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An evaluation of CAncer Staging using ProformA Reporting in Radiology (CASPAR)

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Abstract

Objectives: Following a diagnosis of cancer, the detailed assessment of prognostic stage by radiology is a crucial determinant of initial therapeutic strategy offered to patients. Pre-therapeutic stage by imaging is known to be inconsistently documented. We tested whether the completeness of cancer staging radiology reports could be improved through a nationally introduced pilot of proforma-based reporting for a selection of six common cancers.

Design: Prospective interventional study comparing the completeness of radiology cancer staging reports before and after the introduction of proforma reporting

Setting: Twenty one UK NHS Hospitals

Participants: 1283 cancer staging radiology reports were submitted

Main Outcome Measures: Radiology staging reports across the six cancers types were evaluated before and after the implementation of proforma based reporting. Report completeness was assessed using scoring forms listing the presence or absence of pre-determined key staging data. Qualitative data regarding proforma implementation and usefulness was collected from questionnaires provided to radiologists and end-users.

Results: Electronic proforma based reporting was successfully implemented in 15 of the 21 centres during the evaluation period. A total of 787 pre-proforma and 496 post-proforma staging reports were evaluated. In the pre-proforma group, only 48.7% (5586/11470) of key staging items were present compared with 87.3% (6043/6920) in the post-proforma group. Thus, proforma reporting achieved an absolute improvement in staging completeness of 38.6% (95%CI,0.37-0.40%,p<0.001). An increase was seen across all cancer types and centres. The majority of respondents found proforma reporting improved report quality.

Conclusion: The implementation of proforma reporting results in a significant improvement in completeness of cancer staging reports. Proforma based assessment of stage by radiology facilitates objective comparison of quality and outcomes. It should become an auditable quality standard.

Strengths and Limitations

- This study demonstrated a significant improvement in the completeness of reports following the introduction of proformas. However, it was beyond the scope of this study to look at the accuracy of the report content, which is another useful measure of quality.

- The post-proforma cohort was underpowered to detect an improvement of 20% in completeness of reports. However, the post-proforma cohort in fact showed improvements of greater than 30% for all cancer types apart from lung cancer, and the study was adequately powered to detect this.

- The trial was a non-blind study (both pre- and post-proforma cohorts) and consequently this may have influenced the report quality (a Hawthorne effect).

- The sample may have been biased by the fact centres volunteered to participate in the study, and therefore are likely to be those already more receptive to proforma reporting.

Introduction

Once a patient is diagnosed with cancer the next steps in patient care are crucial and result in life changing management decisions such as intensity and radicality of treatment. Such decisions hinge on the accuracy and completeness of cancer staging provided to the clinical teams and patient. The majority of initial cancer treatment decisions are almost entirely based on radiological assessment of both the cancer prognostic stage and anatomic distribution of disease (examples summarised in appendix 1). Thus, clear documentation of imaging derived staging is required of radiologists to facilitate multidisciplinary team (MDT) based decisions. In many cancers, radiological staging assessment is used to guide radiotherapy and surgical planning, and to select patients for preoperative (neoadjuvant) chemotherapy. In studies of patients with rectal cancer, preoperative radiological staging and MDT discussion increased the proportion of patients receiving neoadjuvant treatment and R0 resection rates and local disease control(1,2).

Despite the importance of preoperative imaging assessment, prospective audits of imaging reports for cancer have shown significant deficiencies in documented staging information. A single centre study tumour found resectability status in rectal cancer, which informs the decision for preoperative chemoradiotherapy, was missing in 40/55 (73%) of free-text radiology reports and proforma reporting improved these measures significantly (3). An audit of practice by Ontario Cancer Care showed similar findings with missing data noted in 40% of reports submitted by radiologists for cancer staging (4).

The concept of minimum dataset included in cancer staging histopathology reports using a proforma-based system is well established (5–8). Audits of histopathology reporting of cancer stage have shown an increase in minimum staging data in histopathology reports from 31% to 100% in colorectal cancer following the introduction of proforma reporting (9)(10). Similar improvements in data completeness have been found seen in pathology reporting of other cancers, such as pancreas, prostate and melanoma, following standardisation (11–17). The impact on clinical outcomes was demonstrated by a study showing that patients with incomplete staging reports with dataset items missing had poorer survival outcomes (19). Moreover, proforma reporting has the potential to improve patient treatment, enabling more consistent identification of high-risk patients who can be offered postoperative adjuvant therapy. As a

consequence, minimum data set reporting of prognostic histopathological data for resected cancers has become a global standard of care (9,18).

Guidelines for cancer care do not consider radiologic structured reporting, unlike histopatholgy, as mandatory. At present, there is paucity of evidence showing such an intervention can improve the quality and completeness of cancer reporting. This quality improvement study tests whether the completeness of radiological cancer staging can be improved through a nationally introduced pilot of proforma-based reporting for a selection of common cancers.

Methods

The project was jointly initiated by the Royal College of Radiologists (RCR) and the National Cancer Intelligence Network (NCIN). The project was also designed in consultation with representatives from the Royal College of Physicians, Royal College of Surgeons of England, and the Royal College of Pathologists and thus a collaborative proposal was jointly funded by the Academy of Medical Royal Colleges and RCR.

This study did not require Research Ethics Committee (REC) approval as only anonymised patient data (MDT Radiology reports) and NHS staff interview/questionnaires were used (20). The requirements of the Data Protection Act 1998 and the clinician's common law duty of confidentiality were met by the pre-anonymisation of all patient records by clinical care staff. Only centres that obtained written approval from the Trust Data Protection Officer (Caldicott Guardian) to release anonymised radiology reports to the CASPAR team for analysis were included. All but one centre successfully obtained Caldicott agreement.

Primary Objective

- To compare the minimum datasets of prognostically and therapeutically important staging data from radiology reports before and after adoption of proforma based reporting.

Secondary Objectives

- To determine:
  - how pilot centres implemented proforma reporting and any areas of difficulty.
  - the usefulness of support workshops and guidelines.

