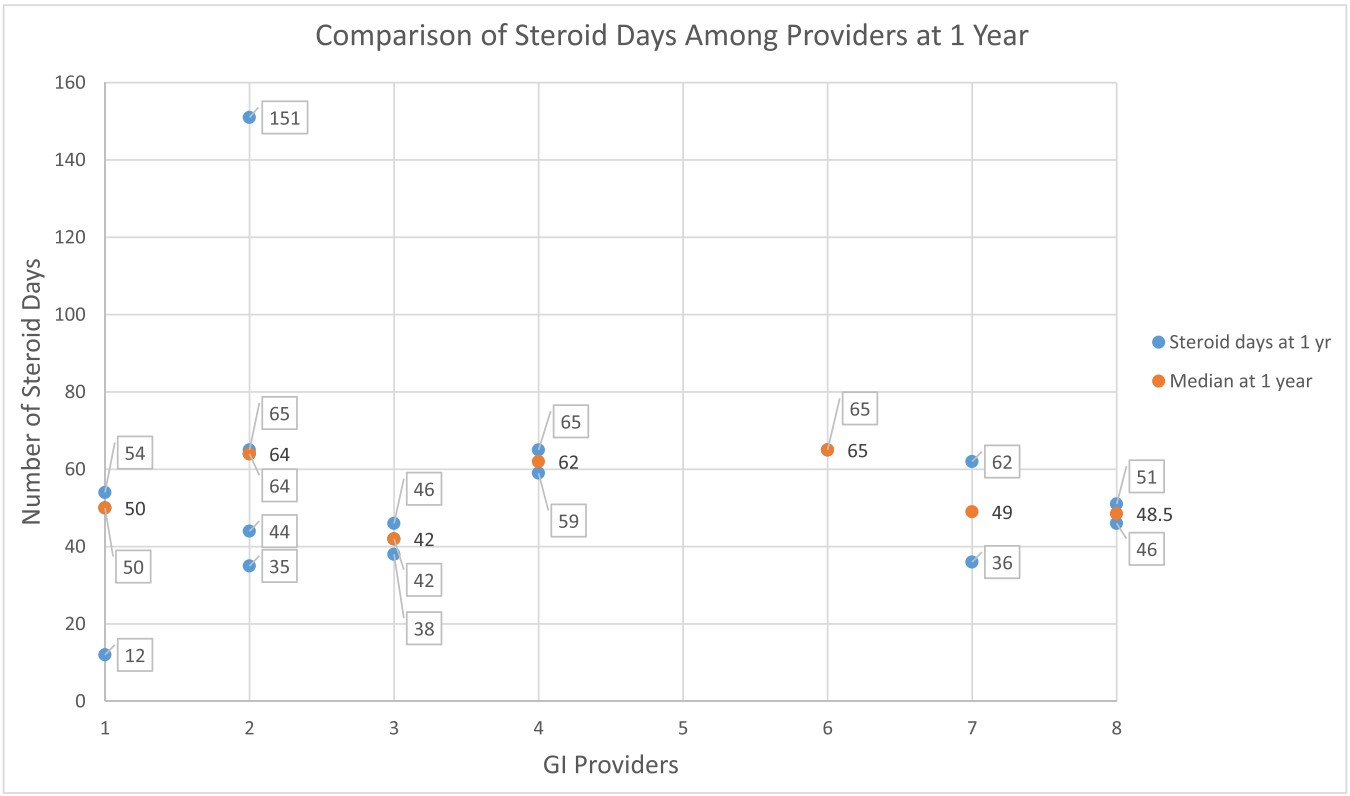

FIGURE 3 Comparison of steroid days among providers at 1 year.

wean their steroids weekly. However, as our initiative showed, some patients required a slower wean, and our protocol was able to identify those patients and respond appropriately. We did not have an increase in number of patients admitted for a flare during the steroid wean with this initiative, illustrating our protocol provided an appropriate balance of weaning steroids efficiently without increasing hospitalization and subsequently healthcare costs.

