

Report

Quality improvement project: An evaluation of cancer staging using proforma reporting in Radiology (CASPAR)

April 2014

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REPORT SYNOPSIS

Project title: Quality improvement project: An evaluation of <u>c</u> ancer <u>s</u> taging using <u>p</u> roforma <u>r</u> eporting in Radiology (CASPAR)
Protocol: Final version 3.0 Date 16.03.12
Name of sponsor: The Royal College of Radiologists
Participating centres: Addenbrookes Hospital Bedford Hospital Bristol Royal Infirmary Cumberland Infirmary Guys and St Thomas' Heart of England NHS Foundation Trust Hull and East Yorkshire Llandough Hospital Maidstone and Tunbridge Wells Norfolk and Norwich University Hospital Nottingham University Hospitals NHS Trust Poole Hospital NHS Trust Royal Cornwall Hospital Royal Devon and Exeter Hospital Royal Glamorgan Hospital Royal Gwent Hospital Royal Lancaster Infirmary Salisbury District Hospital St Georges Hospital West Middlesex University Hospital NHS Trust Wythenshawe Hospital
Number of reports (analysed): Pre proforma reports - 787, Proforma reports - 496
Studied period: February 2012 to April 2013
Project objectives: To conduct and evaluate a pilot of implementation of proforma reporting for lung, gynaecological (cervical & endometrial), colorectal, and prostate cancers. Primary objective: <ol style="list-style-type: none">1. To compare data provided to the multi-disciplinary team (MDT) from Radiology cancer staging reports necessary to support clinical decision making before and after proforma adoption. Secondary objectives: <ol style="list-style-type: none">1. To test whether standardised proforma reporting for cancer staging in the MDT setting can be achieved in multiple centres.2. To describe how pilot centres implement proforma reporting.3. To identify areas of difficulty in implementation of proforma reporting and describe how they are overcome by the different centres.4. To evaluate the impact/usefulness of support workshops and proforma completion notes (are

either or both necessary?)

5. To receive feedback on the proformas from the MDT end users and adjustments from their use.
6. To determine the appropriateness of detail in the proforma: clinical impacts/decision pathways.
7. To compare our experience with the Ontario Cancer Care initiative (led by Dr Erin Kennedy, Toronto LHIN) and comparison of the equivalent evaluation forms for the participating centres in Ontario.

Project design and methodology:

A service evaluation comparing pre- with post-proforma implementation using a mixed retrospective (pre-proforma data) and prospective (post-proforma implementation data) methodology for data collection. Feedback from users of the proformas was also sought and analysed using both qualitative and quantitative methods.

Data analysis methodology:

Data were analysed by pH Associates using Microsoft Excel™ according to the agreed end points described in the study protocol. Data were analysed for the whole sample and stratified by tumour site.

Summary of key findings:

Completeness of reports

Using proforma reporting substantially increased the mean completeness of reports, with the overall mean percentage completeness of reports increasing from 48.1% (without proformas) to 86.9% for the 6 tumour sites evaluated. Lung increased from 47% to 89% (mean % completeness increased from 76.6% to 90.9%), prostate from 8% to 60% (mean % completeness increased from 45.4% to 80.1%), endometrial none to 58% (mean % completeness increased from 41.0% to 87.0%), cervical 5% to 61% (mean % completeness increased from 48.2% to 82.4%), rectal 1% to 72% (mean % completeness increased from 39.3% to 87.5%) and colon none to 90% (mean % completeness increased from 39.9% to 92.7%).

Value of impact/usefulness of support workshops

Of the 235 responses from 37 attendees of the support workshops 57% of the responses agreed or strongly agreed that the support objectives had been met (the range was 34% - 67% by tumour site). The workshop scoring 34% was repeated as a teleconference so that the objectives were met by further clarification and information.

Value of reports

Feedback from the Radiology MDT Leads regarding the actual proforma reports was overall positive with 87% of 212 collated responses from 32 respondents showing neutral to strong agreement with the statements that proformas were: easy to complete, self-explanatory, contained all key items, categories and order of terms, resulted in an improvement in the quality of reports and would consider using proformas for reporting in future. Feedback was also obtained from end users, MDT members, 78% of 165 responses from 35 respondents indicated that the reports had an impact on: staging, overall management plan, efficacy of MDT working, MDT data collection and clinical trial entry.

Feasibility of proforma implementation

One third of respondents felt the proforma reports took much longer to complete. Of 20 respondents reporting difficulties with implementation, 19 cited pressures at work (including colleagues' resistance) and all 20 I.T. problems as obstacles that needed to be overcome in the implementation. 16/19

respondents reported steps to overcome pressures at work and 11/20 reported overcoming IT obstacles. Not all centres successfully implemented the proforma reports and 15/21 returned reports for evaluation; this varied by tumour type. The most common problems encountered in implementing the reports were: IT systems/RIS not supporting the reports, pressure of time and colleague resistance. In order to try and overcome these obstacles centres worked with their IT departments/PACS teams, allocated more time for reporting and encouraged colleagues to take part. These measures were not always successful and the biggest barrier to implementing the reports seems to have been difficulties incorporating the proformas into HSS IT systems so the voice recognition system (VRS) could be used. VRS makes reporting much quicker and not being able to use this created a significant problem.

Overall, 81% of 32 respondents who had implemented at least one proforma agreed or strongly agreed that overall the exercise had been worthwhile and they would be happy to participate in a similar exercise in future.

Conclusions:

- There was a statistically significant improvement in completeness of cancer stage reporting through the use of proforma reporting for all cancer sites examined.
- A major barrier to the implementation of proforma assisted reporting was the difficulty of incorporating these types of forms into present electronic reporting systems.
- Two further related obstacles are the considerable change in current practice of proforma reporting from free text reports combined with a real concern that such practice would be more time consuming to the radiologist.
- Despite these concerns, 26/32 radiologists who provided feedback either 'agreed' or 'strongly agreed' that overall the exercise had been worthwhile from their point of view.
- From the project data it is evident that structured (proforma) reporting leads to more accurate information to aid an individual patient's staging and management, as well as providing comprehensive data for monitoring treatment and outcomes.

Recommendations:

- Radiologists in the UK should progress the implementation of structured (proforma) reporting for staging cancer so that it becomes the standard for all patients diagnosed with cancer.
- To facilitate this evolution, minimum data sets should be developed and piloted for each major cancer site by the relevant radiologists working in collaboration with other relevant clinicians and members of the multi-disciplinary team. These minimum data sets should be consistent with the National Data Set in order to facilitate data collection and reporting at a national level.
- IT problems and obstacles that prevent the integration of structured reports within existing IT systems/RIS should be addressed at a national level to ensure that structured reporting can be implemented efficiently without becoming burdensome or time consuming for radiologists.
- Steps should be taken to raise radiologists' awareness, understanding and enthusiasm for structured reporting. This will help radiologists to understand the benefits of structured reporting and support the evolution of this as a standard of care. This should build on the current acceptance of a checklist approach as a means of improving the quality and reliability of clinical practice, particularly amongst those in training (the workforce of the future).

GLOSSARY

Term	Definition
CRIS	Computerised Radiology Information System
CRMi	Involved circumferential margin
CT	Computed Tomography
HSS	Healthcare Software Systems (a commercial RIS provider)
IQR	Interquartile range
LHIN	Local Health Integration Network
LNi	Lymph node involvement
MDT	Multi-disciplinary team
MRF	Mesorectal fascia
MRI	Magnetic resonance imaging
NCIN	National Cancer Intelligence Network
NBOCAP	National Bowel Cancer Audit Programme
NHS	National Health Service
PACS	Picture Archiving Communication System
RCR	The Royal College of Radiologists
REC	Research Ethics Committee
RIS	Radiology Information System
R&D	Research & Development
SHA	Shared Health Authority
SIG	Special Interest Groups
VRS	Voice recognition system

1 INTRODUCTION

1.1 Background

In 1997, the Royal College of Pathologists introduced proforma reporting for cancers. An audit of histopathology reporting showed improvements in colorectal cancer reporting from 31% to 100% following the introduction of proforma reporting^{1 2}. Consequently, minimum data set reporting of prognostic histopathological data in colorectal cancer is now promoted as the standard of care that enables high-risk patients to benefit from postoperative adjuvant therapy³. In 2009, a prospective audit of prognostic factor reporting for colorectal cancer, with and without the use of a structured radiology reporting proforma, was performed in a single UK colorectal cancer network where initial staging reports of all newly diagnosed colorectal cancer patients were surveyed over six months⁴. Completeness of staging information using non-proforma reporting was compared with proforma reports. There were missing data in 118/121 (97.5%) of free-text reports. Information regarding the presence or absence of metastatic disease was missing in 90/121 (74.3%) of non-proforma CT reports. Tumour resectability status which informs the decision to treat with preoperative radiotherapy, was missing in 40/55 (73%) of free-text radiology reports. Using proforma reporting these measures improved significantly compared with free-text reporting, data were missing in only 4/121 radiology reports (3.0%, $p < 0.001$) and resectability status was missing in 2/55 (4%, $p < 0.001$). Proforma based reporting significantly improved the quality and completeness of staging reports compared with current practice. This approach needs to be validated in a wider cancer care setting.

1.2 Rationale for evaluation

There are documented wide geographical variations in cancer treatment and outcomes^{5 6}. Interpretation of this from national data collection in cancer has been hampered by a low level of staging data, much of which should, in theory, be available from imaging examination reports. The major reason for this is that there is no requirement for radiologists to deliver structured reports that deliver all the information required for consistent and equitable cancer management. Current radiological guidance in the UK does not consider structured reporting as essential and at the present time there is little evidence

to support its use. If such evidence was available, this would be likely to encourage rapid, consistent use of structured reports, not just in the United Kingdom but in other countries which have similar data collection problems in imaging.

2 STUDY AIMS & OBJECTIVES

2.1 Aim

The aim of this project was to carry out and evaluate a pilot of implementation of proforma-based reporting for lung, gynaecological (cervical & endometrial), colorectal and prostate cancers.

2.2 Objectives

Primary objective:

To compare minimum data provided in MDT Radiology reports to support clinical decision making before and after proforma adoption.

Secondary objectives:

- To test whether standardised proforma reporting for cancer staging in the MDT setting can be achieved in multiple centres.
- To describe how pilot centres implemented proforma reporting.
- To identify areas of difficulty in the implementation of proforma reporting and describe how these were overcome by the different centres.
- To evaluate the impact/usefulness of support workshops and proforma completion notes. (ie. are either or both necessary?)
- To receive feedback on the proformas from the MDT end users and adjustments from their use.
- To determine the appropriateness of detail in the proforma: clinical impacts/decision pathways.
- To compare the experience with the Ontario Cancer Care initiative (led by Dr Erin Kennedy, Toronto LHIN) and comparison of the equivalent evaluation forms for the participating centres in Ontario.

2.3 Null Hypothesis

There is no difference in the completeness of staging data in MDT Radiology reports made with or without the use of a proforma.

3 METHODOLOGY

3.1 Design

Centres taking part in the study agreed to implement proforma reporting for lung, gynaecological (cervical & endometrial), colorectal and prostate cancers. In order to compare minimum data provided in MDT Radiology reports produced to support clinical decision making, centres were asked to provide reports from the periods before and after introduction of proforma reporting. Centres were also requested to provide feedback from staff on the implementation and use of the proforma reports.

3.2 Centre recruitment & selection

The evaluation was conducted in NHS hospital cancer MDTs managing lung, prostate, gynaecological and colorectal cancers. Expressions of interest were sought from UK Radiology departments via the RCR website and an email invitation to all RCR Regional Chairmen, the Leads of all Special Interest Groups and members of the NCIN Site Specific Clinical Reference Groups. A good level of interest was shown and the study was over-subscribed with 36 Radiology departments from across England and Wales expressing an interest in taking part in the evaluation. (There were no expressions of interest from departments in Scotland and Northern Ireland). Following completion of a screening questionnaire (see appendix 3) to obtain information about current proforma use, type of RIS in use, staging report workload and capacity to undertake the CASPAR project, centres were selected by members of the CASPAR Project Reference Group using criteria which included the following;

- 2011/12 SHA Regions (equal representation of regions)
- Teaching/non-teaching hospital (1:2 ratio)
- RIS system (a variety of makes of systems represented)

- Provision of estimated weekly numbers of reports prior to the selection meeting
- Tumour groups offered for participation in the evaluation (to ensure sufficient centres/estimated numbers to provide the required sample size for each tumour group)
- No member of the project team working at the hospital.

21 centres were selected to take part in the evaluation, providing a 25% margin in the estimated numbers of reports to allow for the possibility that some centres would not be able to implement the proforma reporting and so would be unable to contribute to the proforma report sample size.

3.3 MDT Radiology report selection & sample size

It was planned, mainly for practical study scheduling purposes that reports submitted should be selected from specific time periods within the 3 months prior to introduction of proforma reporting and the 3 months following introduction of proforma reporting. The specific periods were different for each tumour group to reflect the difference in prevalence of the cancers (and therefore the number of reports likely to be available). Each centre was also given a centre-specific target number of reports for each tumour group which reflected the stated activity in their centre. In practice these time periods and centre-specific targets were not strictly adhered to as many estimates of the rate of reporting in normal practice proved to be optimistic and it was considered more important to have an adequate number of reports for inclusion in the analysis.

This was a Quality Improvement project to pilot the use of proforma Radiology reporting and not a formal research study. Thus the sample size was not primarily pre-determined by statistical calculations of what is required for reliable generalisability of the results, but pragmatically according to the number of centres judged to be necessary to provide a reasonable pilot of the proformas.

However, as a guide, sample size calculations were performed with the following assumptions:

- Difference in proportions = 0.2
- Current proportion (pre-proforma) = 0.5

- Improved proportion (with proforma) = 0.7
- Allocation ratio = 1 (i.e. equal sample size for two groups)

90% power, 5% significance⁷:

$$\text{Sample size} = \{1.96\sqrt{[(1+1)*0.5(1-0.5)]} + 1.2816\sqrt{[1*0.5(1-0.5)+0.7(1-0.7)]}\}^2 / 1*0.2^2 = 124$$

i.e. The recommended sample size at 90% power, 5% significance was **124** in each tumour group.