- the clinical impact proformas from the radiology MDT lead and end-users (core MDT members).

The project was conducted in UK NHS hospitals by radiologists reporting newly diagnosed lung, prostate, endometrial, cervical, colon and rectal cancer working within their respective MDTs. 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 (SIG) and members of the NCIN Site Specific Clinical Reference Groups (SSCRG). Participating centres were selected by the CASPAR Steering Group to represent a spectrum of UK NHS hospitals, to maximise participation from the 2012 strategic health authority (SHA) regions, ensuring the ratio of non-teaching to teaching hospitals was weighted proportionately.

Based on the criteria above, 21 centres were selected to take part in the evaluation. Sample size estimate allowed for a 10-15% dropout rate.

A workshop was held to launch the project, this provided a project overview and demonstrated the six pilot proformas (lung, prostate, endometrial, cervical, rectal and colon). The pilot proformas were designed by the tumour site leads, with input and feedback from the relevant SIG and SSCRG. Breakout groups were held for each tumour site, where the individual proformas and guidance were explained in greater detail. Participants were requested to complete feedback forms. A follow-up teleconference held to answer remaining queries.

This was an interventional “before and after” study. In order to reduce the risk of bias in reporting standards pre-proforma introduction, reports were submitted from 3 months prior to and following the introduction of proforma reporting. To account for differences in the estimated cancer specific diagnosis rates between centres, the specific periods were modified for recruiting site and tumour type.

Pre-treatment MDT radiology cancer staging report staging for the six cancer types were eligible for inclusion. For pelvic malignancies, this included local staging pelvic MRI report and CT assessment for metastatic disease. For lung and colon cancers this included a CT report for both primary and metastatic disease staging. Only tumour staging reports as documented by

the radiologist (either MDM radiology report, report addendum following MDM or staging cancer report) were acceptable. Annotations made by the clinical teams or MDT co-ordinators during MDT discussions were not accepted. Imaging reports submitted not fulfilling the above criteria were excluded.

- **Cohort 1** (pre-proforma (free-text) reporting) - consecutive patients for whom a cancer staging radiology report was submitted prior to implementation of proforma reporting.
- **Cohort 2** (post-proforma reporting) - consecutive patients for whom a cancer staging radiology report was submitted following implementation of proforma reporting.

The radiology reports were completed by consultant radiologists. The study was non-blind, radiologists were aware of participation in the study in the pre- and post-proforma cohorts.

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 had used at least one proforma report for decision-making.

MDT Radiology reports and staff feedback questionnaires were collected between March 2012 and April 2013. The project was extended from the original 3 month pre- and 3 month post-proforma duration to allow for differences in the rates of cancer incidence and to allow time for implementation of proformas into the RIS systems.

The key minimum staging items considered essential to making clinical treatment decisions were defined by consultation with the NCIN SSCRGs comprising lead specialist multidisciplinary representatives. Cancer specific proforma report templates were produced to include these key data items considered clinically important for cancer treatment and prognosis (Appendix 1, tables 1-6). These were approved by the respective UK specialist interest groups (SIG) and the NCIN SSCRGs. The completeness of reports was assessed using scoring forms (designed by project leads) that listed the presence or absence of the pre-determined key staging data. Staging items that were not applicable to a particular case were deducted from the 'total' count to produce a 'total needed' count.

All free text (pre-proforma) report scoring was carried out by experienced members of the project team. All proforma report scoring was carried out by an independent data analyst team and queries were referred to the project team.

Standardised questionnaires were used to solicit staff feedback on the usefulness of proformas in reporting imaging findings (radiologists) and facilitating clinical decision-making (end-users).

Data analysis

A project database was developed by the independent data analyst team. The database was checked by the independent data analyst team for completeness and checked against the data collection form, any missing data was identified and corrected as appropriate. A 10% sample of coded and source reports were sent to the independent data monitoring committee (DMC) to assess quality and fairness of coding of pre-proforma and proforma reports (Appendix 2). The DMC also checked that recruitment was adequate to meet the number needed based on the power calculations (table below).

Statistical analysis for the primary endpoint

Hypothesis: the introduction of proforma reporting improved the completeness of reporting in the cancers tested by an expected 20% with an expected completeness rate pre-proforma of 50% (based on an internal audit). A difference in the percentage of completed data items between proforma and non-proforma reports of at least 20% following proforma introduction required a sample size of 124 cancer reports per cancer type prior to and after the introduction of proforma reporting, with 90% power and 5% significance.

Sample size calculations with variable proportion differences in completeness of reports to achieve at least 90% power and 5% significance were calculated as follows:

Proportion difference	Power	Significance	Sample size needed
0.10	90%	5%	518
0.20	90%	5%	124
0.30	90%	5%	51

Thus, a total of 248 (124 free-text and 124 proforma) cancer reports per cancer type were required to show an increase of 20% completeness of reports between pre and post-intervention cohorts (21).

Primary objective

Differences in completeness of reporting of the predefined minimum staging data were calculated before and after proforma implementation. The data was analysed for the whole sample and stratified by tumour site and reporting hospital. The 95% confidence intervals for proportions of completed data items were calculated by the Method of Wilson (22). Differences in proportions of completed data items pre- and post-proforma reporting were calculated and confidence intervals for these differences calculated using Method 10 of Newcombe (23).

Secondary objective

A qualitative analysis through questionnaire responses was undertaken to evaluate the secondary objectives.

Results

The study flow and landmarks are summarised in figure 1. A total of 36 Radiology departments expressed an interest in taking part in the evaluation. Twenty-one centres attended the launch meeting workshop and enrolled to participate in the project.

Primary endpoint

Two centres (5 and 16) failed to supply any data, sixty-two pre-proforma and 3 proforma reports did not comply with the inclusion criteria, and were excluded.

Nineteen centres provided pre-proforma free text reports for inclusion in the study (table 1). Of these, four centres provided pre-proforma reports only (centres 6, 8, 14 and 21). In total 15 of the 19 centres provided both pre and post proforma reports for at least 2 tumour types (table 1). The total number of reports provided by cancer type is summarised in table 2.

