Audit of the reporting adequacy of Magnetic Resonance Enterography performed in patients with Crohn's Disease at Groote Schuur Hospital.

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ACKNOWLEDGEMENTS, FORMAT AND CONTRIBUTIONS

This dissertation is presented in journal-ready format according to the structure outlined by the South African Journal of Radiology for submission of original research. The dissertation has not been submitted for publication but may be submitted in the future.

The dissertation was prepared with guidance and editorial assistance from my supervisor, Ass. Prof. Sulaiman Moosa.

The dissertation is based on my original work and is not derived from work started by another person.

Signature:

Date: 28 December 2024

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LIST OF ABBREVIATIONS

CD: Crohn's Disease

MRE: Magnetic Resonance Enterography

MR: Magnetic Resonance

CT: Computed Tomography

GSH: Groote Schuur Hospital

LITERATURE REVIEW

Introduction

Crohn's disease(CD) is a chronic inflammatory bowel disease that can affect any part of the gastrointestinal tract, with a specific predilection for the terminal ileum and the colon. (1) It is characterized by chronic inflammation with non-specific symptomatology such as abdominal pain, diarrhoea, and weight loss. The exact aetiology of Crohn's disease remains unknown but current theories include a combination of genetic, environmental and immune mediated factors, that leads to chronic inflammation of the intestinal mucosa. (2)

The diagnosis of Crohn's disease can be challenging due to its diverse presentation and overlap with other gastrointestinal conditions. Radiology plays a crucial role in the diagnosis, management and treatment of Crohn's disease, with magnetic resonance enterography (MRE) being an important imaging modality for evaluating disease activity, extent, and complications. MRE is a non-invasive and non-ionizing imaging technique that provides superior soft tissue detail, allowing for accurate assessment of intestinal inflammation, transmural involvement, small bowel segments, and complications such as collections, fistulae, strictures, and perianal involvement. (3)

Accurate and comprehensive radiology reports play a crucial role in the effective management and treatment of Crohn's disease. They provide essential information that aids the clinical team in making informed decisions regarding patient care. (4)

Optimisation and standardisation of MRE reports have until recently been an unmet need, that was addressed by the 2022 “ECCO-ESGAR Topical Review on Optimising Reporting for Cross-Sectional Imaging in Inflammatory Bowel Disease”. This review document identified standardized parameters and core elements that should be included in each MRE radiology report for Crohn's disease, to facilitate effective communication, collaboration, and treatment planning between radiologists, gastroenterologists, and surgeons and to facilitate the comparison between different reports and follow-up imaging. (5)

This audit aims to assess the adequacy of radiology reports for patients with Crohn's disease undergoing MR enterography at Groote Schuur Hospital, using the 2022 ECCO-ESGAR Topical Review document as a standard for adequacy and structure and the 2020 RadioGraphics

article "Small Bowel Crohn's Disease at CT and MR Enterography: Imaging Atlas and Glossary of Terms" to evaluate the adherence to standardised nomenclature.

If the audit finds that the radiology reports are not adequate, recommendations will be made on how to improve them to ensure accurate and comprehensive reporting.

Crohn's Disease:

Definition:

Crohn's disease is a chronic relapsing, remitting disease, characterized by chronic inflammation of the gastrointestinal tract. It is a type of inflammatory bowel disease, along with ulcerative colitis. While ulcerative colitis primarily affects the colon, Crohn's disease can involve any part of the gastrointestinal tract from the mouth to the anus, making it a more challenging condition to diagnose and manage.(1)

The chronic bowel inflammation in Crohn's disease can lead to various complications such as strictures, fistulas, abscesses, and penetrating disease. Identifying these complications is crucial as they may indicate a more aggressive course of the disease and require different treatment approaches. (6)

Incidence and prevalence:

The incidence and prevalence of Crohn's disease exhibit regional disparities worldwide, with higher rates documented in developed countries. (7) Developing countries have experienced a gradual rise in both the occurrence and frequency of Crohn's disease cases throughout recent years. (8)

Diagnosis:

The diagnosis of Crohn's disease is established through a comprehensive evaluation that incorporates clinical symptoms, endoscopic examination, radiological imaging, and histopathological analysis, as no single test is set as the reference standard. (4)

Crohn's disease is a chronic inflammatory condition that affects the entire digestive tract, that is often symptomatic for several years before diagnosis. It presents with various clinical symptoms such as persistent abdominal pain, frequent episodes of diarrhoea, unexplained weight loss, fever, and less commonly, rectal bleeding. These symptoms can significantly impact an individual's quality of life and often require prompt medical attention for accurate diagnosis and management.(2)

In recent years, there has been a growing concern regarding the rising incidence of inflammatory bowel diseases, including Crohn's disease, in daily clinical practice. This can be attributed to both an increase in the number of cases and advancements in imaging techniques for detection. While the diagnosis of Crohn's disease traditionally relies on clinical presentation, laboratory tests, and endoscopy with biopsy, these methods are limited to assessing the mucosal layer of the gastrointestinal tract.

This is where imaging modalities, such as CT and MR enterography, play a pivotal role in providing a more comprehensive assessment of Crohn's disease. CT imaging has proven to be a valuable tool for detecting complications and assessing disease severity in patients with Crohn's disease. However, MR enterography has emerged as a preferred imaging modality for the evaluation of Crohn's disease, particularly in the small bowel, which is often difficult to assess with endoscopy. In addition to providing detailed information about the extent and severity of inflammation, MR enterography can also detect complications such as fistulas, strictures, abscesses, and perianal involvement. (9) Moreover, MR enterography offers the advantage of being non-invasive and non-ionizing, making it a safer option for patients, especially young patients and children who require repeated imaging studies for disease monitoring. (9)

Management:

In recent years, there have been significant changes in the approach to treating Crohn's disease. These changes are driven by a growing understanding of certain biomarkers that indicate a higher risk of progression of disease and disabling complications. (10)

There is an increasing recognition of the importance of achieving mucosal healing, which involves restoring the lining of the intestines and reducing or eliminating endoscopic lesions.

This achievement has shown positive short-term outcomes such as lower relapse rates, decreased hospitalization rates, remission without needing steroid medications during follow-up examinations, and longer periods between surgical interventions. Patients with CD who achieve mucosal healing experience reduced risks for complications due to penetrating disease.(10)

Mucosal healing is, therefore, an important treatment goal, with currently recommended management strategies striving for complete remission, which is defined as both symptomatic and endoscopic remission. Historically, most randomized control trials assessed response using symptomatology, with only more recent studies including endoscopic and imaging findings when assessing response/remission. (10)

When mucosal healing has been achieved, the next treatment goal is transmural healing, which is best assessed by cross-sectional imaging techniques and histology.(10) This is where radiology plays an important role in the management and follow-up of patients with Crohn's disease.

The management of Crohn's disease involves a combination of medical therapy, surgical intervention, and lifestyle modifications, which is beyond the scope of this article.