80% power, 5% significance:

$$\text{Sample size} = \{1.96\sqrt{[(1+1)*0.5(1-0.5)]} + 0.8416\sqrt{[1*0.5(1-0.5)+0.7(1-0.7)]}\}^2 / 1*0.2^2 = 93$$

i.e. The recommended sample size at 80% power, 5% significance was **93** in each tumour group.

It was expected that most centres would review at least one new patient per week for staging in any one of the cancers within the scope of this evaluation. Hence within a 3 month evaluation period, 15 centres should have provided a minimum of 180 patients' data for the pre and 180 for the post-proforma periods, even if each centre only implemented one proforma. The maximum would be 1080 in each group (pre- and post-) if all centres implemented all 6 proformas. In practice it was expected that the number of patients included would be between these extremes as some but not all centres would implement more than one proforma, and so from a maximum of 3 months' reports in 15 centres the recommended sample size of 124 reports per tumour group was expected to be reached.

3.4 Launch meeting

On the 27th February 2012 a workshop was held for all participating centres to launch the project. The purpose of this was to provide an overview of the CASPAR project, explain the project aims and to demonstrate the six pilot proformas (lung, prostate, endometrial, cervical, rectal and colon) which had been designed by the tumour site leads with input and feedback from the relevant Special Interest Groups (see appendix 4). After the initial introductory session support workshops were held for each of the following tumour sites: lung, prostate, cervical & endometrial and colon & rectal, where the individual proformas and accompanying guidance notes were explained in more detail. Participants were asked

to provide feedback using a structured feedback form (see appendix 5) regarding the pilot proforma reports and accompanying guidance notes and following the workshop some changes were made. Also, worked examples were provided for reference and a teleconference held for centres implementing lung proformas, to answer remaining questions and confirm the requirements of the project. Analysis of the feedback provided from this workshop is included in the results section of this report.

3.4.1 Report inclusion criteria

The following MDT Radiology reports were eligible for inclusion in the evaluation;

- Patients with an MDT Radiology report relating to the staging of cancer of one of the following; lung, prostate, endometrium, cervix, rectum, colon, which includes an MRI report or in the case of colon cancer a CT scan report. Only tumour staging reports as documented by the radiologist (either MDT radiology report, report addendum following MDT or staging cancer report) were acceptable. MDT minutes or reports by MDT co-ordinators were not acceptable.
- **Cohort 1** (pre proforma reporting) - consecutive patients for whom an MDT Radiology report was produced without the use of a proforma prior to implementation of proforma reporting.
- **Cohort 2** (post proforma reporting) - consecutive patients for whom an MDT Radiology report was produced following implementation of proforma reporting.

3.4.2 Staff inclusion criteria

The following staff were eligible to provide feedback on the use of the proforma reports;

- Radiologists who had completed at least one proforma report.
- Clinical end-users (MDT core members) who have received at least one proforma report for use in cancer management decision-making. These could include Surgeons, Physicians, Medical Oncologists, Palliative Care Physicians, Clinical Nurse Specialists, MDT Co-ordinators and MDT Audit Officers/Data Managers.

3.5 Participant Recruitment

- As the study only involved the review of anonymised routine MDT Radiology reports no patient consent was necessary. However, the Radiologist leading the CASPAR project at each centre was required to obtain written approval from the Trust Data Protection Officer (Caldicott Guardian) to release anonymised radiology reports to the CASPAR team for analysis. Only reports from centres providing a copy of this written approval were accepted for inclusion in the evaluation.
- Staff at each centre were approached to provide feedback on the use of the proforma report by the MDT Radiology Lead for each tumour site and responses were collated by the Radiology Lead acting as the local collaborator for the evaluation.

3.6 Observation period

MDT Radiology reports and staff feedback questionnaires were collected between March 2012 and April 2013.

3.7 Data collection

It was planned to assess the completeness of the non-proforma free text reports by using the information provided to complete relevant proformas. A trial attempt at completing proformas from free text reports identified problems with this proposal particularly in relation to data items becoming not applicable as a result of other responses recorded. In the circumstances it was decided to simplify the process by using coding forms which were derived from the proforma reports. The coding forms provided a checklist for presence or absence of key data items, accounting for non-applicability of data fields following a stated 'absent' response on the original report (see appendix 6). The coding forms were designed with input from the Project Leads from the relevant tumour sites. These were then completed using the data from the pre and post proforma reports and a record made of data fields with information recorded.

For the free text (pre proforma) reports this coding was carried out by a member of the project team experienced in reporting radiological images for the relevant tumour site.

For the proforma reports this coding was carried out by a member of staff from pH Associates with any queries being referred to the project team.

Standardized questionnaires were used to solicit staff feedback on the usefulness of proformas in reporting imaging results (Radiologists) and assisting clinical decision-making based on the reported information (MDT members) (see appendix 7).

3.8 Data management & quality control

3.8.1 Staging reports

Fifty-eight reports submitted (55 pre proforma, 3 proforma) had to be excluded. Reasons for exclusion varied but the most common were; report did not refer to staging of a cancer and did not include an MRI report.

3.8.2 Database management

A project database was developed to support data analysis by pH Associates using Microsoft Excel™. The database included data validation and drop down lists to restrict data entry values and minimize data entry errors.

Data from the coding forms and staff questionnaires were entered into the study database.

Throughout the study access to the database was password restricted to only those members of pH Associates staff directly involved with data entry and analysis.

3.8.3 Data quality checks

Data entered into the database was checked by pH Associates for data completeness using both visual and programmed validation checks. This included filtering columns (columns containing entered data or additional calculated columns) to identify missing data. The database was checked against the data collection form for any missing data that was identified, and corrected as appropriate. Self-evident corrections were undertaken by pH Associates.

3.8.4 Assumptions

The following assumptions were applied when transferring data from reports to the coding forms.

Tumour site proforma	Assumption
Colon	If 'no primary tumour seen' is recorded - data fields 1 to 6 become not applicable
Colon	If 'not easily seen' recorded next to tumour location - data fields 1 to 3 become not applicable
Prostate	If 'no lesion seen' recorded - data fields 3 to 9 become not applicable.
Prostate	If 'no positive nodes' recorded - data fields 11 & 12 become not applicable.
Cervical	If 'no tumour identified/seen' is recorded then data fields 1 to 3 become not applicable
Cervical	References to 'free fluid' accepted as evidence of data recorded for the ascites data field.

3.8.5 Data analysis

Pooled data from all centres were analysed by pH Associates, using Microsoft Excel™. The data were analysed for the whole sample and stratified by tumour site. No centre specific analysis was carried out. The data were analysed according to the end points pre-specified in the study protocol:

- Difference between reports made with and without the use of a proforma in the proportion of reports with a predefined minimum amount of information required to make a clinical decision on treatment (overall and stratified by tumour group)
- Distribution of elements of missing information in reports produced with and without a proforma
- Proportion of pilot centres able to implement proforma reporting (overall and stratified by tumour group)
- Distribution of number of proformas implemented by pilot centres
- Distribution of models of implementation
- Description of obstacles to implementation – those overcome and not overcome
- Centre 'case study' descriptions of how barriers to implementation were overcome
- Qualitative results of participant evaluations of support workshops
- Distribution of comments from clinical end-users of proforma reports (grouped thematically)

- Distribution of comments from Radiologist and MDT users of proforma reports, relating to appropriateness of detail in proformas
- Comparison of outcomes of this evaluation with the equivalent Canadian outcomes

Despite providing a signed Caldicott Approval Form one centre failed to supply any data (pre or post proforma reports, feedback forms) for inclusion in the evaluation. Another centre supplied pre proforma reports and feedback questionnaires, however as they had failed to provide a signed Caldicott Approval Form only the staff feedback forms could be included in the analysis.

4 RESULTS

4.1 Study sample

- 20 centres provided pre proforma free text reports for inclusion in the study.
- 15 centres provided proforma reports for inclusion in the study
- 11 centres provided feedback questionnaires

Table 1: Study centres

Centre No.	Centre	RIS System
1	Addenbrookes Hospital	HSS
2	Bedford Hospital	Agfa
3	Bristol Royal Infirmary	CSC
4	Cumberland Infirmary	HSS
5	Guys and St Thomas'	HSS
6	Heart of England NHS Foundation Trust	HSS
7	Hull and East Yorkshire	i-soft
8	Llandough Hospital	RADIS
9	Maidstone and Tunbridge Wells	HSS
10	Norfolk and Norwich University Hospital	Mckesson
11	Nottingham University Hospitals NHS Trust	HSS
12	Poole Hospital NHS Trust	HSS
13	Royal Cornwall Hospital	HSS
14	Royal Devon and Exeter Hospital	HSS
15	Royal Glamorgan Hospital	RADIS
16*	Royal Gwent Hospital	RADIS
17	Royal Lancaster Infirmary	HSS
18	Salisbury District Hospital	HSS
19	St Georges Hospital	i-soft
20	West Middlesex University Hospital NHS Trust	i-soft
21	Wythenshawe Hospital	Sunquest RIS

*Reports provided by centre 16 were excluded as a signed Caldicott Approval Form was not received.

Table 1 shows which centres were selected to provide data for inclusion in the study. No centres from either Scotland or Northern Ireland expressed an interest in being included in the study.

Figure 1: Geographic spread of study centres



4.2 Primary outcome

The completeness of reports produced pre and post implementation of proforma reporting was compared for each tumour site. Data from the reports were used to complete coding forms and these data were then used to calculate % completeness for each report.

(Percentage completeness equals proportion of applicable data fields with data recorded.)

Individual percentage completeness scores were then used to calculate mean values.

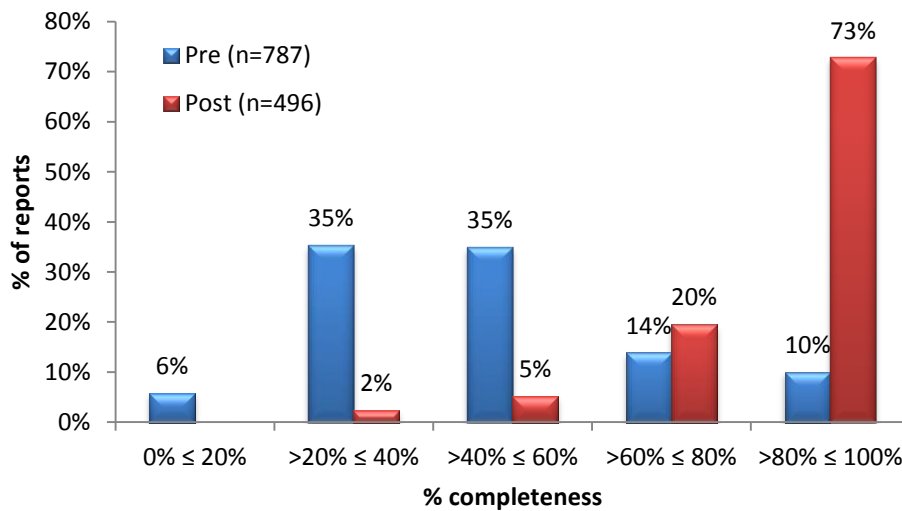
Table 2: Completeness of reports

Tumour site	Mean % completeness		Comparison of means Student T-test
	Pre proforma	Post proforma	
Overall	48.1% (n=787)	86.9% (n=496)	P<0.001
Lung	76.6% (n=125)	90.9% (n=84*)	P<0.001
Prostate	45.4% (n=156)	80.1% (n=108)	P<0.001
Endometrium	41.0% (n=112)	87.0% (n=59)	P<0.001
Cervix	48.2% (n=117)	82.4% (n=46)	P<0.001
Rectum	39.3% (n=135)	87.5% (n=111)	P<0.001
Colon	39.9% (n=142)	92.7% (n=88)	P<0.001

Overall, and for all 6 tumour sites individually, completeness of reports improved following the implementation of proforma reporting. T testing confirmed a significant difference at the 0.1% level (P<0.001) between mean percentage completeness of reports, overall and in all tumour groups, pre and post proforma implementation. The most noticeable improvements were in the completeness of reports for colon and rectal cancer. Lung reports showed the smallest improvement, being more complete than reports for other tumour groups without the use of a proforma.

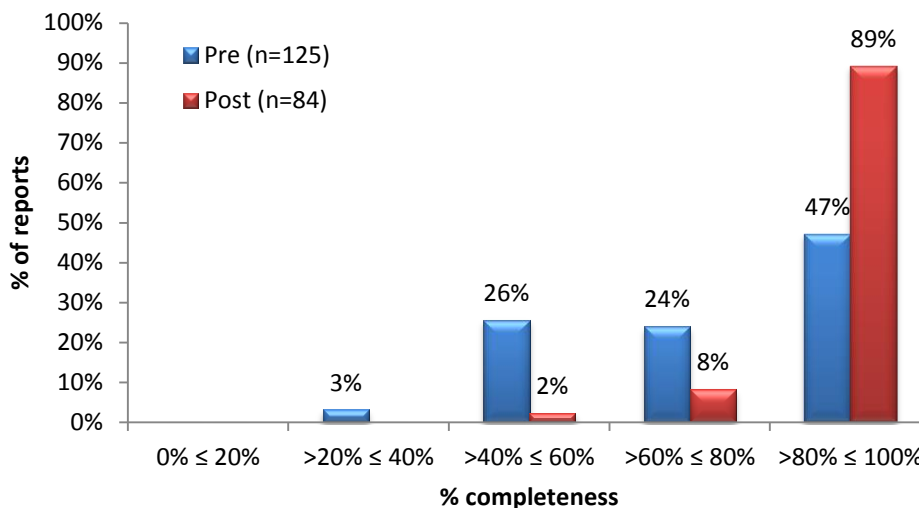
*Includes 10 reports from one centre which used a modified shorter version of the lung proforma. The modifications were made by the centre, without prior consultation with the project team. Where the modification removed a required data field, this contributed to incompleteness of the report vs proforma completeness measure. Mean % completeness for these 10 reports was 72.5%.

