A critical analysis of a locally agreed protocol for clinical practice

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Abstract Within the traditional scope of radiographic practice (including advanced practice) there is a need to demonstrate effective patient care and management. Such practice should be set within a context of appropriate evidence and should also reflect peer practice. In order to achieve such practice the use of protocols is encouraged. Effective protocols can maximise care and management by minimising inter- and intra-professional variation; they can also allow for detailed procedural records to be kept in case of legal claims. However, whilst literature exists to encourage the use of protocols there is little published material available to indicate how to create, manage and archive them.

This article uses an analytical approach to propose a suitable method for protocol creation and archival, it also offers suggestions on the scope and content of a protocol. To achieve this an existing clinical protocol for radiographer reporting barium enemas is analysed to draw out the general issues. Proposals for protocol creation, management, and archival were identified.

The clinical practice described or inferred in the protocol should be drawn from evidence, such evidence could include peer-reviewed material, national standards and peer practice. The protocol should include an explanation of how to proceed when the radiographers reach the limit of their ability. It should refer to the initial training required to undertake the clinical duties as well as the ongoing continual professional updating required to maintain competence. Audit of practice should be indicated, including the preferred audit methodology, and associated with this should be a clear statement about standards and what to do if standards are not adequately met. Protocols should be archived, in a paper-based form, for lengthy periods in case of legal claims. On the archived protocol the date it was in clinical use should be included.

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Introduction

This article analyses an ‘existing’ clinical protocol for radiographer reporting barium enemas, to draw out general issues related to the creation, management and archival of protocols on which the practice is based; this ‘existing’ protocol had been used to guide routine radiographic practice in a large teaching hospital. The purpose of this article, using the barium enema reporting protocol as a vehicle, is to suggest practical advice on the development, use and on-going appraisal of clinical protocols. This article has value to radiographic practice at consultant, advanced practitioner, assistant practitioner and practitioner levels. Since standards should be set for the responsibilities, rather than for any one professional group, the protocol would have universal value to professions other than radiographers. Notwithstanding this, ‘radiographers’ will be referred to throughout the text because this article is focused to radiographic practice.

A protocol may be described as an official formality of etiquette—put more simply, an agreed [documented] system under which ‘something’ is conducted.1 For clinical purposes, a protocol should describe a detailed framework within which a patient is managed. Furthermore, given the research-based climate in which we operate, the framework should be based upon good quality evidence.2 Typically, in imaging and therapy, the protocol is likely to apply to a ‘category’ of patients—for barium enema reporting this is clearly the case. Thus, in the context of imaging and therapy, the primary purpose of the protocol is to provide a clear indication of how, certain categories of, patients will be managed and by whom. Consequently, if the protocol is based upon good research evidence, and the radiographer adheres to it, then one should be assured of the best available management and care. If all professionals work to the same protocol then all patients should be assured of the same quality of service, reducing inter- and intra-operator variability.

In the context of clinical negligence claims, it is essential that practice is based upon best evidence and peer practice.3,4 Some argue that such practice need not be documented (ie presented in a written form), and it is known that in a number of clinical centres this is the case. However, given that clinical negligence claims may arise some 21 years after the patient’s examination has been conducted (ie for children) it becomes difficult, even impossible, to construct a legal defence when what was actually done, and also why it was done, was not remembered.3 In this context alone the argument for not having written protocols is refuted. The value of evidence-based written protocols is therefore established.

The main body of this article is presented in three sections. First, in the section ‘Description of the ‘existing’ barium enema reporting protocol’, there is an explanation of how the ‘existing’ clinical protocol for radiographer reporting barium enemas was created; the protocol will then be presented. Second, in the section ‘Analysis of the protocol’, there is a critique of the protocol and the approach taken to its creation and review/management. Finally, in the section ‘Development and ingredients of a clinical protocol—a suggestion’, a proposal is made to indicate how a protocol might be created and managed effectively. At the end of the process, suggestions are made as to what YOU need to think about when developing your own protocols.