Medical treatment aims to treat the inflammatory process and its associated complications, with the goal of achieving and maintaining remission. Surgery is usually reserved for patients with complications such as strictures, fistulas, or abscesses that do not respond to medical therapy. (2)

Disease monitoring:

Due to the relapsing-remitting nature of Crohn's Disease, regular monitoring of disease activity is crucial to assess treatment response and identify any potential complications. This is particularly important following any change in management strategy, drug dosage or frequency. (2)

Various methods are used to monitor disease activity, including clinical evaluation of symptomatology, laboratory markers such as C-reactive protein, faecal calprotectin, endoscopy and cross-sectional imaging techniques such as MR enterography.(1)

Imaging plays a vital role in monitoring disease activity, as it provides objective evidence of transmural inflammation, complications and extra-intestinal manifestations. In the context of Crohn's disease, MR enterography has emerged as a valuable imaging technique for disease monitoring as it provides superior soft tissue detail, is non-invasive and non-ionising, making it ideal for long-term follow-up and repeat studies.(10)

Crohn's Disease and MR enterography:

Ileocolonoscopy with histology has long been considered the two cornerstone methods for the diagnosis of Crohn's disease. It is however an invasive procedure with the risk of bowel perforation and is limited by incomplete bowel evaluation and its inability to assess transmural involvement/penetrating disease and extra-intestinal complications. (11)

The diagnostic imaging armamentarium available to help aid in the diagnosis and follow-up of Crohn's disease, includes ultrasonography, barium contrast radiology, computed tomography (CT), MR enterography, and nuclear medicine techniques. Plain film radiology is reserved for the assessment of specific emergency complications. (4)

Of these imaging techniques, CT and MR enterography have emerged as the preferred imaging modalities. They have similar diagnostic accuracy for Crohn's disease, although both depend on adequate bowel distension. CT however carries a radiation burden, which is less desired, especially in young patients and those undergoing repeat evaluations to monitor long-term disease activity. (12)

MR Enterography provides superior soft tissue detail compared to other imaging modalities, allowing for accurate evaluation of the small bowel segments and transmural involvement of the disease. (13)

It is non-invasive and does not involve ionizing radiation, making it a safe option for frequent monitoring of disease activity. However, early disease recurrence cannot be assessed with MR enterography, as small aphthoid ulcers will only be visible on endoscopy. As disease activity increases, the bowel wall changes will become evident on MR enterography. (4)

MR enterography also allows for the assessment of complications such as collections, fistulae, strictures, and perianal involvement, which is beyond the reach of endoscopic assessment.

In this way, MR enterography is valuable in treatment planning, helping to identify the extent and severity of the disease, and enabling clinicians to make informed decisions regarding medical therapy or surgical interventions.

Paediatric patients with Crohn's disease can particularly benefit from MR enterography due to its ability to provide detailed information while avoiding ionizing radiation exposure. (2)

Some major disadvantages of MR Enterography are the duration of time required to perform the study and the availability.

Newer fast imaging acquisition techniques have however greatly improved imaging acquisition times, also resulting in less bowel motion artefact. (4)

MR Enterography, is however only available in large centres, particularly in resource-poor settings like the public health sector in South Africa. (8)

Importance of adequate reports:

Collaborative care is essential in the management of patients with Crohn's disease. Accurate and comprehensive radiology reports are crucial for effective collaboration among healthcare professionals involved in the care of these patients. Standardized reports and nomenclature are necessary to prevent confusion and ensure that all clinicians have a clear understanding of the imaging findings. (4)

Factors affecting radiology report quality:

Several factors can impact the quality of radiology reports for patients with Crohn's disease undergoing MR enterography.

Patient factors, such as suboptimal bowel preparation or the presence of MR artefacts, can affect the quality and interpretation of the images. (14)

Study factors, such as the use of adequate oral fluid and proper administration of antimotility drugs, movement artefacts, and appropriate field of view coverage also play a role in the quality of the radiology report. (14)

Using standardized reporting templates can improve the consistency and clarity of the reports.

In addition to these factors, the experience and comfort level of the radiologist, as well as their previous exposure to cases of Crohn's disease, can also impact the quality of the radiology report. (6, 15)

Consequences of inadequate radiology reports:

Inadequate radiology reports for patients with Crohn's disease undergoing MR enterography can have significant consequences:

Delayed or missed diagnosis:

Inadequate radiology reports can potentially result in delays or even missed diagnoses of Crohn's disease. This can lead to a delay in appropriate treatment initiation and potential progression of the disease, resulting in poorer patient outcomes. (5)

Incorrect treatment decisions:

When radiology reports lack sufficient detail or clarity to guide clinicians in their management plans, this can result in patients receiving suboptimal or inappropriate treatment, potentially exacerbating their symptoms or leading to complications. (5)

Increased risk of complications:

As inadequate radiology reports may lead to a delay in diagnosis or incorrect treatment decisions, there is an increased risk of disease progression and the development of complications.

Failing to accurately describe already present complications such as collections, fistulae, strictures, or perianal involvement, may lead to further complications and disease morbidity. (5)

Unnecessary or repeat tests and investigations:

Substandard radiology reports may lead to the need for additional tests and investigations. This can occur when the initial report lacks sufficient information to guide clinical decision-making or when there is ambiguity in the findings. As a result, clinicians may feel the need to order additional tests or repeat MR enterography, leading to increased healthcare costs and patient inconvenience. (6)

Impaired monitoring of disease progression:

Without clear and comprehensive reports, it becomes challenging to accurately assess the response of the disease to treatment and make appropriate adjustments in management plans. This can result in inefficient disease monitoring and potentially lead to delayed interventions or missed opportunities for optimizing patient care. (13)

Patient anxiety and dissatisfaction:

Inadequate radiology reports can contribute to patient anxiety and dissatisfaction. This is because patients may feel unsettled or uncertain about their condition if the radiology report is incomplete or unclear.

They may have unanswered questions or concerns about their disease status, treatment plan, or potential complications.

Legal and medicolegal implications:

As Crohn's disease can be a severely debilitating disease with a significant impact on a patient's quality of life, any shortcomings in radiology reports can have serious legal and medicolegal implications. Radiology reports play a critical role in providing accurate and comprehensive information about the imaging findings of patients with Crohn's disease undergoing MR enterography. They serve as important documentation for communication among healthcare providers, as well as for medico-legal purposes. (5)

Assessing the adequacy of radiology reports:

Radiology reports for patients with Crohn's disease undergoing MR Enterography can be assessed using various criteria. These criteria include adherence to guidelines and nomenclature, inclusion of essential elements, and the use of a coherent and well-structured format that is easy to read. The clarity and conciseness of the report, as well as the accuracy and completeness of the information provided, are also important factors to consider when evaluating the adequacy of radiology reports.(5, 6, 15)

Criteria used to assess reports:

Until recently, guidelines to optimise and standardise MR Enterography reports for patients with Crohn's Disease have not been available. That need was met with the publication of the ECCO-ESGAR Topical Review on Optimizing reporting for Cross-Sectional Imaging in Inflammatory Bowel Disease. Although this document is not yet regarded as a consensus guideline, it serves as a useful guide in assessing the adequacy of radiology reports for patients with Crohn's disease undergoing MR enterography. Adherence to these recommendations, including the use of consistent nomenclature and incorporating essential elements such as disease location, extent, and severity, is essential for ensuring the adequacy of radiology reports. (5)

The use of standardised nomenclature in radiology reports ensures clear and consistent communication between different specialities. It helps to avoid ambiguity and misunderstanding, that could potentially lead to clinical errors, complications in patient care, or misinterpretation of imaging findings. (6)

Important nomenclature categories to adhere to include clearly defined terms for bowel wall findings, features of penetrating disease, mesenteric findings and most importantly, using standardised impression/conclusion statements. (15)

Although structured reporting is not used by all radiologists at Groote Schuur Hospital, providing a well-structured report with clearly indicated categories of interpretation, results in a better reading experience and communication with the clinicians. Importantly, it improves the reproducibility of the report, which is essential for follow-up studies. (5, 16)

Essential elements to include in every MR Enterography report fall under the following categories:

- Technical factors
- Radiological findings
- Report conclusion / impression

Including technical factors in all radiology reports is important for two reasons:

- It alludes to the confidence of the findings interpretation of the study. Accurate MRE interpretation is heavily dependent on a good quality study. Any factors detracting from the quality of the study (motion artefact, poor bowel distention etc.) will decrease reporting confidence. (5)
- Including the technical factors in a report enables easy reference during follow-up studies. Even though institutional imaging protocols are used, occasionally patients are scanned with different strength magnets (1.5T vs 3T) or a full imaging protocol cannot be followed due to patient or technical factors. In these cases, this needs to be highlighted in the report, so that findings are interpreted accordingly.
- Additionally, although not as important, elaborating on the technical factors within the report also communicates to the clinician exactly which protocols were followed.