The total number of pre-proforma reports for cervical and endometrial cancer and post-proforma reports for all of the tumour types was less than 124, meaning these were under-powered to detect a 20% difference. However, for all but cervical cancer post-proforma reports, there were greater than 51 reports meaning numbers were adequate to detect a 30% difference with 90% power.

Table1: Percentage of data field completed by centre

Centre	PRE				POST				Proportion difference in completeness	95% Confidence Intervals
	Total number of reports	Number of data items completed	Total needed	Total % Completeness	Total number of reports	Number of data items completed	Total needed	Total % Completeness		
1	62	401	920	43.6%	34	312	440	70.9%	0.27	0.22-0.32
2	18	109	265	41.1%	30	390	433	90.1%	0.49	0.45-0.55
3	40	225	523	43.0%	18	226	240	94.2%	0.51	0.45-0.56
4	52	373	717	52.0%	52	672	718	93.6%	0.42	0.37-0.46
5	0	-	-	-	0	-	-	-	na	na
6	12	127	201	63.2%	0	-	-	-	na	na
7	84	516	1210	42.6%	45	559	702	79.6%	0.37	0.33-0.41
8	56	447	899	49.7%	0	-	-	-	na	na
9	32	268	508	52.8%	56	884	917	96.4%	0.44	0.39-0.48
10	20	126	295	42.7%	23	274	352	77.8%	0.35	0.28-0.42
11	57	495	836	59.2%	45	507	586	86.5%	0.27	0.23-0.32
12	41	317	602	52.7%	27	391	419	93.3%	0.41	0.36-0.45
13	43	347	600	57.8%	36	432	460	93.9%	0.36	0.31-0.40
14	45	252	648	38.9%	0	-	-	-	na	na
15	61	452	879	51.4%	44	440	550	80.0%	0.29	0.24-0.33
16	0	-	-	-	0	-	-	-	na	na
17	72	500	1053	47.5%	20	238	272	87.5%	0.40	0.35-0.45
18	36	224	519	43.2%	27	279	302	92.4%	0.49	0.44-0.54
19	14	69	186	37.1%	16	203	210	96.7%	0.60	0.52-0.66
20	20	106	281	37.7%	23	236	319	74.0%	0.36	0.29-0.43
21	22	232	328	70.7%	0	-	-	-	na	na
TOTAL	**787**	**5586**	**11470**	**48.7%**	**496**	**6043**	**6920**	**87.3%**	**0.39**	**0.37-0.40**

Table 2: Percentage of data fields completed by tumour type

	Lung Cancer		Prostate Cancer		Cervical Cancer		Endometrial Cancer		Colon Cancer		Rectal Cancer		Overall Cancer	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
No. of proformas	125	84	156	108	117	46	112	59	142	88	135	111	787	496
Staging item completed	1509	1236	885	871	918	596	823	921	707	1049	744	1370	5586	6043
Staging items needed	1969	1359	1944	1086	1877	720	2005	1059	1775	1132	1900	1564	11470	5920
AP totals	76.6%	90.9%	45.5%	80.2%	48.9%	82.8%	41.0%	87.0%	39.8%	92.7%	39.2%	87.6%	48.7%	87.3%
Proportion difference	0.14		0.35		0.34		0.46		0.53		0.48		0.39	
95% Confidence Intervals	0.12-0.17		0.30-0.37		0.30-0.37		0.43-0.49		0.50-0.55		0.46-0.51		0.37-0.40	
Mean completed	76.6%	90.9%	45.4%	80.1%	48.2%	82.4%	41.0%	87.0%	39.9%	92.7%	39.3%	87.5%	48.1%	86.9%
Median completed	76.5%	93.8%	41.7%	90.9%	47.1%	88.2%	44.1%	94.4%	38.5%	92.3%	40.0%	92.9%	46.2%	92.9%
St Dev	19.8%	10.4%	19.1%	23.4%	17.5%	15.7%	13.5%	13.7%	14.9%	8.8%	17.4%	14.7%	21.4%	9.3%
Min	25.0%	56.3%	0.0%	33.3%	11.8%	41.2%	0.0%	66.7%	7.7%	69.2%	0.0%	41.7%	0.0%	33.3%
Max	100.0%	100.0%	92.3%	100.0%	88.2%	100.0%	77.8%	100.0%	76.9%	100.0%	93.3%	100.0%	100.0%	100.0%
IQR 1	60.0%	87.5%	30.8%	63.6%	35.7%	70.6%	33.3%	72.2%	30.8%	84.6%	27.9%	78.6%	33.3%	78.6%
IQR 3	100.0%	100.0%	58.3%	100.0%	58.8%	94.1%	50.0%	100.0%	46.2%	100.0%	50.0%	100.0%	60.0%	100.0%

A total of 787 pre- and 496 post-proforma staging reports met inclusion criteria for analysis. The proportion of completed staging data from 787 pre-proforma staging cancer reports were 5586 of 11470 staging items (48.7%), compared with 6043 of 6943 staging items using proforma reports (87.3%). The improvement in cancer staging achieved by proforma reporting amounted to an absolute increase of 38.6% (95% CI: 37- 40%). Thus the overall improvement was significant and surpassed the predicted 20%. An improvement of greater than 20% with proforma reporting was seen for all 15 centres that submitted pre- and post-proforma reports (table 1).

An improvement in completeness was seen across all tumour types, and the improvement was greater than 30% for 5 of the 6 tumour types. For lung cancer however, the percentage improvement was 14% (95% CI 12 - 17%), this probably relates to the high percentage completeness of the pre-proforma lung cancer staging reports (76.6%).

The distribution of elements of staging data by cancer site is summarised in Appendix 3 (tables 1-6). For lung cancer, two staging items (differentiation from consolidation and metastases) were less complete on the proforma reports compared to free-text reports, but the difference was small: 3% and 7% respectively. There were no other instances of a decrease in the completeness of staging items when proforma reports were compared with pre-proforma reporting.