Description of the ‘existing’ barium enema reporting protocol

The protocol to be discussed can be seen in Fig. 1. The protocol for radiographer reporting of barium enema examinations was developed from an existing protocol for Radiology Registrar reporting of the same examination. (The consultant GI radiologist developed the original protocol.) This was augmented by a new protocol on report content following the RCR audit of 2003 recommendations.5

The Gastrointestinal (GI) Radiographer wrote the protocol, who then passed it to the consultant radiologist and Radiology Business Manager for comment. It is marked with a creation date, and review date, however no names or signatures appear on the protocol document itself.

The protocol sets out to say how and when examinations are to be reported. How significant findings should be communicated to the referrer and wider GI team. What to do in the case of inpatient reports, and how to deal with examinations where there is doubt as to the presence of pathology.

At the time the protocol was developed, several other hospitals in the region were contacted in an attempt to acquire copies of their protocols, to look at peer practice, however none were available. This may have been due to the fact that radiographer reporting of barium enemas was in its infancy at that time, with the first cohort of students on the GI reporting course having just
qualified. A similar exercise carried out now would undoubtedly yield more information.

Analysis of the protocol

As already suggested, there is limited literature readily available to guide how protocols are developed and managed. Given this it becomes difficult to perform a fully evidence-based analysis of the above protocol. Nonetheless, the approach taken here will be to use the limited available evidence, from the professional bodies, special interest groups, peer-reviewed papers on best practice and the website national electronic library for health, combined with some examples of existing clinical practice. For the purpose of analysis, the items from the above protocol will, where possible, be taken sequentially to assist with information assimilation.

Authorship

Two professional groups (a radiographer and the radiologists) developed the protocol. Literature suggests that all stakeholders should be involved.⁶,⁷ The Special Interest Group in Radiographic Reporting (SIGRR)⁸ supports the view that a team should be set up to develop reporting protocols. Ideally, in addition to the radiographer and the radiologists, the stakeholder group might have been broader. Thus the development team may have included professionals such as the GI nurse specialist, secretaries, receptionists, radiographer aids, assistant practitioners and the surgical and medical teams.⁷ The difficulty in this approach is that widening the development team would almost certainly lead to difficulty in reaching a consensus of opinion. NICE⁷ suggest that a team of 6–10 is the optimal number for such a group. This document also suggests ways of selecting team members.

A quite important point not explicitly stated on the protocol is the authorisation of its use. Again SIGRR⁸ provides valuable information. At 4.5 this document indicates that

The scope of reporting is defined in the protocol and must be agreed by reporting radiographers, the professional head of radiography within the trust, and the clinical director of the clinical radiology department. It must also be authorised at trust board level.

The National Electronic Library for Health gives an example of an X-ray protocol where there is provision for all of the above to authorise its usage.

Dates

The date the protocol was implemented was indicated on the protocol, which complies with Alderson and Hogg’s suggestion,³ this is also supported by SIGRR.⁸ However, on the protocol itself there was no indication of what should happen when it is updated; similarly there was no indication of what should happen to the "old" protocol when the original protocol has been updated and it is no longer used. As suggested earlier, particularly for clinical negligence claims, Alderson and Hogg³ suggest that once a protocol is

<table>
<thead>
<tr>
<th>The Protocol</th>
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<tbody>
<tr>
<td>1. The person who performed the barium enema should sign the request form</td>
</tr>
<tr>
<td>2. All images must be ‘double read’. The names of both reporters should appear on the final report.</td>
</tr>
<tr>
<td>3. Significant findings (eg carcinoma) must be communicated immediately to the referring physician and also the GI nurse practitioner.</td>
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<tr>
<td>4. All in-patients must have a preliminary report placed into their case notes on a blue sticker.</td>
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<tr>
<td>5. The second report (ie the double report) will be done daily between 08.00 and 08.45. The first report must be available in this reporting session for the second person to check</td>
</tr>
<tr>
<td>6. Double reporting must be completed within 48 hours of the barium enema examination being performed.</td>
</tr>
<tr>
<td>7. Only radiographers who have undertaken and passed a recognised training programme will be allowed to participate in the reporting process.</td>
</tr>
<tr>
<td>8. If there is doubt as to the presence of pathology a further opinion must be sought, ideally from the specialist GI radiologist.</td>
</tr>
<tr>
<td>9. Audit of radiographer [double] reported examinations should be carried out every 3 months. Audit should comply with TRMER 2000.</td>
</tr>
<tr>
<td>10. The following should be indicated within the report:</td>
</tr>
<tr>
<td>• Patient history</td>
</tr>
<tr>
<td>• Technical quality of the examination, for example completeness (eg did the barium flow throughout the required regions and bowel preparation?)</td>
</tr>
<tr>
<td>• A comment on pathology - indicating the most serious first</td>
</tr>
<tr>
<td>• Sizes and positions of polyps and tumours</td>
</tr>
<tr>
<td>• Malignancy for tumours should be indicated</td>
</tr>
<tr>
<td>• Recommendation of further examinations, if required</td>
</tr>
<tr>
<td>• Name of the people who [double] reported the examination</td>
</tr>
<tr>
<td>11. Radiographers can check only barium enemas at the present time.</td>
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</table>