The radiological findings are the meat of a report. This is where all the positive and relevant negative findings should be described in detail.

As this section can be very information-dense, it is important to provide some structure with clear headings in this section. This is for both ease of reading and ease of future reference.

The complete list of important findings can be found in Addendum A, but the main categories include:

- **Missing segments due to previous surgery**: Up to 57% of patients with Crohn's disease will have some surgery related to their illness. Most surgeries are for the management

of perianal CD, drainage of abscesses and the management of fistulae. (9) However, terminal ileum resection is commonly seen in our population and should be reported.

- **Abnormal bowel findings**: Abnormal bowel and mesenteric findings are the core radiological indicators of active intestinal disease in CD. This should therefore be described in detail, mostly to facilitate the comparison of follow-up imaging. Although there are no global image scoring systems currently in use to assess the severity of CD (14), providing detailed descriptions of inflammatory changes may be of use should validated scoring systems emerge in the future

- **Complications**: A clear and detailed description of complications is of the utmost importance, as it usually prompts a change in treatment approach and often results in surgical intervention. (9) The most common complications include stricture formation, fistulae/sinus tracts, mesenteric mass/abscess, toxic megacolon and vascular complications like mesenteric vessel thrombosis. (4)

- **Perianal CD:** Perianal imaging is not performed routinely in all patients with CD at Groote Schuur Hospital, but is limited to those patients with specific perianal complaints or clinical symptoms. When perianal imaging is performed, a detailed fistula description, including the Park's classification should be provided.

- **Extra-intestinal manifestations**: Although MRE cannot detect all extra-intestinal manifestations of CD, important areas of assessment include the sacroiliac joints (sacroiliitis), biliary system (sclerosing cholangitis and cholelithiasis) and femoral heads (avascular necrosis). (9)

Although the radiological findings section is the meat of the report, the comment/conclusion is the most important section of the report to the clinical team. This is where the radiologist should provide a comprehensive analysis and interpretation of the findings, using standardised impression statements that clinicians can rely on to make treatment and management decisions. (15)

It is essential that initial imaging and imaging done to assess treatment response be differentiated from each other. The impression statement should clearly categorise the

treatment response into one of the acceptable categories of transmural remission, significant transmural response, stable disease or disease progression. (5)

Interventions on how to improve report quality:

Improving the quality of radiology reports for patients with Crohn's disease undergoing MR Enterography requires a multi-faceted approach. Firstly, providing education and training to radiologists on the use of standardised reporting templates and the importance of consistent nomenclature can enhance the clarity and comprehensiveness of the reports. Encouraging collaboration between radiologists and gastroenterologists can also improve report quality by promoting a better understanding of each other's perspectives and information needs. Furthermore, implementing regular peer review sessions and feedback mechanisms can help identify areas for improvement and facilitate continuous learning and growth among radiologists. (17)

Conclusion:

Adequate radiology reports play a crucial role in the effective management and treatment of Crohn's disease in patients undergoing MR Enterography. Accurate and comprehensive reports provide crucial information for diagnosis, treatment planning, disease monitoring, and collaboration between healthcare professionals. They help prevent delays or missed diagnoses, ensure appropriate treatment decisions, and minimize the risk of complications.

Therefore, the adequacy of radiology reports for patients with Crohn's disease undergoing MR Enterography at Groote Schuur Hospital is an important aspect that needs to be assessed and improved if necessary.

ABSTRACT

Background

CD is an idiopathic inflammatory bowel disease with a predilection for the terminal ileum and the colon. MRE is the cornerstone imaging modality for evaluating and monitoring CD. This audit aims to assess the adequacy of radiology reports for MRE in CD patients, performed at GSH.

Objectives

- Determine the proportion reporting elements included in MRE reports for patients with CD, and compare it to international recommendations of essential elements to include in MRE reports.
- Evaluate the lexicon usage.
- Evaluate the structure and clarity.

Method

Retrospective audit, assessing adequacy of radiology reports for patients with CD who underwent MRE examinations at GSH.

This forms the first leg of an audit cycle assessing local practice standards and make recommendations for future improvements should target standards not be met.

Results

Overall, none of the data points collected met our 70% cut-off for minimum requirements.

Technical factors were particularly poorly reported (8%), with some improvement in Radiological factors (66%).

There was suboptimal use of correct nomenclature and documentation of treatment response.

Structured reporting was not correlated to improved documentation, but did increase readability ($p<0.01$).

Conclusion

This audit shows there is suboptimal documentation of essential elements in the MRE reports for patients with CD at GSH, including poor use of correct nomenclature and documentation of treatment response.

Structured reporting has a role to play in increasing readability of reports.

Contribution

The findings suggest a complete audit cycle should be implemented with targeted education on reporting of MRE studies, followed by reauditing of the findings.

DISSERTATION (PUBLICATION READY FORMAT)

Introduction

Magnetic Resonance Enterography (MRE) has become the preferred imaging modality for diagnosing and monitoring Crohn's disease (CD), offering detailed visualization of the bowel and extraintestinal structures without ionizing radiation. (3) Despite its technical advantages, the value of MRE in clinical practice heavily depends on the adequacy and clarity of radiological reporting. (6) Accurate, standardized, and comprehensive reports are critical for effective communication between radiologists and clinicians, guiding clinical decision-making and treatment planning. (5, 18) However, variability in reporting practices and the lack of standardized templates can undermine the diagnostic utility of MRE, particularly in resource-limited healthcare settings where repeat imaging is not always possible.

This audit evaluates the adequacy of MRE reporting for CD at our institution, assessing compliance with international reporting guidelines and identifying key areas for improvement. By analysing data fields related to technical factors, radiological findings, and reporting style, this study aims to highlight deficiencies and propose actionable recommendations to standardise reporting practices. This audit underscores the importance of fostering collaboration between radiologists and clinicians to enhance the quality of MRE reports, thereby improving patient outcomes and optimising resource utilisation in the management of Crohn's disease.

Research Methods and Design

A retrospective descriptive clinical audit was performed to assess the adequacy of radiology reports for patients with known Crohn’s Disease who underwent MRE examinations at GSH.

The study population included 100 consecutive MRE studies performed in patients with known Crohn’s disease, between 1 December 2021 and 31 August 2023.

This data set volume was chosen to assess the most recent practices and meet investigator time constraints. Older studies may not represent current reporting practices.

The report-generating tool within Philips XIRIS (radiology information system used at Groote Schuur Hospital at time of audit period) was used to identify all MRE studies performed at Groote Schuur Hospital before 31 August 2023, filtering the modality to “MR” and study to “MR Enterography”.