For lung cancer staging, significant improvements in 6/17 minimum data cancer staging items were observed. There was a notable improvement in the documentation of endobronchial and pleural disease using proformas. Prostate proforma introduction saw 20% or greater improvement in 10/13 staging items – of particular clinical relevance was the improvement in documentation of local invasion and TNM stage. Proforma reporting of endometrial cancer produced a 20% or greater improvement in reporting of 16/18 staging items. The most striking improvements were in involvement of the serosa and pelvic organs, all crucial to surgical decision making and prognosis. For cervical cancer an improvement of greater than 20% was seen in 11/17 staging items following proforma reporting. One of the greatest improvements was for pelvic sidewall invasion, a predictor of pelvic nodal involvement. For rectal cancer staging proforma reports, improvements were seen in 14/15 staging items including extra-mural spread and extra-mural vascular invasion. Both are important prognostic markers and guide selection for neo-adjuvant therapy. Marked improvement in 10/13 staging items was seen by the use of the colon cancer proforma

reports. The greatest improvements were for peritoneal infiltration and resectability- both critical surgical determinants.

A wide range of percentage completeness in individual reports was seen, before and, to a lesser degree, after the introduction of proformas. For example, the range of completeness of lung cancer report was 25-100% (pre-proforma) and 56-100% (post-proforma) and for prostate was 0-92% (pre-proforma) and 33-100%(post-proforma). This probably, at least in part, reflects the difference in reporting style between individual radiologists. The effect of proforma reporting was not studied in individual radiologists. The range of percentage completeness reduced and the mean completeness increased for all cancer types after the introduction of the proforma. Of note however, was that even in the post-proforma groups, there did remain incomplete reports. It remains unclear without further study, whether this is due to the radiologist's experience or a limitation of imaging.

Secondary endpoints

Some queries were raised regarding the lung staging proforma were resolved by teleconference. For the remaining cancer specific workshops 100% of the attendees agreed that "the presentation given in this session was very clear" and 80-100% agreed that "[they can see how [they] can use this proforma in clinical practice". There was an average of 67% agreement amongst the workshop attendees that "[they] feel confident to explain the use of this proforma to colleagues".

During the study, six sites reported problems encountered with implementation of the proforma into their RIS systems. These included unavailability of the software upgrade within the project timeframe. For one site, the RIS system did not use voice recognition so paper versions of the template were manually completed.

Feedback was received from eleven of twenty-one centres participating in the launch meeting. All sites indicated moderate to strong agreement that the proformas were self-explanatory, included all key items and improved report quality. Feedback from those centres unable to submit proforma reports is summarised in table 3. Suggestions for improving proforma design included: mechanisms to document equivocal findings, reduce the time taken document negative findings and to include incidental findings. For three sites, inability to engage colleagues and time pressure were cited as limiting factors and four sites indicated that lack of IT support from RIS suppliers resulted in failure to implement the proformas.

Table 3: Summary of feedback from centres failing to submit completed cancer staging proformas

Proforma design
• Better section for documenting other findings (site 3). • An alternative approach might be to follow an algorithm only specifically mentioning positive findings as they are observed, rather than producing a report characterised by a long list of negative findings.(Site 17) • The proforma seemed to be designed for staging much more advanced disease than we are normally asked to scan. • Without nicely laid out proformas which can easily be completed, uptake and usage will generally be restricted. • Extra work to input pathology/histology and clinical information outside MDT. (Site 21) • Having transcribed the form into VR we had a difficulty for example with lymph nodes - if they were negative I had to manually select and delete all the individual nodes if I had said no to lymph node involvement. • Very comprehensive many more items included than normally explicitly mentioned in my usual reports. • Comprehensive but much more time consuming than our current (Site 17,21)
Support guidance
• More detailed guidance would have been helpful (4)
Ability to report equivocal findings
• Ability to state equivocal findings . Proforma doesn't work well in cases which are not definite cancers or where there is uncertainty. (Site 4,17,21). • Don't like the grade 1 to 5 for likelihood of prostate cancer as I don't think we can be that specific on MRI (site 21)
Importance of Proforma Reporting
• Although unable to implement the proforma this is considered it important to standardise the reporting of cancer without missing many important or relevant findings. In some respects they are a good template for primary reporting, not just for reviews. Proforma reporting in principle is a good idea (site 4,17) • The reporting format should be made available to RIS/PACS all over NHS and should be mandatory (site 4).
Constraints in implementing proforma due to work pressures
• Heavy workload. Have lost colleagues. Concerns over prescriptive proforma based reporting (site 3) • Cannot force colleague radiologists to do it (site 4) • One to one conversations and email reminders to colleagues. Most colleagues made one attempt to complete a proforma report and abandoned it due to the amount of time required compared to unstructured reporting. Not prepared to reconsider despite attempts to persuade them.(site 17)
RIS implementation problems
• RIS not supportive of proforma. We explored possibility of setting up a template, but given the potential difficulties, we went for a pragmatic solution of manually filling in proformas alongside radiology report. (Site3) • The forms had to be scanned on CRIS – not ideal. In support of the concept but the only way it can work is if it is tightly integrated into CRIS so the radiologist can electronically tick they boxes as images are reported. HSS have still not incorporated the proformas into CRIS for digital reporting; if they had, I feel we could all be persuaded to continue to use the proformas whenever possible/routinely. Early implementation in a PACS/CRIS friendly format is what I look forward to. Enthusiasm was very high in our department but the lack of integration into CRIS has meant that participation will not be ongoing until we can integrate. (site 4) • Sunquest RIS did not have ability for e-form, but we did put equivalent of proformas on VRS for endometrium, cervical and prostate. The RIS system was complicated and the reports produced were not user friendly. The report produced in our RIS system looked very cluttered found them very difficult to follow.(site 21)

End-user feedback was received from 35 MDT participants (across 7 centres), including surgeons, medical and clinical oncologists and CNSs (figure 2). Most respondents, 27/35 (77%), found proforma reports contributed positively to cancer staging, 27/35 (77%) and 28/35 (80%) agreed they improved MDT efficiency and data collection respectively. Interestingly 15/35 (43%) end-users felt that proforma reports had no impact on diagnosis, this maybe because diagnosis is often multifaceted i.e. based on clinical examination and histological information. Feedback was received from 32 MDT lead radiologists (figure 3), 26/32 (81%) respondents found it a worthwhile exercise and 16/32 (50%) felt proforma reporting improved the quality of their reports, whereas 5/32 (16%) respondents did not it improved quality and 9/32 (34%) were neutral. Eighteen of 32 (56%) radiologists reported no technical difficulties completing the form. However, of 28 responses, the majority, 20/28 (71%) found proforma report took longer to complete than free-text reports (figure 4).

