

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Can the completeness of radiological cancer staging reports be improved using proforma reporting? A prospective multicentre non-blinded interventional study across 21 centres in the UK.
AUTHORS	Patel, Anisha; Rockall, Andrea; Guthrie, Ashley; Gleeson, Fergus; Worthy, Sylvia; Grubnic, Sisa; Burling, David; Allen, Clare; Padhani, Anwar; Carey, Brendan; Cavanagh, Peter; Peake, Michael; Brown, Gina

VERSION 1 – REVIEW

REVIEWER	Dr Kieran Foley Division of Cancer & Genetics, School of Medicine, Cardiff University
REVIEW RETURNED	06-Aug-2017

GENERAL COMMENTS	<p>This non-blinded interventional study investigated the completeness of staging information in 6 common cancer types across 21 centres in the UK. The study found that completeness of staging information increased from 48.7% pre-proforma to 87.3% post-proforma, in 1,283 reports. In addition, end-user rating feedback suggested that proforma reporting improved several aspects of cancer staging and the treatment decision pathway, and that lead MDT radiologists felt the benefit of proforma reporting in terms of quality.</p> <p>Firstly, the authors must be commended for completing this study, which is an excellent example of collaborative radiology research in the UK. The study is well-designed to test the hypotheses and objectives.</p> <p>There are substantial difficulties in implementing a standardised reporting template into reporting scenarios, which have been discussed briefly. Major hurdles include IT and radiologist engagement. Despite using proformas, some staging information was still incomplete, even in users that volunteered to participate in the study. Perhaps the authors could elaborate on or suggest additional methods to improve radiologist engagement, thereby achieved a truly standardised system?</p> <p>The authors have discussed appropriate limitations of the study, including the power of detecting a difference in completeness of 20%, although they have achieved sufficient power at 30% difference. They have also briefly mentioned that accuracy was not assessed.</p> <p>The real benefit of complete cancer staging reports should translate into improved patient outcomes i.e. significant improvements in survival, time-to-treatment etc. This will need to be investigated in future studies.</p> <p>Minor Comments:</p>
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	<p>There are several typographical and grammatical errors throughout the manuscript, including in figures and appendices, which must be addressed. Some of these errors are included below.</p> <p>Abstract:</p> <ul style="list-style-type: none"> • “Proforma based assessment of stage of radiology facilitates..” should be replaced with “radiological stage”. <p>Introduction:</p> <ul style="list-style-type: none"> • The reference to appendix 1 would be better placed in the Methods section. • “A single centre study tumour found...” • “Similar improvements in data completeness have been found seen in pathology...” • “histopatholgy” <p>Methods:</p> <ul style="list-style-type: none"> • One centre did not successfully obtain Caldicott agreement, but it is not clear if this centre was included. The previous sentence says only centres that obtained written approval were included. Please clarify. • “clinical impact proformas” • Please expand MDM • The scoring forms used to assess the completeness of reports should be cross-referenced to the appropriate appendix. • The table containing power calculation data needs to be numbered e.g. Table 1 and subsequent tables re-numbered. <p>Results:</p> <ul style="list-style-type: none"> • The is some repetition of data between text and tables, which should be kept to a minimum. <p>Discussion:</p> <ul style="list-style-type: none"> • “...reports to 87.3% using proformas. An absolute overall improvement...” • “- the Hawthorne effect. Although, this could be an argument...” <p>These sentences need re-writing and the rest of the manuscript should be checked.</p> <p>References:</p> <ul style="list-style-type: none"> • Please check accuracy of references. For example, reference 2 does not appear complete. <p>Appendices:</p> <ul style="list-style-type: none"> • Appendix 3 is labelled as appendix 2 and Table 4 in appendix 3 is missing a table heading. • “precdictive” misspelt in cervical cancer, appendix 1. <p>Figures:</p> <ul style="list-style-type: none"> • Typos in the axis labels of Figure 3.
REVIEWER	Jenny Montgomery Queen Elizabeth University Hospital Scotland, UK
REVIEW RETURNED	10-Sep-2017
GENERAL COMMENTS	I really commend this paper. Minimal reporting for pathology as you say has greatly improved outcomes and the same should be the