Figure 2: Percentage completeness of reports pre and post proforma reporting - Overall



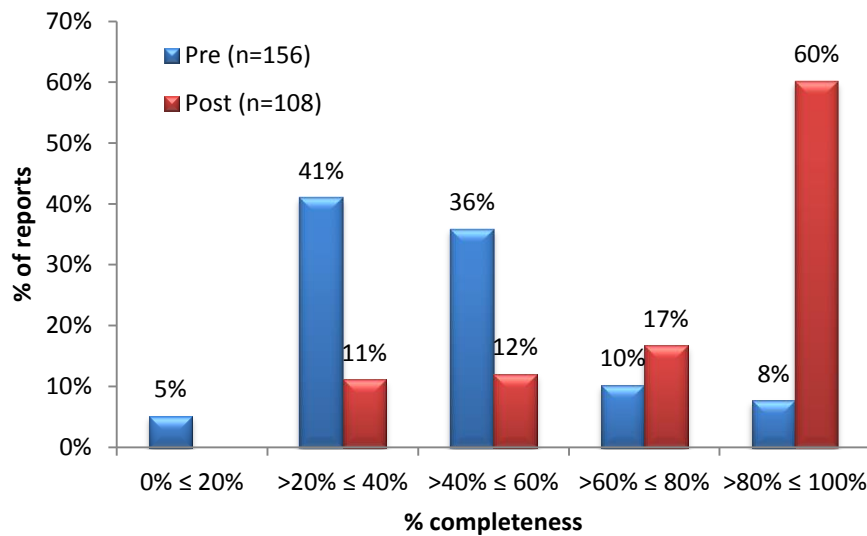
Prior to proforma implementation the median % completeness of reports was 46.2% (IQR 33.3% to 60.0%), post implementation this increased to 92.9% (IQR 78.6% to 100.0%). (see tables 1 & 2, appendix 1)

Figure 3: Percentage completeness of reports pre and post proforma reporting - Lung



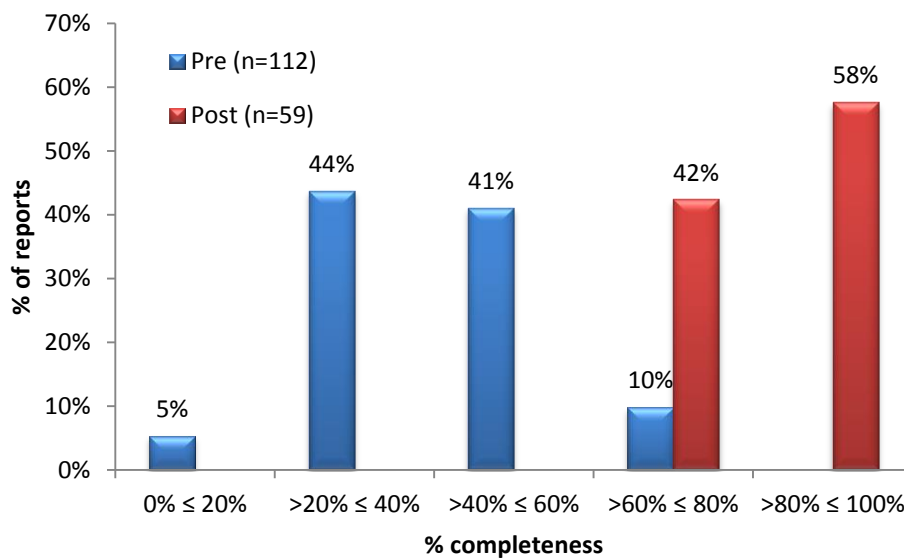
Prior to proforma implementation the median % completeness of reports was 76.5% (IQR 60.0% to 100.0%), post implementation this increased to 93.8% (IQR 87.5% to 100.0%). (see tables 1 & 2, appendix 1).

Figure 4: Percentage completeness of reports pre and post proforma reporting - Prostate



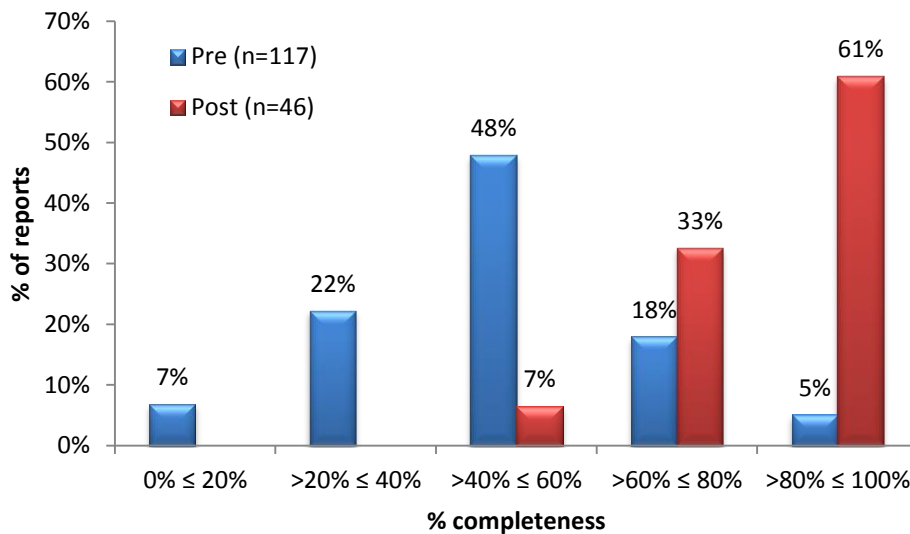
Prior to proforma implementation the median % completeness of reports was 41.7% (IQR 30.8% to 58.3%), post implementation this increased to 90.9% (IQR 63.6% to 100.0%). (see tables 1 & 2, appendix 1)

Figure 5: Percentage completeness of reports pre and post proforma reporting - Endometrial



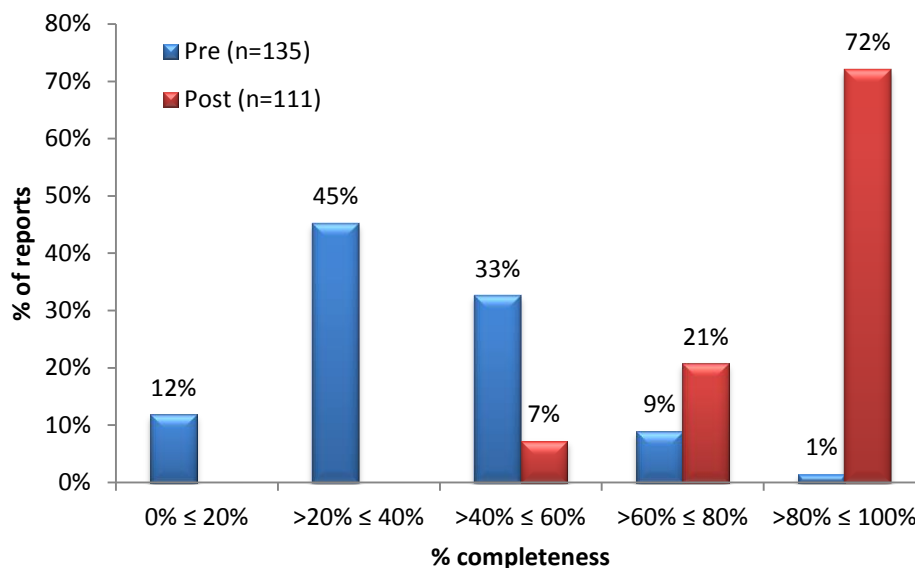
Prior to proforma implementation the median % completeness of reports was 44.1% (IQR 33.3% to 50.0%), post implementation this increased to 94.1% (IQR 72.2% to 100.0%). (see tables 1 & 2, appendix 1)

Figure 6: Percentage completeness of reports pre and post proforma reporting - Cervical



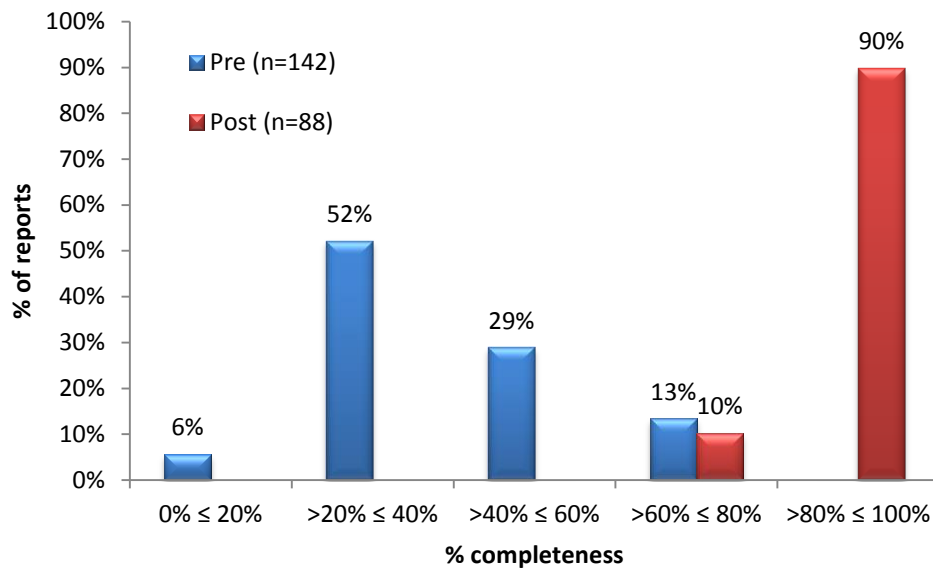
Prior to proforma implementation the median % completeness of reports was 47.1% (IQR 35.7% to 58.8%), post implementation this increased to 88.2% (IQR 70.6% to 94.1%). (see tables 1 & 2, appendix 1)

Figure 7: Percentage completeness of reports pre and post proforma reporting - Rectal



Prior to proforma implementation the median % completeness of reports was 40.0% (IQR 27.9% to 50.0%), post implementation this increased to 92.9% (IQR 78.6% to 100.0%). (see tables 1 & 2, appendix 1)

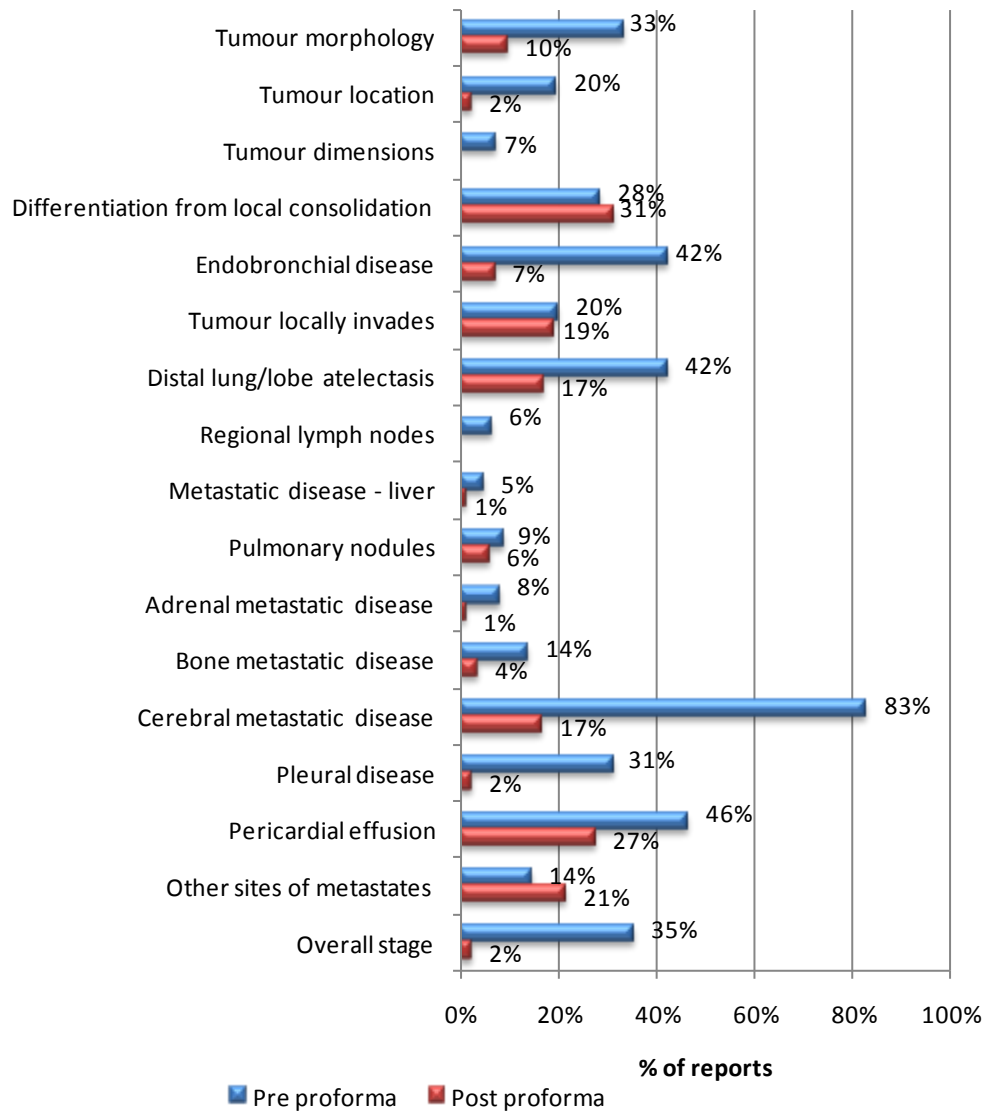
Figure 8: Percentage completeness of reports pre and post proforma reporting - Colon