Discussion

Summary

The study has shown that proforma based reporting was successfully implemented in 15 of the 21 centres with 1283 cancer staging reports submitted. The implementation resulted in a significant global improvement in the proportion of prognostic and therapeutically important imaging cancer features reported by radiologists – from 48.7% completeness using free text reports to 87.3% using proformas. An absolute overall improvement of 38.6% in staging completeness. Improvements were seen across all the cancer types and all 15 centres. Since the quality of this information drives preoperative cancer treatment decisions, this has profound implications for the quality of care in newly diagnosed cancer patients. Proforma reports also improved the consistency of completeness of cancer staging data.

Of the pre-proforma report, lung cancer had the greatest completeness (75%). This was the only cancer type that did not have a greater than 30% improvement following proforma reporting. A possible explanation for this is that lung cancer is the commonest cancer in the UK, furthermore, the TNM staging system is very clear and comprehensive and is the only classification that is included in the core curriculum for radiology trainees. Thus most radiologists, whether they attend the MDT or not, will be familiar staging lung cancer and have a practised approach to reporting

Study feedback reflected high acceptability of structured reports. The clinical teams that make treatment decisions based on radiologic assessment of cancer found proforma reports helpful for treatment planning and MDM efficiency. A few centres, reported inability to deploy the template proformas into RIS systems as a major barrier. The majority of radiologists considered proforma reporting more time consuming than free-text reporting. Arguably, we can infer that less complete free-text reports will take less time to produce compared to more comprehensive structured reports. On the other hand, it seems likely that a structured template would be time saving for those radiologists already undertaking comprehensive free-text reporting. Thus, it is likely that structured proforma reporting will improve the consistency and standards of some whilst maintaining the standards of others.

Proforma reports also provide an educational resource, especially for radiologists and trainees who do not regularly attend the relevant cancer MDM and so may not appreciate the staging items pertinent to clinical decision making.

Progress in cancer treatment has been paralleled by developments in imaging technology that enable more accurate and detailed radiological evaluation. Despite the increase in the complexity and amount of information that needs to be interpreted and conveyed by the radiologist, the reporting style has largely remained unchanged from its' original free prose format. Whilst the deficiencies in some reports may be rectified upon MDM review, this is not a reliable or efficient method and is inconsistently documented. Currently, only clinical T, N and M data are recorded for the cancer registries. Consequently, it may not always be possible to determine the basis on which treatment decisions for patients were made.

Strengths and weaknesses in relation to other studies

Previous studies have highlighted deficiencies in cancer staging information from free-text reporting for various cancer types (24,25). Furthermore, studies have shown structured reports to improve completeness and clarity (11–17,26–28). A study of radiological assessment of pancreatic cancer, showed proforma reporting improved assessment of resectability and confidence in treatment decisions (25).

The management options in cancer treatment are ever increasing, and there is now an established evidence base for the selective use of preoperative treatment to improve outcomes in many cancers. However, there remain wide variations in cancer care and outcomes in the UK, as demonstrated for lung cancer management in a recent large UK study (29). A retrospective study of 13722 breast cancer patients showed that MDT working

resulted in improved survival and reduced variation in survival between hospitals in Scotland (30). Radiology proforma reporting could improve cancer staging data available for national cancer statistics, which in turn could be used to identify the causes of variation in cancer care.

The pathology model has shown that a structured report template provides an effective conduit for capturing and storing data, which in turn is easier to extract and view (12,31). Structured radiology cancer reporting provides high-quality and more complete information that is more conducive to data gathering. With the increasing emphasis on healthcare systems to demonstrate regular and robust quality assessment followed by improvement, the structured format is well suited to audit and research. It also facilitates the development of 'bioregistries' and tumour databanks.

Limitations of this study

A limitation of this study was that, despite extending the period for report submission, the post-proforma cohort was underpowered across all tumour types and the pre-proforma cohort was underpowered for cervical and endometrial cancers to detect a difference in completeness of 20%. However, the improvement was in fact greater than 30% across all tumour types except lung cancer and the study was adequately powered to detect this. A further limitation of our study is that whilst improving the content and quality of the report through measuring completeness, it did not evaluate the accuracy of the reports. However, the accuracy and limitations of these modalities in cancer staging have already been extensively evaluated. The implementation of the structured reporting template was a non-blinded intervention, thus the scale of the improvement, including in the pre-proforma cohort, may have been inflated by the process of this as an audited measure - the Hawthorne effect. Although, this could also be an argument for introducing standardized proforma reporting in radiology as a nationally audited quality measure of excellence in cancer care.

Implications for doctors and policy makers

We believe minimum dataset cancer staging radiology reports, like pathology minimum dataset reports, should be a mandatory standard for patients with newly diagnosed cancers. This model of proforma reporting is amenable to modifications, and could be expanded to other cancer types, developed with the input of relevant SIGs. In the future, the aim should be toward developing evidence based validated reporting templates with a standardised structure and content including expert consensus agreed essential reporting elements.

Structured proforma reporting clearly improves the information available that is needed for patient care. However, to facilitate ongoing use of proforma reporting, support through training, education and IT infrastructure improvement is needed. This would necessitate collaboration with RIS providers and the RCR to provide funding for workshops and implementation.

Sufficient resource will be necessary to maintain and test radiological competence in such a crucial component of cancer care to safeguard the consistency of standards. Measuring the quality and accuracy of radiology reports against pathology (where available) and outcomes will contribute to this as well as identifying regional variations in management and outcome.