Reports were then individually checked to see if the clinical history supplied or the final radiological diagnosis was in keeping with Crohn’s Disease.

The following inclusion criteria were used:

- All MRE studies performed at Groote Schuur Hospital, back-dated from 31 August 2023.
- Patients with known Crohn’s Disease, as indicated by the clinical history provided in the radiology request.
- Patients with first imaging where the main radiological diagnosis suggests newly diagnosed Crohn’s disease.

The following studies were excluded from data collection:

- Patient age < 18 yrs.
- Where the final diagnosis was uncertain, as indicated by the clinical history and/or the radiological assessment.
- Studies reported as normal, except where the study was done for treatment response in known Crohn’s disease.

Data collection:

Data was retrospectively collected by accessing the radiology reports on RIS, anonymised and captured in a RedCap database, designed specifically for this project.

The data was captured in a quantitative manner with report features captured as Yes (reported), No (not reported) or N/A (not applicable to the specific report).

For a complete description of individual data points collected, please see “Appendix B: Data Collection Details”.

Clinical History Provided	Known or suspected Crohn's Disease
	First or follow-up MRE imaging
	Previous bowel surgery
Technical factors	Magnet strength
	Oral contrast
	Antiperistaltic drugs
	Adequate bowel preparation and distention
	Scan coverage
	Artefacts
Radiological factors	Missed segments due to previous surgery
	Disease activity, as assessed by bowel wall changes
	Complications
	Disease extent/localisation
	Peri-anal Crohn's Disease
	Extra-intestinal manifestations
Conclusion	Treatment response
Overall impression	Structure
	Nomenclature use
	Readability

Table 1 shows a summary of the categories under which data was collected.

Data analysis

Findings were summarized using frequency tables and percentages. Comparisons were done using crosstabulations with the Chi-square/Fisher exact test, and Cohen's kappa. Sensitivity and specificity with corresponding confidence intervals were reported where applicable.

A 5% significance level ($p<0.05$) was used as a guideline for statistical significance.

Ethical considerations

Approval for this study was obtained from the University of Cape Town Human Research Ethics Committee (HREC reference number 976/2023). Participant consent was not obtained due to the retrospective nature of the study and strict precautions were taken to protect personal identifying information.

Results

A total of 100 MRE reports were reviewed, with up to 86 data fields collected per report.

A previously confirmed diagnosis of Crohn's disease was documented in the clinical history provided in 92% of the cases, while MRE was being performed for suspected, unconfirmed CD in 8% of cases.

Most cases were follow-up imaging, 72%, and according to the clinical history provided, 58% of patients had undergone previous bowel surgery.

Technical factors:

Technical factors were generally poorly captured, with only 8% of data fields captured. Only 3% of reports stated the type of oral contrast used, while none stated the volume or on which magnet strength MR the study was performed.

The type of antiperistaltic drug used was documented in 3% of cases, but no reports documented the dose or route of administration.

Bowel preparation and distension were the best documented technical factor with 43% commenting on the adequacy of bowel distension and 16% commenting on the adequacy of bowel preparation.

Only 1% of reports commented on the scan coverage and 11% stated if there were any imaging artefacts affecting image quality.

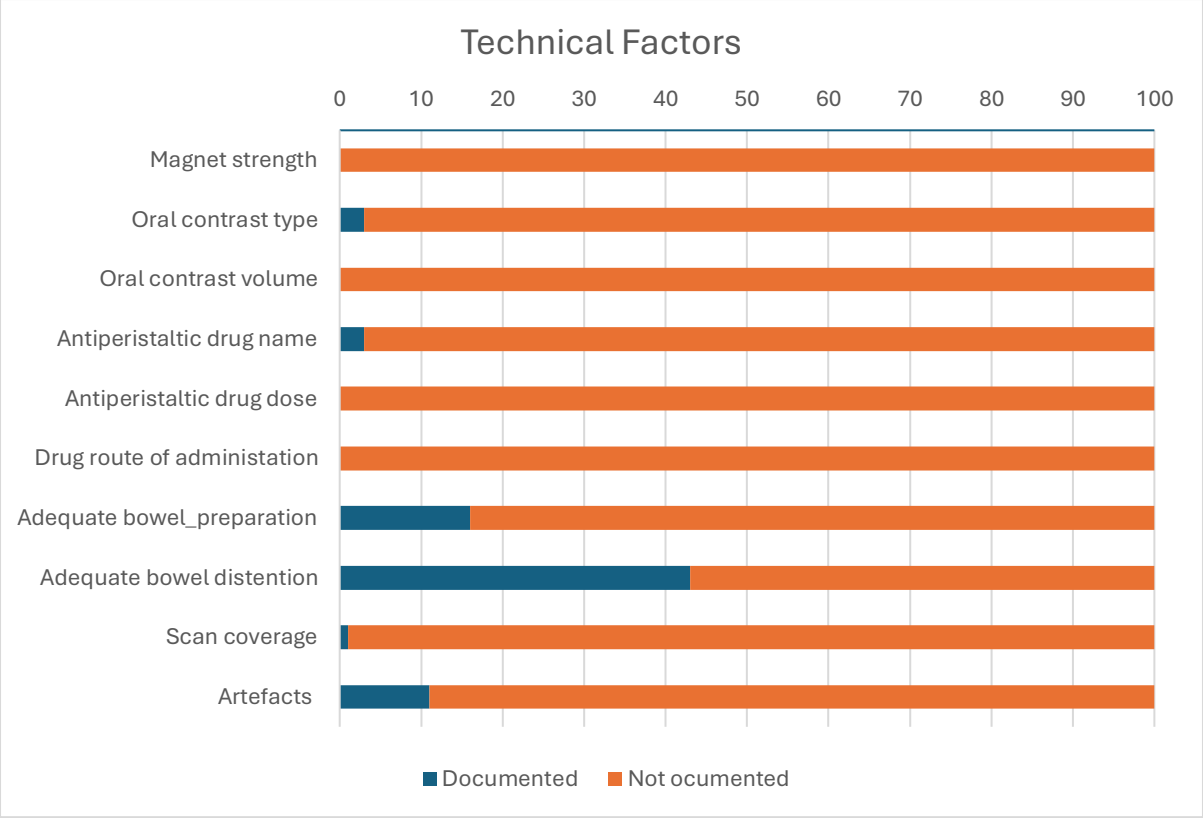

Table 2: Technical factors documented

Radiological findings:

Data fields related to radiological findings were documented in 66% of cases.

Although clinical history provided stated that 58% of patients had undergone previous bowel surgery, only 50% of radiology reports documented on the missing segments.

Disease activity was documented as present in 69% of cases, not present in 28% of cases and no comment was made on active disease in 3% of cases.

Of the 69% of cases that showed disease activity, descriptors of active bowel disease were commented on as follows; bowel wall thickening 87%, bowel wall oedema 64%, mucosal ulceration 32%, vascular engorgement 77%, perienteric inflammatory changes 67% and restricted diffusion within the bowel wall in 76% of cases.