	case for radiology. This study is not perfect - results are underpowered but I don't feel that should get in the way of this being published. Another criticism is the planning of the study and this could be acknowledged in the discussion. Many research projects use feasibility studies to assess the usefulness of an intervention prior to introduction and I wonder if this had been done would these IT glitches between RIS/ PACS/ reporting systems etc been ironed out and would have increased the usefulness of the intervention. More and more in the NHS now adding to workload and time spent on reporting and administration adds difficulty to time pressured services and introducing a pro forma would have to be slick, time saving and not add burden. Overall though I have to say this is an ambitious attempt to improve cancer staging and would be a welcome change. The paper is well written. Well done.
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REVIEWER	Nick Woznitza Homerton University Hospital & Canterbury Christ Church university, UK.
REVIEW RETURNED	18-Sep-2017

GENERAL COMMENTS	<p>Many thanks for the opportunity to review this interesting manuscript that outlines the development and evaluation of a standardised reporting template for cancer staging using radiology investigations.</p> <p>With cancer imaging playing a crucial role in prognostic and therapeutic decision making this is an important area, and the initial results of this work seem to indicate improvement in the information available to the MDT when a proforma report is used. A range of clinical centres and tumour sites have been included. However, given the scale of planned recruitment (time, number of centres) the overall sample size is small.</p> <p>The authors have identified one aspect that could have contributed, namely the increased time taken by radiologists to provide a template report. This area has not been discussed in sufficient detail, and is likely to be a significant barrier if proforma reporting for cancer staging is to be adopted.</p> <p>The manuscript is well written with a logical flow. Some areas would benefit from additional references to support positions.</p> <p>Appendices 1-3 not available for review.</p> <p>1. Title Concise and accurate</p> <p>2. Abstract P3 lines 38-40. Clarification on 'respondents ?clinicians receiving reports Results would be more balanced if additional time taken by radiologists to report an investigation was included. P4 lines 18-25. Cervical cancer was underpowered at 30% level, <51 proforma reports. P4 lines 35-38. Also potentially biased by radiologists who chose to use proforma when reporting cancer staging imaging?</p> <p>Introduction 3. Description of problem Scale and impact of incomplete radiology cancer staging reports provided.</p>
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	<p>4. Available knowledge Well structured summary. P5 lines 5-10. Could benefit from referencing P5 line 30. "A single centre study tumour found resectability...." Should this read "A single centre study found tumour resectability..."? P5 lines 33-34. What were the improvements with proforma reporting? From 27% completeness to...? P5 lines 35-37. Tumour site and number of reports for Ontario audit would be helpful P5 lines 52-55. Reference</p> <p>5. Rationale Provided. Structured reporting has improved histopathology reports but as yet has not been widely adopted in radiology.</p> <p>6. Specific aims Clearly defined question to be answered. This is a quality improvement study to examine the impact of structured proforma reporting on completeness of cancer staging imaging reports.</p> <p>Methods</p> <p>7. Context The study was conducted in a range of radiology departments across England to include common tumour sites.</p> <p>8. Interventions Intervention clearly outlined. The authors developed proformas for reporting common tumour site radiology investigations used by MDT for treatment decisions. The proformas were developed by expert groups through consensus and refined with peer feedback. P7 line 13. RCR Regional Chairs in preference to "Charimen"?</p> <p>9. Study of intervention Implementation and evaluation of cancer staging radiology report proforma described. Before and after study design to quantify the impact of reporting proforma on completeness of staging items on cancer imaging. Imaging examinations relevant to tumour sites defined. Time period for data collection given. P7 lines 41-45. Before and after cohort design used. P4 lines 28-30 states that study was non-blinded for both pre- and post-proforma reporting. Were the radiologists reporting the pre-intervention staging imaging aware that anonymised reports would be included? No information given regarding requirement to participate. Was this mandatory for all staging imaging for the relevant tumour sites? Does this represent a consecutive series or, in essence, convenience sampling?</p> <p>10. Measures Primary (staging information available at MDT) and secondary (implementation issues/usefulness of workshops/clinical impact) well defined and appropriate to answer research questions.</p> <p>11. Analysis Sample size calculations with different effect size provided, with target sample of 124 pre- and post-proforma reports for each tumour site. Qualitative and descriptive statistics were used to examine the secondary outcomes (implementation, usefulness, clinical impact). Actual recruitment (n=46 – 111 for tumour sites; overall n=496)</p>