Unanswered questions for future research

Clinical research has already established that items recorded on proforma are of prognostic significance. Future studies will be able to determine whether radiological assessments of individual radiologists are of sufficient quality and consistency, these can be measured against outcome. It will also be important to determine whether analysis of radiology proformas help to understand the differences in regional variations in cancer outcomes that currently exists.

Contributorship statement:

APat contributed to data analysis and interpretation. She drafted and finalised the manuscript. AR designed, developed and finalised the study. She contributed to design of the work and acquisition of data. She read and approved the final manuscript. AG designed, developed and finalised the study. He read and approved the final manuscript. FG designed, developed and finalised the study. He read and approved the final manuscript. SW designed, developed and finalised the study. She contributed to acquisition and interpretation of data. She read and approved the final manuscript. SG contributed to design of the work and developed and finalised the study. She read and approved the final manuscript. DB designed, developed and finalised the study. He read and approved the final manuscript. CA contributed to design of the work, developed and finalised the study. She read and approved the final manuscript. APad contributed to design of the work and acquisition of the data. He read and approved the final manuscript. BC contributed to design of the work and data acquisition. He read and approved the final manuscript. PC developed and finalised the study. He contributed to analysis and interpretation of data. He read and approved the final manuscript. MP contributed to design of the work and developed and finalised the study. He read and approved the final manuscript. GB (PI) conceived, designed, developed and finalised the study. She was involved in data analysis and interpretation. She drafted, read and approved the final manuscript.

Competing interests: The corresponding author has seen and retained the ICMJE form from all co-authors. There are no competing interests to declare.

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Data sharing statement: All data that has been used and analysed for this study has been made available in this publication. There is no outstanding data or results/analysis for later publication.

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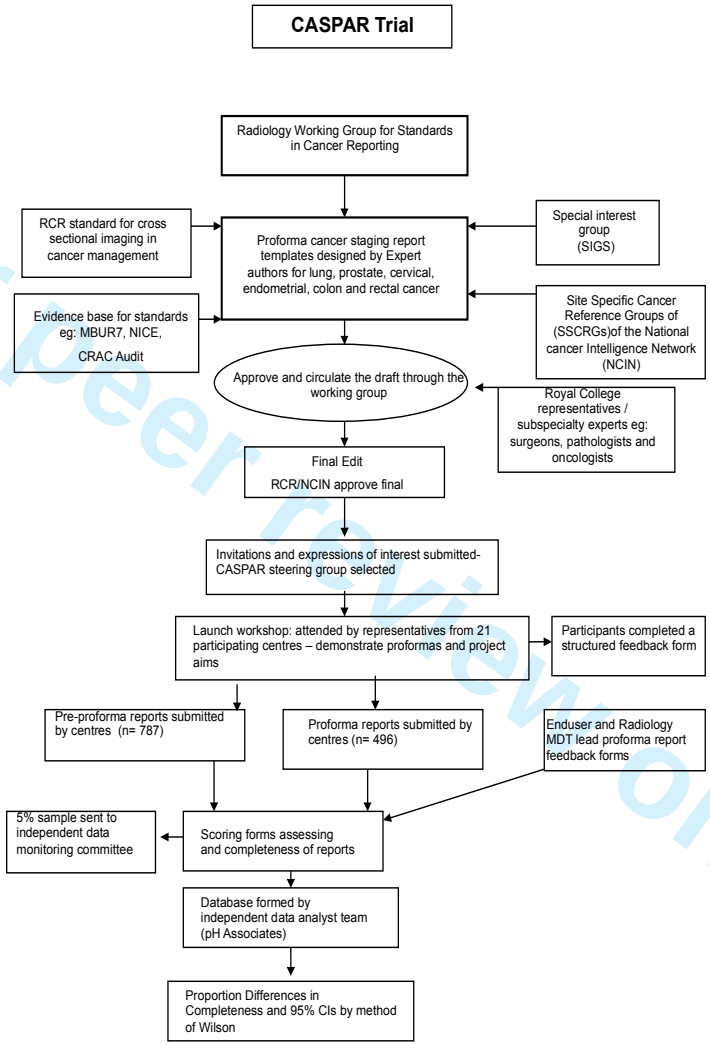