Figure 1 The protocol.
updated the ‘old’ protocol should be archived in a suitable place, marked to indicate when it was in force—i.e. ‘start date’ and ‘end date’. Ideally, archived protocols should be paper-based, rather than stored on digital media. This minimises significantly any possibility of the prosecution suggesting tampering with the protocol after it had been archived. Perhaps in the future read only CD-Roms may have a part to play.

Double reporting

Within the trust double reporting is the norm for all barium examinations, and this is taken to mean that the person who undertakes the examination reviews the images and hand writes a report. This report, along with the images, is then taken to a set session with either a consultant GI radiologist or the GI advanced practice radiographer for review. This is specifically written into the protocol. However, it would be useful here to state how other hospitals in the area were reporting their barium enemas, so that the protocol was in line with local peer practice.

Literature supporting double reporting and the different methods of double reporting could be made reference to within the protocol. When a protocol is updated the literature should be ‘re-searched’ in case more up-to-date reference material has become available. This would ensure that current best practice was being followed.

Time scales

The protocol indicates that the report must be ready within 48 h, with In-patients having a provisional report placed in the medical notes at the time of the examination. The National Audit of Radiographic Reporting Services,5 the Royal College of Radiologists, standard for turnaround of reports on GP, and In-patients was set at 24 h, however the audit showed this to be unachievable, particularly in large acute hospitals. Thus the setting of a lower turnaround time, particularly for an examination where two individual reports are produced is not unreasonable. However, the protocol does not say if this target is to be audited. Within section 3 of the same audit report, it is suggested that:

[4.3.7] It is good practice to write a report directly into the patients records (though this advice indicates it applies when a radiologist carries out the examination)

Thus the protocol complies with the principle of this report.

The Cancer Plan9 also sets time scales for treatment of cancer patients from initial diagnosis. To ensure that these are adhered to, the protocol makes a suggestion as to how this category of patients’ reports should be communicated back to the referrer.

Training for radiographer reporting

The protocol states that only radiographers who have undertaken and passed a recognised training program will be allowed to double report. This complies with statements made by the College of Radiographers.12 Similarly SIGRR8 reflects the need for adequate training and education. The Royal College of Radiologists states that reporting should be carried out by an accredited radiologist or properly delegated. In stating that radiographers should have attended a recognised training course the protocol is reflecting the views of both professional bodies.

Within the protocol a procedure is highlighted as to the path to follow when the [radiographic] reporter is unsure—in this case they are advised to approach a specialist/senior member of staff. Alderson and Hogg,3 exploring case law,10 make clear the legal value of including this within a protocol. Similarly the Society and College of Radiographers also recognise that radiographers, as professionals, must acknowledge their own limitations and scope of practice, as reflected in statement 5 in the Statements for Professional Conduct.11 The SIGRR emphasis this point too.9 Being encouraged to acknowledge ones own limitations, and thus seek help and advice as required, may also engender a culture of learning and team working which in turn may improve service quality even further.

Audit

Although the protocol states that audit will be carried out on a regular basis, there is no definition indicated within the protocol as to what audit is, or indeed what should be audited and why. However, within the protocol reference is made to ‘IRMER 2000’13 and within this Statutory Instrument is a definition of [clinical] audit:

A systematic approach or review of medical radiological procedures, which seeks to improve the quality and outcome of patient
care through structured review. Whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, intended to lead to modification of practices where indicated and the application of new standards if necessary.