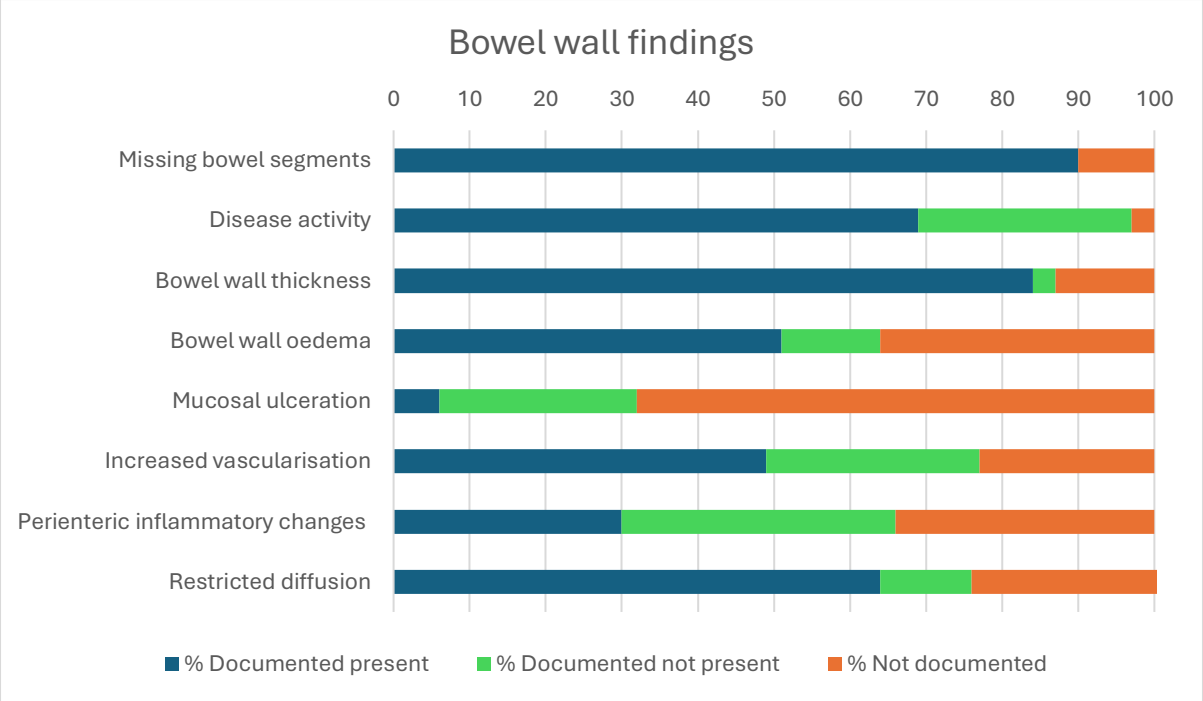

Table 3: Radiological findings indicating disease activity

Bowel complications related to CD were present in 44% of cases, not present in 51% of cases and not mentioned in 5%.

Of the 44% of cases that had CD related bowel complications, specific complications were mentioned as follows; bowel strictures (96%), bowel fistula or sinus (96%), toxic megacolon (46%) and mesenteric mass or abscess formation (84%).

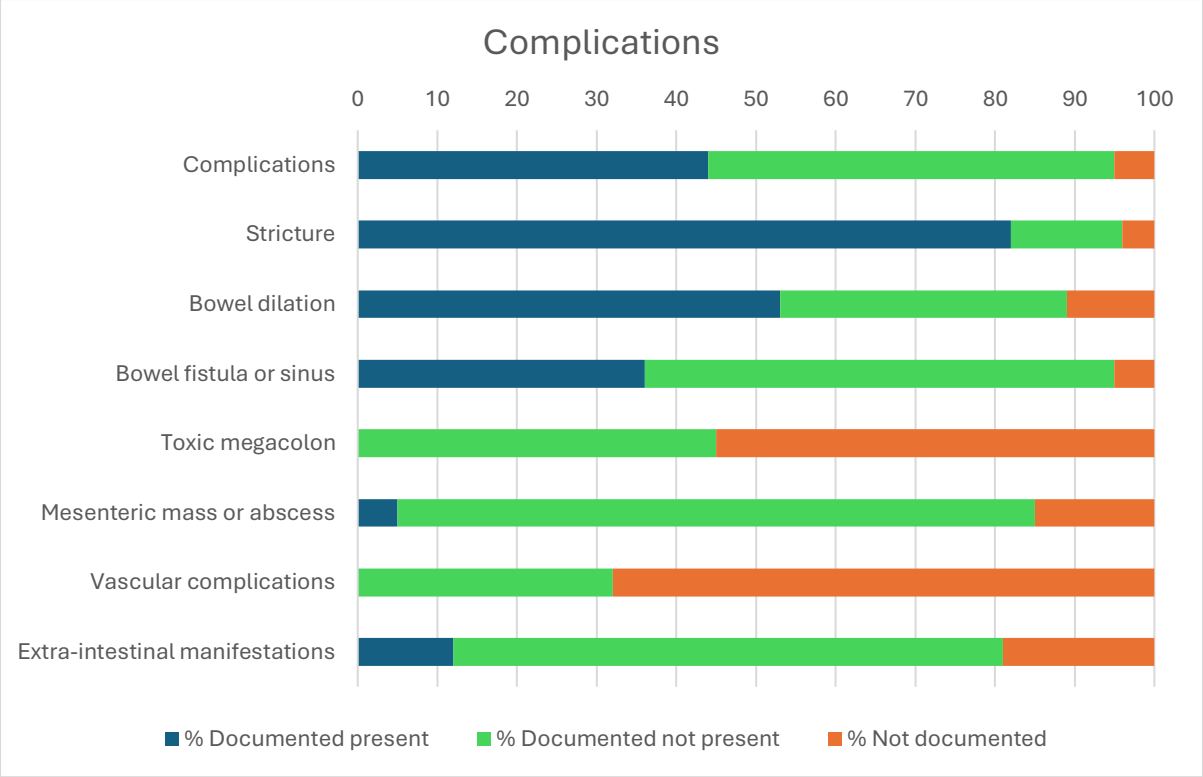

Table 4: Complications related to CD.

A total of 36 patients had bowel strictures. The descriptors of bowel strictures were reported as present as follows: stricture location (86%), number of strictures (94%), length of stricture (53%), signs of inflammation in stricture (69%), relationship to surgical anastomosis (69%), bowel distension upstream to stricture (89%) and degree of bowel distension (67%).

A total of 16 cases had documented bowel fistulae or sinuses. The descriptors of fistulae/sinuses were commented on as follows; fistula site of origin (75%), involved organs (75%), fistula classification/type (25%), fistula relationship to strictures (33%).

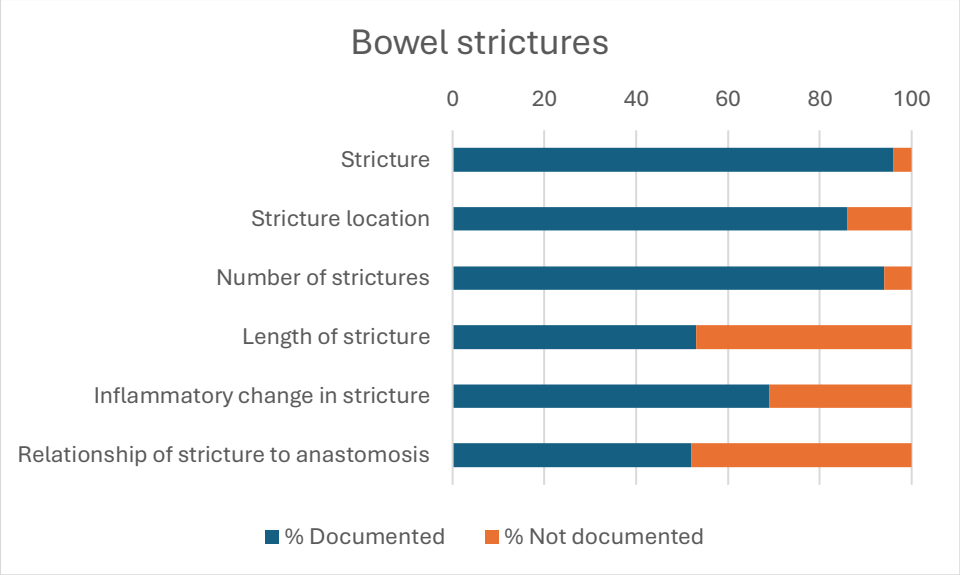

Table 5: Characteristics of bowel strictures.