Figure 1

Figure 2

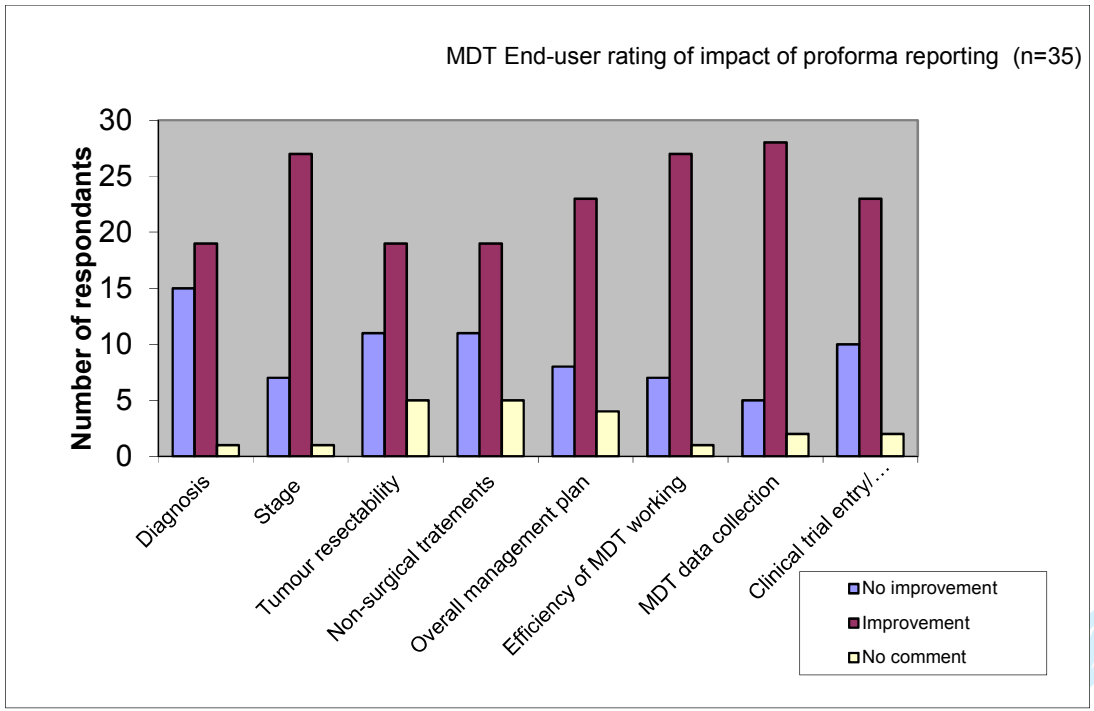


Figure 3

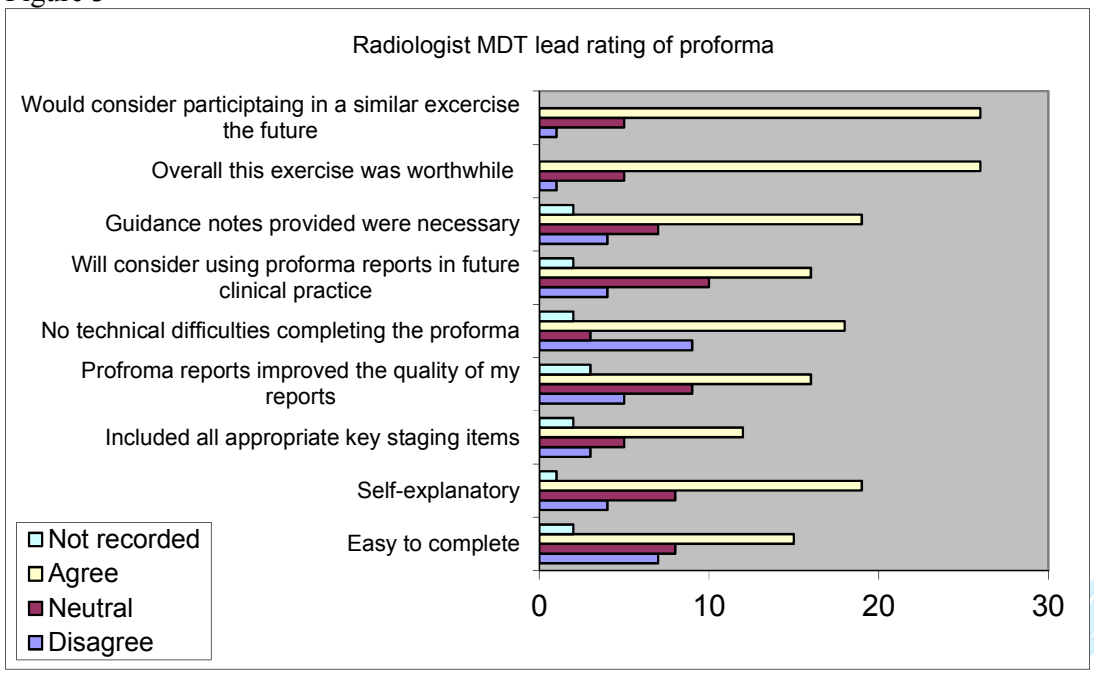
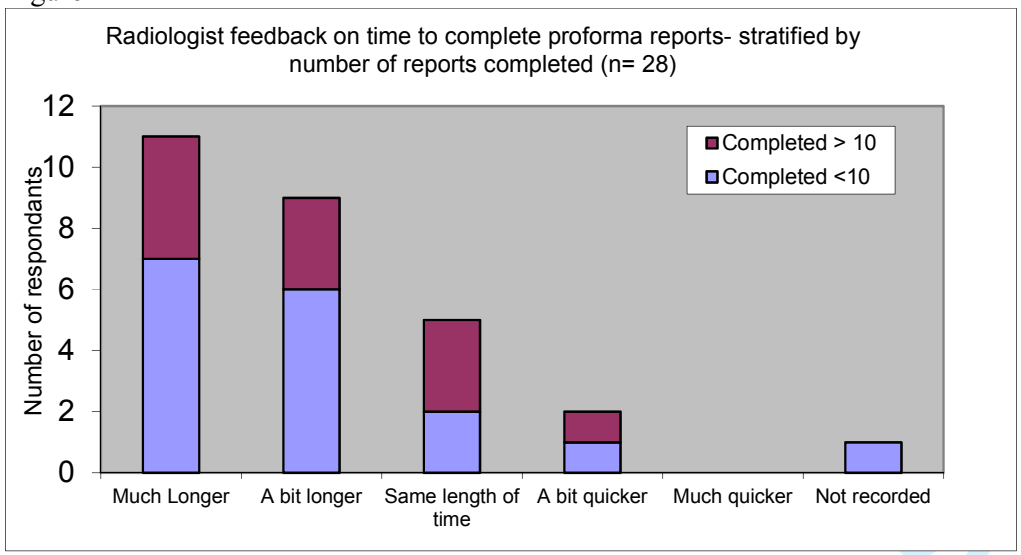


Figure 4



Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
Introduction	*Why did you start?*
3. Problem Description	Nature and significance of the local problem
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies

5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work
6. Specific aims	Purpose of the project and of this report
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest
Results	*What did you find?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data
Discussion	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project

15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps
Other information	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting

Table 2. Glossary of key terms used in SQUIRE 2.0. This Glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They may, and often do, have different meanings in other disciplines, situations, and settings.

Assumptions
Reasons for choosing the activities and tools used to bring about changes in healthcare services at the system level.

Context
Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the interpretation of these factors ("sense-making") by the healthcare delivery professionals, patients, and caregivers that can affect the effectiveness and generalizability of intervention(s).

Ethical aspects
The value of system-level initiatives relative to their potential for harm, burden, and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and value of healthcare services include opportunity costs, invasion of privacy, and staff distress resulting from disclosure of poor performance.