Prior to proforma implementation the median % completeness of reports was 38.5% (IQR 30.8% to 46.2%), post implementation this increased to 92.3% (IQR 84.6% to 100.0%). (see tables 1 & 2, appendix 1)

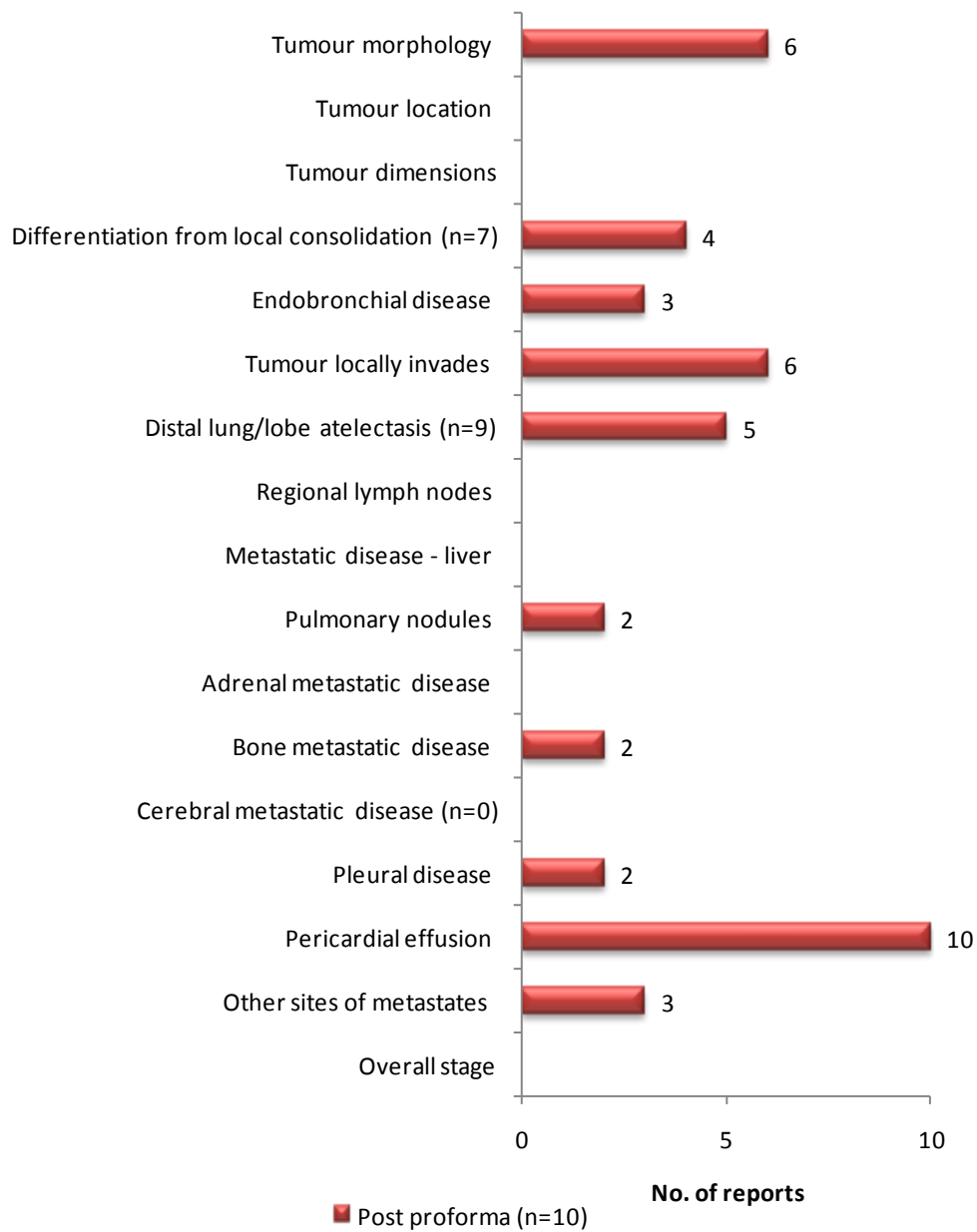
Further analysis of the data showed which data fields were most commonly omitted.

Figure 9: Distribution of missing data fields - Lung



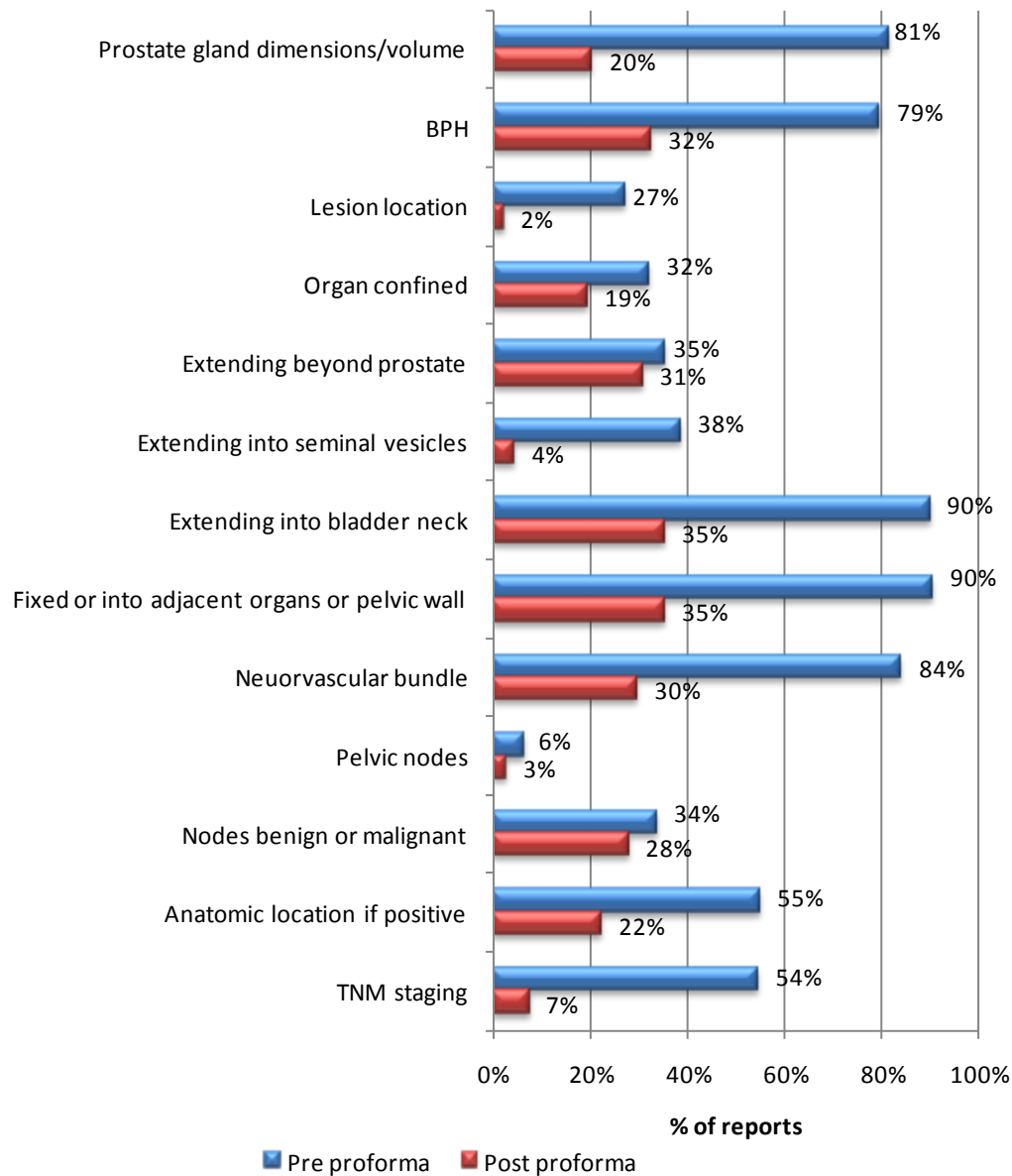
The results showed an overall decrease in the number of lung cancer data fields with data missing following implementation of proforma reporting (see table 3, appendix 1)

Figure 10: Distribution of missing data fields – Lung (modified proforma reports)



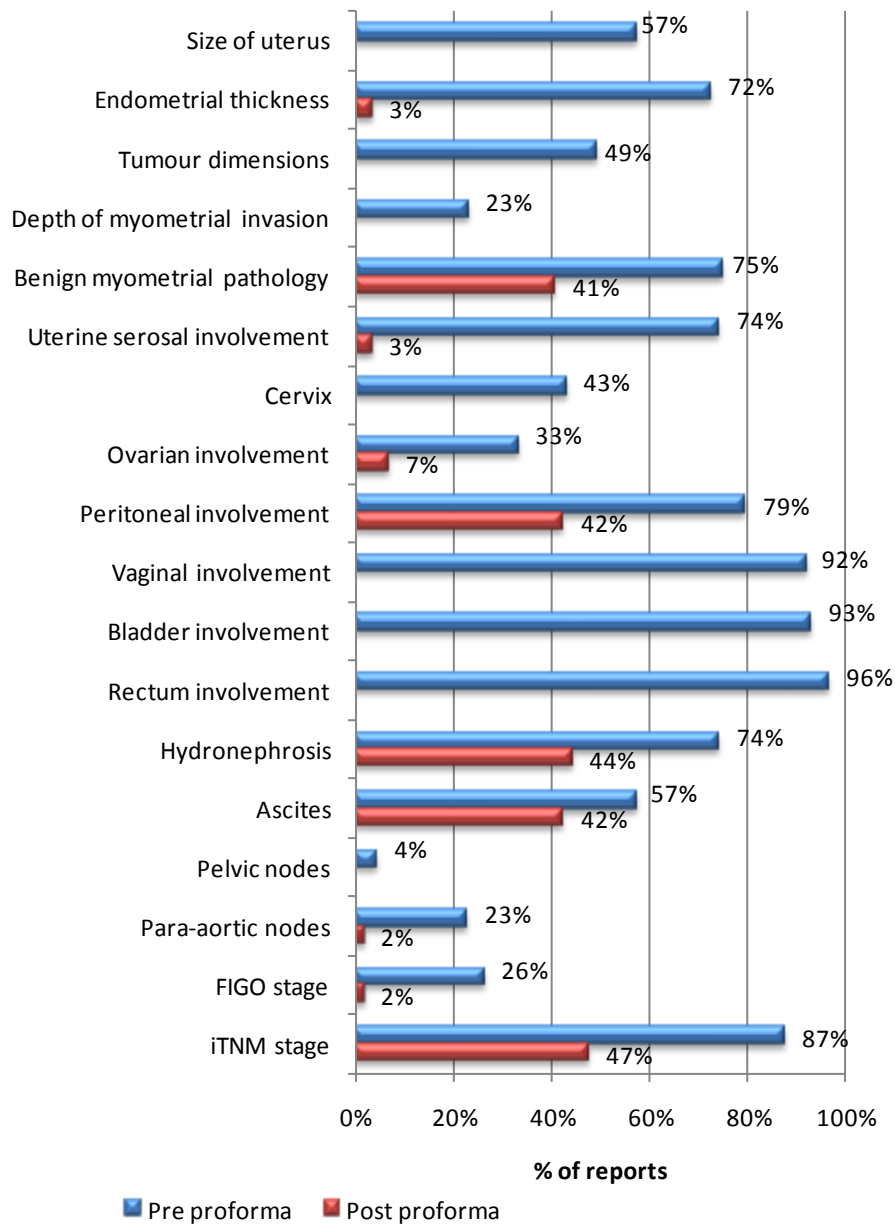
The figure shows which data fields were missing on the 10 lung cancer modified proforma reports. (see table 4, appendix 1)

Figure 11: Distribution of missing data fields - Prostate



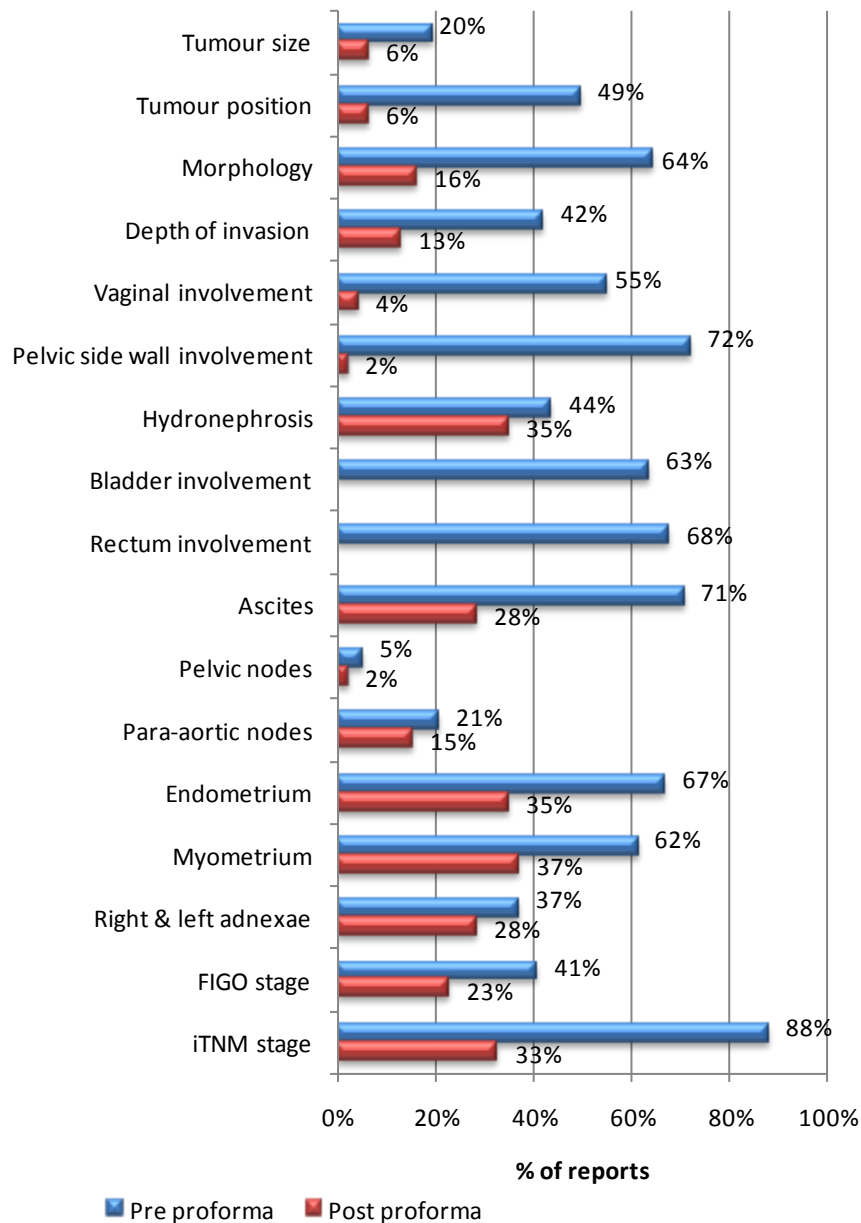
The results showed an overall decrease in the number of prostate cancer data fields with data missing following implementation of proforma reporting. (see table 5, appendix 1)