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	<p>underpowered for 20%, cervical underpowered for 30% (n=46 proforma reports). Number of target participating centres (n=21) allowed for 10-15% withdrawal (P7 lines 24-25). Actual number of participating centres (n=15; P10 lines 52-54) therefore attrition/loss is 28% - does this affect the generalisability of the results?</p> <p>12. Ethical Considerations Confidentiality and clinical/information governance good practice observed. Requirement for HRA approval waived.</p> <p>Results 13. Results Insufficient number of proforma reports (total 496) and for all tumour sites completed. Improvement in overall number of staging items provided with proforma reporting, and for all tumour sites at 30% level, with exception of lung (14%) and cervical (35% but with only n=46 reports). The study was not powered to examine differences in performance at an individual radiologist level. However, it would be of value to indicate the number of radiologists at each clinical site and for each tumour site that provided a pre and post proforma staging report. Examination of Figure 4 (time to report) indicated 28 radiologists completed the questionnaire. Was this the number of participating radiologists? It would be useful to indicate which centres were DGH, tertiary and/or specialist cancer centres. Also, it would be useful to know how many staging reports discussed at MDT were provided by clinical site and tumour type. This will give context, especially as most respondent radiologists to the questionnaire indicated that proforma reporting took considerably longer. Table 1: Centres 6 (63.2%) and centre 21 (70.7%) only provided pre-proforma staging reports. These centres had the highest pre-proforma completeness of all participating centres but were not included in analysis – could the exclusion from the post-proforma analysis (due to non-submission) have influenced the results and degree of overall improvement in completeness of cancer staging? P14 lines 36 – 56. Significance of individual staging items is discussed at the 20% level (prostate, endometrial, cervical, rectal) yet the study was underpowered at 20% level – should 30% level be used? P15 lines 26-27. “Some queries were raised regarding the lung staging proforma were resolved by teleconference.” Should this read “Some queries raised regarding the lung staging proforma and were resolved by teleconference.” OR “Some queries raised regarding the lung staging proforma were resolved by teleconference.” P15 lines 37-42. The technical barriers to implementation should be discussed in greater depth, especially as the authors are advocating national rollout of proforma reporting for cancer staging imaging.</p> <p>Discussion 14. Summary Concise summary of the positive findings of the study, including across the board increases in completeness of key information used for cancer staging with the proforma report. The authors do not address in adequate detail that the study had failed to recruit to target despite extension of the window. P17 lines 48-50. Could be benefit with a reference to support the statement. P17 lines 50-52 Could be benefit with a reference to support the statement.</p>
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	<p>P18 lines 7-17. The authors suggest that the increased time taken to complete proforma cancer imaging reporting is related to the missing information often found in free text reporting. Feedback from the radiologists that used proforma reporting reported a significant time increase per examination, and that this was hampered by a perceived design deficiency with the proformas (Table 3; Proforma Design; point 4) and the time taken to remove negative findings when using the proforma (Table 3; Proforma Design; point 2). Are free text reports quicker because these areas are reviewed (e.g. lymph nodes) yet only reported if they are abnormal or as a summary (e.g. no pathological enlarged lymph nodes)? Given the well documented diagnostic capacity issues across England and a shortage in the consultant radiologist workforce, it would be useful if the authors consider the extra time taken to report each examination and potential impact on output.</p> <p>P18 lines 20-24. Should this single sentence paragraph be included at the end of the previous?</p> <p>P18 lines 26-28. Could be benefit with a reference to support the statement.</p> <p>There has been considerable work done by RSNA and ESR to develop a library of structured radiology report templates. Yet, for most imaging examinations a free-text report is preferred by the reporting radiologist. Why is that? Why has there been poor uptake? Could this hamper roll out of the current project?</p> <p>P18 lines 51-55 Could be benefit with a reference to support the statement.</p> <p>P18 line 58-P19 line 5. What is the link between MDT working in breast cancer improving outcomes at the results of the current study? The pre-proforma reports were still used for MDT discussions and decisions.</p> <p>P19 lines 31-33. Cervical cancer was underpowered at 30% level (46 reports of 51 required). This should be mentioned.</p> <p>The high attrition of clinical sites (15 of 21 recruited) should also be mentioned.</p> <p>P19 lines 33-39. Could be benefit with a reference to support the statement.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Dr Kieran Foley