A mesenteric mass or abscess was only present in 2 cases. One report mentioned the location of the abscess and none of the reports commented on the size or feasibility of image guided drainage.

Vascular complications and toxic megacolon were commented on in 32% and 46% of cases respectively.

The location of bowel disease was only described in 90% of cases and extra-intestinal manifestations of CD were commented on in 81% of cases.

Only three cases had documented peri-anal CD involvement.

Conclusion:

From the sample set, first imaging for CD was performed in 28% of cases. Of these cases, 64% had imaging features of active disease and 36% had no imaging features of active disease.

The other 72% of the sample set was follow-up imaging for patients with known CD. Of this subset, treatment response was only documented in 38% of cases.

Overall impression:

50% of reports where structured, while the other 50% used a free text style of reporting.

71% of reports were considered easy to read and interpret, while only 38% of reports used accepted nomenclature in their conclusion statements.

Correlation:

There was no correlation between documenting radiological findings and structured reporting.

However, there was a strong correlation ($p<0.001$) between the use of structured reporting and the readability of the reports.

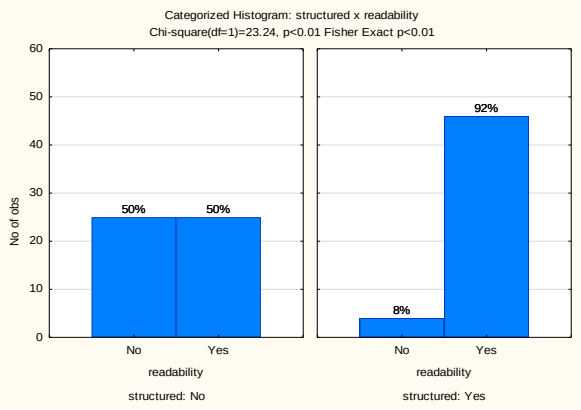

Table 6: Correlation between structured reporting and readability

Very few (3 cases) had dedicated peri-anal imaging included in the study, therefore statistical evaluation of the essential reporting elements and their correlation with structured reporting and readability wasn't possible.

Discussion

MRE is the preferred imaging modality for evaluating and monitoring small bowel Crohn's disease, due to its excellent visualisation of the bowel wall and extraintestinal manifestations without the burden of ionizing radiation. (3) Conveying the radiological findings of the MRE

study to clinicians in an adequate and easy-to-read radiology report is crucial for correct clinical management. (4)

Our audit showed variability in reporting practices at our institution with several key areas of concern regarding the comprehensiveness of the reports. Our cut-off of 70% of reporting elements to include in a radiology report was not met across any of the required reporting categories.

The inclusion of technical factors is not a standard practice at our institution, thus underreporting of this section is not unexpected. Only 8% of the relevant data fields for technical factors were captured across all reports. International guidelines suggest including technical factors in the standard MRE report, for a variety of reasons. This lack of detail regarding contrast agents, antiperistaltic agents, and magnet strength hinders reproducibility and limits the ability to compare studies over time or across institutions. (5)

Documenting technical factors also serves as a record for any untoward drug or contrast reactions.

While bowel preparation and distension were better documented, the scant reporting on scan coverage and imaging artifacts raises concerns about the diagnostic confidence of the examinations and the potential impact on clinical decision making. Proper bowel distension is essential for assessment of mural thickening and enhancement. If proper bowel distension is achieved, it also displaces bowel gas, which limits susceptibility artefacts. (19)

The documentation of radiological findings, while better than technical factors, still presents areas for improvement. Despite 58% of patients having a history of bowel surgery, only half of the reports documented missing bowel segments. This omission could lead to misinterpretation of findings both for the radiological and clinical team, especially when surgical intervention is considered.

While disease activity was documented in most cases, 3% of reports had no comment on if active disease was present or not, which is of concern, as assessment for CD is the indication of the MRE study.

Documentation of bowel complications was present in 44% of cases. It however lacked detailed descriptions of strictures, fistulae, and abscesses, limiting the utility of the reports for surgical planning or other interventions. Image guided percutaneous drainage of

collections are less invasive than open surgical drainage and often the preferred technique for management of abscesses related to penetrating disease. (5)

A specific area of concern is that treatment response was only documented in 63% of studies performed for disease follow-up and monitoring. In our institution, follow-up MRE's are often performed because there is an inaccessible bowel segment at endoscopy. The assessment of residual disease is therefore crucial in determining disease activity and treatment response to assist the clinical team in further management of the patient.

The variability in reporting style, with only 50% of reports structured, likely contributes to the observed inconsistencies. While the majority of reports were deemed easy to read, the fact that only 38% used accepted nomenclature in their conclusions highlights the need for standardized terminology to ensure clarity and avoid ambiguity. Using standardised nomenclature avoids ambiguity in communicating with our clinical colleagues, ensuring adequate diagnosis and disease assessment, so that correct clinical management can follow.

The strong correlation between structured reporting and readability reinforces the importance of adopting standardized templates. The radiology report plays an essential role in communication between radiologists and clinical teams. Many studies have shown that structured reporting with itemised fields are preferred by most clinical teams and leads to improved patient management and clinical outcomes. (18)

Our audit did not show a correlation between structured reporting and improved comprehensiveness ($p>0.05$). This is contrary to most data on structured reporting, where the use of structured reporting is statistically more complete than free form reporting. (16) Our study had many data fields collected (up to 86), much more than the majority of studies looking at comprehensive reporting. This, together with likely deficient reporting templates may be the reason no correlation was shown between comprehensiveness and structured reporting.

The limited number of cases with dedicated peri-anal imaging precluded statistical analysis in this area. Given the prevalence of peri-anal involvement in Crohn's disease, evaluating studies dedicated to perianal fistulae should be reviewed in the next audit cycle.

Limitations

Our audit has a number of limitations, including:

The data was solely collected by a single observer, whom may have internal biases towards some of the qualitative data collected, especially the readability of the reports. As radiology reports are a communication tool between the radiologist and clinical team, readability would likely have been better assessed by a clinical colleague who regularly reads MRE reports as part of their daily practice.

We collected data based on international ECCO-ESGAR recommendations, which include the recommendations of both radiological and clinical societies. However, these recommendations are primarily from a first world setting and might not take into account our unique challenges encountered in a resource poor public health care setting in South Africa.

An arbitrary cut-off of 70% of reporting elements was used to assess reporting adequacy. There are no MRE report audit recommendations available that specify what the minimum percentage of reporting elements are. Assessing the elements that have the greatest impact on clinical management (like features of active inflammation, intra-abdominal collections and toxic megacolon) rather than a purely quantitative evaluation, may be of more clinical value.