Figure 12: Distribution of missing data fields - Endometrial



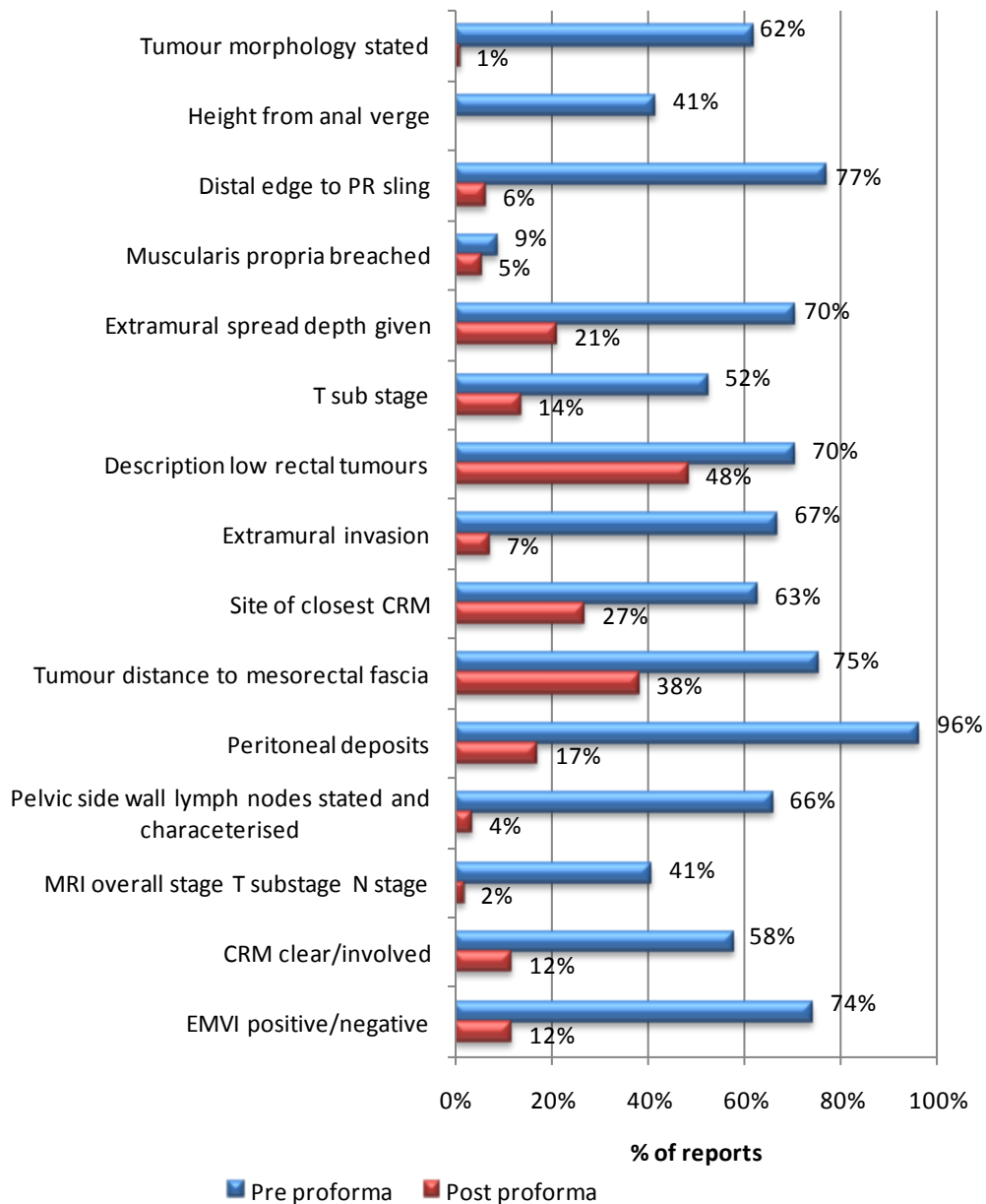
The results showed an overall decrease in the number of endometrial cancer data fields with data missing following implementation of proforma reporting. (see table 6, appendix 1)

Figure 13: Distribution of missing data fields - Cervical



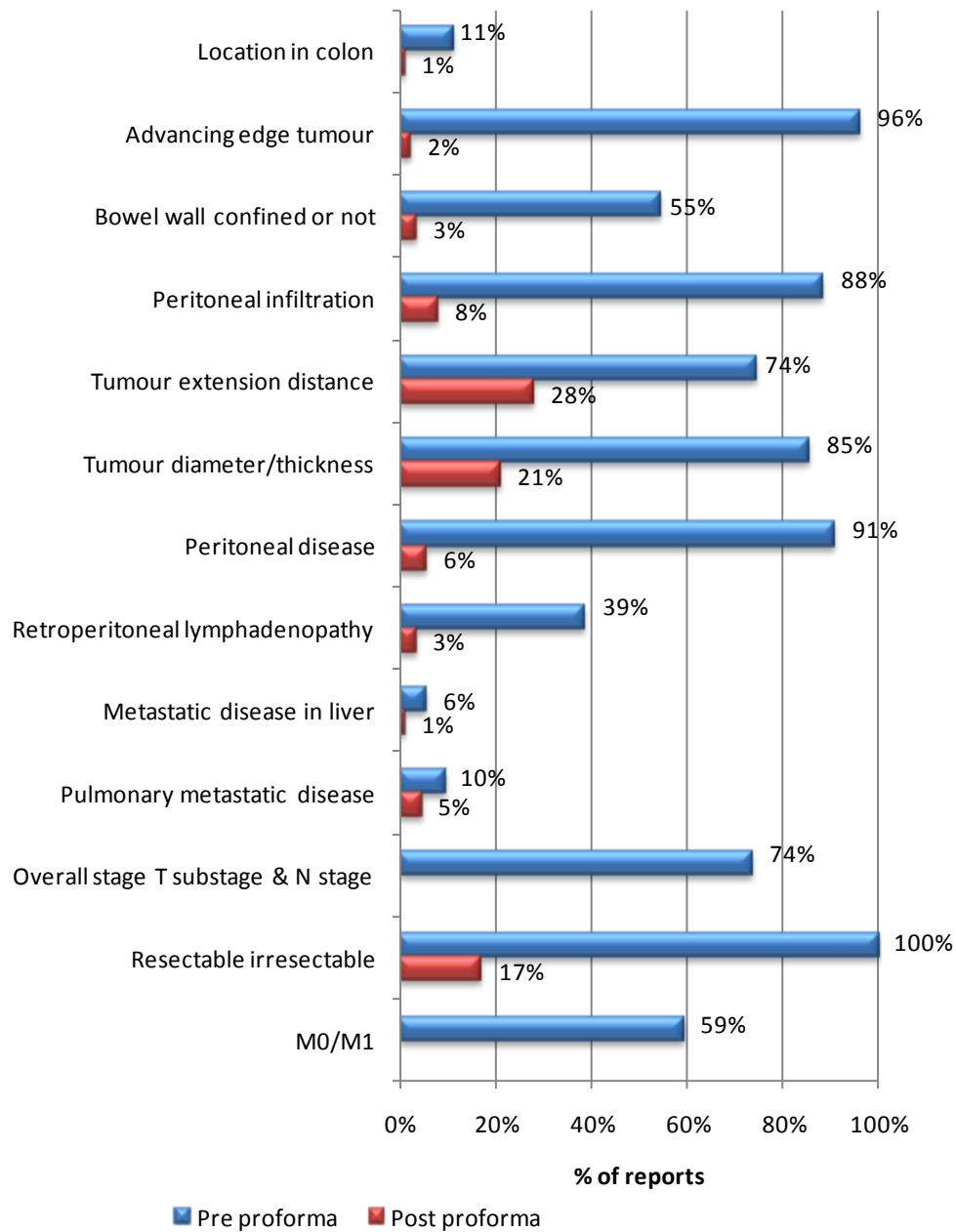
The results showed an overall decrease in the number of cervical cancer data fields with data missing following implementation of proforma reporting. (see table 7, appendix 1)

Figure 14: Distribution of missing data fields – Rectal



The results showed an overall decrease in the number of rectal cancer data fields with data missing following implementation of proforma reporting. (see table 8, appendix 1)

Figure 15: Distribution of missing data fields – Colon



The results showed an overall decrease in the number of colon cancer data fields with data missing following implementation of proforma reporting. (see table 9, appendix 1)

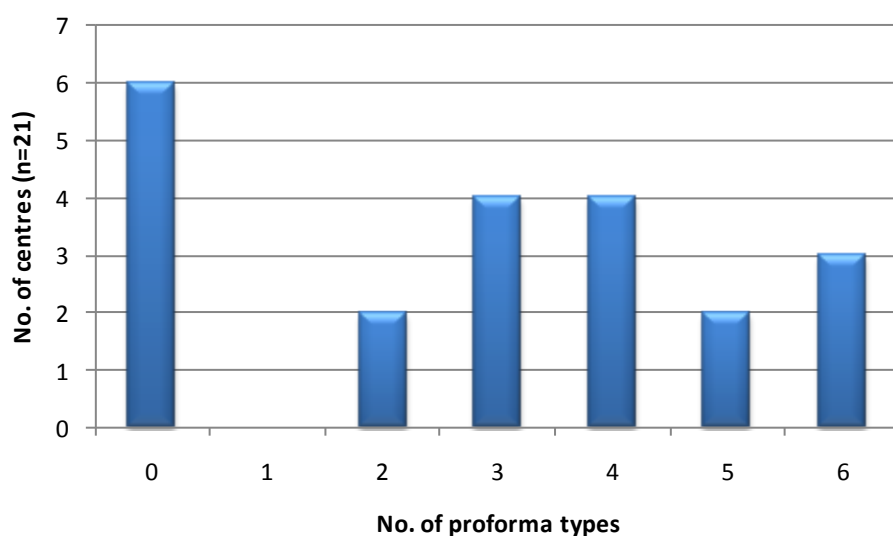
4.3 Secondary outcomes

4.3.1 Centres implementing proforma reporting

Overall 71% (15/21) centres supplied post proforma reports suggesting they had been successful in implementing proforma reporting for at least one tumour site.

- 63% (10/16) centres who had planned to implement the lung cancer proforma supplied reports.
- 64% (7/11) centres who had planned to implement the prostate cancer proforma supplied reports. A further 2 centres who had not planned to implement the proforma also supplied reports.
- 42% (5/12) centres who had planned to implement the cervical cancer proforma supplied reports. A further 2 centres who had not planned to implement the proforma also supplied reports.
- 46% (6/13) centres who had planned to implement the endometrial cancer proforma supplied reports. A further centre which had not planned to implement the proforma also supplied reports.
- 68% (13/19) centres who had planned to implement the rectal cancer proforma supplied reports. A further centre which had not planned to implement the proforma also supplied reports.
- 75% (12/16) centres who had planned to implement the colon cancer proforma supplied reports. A further centre which had not planned to implement the proforma also supplied reports.

Figure 16: Distribution of number of proforma types implemented per centre



13/21 (62%) centres successfully implemented 3 or more of the reporting proformas. (see table 10, appendix 1)

4.3.2 Launch meeting and support workshops

The **launch meeting** commenced with a plenary session explaining the objectives of the project with discussion from participants followed by tumour specific support workshops led by a representative of each of the tumour site leads. The objective of the support workshops was to discuss interpretation of imaging required to complete reporting proformas. The meeting finished with a plenary session clarifying the required input from centres. Attendees completed feedback forms regarding the usefulness of each of these sessions.

Plenary session feedback:

Percentage of respondents **agreeing** or **strongly agreeing** with the following statements;

- The REASONS behind the CASPAR project were well explained – 76%
- The OBJECTIVES of the CASPAR project were made clear – 67%
- The overall METHODOLOGY of the project was clearly explained – 33%
- The DEMONSTRATION of the proformas was helpful – 55%

(see table 11 appendix 1)

Respondents provided comments;

- it was felt the methodology was not clearly explained:
'some remaining questions on methodology'
- that the proformas should have been demonstrated:
'proformas themselves not demonstrated in plenary session'
- and that more time should have been given to the IT options:
'the IT issues were dealt with a bit superficially for me'.

However some respondents did comment that some of these issues were explained in more detail in the support workshops.

Support workshops

Table 3: Feedback support workshop LUNG

Statements	N	% agree or strongly agree
The presentation given in this session was very clear	8	50%
The presentation covered everything I needed to know about completing the proforma	9	33%
All my questions in relation to proforma use were answered	9	0%
I feel confident to explain the use of this proforma to colleagues	9	22%
I can see how I can use this proforma in my clinical practice	9	33%
I will need more support to help me use this proforma before I can take part in the pilot	9	56%
There are some parts of the proforma that I will be unable to complete	9	44%

(see table 12, appendix 1)

Respondents provided comments; it was felt there was still a lot of confusion regarding how to complete the proformas and respondents were disappointed that there hadn't been time to complete test examples.