The aim of the audit therefore becomes clearer, however precisely what should be audited is not obvious. One might consider that accuracy of the ‘reporters’ should be examined, and this would be quite appropriate. However, the [double] reporting process sits within a broader context, such as patient satisfaction, financial and human resource implications, national targets, patient outcomes (including survival rates and quality of life), waiting times and report turnaround time. These might be audited too. Returning to audit of the reporting process itself—exact details of what is to be audited should be indicated.

In 2003, a national audit was conducted to assess the sensitivity of double contrast barium enemas (DCBE) in the diagnosis of colo-rectal carcinoma. This sort of report might prove a valuable resource for [reporting] standard setting against which performance can be measured. Similarly, work by Murphy and Loughran give some insight about the standards of radiographers’ performance on lesion detection in barium enema studies. Similarly, Halligan et al. have conducted work to assess observer variation and suggest a methodology to assess this.

When developing a method for audit/analysis of performance, care should be exercised regarding the limitations of the approach. For example, Shrovon notes deficiencies in Halligan et al.’s work. In academic circles this is common not least because nothing is perfect and intellectual debate is encouraged regarding information in the public domain. Variation in the quality of published material highlights the importance of discriminating, in a scientific fashion, between good and bad evidence. Another important [audit] information not included within the protocol is a definition of what an acceptable level of performance is. This is particularly important here because there is currently no nationally agreed standard. The SIGRR notes that there is an absence of national standards or performance measures, consequently suggesting that local standards may need to be agreed and implemented. The SIGRR goes on to suggest that audit may assess reports for accuracy, structure and effectiveness of communications to referring healthcare practitioners. SIGRR indicates that the outcome of such an exercise ‘should be fed back into the process’. Also, and quite importantly, should performance fall below the locally (or nationally) agreed standard of performance then there should be a clear statement included on what action(s) should be taken to remedy the situation. It might be worth noting that some X-ray departments operate within recognised quality frameworks (eg ISO 9000) and the quality assurance of department protocols falls within this kind of overarching quality framework.

It is evident that the protocol met many of the published suggestions regarding the general approach to developing a protocol and its contents. However, there were several points on which it failed. Nonetheless, the process of analysis does suggest areas in which the protocol could be improved. That said, it is worth noting that if a protocol is too detailed it may significantly restrict practice—this may be particularly restrictive for ‘experienced’ staff. Conversely, if the protocol is not adequately detailed then it may not be sufficiently supportive for ‘less experienced’ staff.

Development and ingredients of a clinical protocol—a suggestion

Reflecting on the protocol for radiographer reporting barium enemas and through examination of the literature whilst taking into account known clinical practice, the following might be seen as a good starting point for the development and management of a clinical protocol and also what could be addressed within it.

Protocol development and management and points that should be addressed within a protocol:

- Precise details of what should be done and when during the [clinical] procedures should be indicated.
- An indication that the protocol has been ‘approved’ for clinical use with ‘appropriate’ authorities.
- Stakeholders should be included in the development (and review) process.
- National standards, where available, should be included.
- Good quality relevant literature (ideally peer-reviewed) should be used, and cited.
- The people responsible for creating it, including names as well as designations (ie job titles), should be included on the protocol.
- The date it was implemented, and also the date by which it should be reviewed/revised, should be indicated.
The date it ceased to be used in clinical practice should be written onto ‘old’ protocols. Old protocols, in a paper version, should be suitably archived.

The audit process for the clinical activity, paying ‘adequate’ detail to methodology and also how data are processed and reported, should be included.

If the protocol sits within other guidance, rules or protocols they should be clearly stated on the protocol.

The required level of training and education including continual professional development for staff should be stated.

Definitions of ‘new’ words and terms or/and definitions of words and terms used in a new context should be included.

What to do/who to seek help from, when an unsure situation is reached, should be outlined.

Finally, considering the need to evidence peer practice and also meet the need to share good/best practice we would suggest that you consider placing your protocols into forums for use by other professionals. Additionally or alternatively, we welcome written comments about your protocol in relation to this article. Such comments should be directed to the Editor in Chief of this journal.

References