Institution and Country: Division of Cancer & Genetics, School of Medicine, Cardiff University Please state any competing interests: None declared

Please leave your comments for the authors below

This non-blinded interventional study investigated the completeness of staging information in 6 common cancer types across 21 centres in the UK. The study found that completeness of staging information increased from 48.7% pre-proforma to 87.3% post-proforma, in 1,283 reports. In addition, end-user rating feedback suggested that proforma reporting improved several aspects of cancer staging and the treatment decision pathway, and that lead MDT radiologists felt the benefit of proforma reporting in terms of quality.

Comment: Firstly, the authors must be commended for completing this study, which is an excellent example of collaborative radiology research in the UK. The study is well-designed to test the hypotheses and objectives.

Response: We thank the reviewer for their kind and helpful feedback.

Comment: There are substantial difficulties in implementing a standardised reporting template into reporting scenarios, which have been discussed briefly. Major hurdles include IT and radiologist engagement. Despite using proformas, some staging information was still incomplete, even in users that volunteered to participate in the study. Perhaps the authors could elaborate on or suggest additional methods to improve radiologist engagement, thereby achieved a truly standardised system?

#R1 comment 1: We agree, and suggest additional methods in the paper as follows:

“Despite using proformas, some staging information was still incomplete, even in users that volunteered to participate in the study. We hope that in future this would be corrected by improvements in radiology user interface software which will not permit a report to be signed off unless all fields have an entry”

Comment: The authors have discussed appropriate limitations of the study, including the power of detecting a difference in completeness of 20%, although they have achieved sufficient power at 30% difference. They have also briefly mentioned that accuracy was not assessed. The real benefit of complete cancer staging reports should translate into improved patient outcomes i.e. significant improvements in survival, time-to-treatment etc. This will need to be investigated in future studies.

#R1 comment 2:

We acknowledge that it was “beyond the scope of this study to assess the accuracy of individual reports and indeed the greater task of whether this translates into improved outcomes. However, the staging items included in the proforma reports have already been shown to be prognostically crucial and have already been validated against survival outcomes. The point we are making is that if the information is not even present on the reports the prognostic information to optimise treatment is not available.”

Minor Comments:

There are several typographical and grammatical errors throughout the manuscript, including in figures and appendices, which must be addressed. Some of these errors are included below.

Response: We thank you for highlighting these, this has been addressed in the final manuscript.

Abstract:

- “Proforma based assessment of stage of radiology facilitates..” should be replaced with “radiological stage”.

Response: Amended.

Introduction:

- The reference to appendix 1 would be better placed in the Methods section.
- “A single centre study tumour found...”
- “Similar improvements in data completeness have been found seen in pathology...”
- “histopathology”

Response: Amended.

Methods:

- One centre did not successfully obtain Caldicott agreement, but it is not clear if this centre was included. The previous sentence says only centres that obtained written approval were included. Please clarify.

#R1 comment 3: We agree that the sentence is confusing and has been revised.

- “clinical impact proformas”
- Please expand MDM
- The scoring forms used to assess the completeness of reports should be cross-referenced to the appropriate appendix.

Response: Amended.

- The table containing power calculation data needs to be numbered e.g. Table 1 and subsequent tables re-numbered.

Response: Amended.

Results:

- There is some repetition of data between text and tables, which should be kept to a minimum.

Discussion:

- “...reports to 87.3% using proformas. An absolute overall improvement...”
- “- the Hawthorne effect. Although, this could be an argument...”

Response: Amended.

These sentences need re-writing and the rest of the manuscript should be checked.

References:

- Please check accuracy of references. For example, reference 2 does not appear complete.
- Thank-you, there was an error with the reference manager which has been corrected. All references are now complete.