Table 4: Feedback support workshop RECTAL & COLON

Statements	N	% agree or strongly agree
The presentation given in this session was very clear	16	100%
The presentation covered everything I needed to know about completing the proforma	16	69%
All my questions in relation to proforma use were answered	15	80%
I feel confident to explain the use of this proforma to colleagues	16	63%
I can see how I can use this proforma in my clinical practice	16	94%
I will need more support to help me use this proforma before I can take part in the pilot	16	31%
There are some parts of the proforma that I will be unable to complete	15	27%

(see table 13, appendix 1)

Respondents provided comments; it was felt support would be needed with the IT aspect of the project.

Table 5: Feedback support workshop PROSTATE

Statements	N	% agree or strongly agree
The presentation given in this session was very clear	6	100%
The presentation covered everything I needed to know about completing the proforma	6	67%
All my questions in relation to proforma use were answered	6	67%
I feel confident to explain the use of this proforma to colleagues	6	50%
I can see how I can use this proforma in my clinical practice	6	83%
I will need more support to help me use this proforma before I can take part in the pilot	6	33%
There are some parts of the proforma that I will be unable to complete	6	67%

(see table 14, appendix 1)

Attendees provided comments; it was felt the session had been a very useful lecture on the nature of prostate cancer but more discussion re the proforma would have been welcome.

Table 6: Feedback support workshop CERVICAL & ENDOMETRIAL

Statements	N	% agree or strongly agree
The presentation given in this session was very clear	3	100%
The presentation covered everything I needed to know about completing the proforma	3	33%
All my questions in relation to proforma use were answered	3	33%
I feel confident to explain the use of this proforma to colleagues	3	67%
I can see how I can use this proforma in my clinical practice	3	100%
I will need more support to help me use this proforma before I can take part in the pilot	3	33%
There are some parts of the proforma that I will be unable to complete	3	0%

(see table 15, appendix 1)

Attendees provided comments; it was felt the session had been helpful.

Table 7: Feedback afternoon plenary session

Statements	N	% agree or strongly agree
I know what retrospective reports I need to provide for CASPAR and how I will submit these	31	77%
I know what approval I need to obtain to release these data to CASPAR	32	94%
I have been given enough help to allow me to seek this approval	31	84%
I understand the technical aspects of implementing the proforma(s)	32	47%
I know what to do to seek help in the technical implementation of the proforma(s)	32	44%
I know WHO to send the proforma-based data to for the CASPAR pilot	31	94%
I know WHEN to send data for the CASPAR pilot	31	81%
All my questions about CASPAR were answered	30	37%
I know who to contact if I have any queries about the project once we begin	30	87%

(see table 16, appendix 1)

Attendees provided comments: confusion still remained regarding how to import the report proformas in to existing reporting systems, but some attendees felt they had a better understanding of what data were required.

Table 8: Overall evaluation of workshop

Statements	N	% agree or strongly agree
The meeting was a comprehensive introduction to the CASPAR pilot project	33	70%
I feel equipped to implement the project at my centre	33	39%
I anticipate major hurdles in implementing the CASPAR pilot in my hospital	33	33%
I would like to attend another meeting for further support	33	18%
There needs to be another similar meeting for my colleagues to attend	33	18%
I no longer feel able to volunteer to participate in the CASPAR pilot	32	0%
The meeting was well organised	32	84%
The meeting was too long	32	0%
The venue was suitable	33	82%
The location of the meeting was convenient	33	67%
The pre-meeting arrangements were efficient	33	82%

(see table 17, appendix 1)

Attendees provided comments; mainly regarding the difficulty in converting interest in to action among colleagues and the amount of work involved.

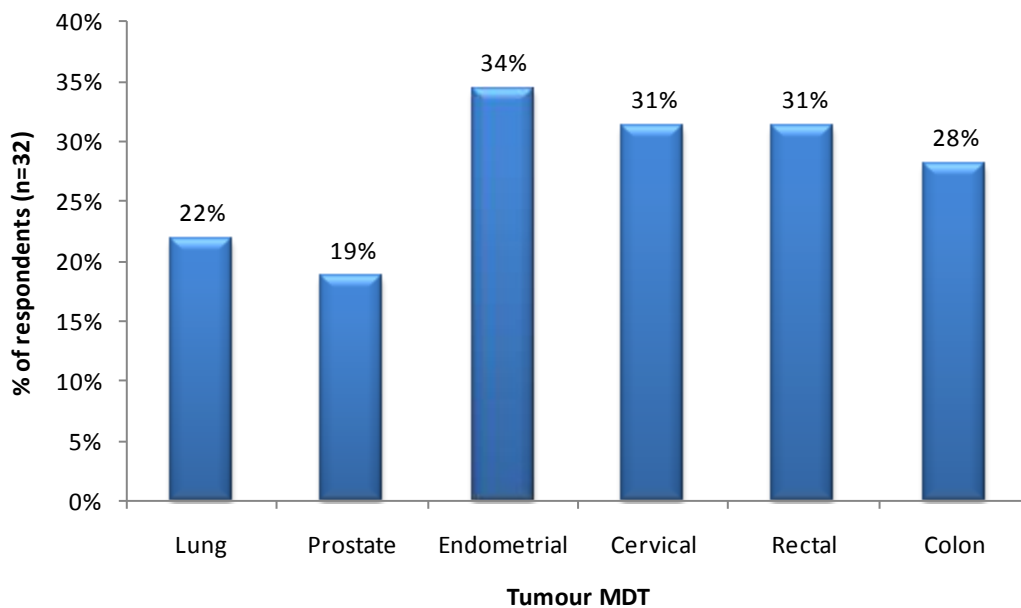
4.3.3 End user feedback

MDT questionnaire

7 centres returned 39 questionnaires. Four of these had to be excluded as the respondents commented that they hadn't actually seen any proforma reports, leaving 35 questionnaires from 7 centres.

Respondents belonged to the following tumour MDTs:

Figure 17: Tumour MDTs of respondents

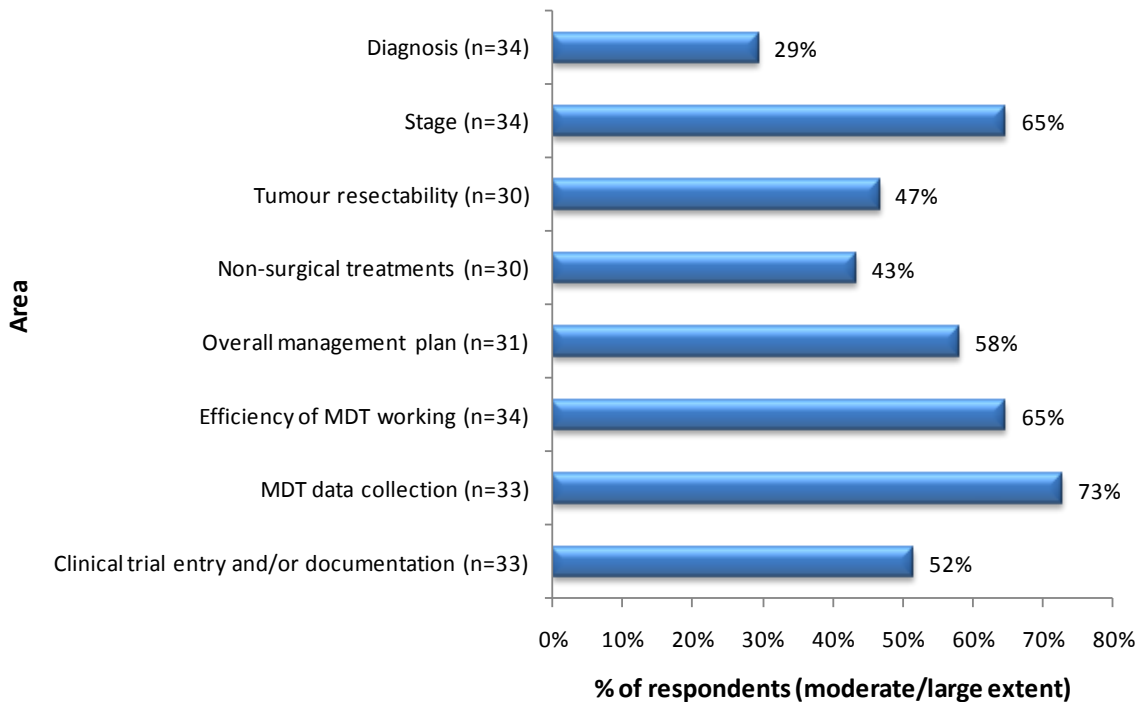


The percentage of respondents attending each type of MDT was fairly similar for all the tumour groups. Results are not mutually exclusive; some respondents attended more than one MDT (see table 18, appendix 1)

- 16 respondents were surgeons, 7 clinical oncologists, 4 physicians, 2 medical oncologists, 2 MDT co-ordinators and 1 clinical nurse specialist. (see table 19, appendix 1)
- 18 respondents said their MDT meetings were held at a Cancer Centre, 11 at a Cancer Unit and 3 at both locations. (see table 20, appendix 1)

Respondents were asked to comment on the extent to which they felt the introduction of structured proforma-based radiology reporting had improved their and/or their team’s ability to manage patients with reference to the areas illustrated in figure 18. Respondents rated the impact of proforma reporting as either; ‘not at all’, ‘to a small extent’, ‘to a moderate extent’ or ‘to a large extent’. Percentage of respondents who felt the impact was **moderate** or **large** is show in the figure below.

Figure 18: Impact of proforma reporting



(see table 21, appendix 1)

It was commented that the proforma reports would be moderately helpful with NBOCAP data entry and that it was useful to have staging available on the report;

‘Having an overall stage box is useful’.

Anything further that should be incorporated into the reports?

Some respondents felt nothing further needed adding and others commented on the need for more free text areas;

‘Text for clinical history at beginning and free text at the end is essential’.

a clear summary of staging;

‘Summary of staging at the end of report to save time in clinic when reporting to patients.’

Some suggested the proformas should be used in conjunction with present reports;

‘Proforma reporting should be in addition to the detailed reporting.’

Further comments

Respondents provided further comments. Some respondents felt the proforma reports were useful;

‘Very pleased with staging information presentation - very useful.’

Others felt they were confusing and difficult to follow;

‘It is difficult to interpret report not easy to read and follow.’

or complicated to complete;

‘The proforma is too long and complicated.’

Respondents also commented that it helped to standardise reporting;

‘.. main advantages of the structured proforma based reports is in comparison and standardisation..’.

Radiology MDT Lead Feedback

32 respondents from 11 centres provided feedback.

Centres recorded details of which proformas they had aimed to implement and which they had been able to implement.

Table 9: Proforma implementation

Tumour site	No of centres		No. of respondents (n=32)	
	Aimed to implement	Implemented	Aimed to implement	Implemented
Lung	9	7	16 (50%)	11 (34%)
Prostate	10	6*	16 (50%)	7 (22%)
Endometrium	9	5*	11(34%)	6* (19%)
Cervix	7	3*	9 (28%)	4* (13%)
Rectum	8	7*	14 (44%)	10* (31%)
Colon	8	6	14 (44%)	8 (25%)

*one centre/respondent commented that they only managed to implement the proforma in respect of a few reports

One centre which had not successfully implemented any of the proformas commented that they produced a few reports but did not submit these.

Radiologists recorded details of the obstacles they had encountered in implementing the proformas and how these had been overcome.

Table 10: Obstacles encountered

Obstacle	No. of centres	No. of respondents (n=32)
Pressure of work/time needed to implement	7	19 (59%)
IT problems/RIS did not support the proformas	8	20 (63%)
Colleague resistance to proforma reporting	8	9 (28%)
Other	5	5 (16%)

Not mutually exclusive

Other obstacles included;

- Getting non specialist radiologists to remember to use the proformas
- Poorly designed over-long proformas
- Proforma doesn't work well for cases with uncertainty
- Excluded from cervical and endometrial as another consultant from their centre had been involved in developing the proforma.
- Reports more time consuming to complete.

Centres tried various ways to overcome these obstacles;

Talking to/ working with their IT department, PACS team and HSS regarding integrating the proformas into their reporting systems. Some were able to integrate the proformas into their reporting systems but others resorted to filling in paper forms and scanning into CRIS.

'Used MACRO editor in HSS CRIS to import 'Word' versions of proformas into live reports.'

'Talked to IT - not able to support proforma with VR dictation.'

'Scanned onto CRIS from paper copies.'

As the proformas took longer to complete some sites allocated more time to the task;

'Tried to give more time in reporting these cases.'

Other centres developed shorter proformas which were quicker and easier to complete;

'We created a shorter, more user friendly proforma.'

Staff explained the project to colleagues and encouraged them to take part, but were not always successful;

'Remind colleagues about the project and encourage them to attempt at least one or two proformas.'

Colleagues were circulated by email with the proformas relevant to their specialty but got no response.

One to one demonstration of the proformas within CRIS

'Can't force colleague radiologists to do it.'

Implementation of CASPAR proforma reporting

11 centres provided details of how they implemented the proformas on to their reporting systems for the CASPAR project, only 9 of these supplied proforma reports for inclusion in the study. The remaining 2 centres only had limited success implementing the proformas.