Subjectively, our standardized process was accepted positively. There was less confusion at time of discharge regarding directions for the steroid wean, as all patients were provided the same instructions to await a telephone call. In addition, the nurses appreciated that there was a standardized process for all patients and among all providers, resulting in fewer calls between nurses and providers to clarify weans, especially when cross covering. The protocol only addressed weaning of prednisone, and a request was made by providers and nurses to develop a weaning schedule for prednisolone, which will be a future endeavor. Families provided feedback that they appreciated the weekly calls to check in, as it helped them feel more at ease during a time of adjustment to a new diagnosis of a chronic disease.

As monthly evaluations were performed, some pitfalls were noted. One drawback included the inability to automate our weaning questionnaire in the electronic medical system. There was also a lack of automation in identifying new IBD patients discharged on systemic CS. Instead, we relied on our inpatient nurse to task the respective outpatient nurses upon discharge. This in turn created a process failure on days when any of our inpatient or outpatient nurses were out of the office. Specifically, we noted a decline in the percentage of patients called for symptom assessment and CS taper in November and December. This was likely due to absences during the holidays, resulting in failure of the communication process from inpatient to outpatient. Additionally, we did find that it was difficult to reach some families via phone. Multiple attempts were made to reach families, which extended CS days, but not significantly. There was less variability in the total number of steroid days after 1 year, and the patient who was on steroids the longest was due to steroid dependency.

There were unintended consequences related to our initiative, mainly reflected in increased calls to the office, resulting in an increase workload on our secretaries to answer those calls. This balance measure will need to be evaluated in future cycles, especially with implementation of the new electronic medical record (EMR). The new EMR may allow greater opportunities for electronic communication which may increase opportunities to reach families,

but will need to be balanced with whether accurate information or nuances could be obtained electronically compared to verbally.

Our experience also illustrated the importance of involving stakeholders. We collaborated with all providers and outpatient nurses to develop a standardized protocol that was safe, effective, and easy to use. Leveraging the EMR is also an important factor, as it has been shown to be useful in collecting and organizing data, setting reminders related to patient care, and creating evidence based practice support tools.[16,17] In our protocol, we distributed a dot phrase with standardized questions to be asked during weaning, followed by instructions on how to wean based on patient symptoms. Nurses were also encouraged to use the EMR to create future task reminders for continued weekly calls to patients undergoing a CS taper.

National pediatric IBD quality initiatives such as those established by ImproveCareNow Network have proposed specific outcome measures including CS-free remission, and satisfactory nutrition and growth.[18] Although we met our specific outcome measure and effectively decreased the median number of CS days in our newly diagnosed IBD patients, we did not see a change in the above outcomes. This is likely due to the fact that these outcomes are affected by other key drivers, such as use of CS on other IBD patients, and not only newly diagnosed patients, frequency of patient follow-up, and access to resources such as a dietitian and nutritional supplements. Our initiative was limited to a small population within our IBD patients, but illustrated that by using principles of QI methodology, multiple small changes can lead to larger outcome changes.

Future endeavors include standardizing a protocol for patients discharged on prednisolone, and extending the protocol for all IBD patients started on CS, including during flares. Since the protocol implementation, our practice has now transitioned to initiating biologic therapy on an outpatient basis, especially if patients are not having severe symptoms. We will also be evaluating the process for these patients, since the protocol for these patients will no longer be triggered by the inpatient nurse. As our hospital system transitions to a new EMR over the next year, we hope to automate the protocol to increase sustainability. There will be greater opportunities to communicate with families electronically, especially for those who may be more difficult to reach via telephone.