Peri-anal involvement is a frequent and debilitating feature of CD. Our sample size only included 3 cases where peri-anal imaging was included in the primary MRE study and report. A dedicated audit looking at peri-anal imaging will be of value.

The audit primarily assessed the adequacy of radiology reports, not the accuracy of the MRE findings themselves. While important, addressing reporting adequacy is only one component in improving diagnostic accuracy or patient outcomes.

Recommendations

The following recommendations are suggested prior to a repeat audit being performed:

- Standardise reporting practices by adopting structured reporting templates and using accepted nomenclature. Especially within a single institution, this will be of great value in order to ensure consistency, reproducibility and easily compare follow up studies.

- Implement the documentation of technical fields as a standard within MRE reporting in our institution.
- Strengthen the documentation of radiological findings by focusing on critical clinical findings like documenting missing bowel segments and including detailed descriptors of strictures (location, number, length, inflammation, and degree of bowel distension), fistulae (origin, involved organs, classification, and relation to strictures) and (location, size, and feasibility of drainage).
- Ensure assessment of treatment response is included in all follow up imaging, highlighting the importance of documenting residual disease and treatment response.
- Improve collaboration with clinical teams by getting feedback on readability and usefulness from clinicians who frequently read MRE reports. By strengthening multidisciplinary relationships and collaboration, reporting practises can be aligned with clinical needs.

The majority of these recommendations can be implemented by including didactic teaching in the academic programme at GSH, using the following sources as a basic starting point:

- Bruining DH, Zimmermann EM, Loftus EV, Jr., Sandborn WJ, Sauer CG, Strong SA, et al. Consensus Recommendations for Evaluation, Interpretation, and Utilization of Computed Tomography and Magnetic Resonance Enterography in Patients With Small Bowel Crohn's Disease. Radiology. 2018;286(3):776-99.
- Guglielmo FF, Anupindi SA, Fletcher JG, Al-Hawary MM, Dillman JR, Grand DJ, et al. Small Bowel Crohn Disease at CT and MR Enterography: Imaging Atlas and Glossary of Terms. RadioGraphics. 2020;40(2):354-75.
- Maaser C, Sturm A, Vavricka SR, Kucharzik T, Fiorino G, Annese V, et al. ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: Initial diagnosis, monitoring of known IBD, detection of complications. J Crohns Colitis. 2019;13(2):144-64.
- Sturm A, Maaser C, Calabrese E, Annese V, Fiorino G, Kucharzik T, et al. ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 2: IBD scores and general principles and technical aspects. J Crohns Colitis. 2019;13(3):273-84.

- Kucharzik T, Tielbeek J, Carter D, Taylor SA, Tolan D, Wilkens R, et al. ECCO-ESGAR Topical Review on Optimizing Reporting for Cross-Sectional Imaging in Inflammatory Bowel Disease. J Crohns Colitis. 2022;16(4):523-43.

The findings of this audit underscores the need for interventions to improve the quality of MRE reporting for Crohn's disease patients. Education and training on nomenclature use, standardised reporting templates and fostering collaboration between radiologists and gastroenterologists are crucial steps towards achieving this goal. By improving the clarity, consistency, and comprehensiveness of radiology reports, we can enhance the management and treatment of Crohn's disease and ultimately improve patient outcomes.

Contribution

The findings suggest a complete audit cycle should be implemented with further targeted education on the reporting or MR enterography studies, followed by reauditing of the findings.

Conclusion

This audit highlights significant variability in MRE reporting practices at our institution, with key areas requiring improvement to enhance the utility and quality of radiology reports for Crohn’s disease. Across the reviewed sample, none of the reporting categories met the threshold of 70% adequacy, identifying gaps in both technical documentation and radiological findings.

The lack of structured reporting templates and standardized nomenclature appears to contribute to the lack of readability, but did not show a correlation with increasing reporting adequacy, likely related to templates that are not comprehensive enough.

The poor documentation of technical factors, such as contrast agents, antiperistaltic drugs, magnet strength, and imaging artifacts, limits the reproducibility and comparability of studies over time and across institutions. Similarly, incomplete reporting of radiological findings, particularly descriptions of bowel complications, missing bowel segments, and treatment

response, reduces the clinical utility of these reports, particularly in surgical planning and disease monitoring.

Structured reporting was strongly correlated with improved readability and emphasises the need for adopting standardized templates. These templates should prioritize critical clinical findings, ensuring that reports align with clinical decision-making needs.

To address these issues, a comprehensive educational initiative targeting structured reporting, standardized nomenclature, and critical clinical elements is recommended. Additionally, feedback from clinicians and repeat auditing cycles will be essential to measure progress and sustain improvements.

By implementing these recommendations, the quality and consistency of MRE reporting for patients with CD at GSH can be significantly enhanced, ultimately improving patient management and outcomes.

Acknowledgements

The author, E.J.S., expresses her gratitude to her supervisor, S.M., for his guidance, and to Prof. Martin Kidd for his assistance with data analysis.

Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

Author contributions

E.J.S. was the principal investigator responsible for the literature review, data collection and preparation of the manuscript. S.M. was responsible for supervision and assisted with editing.

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of this article.

Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author, E.J.S. upon reasonable request.

Disclaimer

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of any affiliated agency of the authors.

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APPENDICES

Appendix A: Data Collection Details

Clinical history provided	
Crohn's disease	Known
	Suspected
MRE imaging	First
	Follow-up
Previous bowel surgery	Yes
	No

Technical factors			
Magnet strength	1.5T		
	3T		
	Not documented		
Oral contrast	Type	Y/N	
	Volume	Y/N	
Antiperistaltic drugs	Drug	Y/N	
	Dose	Y/N	
	Route of administration	Y/N	
Adequate bowel preparation	Y/N		- Optimal - Suboptimal - Insufficient
Adequate bowel distension	Y/N		- Optimal - Suboptimal - Insufficient
Scan coverage	Y/N		- Optimal - Insufficient
Artefacts	Y/N		- Peristalsis - Breathing - Foreign bodies / prosthesis - Lack of fat between bowel loops

Radiological findings			
Missing segments due to previous surgery:	Y/N/na		
Disease activity	Y/N/na		
- Disease present	Abnormal bowel	Thickness	Y/N/na
		Oedema	Y/N/na
		Ulceration	Y/N/na
		Vascularisation	Y/N/na
		Perienteric inflammatory changes	Y/N/na
		Resticted diffusion	Y/N/na
- Complications	Stricture	Location	Y/N/na

		Number	Y/N/na		
		Length	Y/N/na		
		Signs of inflammation	Y/N/na		
		Relation to surgical anastomosis	Y/N/na		
		Upstream bowel dilation	Y/N/na		
			Degree	Y/N/na	
	Fistula / sinus	Y/N/na			
		Site of origin	Y/N/na		
		Involved organs	Y/N/na		Entero-enteric Entero-vesical
		Classification	Y/N/na		Simple Complex
		Relationship to strictures	Y/N/na		
	Toxic megacolon	Y/N/na			If acute colitis
	Mesenteric mass / abscess	Y/N/na			
		Location	Y/N/na		
		Dimensions	Y/N/na		
		Feasibility for image guided drainage	Y/N/na		
	Vascular complications	Y/N/na			Mesenteric thrombosis Collateral pathways
Extension / localisation of disease	Y/N/na				
Peri-anal CD	Y/N/na				Yes – disease present No – no disease NA – perineal imaging not done
	Number of fistulae	Y/N/na			
	For each fistula	Complexity	Y/N/na		- Simple - Complex
		Type	Y/N/na		Park's classification
		Seton	Y/N/na		
		Internal opening	Clock face position	Y/N/na	
			Distance from anal verge	Y/N/na	
		External opening	Clock face position	Y/N/na	
			Distance from anal verge	Y/N/na	