Appendices:

- Appendix 3 is labelled as appendix 2 and Table 4 in appendix 3 is missing a table heading.
- “predictive” misspelt in cervical cancer, appendix 1.

Response: Amended.

Figures:

- Typos in the axis labels of Figure 3.

Response: Amended.

Reviewer: 2

Reviewer Name: Jenny Montgomery

Institution and Country: Queen Elizabeth University Hospital, Scotland, UK Please state any competing interests: None declared

Please leave your comments for the authors below

Comment: I really commend this paper. Minimal reporting for pathology as you say has greatly improved outcomes and the same should be the case for radiology. This study is not perfect - results are underpowered but I don't feel that should get in the way of this being published.

Response: We thank-you for you kind and helpful comments.

Comment: The study was originally powered to detect a 20% difference in improvement, and required a sample size of 124. However the detected improvement was in fact much greater and was over >30% for four of the 6 cancers types and overall. Thus, the study was sufficiently powered to detect this. The study found that for lung cancer, the baseline rates for completion were better than the other common cancers and also highlights that in relatively rare cancers such as cervical cancer, it would have taken longer to reach an adequate sample size. However, we don't believe that this detracts from the overall finding of a global improvement in radiological cancer staging.

Another criticism is the planning of the study and this could be acknowledged in the discussion. Many research projects use feasibility studies to assess the usefulness of an intervention prior to introduction and I wonder if this had been done would these IT glitches between RIS/ PACS/ reporting systems etc been ironed out and would have increased the usefulness of the intervention.

#R2 comment 1: The project was deliberately co-ordinated through the Royal college of Radiologists who were aware of the limitations of the problems in the UK with RIS systems and the challenges faced by hospitals in the procurement of RIS systems fit for purpose. This study highlights that the manufacturers need to improve functionality to enable easier integration of proforma reports into RIS systems. We hope that this paper will highlight the need sufficiently for national progress to be made.

Comment: More and more in the NHS now adding to workload and time spent on reporting and administration adds difficulty to time pressured services and introducing a pro forma would have to be slick, time saving and not add burden. Overall though I have to say this is an ambitious attempt to improve cancer staging and would be a welcome change. The paper is well written. Well done.

#R2 comment 2: We thank the reviewer for their supportive comments and insight.

Reviewer: 3

Reviewer Name: Nick Woznitza

Institution and Country: Homerton University Hospital & Canterbury Christ Church university, UK.

Please state any competing interests: None declared.

Please leave your comments for the authors below

Cooment: Many thanks for the opportunity to review this interesting manuscript that outlines the development and evaluation of a standardised reporting template for cancer staging using radiology investigations.

Response: We thank the reviewer for their helpful feedback and suggestions.

Comment: With cancer imaging playing a crucial role in prognostic and therapeutic decision making this is an important area, and the initial results of this work seem to indicate improvement in the information available to the MDT when a proforma report is used. A range of clinical centres and tumour sites have been included. However, given the scale of planned recruitment (time, number of centres) the overall sample size is small.

#R3 comment 1: We took independent statistical advice and we understand that “given the scale of the improvements we observed across the common cancer types the sample size was in fact too large and we had effectively overpowered the study for the primary endpoint”. We prolonged study to meet our secondary objectives of improvements in all cancers – clearly this was a challenge for the more rare cancer types. We do not think that this negates the overall finding and that sample size was appropriate for the question we had.

Comment: The authors have identified one aspect that could have contributed, namely the increased time taken by radiologists to provide a template report. This area has not been discussed in sufficient detail, and is likely to be a significant barrier if proforma reporting for cancer staging is to be adopted.

#R3 comment 2: The reviewer is correct in noting that the “perceived” additional time to provide a template report may be a potential barrier. Clearly, a report that comprises a few sentences of non meaningful data without clinically relevant information will take less time and will not be deemed “inaccurate”. Our findings indicate that such practice would result in poorer quality reports which would be detrimental to patient care. When a structured report is used, it is arguably quicker to complete than composing a lengthy descriptive yet uninformative report. This has been our consistent observation and accounts for the lack of minimal cancer items in the pre-proforma test set even amongst the same individual radiologists who performed significantly better using the proformas. As with pathologists who are subjected to regular audit of their reports for revalidation of their service the same should be in place for radiologists given the importance of cancer imaging assessment in pre-treatment decision making.