Overall, our initiative illustrated that QI interventions can lead to optimized steroid use in pediatric patients with IBD. Specifically, in our institution, initiation of a standard protocol for steroid weaning helped to prevent missed opportunities for weaning and shortened steroid duration times without increasing risk of flares and readmissions.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

ORCID

Denise D. Young http://orcid.org/0000-0001-8722-6376

REFERENCES

1. Ruemmele FM, Veres G, Kolho KL, European Crohn's and Colitis Organisation. Consensus guidelines of ECCO/ESPGHAN on the medical management of pediatric Crohn's disease. *J Crohn Colitis*. 2014; 8(10):1179-1207.
2. Ford AC, Bernstein CN, Khan KJ, et al. Glucocorticosteroid therapy in inflammatory bowel disease: systematic review and meta-analysis. *Am J Gastroenterol*. 2011;106(4):590-599; quiz 600.
3. Bruscoli S, Febo M, Riccardi C, Migliorati G. Glucocorticoid therapy in inflammatory bowel disease: mechanisms and clinical practice. *Front Immunol*. 2021;12:691480.
4. Faleck DM, Shmidt E, Huang R, et al. Effect of concomitant therapy with steroids and tumor necrosis factor antagonists for induction of remission in patients with Crohn's disease: a systematic review and pooled meta-analysis. *Clin Gastroenterol Hepatol*. 2021;19(2):238-245.
5. Waljee AK, Wiitala WL, Govani S, et al. Corticosteroid use and complications in a US inflammatory bowel disease cohort. *PLoS One*. 2016;11(6):e0158017.
6. Lichtenstein GR, Feagan BG, Cohen RD, et al. Serious infection and mortality in patients with Crohn's disease: more than 5 years of follow-up in the TREAT™ registry. *Am J Gastroenterol*. 2012;107(9):1409-1422.
7. Steinhart AH, Ewe K, Griffiths AM, Modigliani R, Thomsen OO. Corticosteroids for maintenance of remission in Crohn's disease. *Cochrane Database Syst Rev*. 2003;4:CD000301.
8. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517. doi:10.1038/ajg.2018.27; Erratum in: *Am J Gastroenterol*. 2018;113(7):1101.
9. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
10. Turner D, Otley AR, Mack D, et al. Development, validation, and evaluation of a pediatric ulcerative colitis activity index: a prospective multicenter study. *Gastroenterology*. 2007;133(2):423-432.
11. Hyams JS, Ferry GD, Mandel FS, et al. Development and validation of a pediatric Crohn's disease activity index. *J Pediatr Gastroenterol Nutr*. 1991;12(4):439-447.
12. Chhaya V, Saxena S, Cecil E, et al. Steroid dependency and trends in prescribing for inflammatory bowel disease—a 20-year national population-based study. *Aliment Pharmacol Ther*. 2016;44(5):482-494.
13. Jeuring SFG, Biemans VBC, van den Heuvel TRA, et al. Corticosteroid sparing in inflammatory bowel disease is more often achieved in the immunomodulator and biological era—results from the Dutch population-based IBDSL cohort. *Am J Gastroenterol*. 2018;113(3):384-395.
14. Narula N, Borges L, Steinhart AH, Colombel JF. Trends in narcotic and corticosteroid prescriptions in patients with inflammatory bowel disease in the United States ambulatory

care setting from 2003 to 2011. *Inflamm Bowel Dis*. 2017;23(6):868-874.
15. Kandavel P, Eder SJ, Adler J. Reduced systemic corticosteroid use among pediatric patients with inflammatory bowel disease in a large learning health system. *J Pediatric Gastroenter Nutr*. 2021;73(3):345-351.
16. Ornstein SM, Oates RB, Fox GN. The computer-based medical record: current status. *J Fam Pract*. 1992;35(5):556-565.
17. Breton J, Witmer CM, Zhang Y, et al. Utilization of an electronic medical record-integrated dashboard improves identification and treatment of anemia and iron deficiency in pediatric inflammatory bowel disease. *Inflamm Bowel Dis*. 2021;27(9):1409-1417.
18. Kandavel P, Eder SJ, Adler J. Reduced systemic corticosteroid use among pediatric patients with inflammatory bowel disease in a large learning health system. *J Pediatric Gastroenter Nutr*. 2021;73(3):345-351.

SUPPORTING INFORMATION

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

How to cite this article: Lendner N, Perry S, Sferra TJ, Moses J, Young DD. Standardizing steroid protocols for newly diagnosed inflammatory bowel disease patients: a quality improvement initiative. *J Pediatr Gastroenterol Nutr*. 2024;1-8. doi:10.1002/jpn3.12246