			Position	Y/N/na	- Perineum - Gluteal - Vaginal
			Extension	Form	Y/N/na
				Type	Y/N/na
				Position clockface	Y/N/na
				End position	Y/N/na
		Abscess / collection	Y/N/na		
			Size	Y/N/na	
			Clockface position	Y/N/na	
			Type	Y/N/na	
	Anal sphincter integrity	Internal sphincter	Y/N/na		
			Intact		
			Defect	Angle of defect	Y/N/na
				Position of defect	Y/N/na
		External sphincter	Y/N/na		
			Intact		
			Defect	Angle of defect	Y/N/na
				Position of defect	Y/N/na
		Puborectalis muscle	Y/N/na		
			Intact		
			Defect	Angle of defect	Y/N/na
				Position of defect	Y/N/na
	Baseline fistula activity	Y/N/na			- Hyperintensity on T2 - Post contrast enhancement of primary tract
	Activity category	Y/N/na			
Extra-intestinal manifestations	Y/N/na				

Conclusion / Comment				
Initial diagnosis	Evidence of active disease	Y/N/na		
Follow-up imaging	Treatment response	Y/N/na		- Transmural remission - Significant transmural response - Stable disease - Progression of disease
		Bowel	Y/N/na	
		Perianal CD	Y/N/na	

Overall impression of report	
Structured	Y/N
Easy to read	Y/N
Accepted nomenclature used	Y/N

Appendix B: HREC Approval Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

19 December 2023

HREC REF: 976/2023

A/Prof S Moosa
Department of Radiology
Email: Sulaiman.moosa@uct.ac.za
Student: ejsmit1986@gmail.com

Dear A/Prof Moosa

PROJECT TITLE: AUDIT OF THE REPORTING ADEQUACY OF MAGNETIC RESONANCE ENTEROGRAPHY PERFORMED IN PATIENTS WITH CROHN'S DISEASE AT GROOTE SCHUUR HOSPITAL.
(MMED DEGREE - DR ELSABE JACOBA SMIT)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 December 2024.

Please submit a progress form, using the standardised Annual Report Form (FHS016) or FHS017 if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Elsabe Smit will also be involved in this study.

Please quote HREC REF 976/2023 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signed by candidate

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of

Appendix C: Hospital Approval Letter

Western Cape Government

GROOTE SCHUUR HOSPITAL
Enquiries: Mr Lionel Naidoo
e-mail: GSHResearch.Request@westerncape.gov.za

A/Professor S. Moosa
Department of Radiology

E-mail: sulaiman.moosa@uct.ac.za

Dear A/Professor Moosa

RESEARCH PROJECT: Audit of the Reporting Adequacy of Magnetic Resonance Enterography Performed in Patients with Crohn's Disease at Groote Schuur Hospital

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 December 2024**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) **Confidentiality must always be maintained.**
d) No additional costs to the hospital should be incurred as indicated in your Annexure 2 i.e. Lab, consumables or stationery. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form and approach Information Management to assist with data.**
e) **No patient folders may be removed from the premises or be inaccessible.**
f) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
i) Please discuss the study with the HOD before commencing.
j) Please introduce yourself to the person in charge of an area before commencing.
k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
l) If the researcher is not GSH staff member, a supernumerary contract is required before commencement of the research.
m) Please contact Michelle Riley (Patient Fees) at ext. 2276 to ascertain if there will be charges for conducting the Research and to obtain a quote or to discuss charges
n) **Kindly submit a copy of the publication or report to this office on completion of the research.**
o) **At no time should any posters encouraging patients to partake in research, be displayed within a clinical area.**
p) **Please adhere to ALL COVID-19 regulations and Groote Schuur Hospital policies.**
q) **All Clinical Trials to be registered on Clinicom with Michelle Riley.**
michelle.riley@westerncape.gov.za

I would like to wish you every success with the project.

Yours sincerely

Signed by candidate

LIONEL NAIDOO
HEAD: ALLIED HEALTH
Date: 19 January 2024
C.C. Mr. L. Naidoo, Mr. A. Mohamed, Dr N. Khumalo

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Appendix D: South African Journal of Radiology Instructions to Authors

Submission status	open
Word limit	4000 words (excluding the abstract, tables, figures, graphs, and references)
Abstract	maximum: 250 words requires structural headings: Background, Objectives, Method, Results, Conclusion and Contribution
Main text	requires structural headings, refer to the full structure 'Ethical considerations' is a sub-section in the manuscript and must include: • Name of the ethical review committee • Study approval number • Manner of consent (written, oral) for human participants • Description of measures taken to maintain the confidentiality of data • If the study was not human or animal research or the study was determined to be non-human subjects research or exempt, the authors must provide a statement with those details in this section.
References	40 or less, adhere to the **Vancouver referencing style**
Tables, figures and graphs	10 or less, adhere to the Illustrations requirements found in the AOSIS House style guide
Formatting requirements	apply the guidelines located on the **Formatting requirements page** and the **AOSIS house style guide**

Compulsory supplementary file(s)	the **Authorship, disclosure statements, copyright, and license agreement form**, **Ethical Clearance/Waiver Documentation** and any other relevant form applicable to your submission
Ethical clearance/waiver documentation	evidence of ethical clearance for the study, such as the study approval letter or certificate from the Institutional Review Board (IRB), a waiver from the IRB et cetera

Original Research Article full structure

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Objectives, Method, Results, Conclusion and Contribution.

- Background: *Why do we care about the problem?* State the context and purpose of the study. (What practical, scientific or theoretical gap is your research filling?)
- Objectives: *What problem are you trying to solve*? What is the scope of your work (e.g. is it a generalised approach or for a specific situation)? Be careful not to use too much jargon.
- Method: *How did you go about solving or making progress on the problem*? State how the study was performed and which statistical tests were used. (What did you actually do to get the results?) Clearly express the basic design of the study; name or briefly describe the basic methodology used without going into excessive detail. Be sure to indicate the key techniques used.

- Results: *What is the answer*? Present the main findings (that is, as a result of completing the procedure or study, state what you have learnt, invented or created). Identify trends, relative changes or differences in answers to questions.
- Conclusion: *What are the implications of your answer*? Briefly summarise any potential implications. (What are the larger implications of your findings, especially for the problem or gap identified in your motivation?)
- Contribution: What key insights into the research results and its future function are revealed? How do these insights link to the focus and scope of the journal? It should be a concise statement of the primary contribution of the manuscript; and how it fits within the scope of the journal.

Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

- Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by the use of evidence from the literature.
- Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic and should clarify the knowledge gap that this study will address. Your argument should be supported by the use of evidence from the literature.
- Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.
- Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

- Study design: An outline of the type of study design.
- Setting: A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.
- Study population and sampling strategy: Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.
- Intervention (if appropriate): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.
- Data collection: Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.
- Data analysis: Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used or steps followed in qualitative data analysis.
- Ethical considerations: Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the **SI convention** and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

- Key findings: Summarise the key findings without reiterating details of the results.

- Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.
- Strengths and limitations: Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.
- Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

Conclusion: Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

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