The manuscript is well written with a logical flow. Some areas would benefit from additional references to support positions.

Appendices 1-3 not available for review.

1. Title

Concise and accurate

2. Abstract

P3 lines 38-40. Clarification on ‘respondents ?clinicians receiving reports Results would be more balanced if additional time taken by radiologists to report an investigation was included.

Response: This was not a primary or secondary outcome measure this was a subjective response by some radiologists. It is hoped that the readers will understand that it is quicker and easier to produce an uninformative report but this does not help patient care.

P4 lines 18-25. Cervical cancer was underpowered at 30% level, <51 proforma reports.

Reviewer 3 comment 3: Thank-you for correctly highlighting this, it has now been explicitly stated in the results.

P4 lines 35-38. Also potentially biased by radiologists who chose to use proforma when reporting cancer staging imaging?

Response: The centres in the post-proforma cohort were required to use a proforma template for reporting all studies that met the inclusion criteria.

Introduction

3. Description of problem

Scale and impact of incomplete radiology cancer staging reports provided.

4. Available knowledge

Response: Well structured summary.

P5 lines 5-10. Could benefit from referencing

Response: We have now referenced the premise for the introductory paragraph.

P5 line 30. "A single centre study tumour found resectability...." Should this read "A single centre study found tumour resectability...?"

Response: Thank you, this has now been amended.

P5 lines 33-34. What were the improvements with proforma reporting? From 27% completeness to...?

#R3 comment 4 : Following the introduction of proforma reporting this reduced to 4%.

P5 lines 35-37. Tumour site and number of reports for Ontario audit would be helpful

#R3 comment 5: Rectal cancer staging reports, 51 of 128 reports had missing data.

P5 lines 52-55. Reference

Response: This statement is now supported with a reference.

5. Rationale

Provided. Structured reporting has improved histopathology reports but as yet has not been widely adopted in radiology.

6. Specific aims

Clearly defined question to be answered. This is a quality improvement study to examine the impact of structured proforma reporting on completeness of cancer staging imaging reports.

Methods

7. Context

The study was conducted in a range of radiology departments across England to include common tumour sites.

8. Interventions

Intervention clearly outlined. The authors developed proformas for reporting common tumour site radiology investigations used by MDT for treatment decisions. The proformas were developed by expert groups through consensus and refined with peer feedback.

P7 line 13. RCR Regional Chairs in preference to "Charimen"?

Response: Thank-you this has been amended.

9. Study of intervention

Implementation and evaluation of cancer staging radiology report proforma described. Before and after study design to quantify the impact of reporting proforma on completeness of staging items on

cancer imaging. Imaging examinations relevant to tumour sites defined. Time period for data collection given.

P7 lines 41-45. Before and after cohort design used. P4 lines 28-30 states that study was non-blinded for both pre- and post-proforma reporting. Were the radiologists reporting the pre-intervention staging imaging aware that anonymised reports would be included?

No information given regarding requirement to participate. Was this mandatory for all staging imaging for the relevant tumour sites? Does this represent a consecutive series or, in essence, convenience sampling?

Response: Yes, the radiologists in the pre-proforma cohort were aware that their reports maybe included, we acknowledge that this may have led to some observer effect. Consecutive reports for pre-treatment staging scans for the six cancer types were included in both the pre-intervention and post-intervention cohorts. Inclusion of consecutive reports (to avoid selection bias by the radiology leads) was emphasised at the launch meeting and they were reassured this was not an audit of the performance of any individual hospital or radiologists.

10. Measures

Primary (staging information available at MDT) and secondary (implementation issues/usefulness of workshops/clinical impact) well defined and appropriate to answer research questions.

11. Analysis

Sample size calculations with different effect size provided, with target sample of 124 pre- and post-proforma reports for each tumour site. Qualitative and descriptive statistics were used to examine the secondary outcomes (implementation, usefulness, clinical impact).