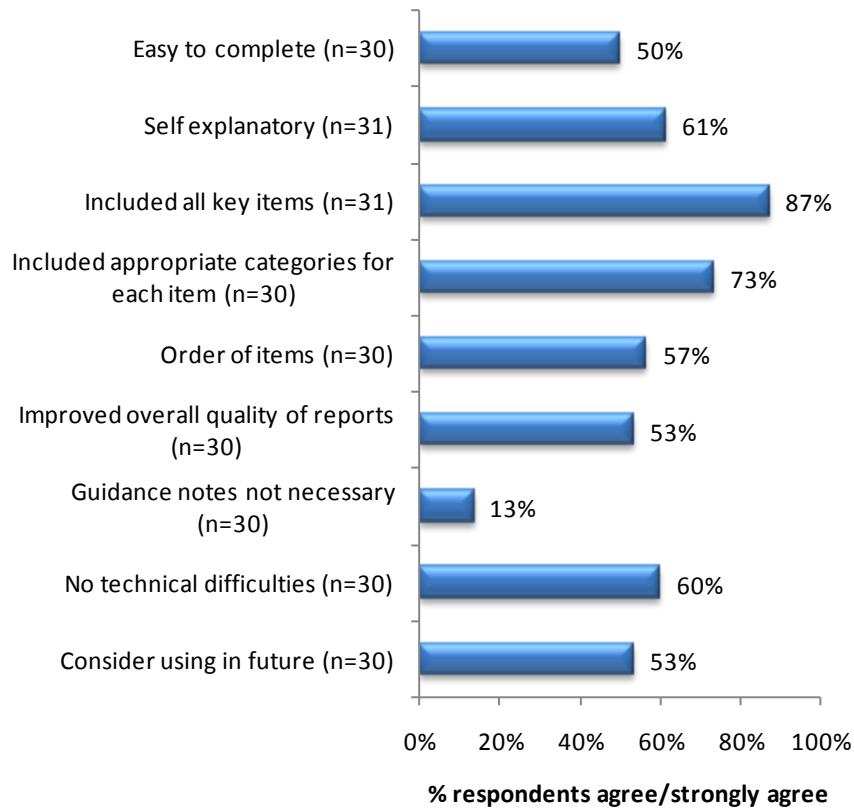
Table 11: Implementation methods

Implementation method	No. of centres
On paper	2
In HSS	2
In HSS via voice recognition system	1
In HSS on paper	1
HSS & CRC via voice recognition, used 'insert CT lung cancer' code with dragon VR'	1
Isoft on paper, proforma 'templated' onto report and completed manually.	1
Isoft via voice recognition system	1
Voice recognition system created a shorter version	1
Sunquest VRS for cervical, endometrial & prostate only	1

5/11 centres were able to implement the proformas using voice recognition software, 4/11 resorted to using paper versions of the proforma.

Respondents were asked to rate various aspects of the proformas

Figure 19: Rating of proformas - overall

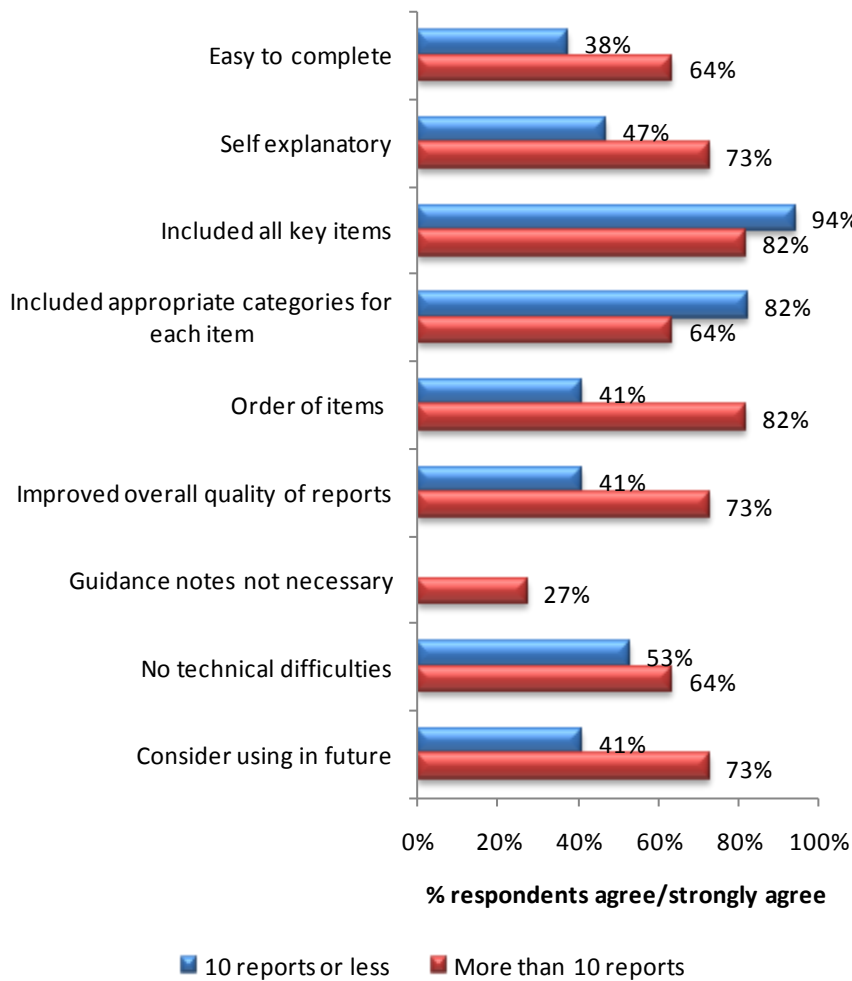


Aspects of the proformas most highly rated were that they 'included all key items' and 'included appropriate categories for each item'. Respondents also considered the guidance notes to be important.

(see table 22, appendix 1)

For a breakdown by proforma type see tables 23 to 26, appendix 1)

Figure 20: Rating of proformas – stratified by number of reports completed



Respondents who had completed more than 10 reports rated certain aspects of the proforma more positively than those respondents who had completed 10 reports or fewer. Interestingly those who had completed 10 reports or fewer rated ‘included all key items’ and ‘included appropriate categories for each item’ more positively than those who had completed more than 10 reports.

(see tables 27 & 28, appendix 1)

39% of respondents had personally produced more than 10 more reports, 25% 6 to 10 reports, 32% 1 to 5 reports and 4% no reports, during the study period. (see table 29 appendix 1)

37% of respondents felt the proforma reports took much longer to complete than their usual narrative reports, 33% a bit longer, 20% about the same length of time and 10% that they were a bit quicker to complete. (see table 30 appendix 1)

When stratified by number of reports completed 44% of respondents who had produced 10 reports or fewer felt the proforma took much longer to complete than their usual narrative report, the figure for respondents who had completed more than 10 reports was 36%. (see table 31 appendix 1)

Some respondents felt that all important items were included and clear on the proforma. Comments were also made regarding;

the difficulty in recording size/extent of tumour;

'difficult to convey the size/extent of primary tumour'

and the need for free text to record other important findings;

'No space for incidental but relevant findings.'

and the need to report drugs administered;

'Whether drugs were administered & dose.'

Some respondents felt that all appropriate categories had been included, other respondents commented on categories they felt were unclear: tumour measurements (colon), chest wall invasion (lung), CT abdomen (cervical), neurovascular bundle invasion (not recorded), bulky fibroids (endometrial) and confined to cervix (cervical).

The grading system was felt to be too restrictive;

'No. Don't like the grade 1 to 5 for likelihood of cancer as I don't think we can be that specific on MRI.'

Respondents provided additional comments/suggestions regarding the proformas. Respondents commented on the need for changes to the structure of the proformas to make them more user friendly;

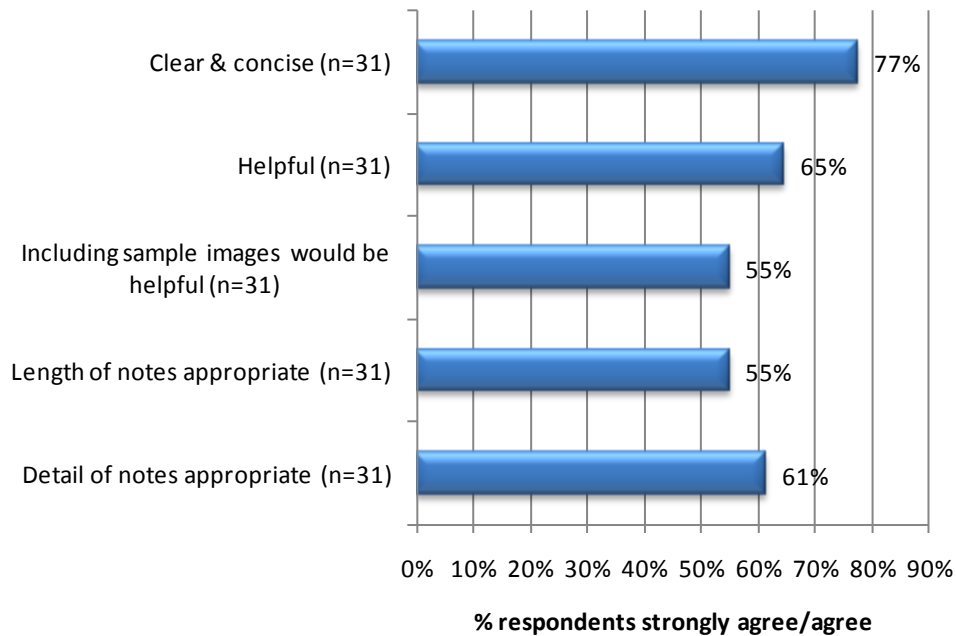
'Change in structure of the proforma (tick boxes) could help. It is a lengthy text now, not user friendly and time consuming.'

and that the proformas took longer to complete than usual reports;

'Took longer to complete proforma as it was in addition to normal report.'

Respondents were also asked to rate the guidance notes which accompanied the reporting proformas.

Figure 21: Rating of guidance notes



Over 60% of respondents felt the guidance notes were clear and concise, helpful and had an appropriate level of detail. Over 50% of respondents felt including sample images would be helpful.

(see table 32 appendix 1)

Respondents provided comments regarding the guidance notes. They commented on the need for detail;

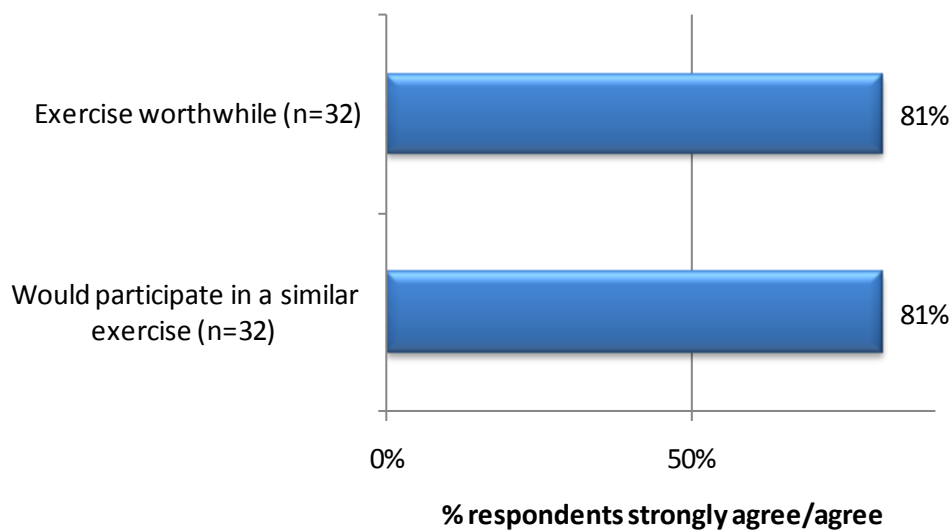
'I think people would appreciate more detail.'

and suggested including references to other articles;

'suggest also to give references for appropriate articles'.

For a breakdown by tumour site see tables 33 to 36 appendix 1.

Figure 22: Overall evaluation of project



81% of respondents felt the project had been worthwhile and 81% would consider participating in a similar project. (see table 37 appendix 1)

Respondents provided additional comments. They commented on the need to integrate the proformas into present electronic reporting systems if the project is to be successful and the use of proformas to continue;

'Enthusiasm was very high in our department but the lack of integration into CRIS has meant that participation has been purely for the study and will not be ongoing until we can integrate.'

and that certain proformas were easier to use than others;

'The proformas for the cervix and endometrium were quite straightforward, but prostate and colorectal in particular too complex.'

Respondents felt standardised reporting was a good idea;

'It is really a good move and it will standardise the reporting of prostate cancer without missing many important or relevant finding'.

However others felt it was difficult to record findings which did not fit easily into the listed data fields;

'Difficult to express uncertainty when reporting with the proforma.'

4.3.4 Comparison with the Ontario study

Based on the views expressed at the Cancer Care Ontario Meeting in 2011, an MRI report audit across the province of Ontario was conducted to assess the completeness of MRI reports for (i) T-category, (ii) distance to the MRF (mesorectal fascia) and (iii) N-category (nodal stage category) and has been previously published⁸. The results of this audit showed that only 40% (51/128) of MRI reports issued across the province captured all three of these key elements. Therefore, these results supported the observations and represented an opportunity to improve the completeness of MRI reports for pre-operative staging of rectal cancer across the province. Seventy three Ontario radiologists evaluated the synoptic MRI report and participated in the Radiology workshop for a response rate of 66% (73/111). 78% and 90%, respectively, agreed or strongly agreed that the synoptic MRI report was easy to use and included all appropriate items. 82% agreed or strongly agreed that the synoptic MRI report improved the overall quality of their report and 83% agreed or strongly agreed they would consider using this report in their clinical practice (Table 12). Feedback from end users of the reports was also positive (Table 13). The evaluation questions for proforma adoption were matched to the UK initiative. Of interest, the RIS and IT systems identified as significant barriers in the UK, did not appear to be a barrier to implementation in Canada.