Actual recruitment (n=46 – 111 for tumour sites; overall n=496) underpowered for 20%, cervical underpowered for 30% (n=46 proforma reports).

Number of target participating centres (n=21) allowed for 10-15% withdrawal (P7 lines 24-25). Actual number of participating centres (n=15; P10 lines 52-54) therefore attrition/loss is 28% - does this affect the generalisability of the results?

#R3 Comment 6: We allowed for a degree of dropout by planning over-recruitment. There was however a higher than expected dropout rate, the reasons for which have been discussed.

This is not felt to effect the generisability of the results as there was still a broad range of hospitals/departments types in terms of district generals, specialist referral and teaching hospitals and a representative geographical cross-section.

12. Ethical Considerations

Confidentially and clinical/information governance good practice observed. Requirement for HRA approval waived.

Results

13. Results

Insufficient number of proforma reports (total 496) and for all tumour sites completed. Improvement in overall number of staging items provided with proforma reporting, and for all tumour sites at 30% level, with exception of lung (14%) and cervical (35% but with only n=46 reports).

#R3 comment 7: Thank-you this has been included in the results.

The study was not powered to examine differences in performance at an individual radiologist level. However, it would be of value to indicate the number of radiologists at each clinical site and for each tumour site that provided a pre and post proforma staging report. Examination of Figure 4 (time to

report) indicated 28 radiologists completed the questionnaire. Was this the number of participating radiologists?

Response: The radiology reports were fully anonymised, including reporting radiologist's details. This was to reassure centres that the performance of individual radiologists would not be assessed, as it was not an endpoint. This was to encourage full submission. Consequently, this also means information such as the number of reporting radiologists at each centre is not available. Twenty-eight radiologists completed the feedback questionnaire, this is not the total number of participating radiologists, as some may not have completed the questionnaire.

Comment: It would be useful to indicate which centres were DGH, tertiary and/or specialist cancer centres. Also, it would be useful to know how many staging reports discussed at MDT were provided by clinical site and tumour type. This will give context, especially as most respondent radiologists to the questionnaire indicated that proforma reporting took considerably longer.

#R3 comment 8: As the reports were pre-treatment cancer staging reports and it is mandatory to discuss all new cancer diagnoses at MDT with full staging. "Our audit has revealed that if pre-proforma reports had been used in MDTs they would not have met the national standards for MDT working. Thus, when staging items are missing on cancer staging reports, the radiologist taking the MDT must provide this information. The more missing data, the longer it will take. This extra time taken to do this is rarely acknowledged."

Table 1: Centres 6 (63.2%) and centre 21 (70.7%) only provided pre-proforma staging reports. These centres had the highest pre-proforma completeness of all participating centres but were not included in analysis – could the exclusion from the post-proforma analysis (due to non-submission) have influenced the results and degree of overall improvement in completeness of cancer staging?

Response: Their inclusion in the pre-proforma cohort will have increased the average percentage completion of this group. We do not know what their post-proforma performance would have been, the most likely 'worst-case' scenario would be that they did not show any improvement, which would reduce the average slightly of the post-proforma cohort. However we feel they are unlikely to have shown no improvement. Of note, centres 11 and 13, which had the next highest levels of pre-proforma completion (59% and 58%) showed improvements of 27% and 36% respectively in the post-proforma introduction.

P14 lines 36 – 56. Significance of individual staging items is discussed at the 20% level (prostate, endometrial, cervical, rectal) yet the study was underpowered at 20% level – should 30% level be used?

Response: Thank-you this has been amended.

P15 lines 26-27. "Some queries were raised regarding the lung staging proforma were resolved by teleconference." Should this read "Some queries raised regarding the lung staging proforma and were resolved by teleconference." OR "Some queries raised regarding the lung staging proforma were resolved by teleconference."

Response: Thank-you this has been amended.

P15 lines 37-42. The technical barriers to implementation should be discussed in greater depth, especially as the authors are advocating national rollout of proforma reporting for cancer staging imaging.

#R3 comments 9 & 10: We agree technical difficulties with proforma implementation certainly have been identified as an important barrier to uptake. There will need to be 'buy-in' from commercial RIS providers who will need to address the issues and ensure that there is an easy user-template interface.

Discussion

14. Summary

Concise summary of the positive findings of the study, including across the board increases in completeness of key information used for cancer staging with the proforma report. The authors do not address in adequate detail that the study had failed to recruit to target despite extension of the window.

Response: For the degree of improvement overall (38%) there was in fact relative over-recruitment. For cervical cancer there was under-recruitment in the post-proforma group, this may reflect an overall lower incidence.

P17 lines 48-50. Could be benefit with a reference to support the statement.

Response: Please see below.

P17 lines 50-52 Could be benefit with a reference to support the statement.

Response: Reference added.

P18 lines 7-17. The authors suggest that the increased time taken to complete proforma cancer imaging reporting is related to the missing information often found in free text reporting. Feedback from the radiologists that used proforma reporting reported a significant time increase per examination, and that this was hampered by a perceived design deficiency with the proformas (Table 3; Proforma Design; point 4) and the time taken to remove negative findings when using the proforma (Table 3; Proforma Design; point 2). Are free text reports quicker because these areas are reviewed (e.g. lymph nodes) yet only reported if they are abnormal or as a summary (e.g. no pathological enlarged lymph nodes)? Given the well documented diagnostic capacity issues across England and a shortage in the consultant radiologist workforce, it would be useful if the authors consider the extra time taken to report each examination and potential impact on output.

#R3 Comment 11: We agree that 'one of the perceived major obstacles to uptake by radiologists is increased time needed to complete a proforma report. A report containing little or no prognostic staging information will inevitably take less time. If it is accepted that a radiology cancer staging report should include all the prognostic information to manage a cancer patient, then it is logical to conclude that a prepopulated template with the required information set out will be much faster to complete than a free-text report. "

P18 lines 20-24. Should this single sentence paragraph be included at the end of the previous?

Response: Amended.

P18 lines 26-28. Could be benefit with a reference to support the statement.

There has been considerable work done by RSNA and ESR to develop a library of structured radiology report templates. Yet, for most imaging examinations a free-text report is preferred by the reporting radiologist. Why is that? Why has there been poor uptake? Could this hamper roll out of the current project?

Response: We believe there is much to learn from the experience of the pathologists and indeed breast screening and other services where template reporting is embedded but there was a similar initial resistance. The solution is very simple, which is to ensure that comprehensive cancer stage reporting by radiologists also becomes mandatory and part of the service specification to enable good patient care. Public and patient awareness of the importance of radiology staging will help to drive this.

P18 lines 51-55 Could be benefit with a reference to support the statement.

P18 line 58-P19 line 5. What is the link between MDT working in breast cancer improving outcomes at the results of the current study? The pre-proforma reports were still used for MDT discussions and decisions.

Response: This has been removed.

P19 lines 31-33. Cervical cancer was underpowered at 30% level (46 reports of 51 required). This should be mentioned.

Response: Thank-you this has now been included and discussed (see comment 7) .

Comment: The high attrition of clinical sites (15 of 21 recruited) should also be mentioned.

Response: This has been addressed earlier (comment 6).

P19 lines 33-39. Could be benefit with a reference to support the statement.

Response: Reference included.

VERSION 2 – REVIEW

REVIEWER	Kieran Foley Cardiff University, Wales
REVIEW RETURNED	17-Nov-2017

GENERAL COMMENTS	I am happy that the authors have addressed the majority of the reviewers' comments. The limitations of the study have been addressed and improved, including the issue of under-powering for cervical and endometrial cancers. There are a few grammatical errors that need amendment, for example Introduction p4 line 22 and discussion p19 line 49. Please check the accuracy of the references.
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REVIEWER	Jenny Montgomery Queen Elizabeth University Hospital, Scotland
REVIEW RETURNED	07-Nov-2017

GENERAL COMMENTS	The paper has been strengthened and I would continue to recommend acceptance.
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REVIEWER	Nick Woznitza Homerton University Hospital & Canterbury Christ Church University, UK
REVIEW RETURNED	09-Nov-2017

GENERAL COMMENTS	Many thanks to the authors for revising the manuscript. This is an important study that will lead to improved cancer reporting and, hopefully, streamlined MDT working and improved patient outcomes.
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