Table 12. Summary Radiologist feedback in Ontario study⁸

(n=72)	n	Mean, (SD)	Median	Strongly Disagree, (n)	Disagree, (n)	Neutral, (n)	Agree, (n)	Strongly Agree, (n)
MRI Synoptic Report								
The synoptic report was easy to complete.	68	4.0 (0.8)	4	0	4	8	41	15
The synoptic report was self-explanatory.	71	3.9 (0.8)	4	0	6	8	47	10
The synoptic report included all appropriate key items.	71	4.2 (0.6)	4	0	1	5	46	19
The synoptic report included appropriate categories within each item.	68	4.1 (0.6)	4	0	1	4	49	14
The order of items on the synoptic report corresponded to the order in which I review the MRI images.	71	3.7 (0.8)	4	0	7	15	43	6
The synoptic report improved the overall quality of my reports.	71	4.2 (0.7)	4	0	0	12	36	23
The synoptic report took me about the same time to complete as my usual narrative report.	71	3.0 (1.1)	3	3	23	20	19	6
The definitions provided on the synoptic report were not necessary.	71	2.0 (0.7)	2	11	42	14	4	0
I will consider using the MRI synoptic report in my clinical practice.	71	4.0 (0.7)	4	0	0	11	37	23

Table 13. Summary of end user feedback in Ontario study8

N = 243	n	Same, % (n)	Better, % (n)
Ease of finding key features	242	12 (29)	88 (213)
Consistency	242	12 (29)	88 (213)
Completeness	243	18 (44)	82 (199)
Accuracy	240	43 (103)	57 (137)
Effect on patient outcome	236	61 (144)	39 (92)
End user understanding	241	23 (55)	77 (186)
End user satisfaction with content	242	19 (46)	81 (196)
Need to contact pathologist to clarify	242	39 (94)	61 (148)

4.3.5 Other documented feedback

Additional, informal feedback was obtained from email correspondence with the centres during the course of the project.

- Centres found implementing and using the proformas was difficult.
- Clinicians felt it involved extra work and disliked all the negative responses required.
- One clinician felt the proformas made the presentation of patients at MDT meeting more succinct.
- Felt that if the proformas could be better integrated into present reporting systems clinicians would be more willing to use them.

5 DISCUSSION OF RESULTS

5.1 Main findings

Completeness of reporting

Reports produced using a proforma contained a greater percentage of the data fields identified as required by the CASPAR project team. This was true of the reports for all six tumour sites, with the most noticeable improvements being in respect of reports for colon and rectal cancers. The percentage of reports containing more than 80% of the agreed data fields increased considerably for all six tumour sites when proforma reporting was used.

Looking at the individual data fields for each of the tumour sites, in nearly all cases there was a considerable reduction in the percentage of reports missing particular data fields following the introduction of proforma reporting. For some data fields reporting increased to 100%.

Implementation

15 centres supplied proforma reports. Lung cancer proforma reports were received from 10 centres, prostate from 9 centres, cervical from 7 centres, endometrial from 7 centres, rectal from 14 centres and colon from 13 centres. The low number of centres for endometrial and cervical reports is likely to reflect the lower prevalence of these types of cancer rather than specific difficulties implementing these particular proforma reports. Three centres supplied reports for all 6 tumour sites, 6 centres failed to supply any proforma reports.

IT obstacles

The biggest single obstacle to implementing structured reporting was lack of adequate Information Technology to integrate electronic proformas into Radiology Information Systems (RIS), with 20 of a total of 35 individual respondents commenting on this. As a result, it was necessary to implement the proformas in an ad-hoc way for the purpose of the evaluation, which resulted in a more time-consuming reporting process. For the proformas to be accepted into routine practice, it will be essential to overcome these technical hurdles.

Launch meeting and support workshops

Attendees provided feedback regarding the launch meeting and support workshops. The majority of respondents felt that at the morning plenary session the reasons behind the CASPAR project were well explained and the objectives of the project made clear. However they did not feel the methodology of the project was clearly explained and felt more time should have been given to demonstrating the proformas. They also felt the IT issues were

dealt with rather superficially. Support workshops were organised for each of the tumour sites (lung, prostate, gynaecological, colorectal). Feedback from the prostate, gynaecological and colorectal sessions was fairly positive, though there were still outstanding questions. Feedback from the lung support workshop was less positive; respondents had outstanding questions and didn't feel everything they needed to know to complete the proformas had been covered. This was reflected in the fact that respondents didn't feel confident they could explain the proformas to colleagues or how they could use them in clinical practice. They would have liked time to have been spent completing test examples.

Following the afternoon plenary session the majority of respondents were confident they knew what reports to submit, what Trust approval was required, who to send the proformas to and when, and who to contact if they had any queries. They were less clear about the technical aspects of implementing the proformas and how to seek technical help if they required it. Nearly two thirds still had outstanding questions mainly regarding how to incorporate the proformas in to their reporting systems.

Overall it was felt the workshop was well organised and provided a comprehensive introduction to the CASPAR project. However 18% of respondents would have liked to attend another meeting for further support and only 39% felt fully equipped to implement the project at their centre.

End user feedback – MDT questionnaire

At each of the centres MDT members were asked to provide feedback on the extent to which they felt the introduction of proforma reporting had impacted on the quality of decision-making within the MDT. 35 completed questionnaires were returned by 7 centres. Feedback was received for all the tumour sites. 16 respondents were surgeons and 7 clinical oncologists. 18 attended MDT meetings held at Cancer Centres. Respondents were asked to comment on the impact of proforma reporting in certain areas. The areas where respondents felt the impact had been greatest were: staging, efficiency of MDT working and MDT data collection, while the area of least impact was diagnosis. Respondents commented that they would like to see free text areas incorporated into the proforma reports for recording additional significant information, also a clear summary of staging at the end of the report. Some respondents felt the proforma reports were useful, others that they were complicated and difficult to read. It was commented that they do help standardise reporting.

Radiology MDT Lead Feedback

Implementation 32 respondents from 11 centres provided feedback on which proformas they had planned to implement and which they had successfully implemented. 7/9 were successful in implementing the lung cancer proforma report, 6/10 the prostate, 5/9 the endometrial, 3/7 the cervical, 7/8 the rectal and 6/8 the colon. Respondents then recorded details of the obstacles they had encountered. The most common problems were in respect of IT systems/RIS not supporting the proformas (8 centres), pressure of work/time needed to implement (7 centres) and colleague resistance (8 centres). Other obstacles recorded included: getting colleagues to remember to use the proformas, proformas poorly designed and overlong, the proforma not working well for uncertain cases.

In order to overcome these obstacles centres worked with their IT department/PACS team to try and find ways to integrate the proformas into their reporting systems, allocated more time to reporting, developed shorter, more 'user-friendly' versions of the proformas and tried to encourage their colleagues to take part.

Centres had difficulty incorporating the proformas in to HSS IT systems, so they could be completed via the voice recognition system; only 5 out of 11 were successful. 4 centres resorted to completing paper version of the forms.

Respondents were asked to provide feedback on the proforma reports. At least 50% felt the proformas were easy to complete, self-explanatory, that data items were in an appropriate order, that they improved the overall quality of reports, hadn't encountered technical difficulties and would consider using them in the future. 87% felt they included all key items, 73% appropriate categories for each item and 87% felt the guidance notes were necessary. Only 39% of respondents had produced more than 10 proforma reports. Approximately one third felt the proforma reports took much longer to complete than their usual narrative reports. Suggestions for improvement included free text areas for recording other relevant findings and a change in structure to make the proformas more user friendly and quicker to complete. Feedback regarding the guidance notes accompanying the proforma reports was positive, it was felt including sample images would be helpful.

Over 80% of respondents felt the CASPAR project had been worthwhile and would be happy to participate in a similar exercise. They commented on the need to integrate the proforma reports into present electronic reporting systems if their use is to continue. Standardisation of reporting was also felt to be important.

5.2 Limitations

The sample may have been biased by the fact centres volunteered to take part and it is unlikely centres would have volunteered if they were not already interested in using proforma reporting. Therefore results may have been biased by the centres being more receptive to and enthusiastic about using proforma reporting. However there was still one centre which submitted neither pre-proforma nor proforma reports and a further 5 centres which did not successfully implement the proforma reports, although they provided pre-proforma reports for the project. It is possible that the inclusion in the evaluation of pre-proforma but not proforma reports from these 5 centres may have biased the results in favour of proforma reports, if completion of proforma reports would have been poorer in these centres than in the sample overall. However, the improvement in completeness of reports following introduction of proformas was so great that the lack of reports from these centres is unlikely to have changed the overall result of the evaluation significantly.

The target sample size for proforma reports was not achieved, however statistical testing confirmed a statistically significant difference at the 99.9% level ($p < 0.001$) when comparing mean levels of completeness for reports produced with and without proformas.

In all studies and particularly those with multiple data collectors, some data errors are to be expected. In this study the independent Data Monitoring Group checked a random sample of 10% of the coding forms from the pre proforma reports against the corresponding radiology reports for accuracy of coding, errors were found in 0.2% of the 1250 data items checked. This level of errors was considered to be within acceptable limits and to have had little impact on overall results.

It should also be noted that the study does not allow for the fact that it is normal human nature to feel there is no need to mention things which are not present (e.g. pleural involvement by a lung tumour) and in the pre proforma results section the omission of such items should not be taken as a reflection on the ability of the reporting radiologist.

The technical challenge of incorporating the proformas into established RIS systems to facilitate smooth incorporation into routine practice was a significant factor in the feasibility of this project. Originally, the Project Reference Group included representation from one of the leading RIS providers to NHS Radiology departments, whose plan was to incorporate the proformas into a routine system upgrade for CASPAR centres which already used its system (approximately half of all the participating centres). Unfortunately, due to sudden major changes within that company, which occurred just at the point in the project when the upgrades were due to be provided, the collaboration was terminated. This meant that the Lead Radiologists at these centres were required at short notice to overcome the technical hurdles to implement the proformas without the support of this RIS provider. While peer to peer support was given by a centre Lead who quickly developed a voice-recognition version

of the proformas, this sudden change in the technical aspect of the project undoubtedly affected the experience of it for a proportion of centres.

5.3 Comparison with Canadian results

A similar study carried out in Ontario found that less than 40% of assessed MRI reports captured T-category, CRMi and LNi suggesting that cancer staging reports with missing data is an issue which is not unique to the UK.

6 CONCLUSIONS

- There was a statistically significant global improvement in completeness of cancer stage reporting through the use of proforma reporting.
- A major barrier to the implementation of proforma assisted reporting is the difficulty of incorporating these types of forms into present electronic reporting systems.
- Two further related obstacles are the considerable change in current practice of proforma reporting from free text reports combined with a real concern that such practice would be more time consuming to the radiologist.
- Despite these concerns, 26/32 radiologists who provided feedback either 'agreed' or 'strongly agreed' that overall, piloting and evaluating proforma reports had been worthwhile from their point of view.
- From the project data it is evident that structured (proforma) reporting leads to more accurate information to aid an individual patient's staging and management, as well as providing comprehensive data for monitoring treatment and outcomes.

7 RECOMMENDATIONS

- Radiologists in the U.K. should progress the implementation of structured (proforma) reporting for staging cancer so that it becomes the standard for all patients diagnosed with cancer.
- To facilitate this evolution, minimum data sets should be developed and piloted for each major cancer site by the relevant radiologists working in collaboration with other relevant clinicians and members of the multi-disciplinary team. These minimum data sets should be consistent with the National Data Set in order to facilitate data collection and reporting at a national level.
- IT problems and obstacles that prevent the integration of structured reports within existing IT systems/RIS should be addressed at a national level to ensure that

structured reporting can be implemented efficiently without becoming burdensome or time consuming for radiologists.

- Steps should be taken to raise radiologists' awareness, understanding and enthusiasm for structured reporting. This will help radiologists to understand the benefits of structured reporting and support the evolution of this as a standard of care. This should build on the current acceptance of a checklist approach as a means of improving the quality and reliability of clinical practice, particularly amongst those in training (the workforce of the future).

8 REFERENCES

- ¹ Cross SS, Feeley KM, Angel CA. The effect of four interventions on the informational content of histopathology reports of resected colorectal carcinomas. *Journal of Clinical Pathology* 1998;51(6):481-2.
- ² Rigby K, Brown SR, Lakin G, Balsitis M, Hosie KB. The use of a proforma improves colorectal cancer pathology reporting. *Annals of the Royal College of Surgeons of England* 1999;81(6):401-3.
- ³ Quirke P, Morris E. Reporting colorectal cancer. *Histopathology* 2007 Jan;50(1):103-12
- ⁴ Mangat N, Koh DM, Ashley S, Brown, G. Colorectal Cancer Radiology Reporting in the Multidisciplinary Setting: The Importance of High Quality Proforma Reporting. *Proc RSNA* 2009; Abstract SST04-09. Available at: http://rsna2009.rsna.org/search/event_display.cfm?em_id=8008806&printmode=Y&autopr_int=N (accessed 3rd March 2014)
- ⁵ Morris EJ, Taylor EF, Thomas JD, *et al.* Thirty-day postoperative mortality after colorectal cancer surgery in England. *Gut* 2011;60:806-813
- ⁶ Beckett P, Woolhouse I, Stanley RA, Peake MD. Exploring Variations in Lung Cancer Care Across the UK - The "Story So Far" for the National Lung Cancer Audit. *Clinical Medicine*, 2012; 12:4-8
- ⁷ Machin, D., Campbell, M., Fayers, P. & Pinol, A. (1997) *Sample size tables for clinical studies*, 2nd edn. Blackwell Scientific Publications, Oxford.
- ⁸ Al-Sukhni E, Messenger DE, Victor JC, McLeod RS, Kennedy ED. Do MRI Reports Contain Adequate Preoperative Staging Information for End Users to Make Appropriate Treatment Decisions for Rectal Cancer? *Ann Surg Oncol*. 2013;20: 1148-1155

9 APPENDICES (available separately)

- Appendix 1 Results tables
- Appendix 2 Data Monitoring Group Terms of Reference
- Appendix 3 Screening questionnaire
- Appendix 4 Pilot proformas
- Appendix 5 Workshop feedback forms
- Appendix 6 Coding forms
- Appendix 7 Project feedback questionnaires