Generalizability
The likelihood that the intervention(s) in a particular report would produce similar results in other settings, situations, or environments (also referred to as external validity).

Healthcare improvement
Any systematic effort intended to raise the quality, safety, and value of healthcare services, usually done at the system level. We encourage the use of this phrase rather than "quality improvement," which often refers to more narrowly defined approaches.

Inferences
The meaning of findings or data, as interpreted by the stakeholders in healthcare services – improvers, healthcare delivery professionals, and/or patients and families

Initiative
A broad term that can refer to organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, planning, execution, and assessment)

Internal validity
Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular healthcare system.

Intervention(s)
The specific activities and tools introduced into a healthcare system with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a system's performance.

Opportunity costs

Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative

Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential

Process
The routines and other activities through which healthcare services are delivered

Rationale
Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

Systems
The interrelated structures, people, processes, and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

Theory or theories
Any "reason-giving" account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to be explicit and well-founded about any informal and formal theory (or theories) that are used.

BMJ Open

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.

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Primary Subject Heading:	Radiology and imaging
Secondary Subject Heading:	Oncology, Diagnostics
Keywords:	RADIOLOGY & IMAGING, cancer staging, Proforma reporting, Structured reporting, synoptic reporting

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.

Word count: 4446

Keywords: radiology and imaging, cancer staging, proforma reporting, structured reporting, synoptic reporting

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Objectives: Following a diagnosis of cancer, the detailed assessment of prognostic stage by radiology is a crucial determinant of initial therapeutic strategy offered to patients. Pre-therapeutic stage by imaging is known to be inconsistently documented. We tested whether the completeness of cancer staging radiology reports could be improved through a nationally introduced pilot of proforma-based reporting for a selection of six common cancers.

Design: Prospective interventional study comparing the completeness of radiology cancer staging reports before and after the introduction of proforma reporting

Setting: Twenty-one UK NHS Hospitals

Participants: 1283 cancer staging radiology reports were submitted

Main Outcome Measures: Radiology staging reports across the six cancers types were evaluated before and after the implementation of proforma based reporting. Report completeness was assessed using scoring forms listing the presence or absence of pre-determined key staging data. Qualitative data regarding proforma implementation and usefulness was collected from questionnaires provided to radiologists and end-users.

Results: Electronic proforma based reporting was successfully implemented in 15 of the 21 centres during the evaluation period. A total of 787 pre-proforma and 496 post-proforma staging reports were evaluated. In the pre-proforma group, only 48.7% (5586/11470) of key staging items were present compared with 87.3% (6043/6920) in the post-proforma group. Thus, proforma reporting achieved an absolute improvement in staging completeness of 38.6% (95%CI,0.37-0.40%,p<0.001). An increase was seen across all cancer types and centres. The majority of respondents found proforma reporting improved report quality.

Conclusion: The implementation of proforma reporting results in a significant improvement in completeness of cancer staging reports. Proforma based assessment of radiological stage facilitates objective comparison of quality and outcomes. It should become an auditable quality standard.

Strengths and Limitations.

- The post-proforma cohort was underpowered to detect an improvement of 20% in completeness of reports. However, the post-proforma cohort in fact showed improvements of greater than 30% for all cancer types apart from lung and cervical cancer, and the study was adequately powered to detect this.

- The trial was a non-blind study and consequently there may have been some observer (Hawthorne) effect on report quality

- There was a greater than expected drop-out rate and only 496 proforma reports were submitted compared to 787 non-proforma reports. The challenge of integrating proforma templates into radiology information systems (RIS) was identified as a significant barrier to uptake.

Introduction

Once a patient is diagnosed with cancer the next steps in patient care are crucial and result in life changing management decisions such as intensity and radicality of treatment. Such decisions hinge on the accuracy and completeness of cancer staging provided to the clinical teams and patient(1,2). The majority of initial cancer treatment decisions are almost entirely based on radiological assessment of both the cancer prognostic stage and anatomic distribution of disease. Thus, clear documentation of imaging derived staging is required of radiologists to facilitate multidisciplinary team (MDT) based decisions. In many cancers, radiological staging assessment is used to guide radiotherapy and surgical planning, and to select patients for preoperative (neoadjuvant) chemotherapy. In studies of patients with rectal cancer, preoperative radiological staging and MDT discussion increased the proportion of patients receiving neoadjuvant treatment and R0 resection rates and local disease control(3,4).

Despite the importance of preoperative imaging assessment, prospective audits of imaging reports for cancer have shown significant deficiencies in documented staging information. A single centre study found tumour resectability status in rectal cancer, which informs the decision for preoperative chemoradiotherapy, was missing in 40/55 (73%) of free-text radiology reports and proforma reporting reduced this to 4% (5). An audit of practice by Ontario Cancer Care showed similar findings with missing data noted in 40% (51/128) of rectal cancer staging reports submitted by radiologists(6).

The concept of minimum dataset included in cancer staging histopathology reports using a proforma-based system is well established (7–10). Audits of histopathology reporting of cancer stage have shown an increase in minimum staging data in histopathology reports from 31% to 100% in colorectal cancer following the introduction of proforma reporting (11,12). Similar improvements in data completeness have been seen in pathology reporting of other cancers, such as pancreas, prostate and melanoma, following standardisation (13–19). The impact on clinical outcomes was demonstrated by a study showing that patients with incomplete staging reports with dataset items missing had poorer survival outcomes (20). Moreover, proforma reporting has the potential to improve patient treatment, enabling more consistent identification of high-risk patients who can be offered postoperative adjuvant therapy (21). As a consequence, minimum data set reporting of prognostic histopathological data for resected cancers has become a global standard of care (11,22).

Guidelines for cancer care do not consider radiological structured reporting, unlike histopathology, as mandatory. At present, there is paucity of evidence showing such an intervention can improve the quality and completeness of cancer reporting. This quality improvement study tests whether the completeness of radiological cancer staging can be improved through a nationally introduced pilot of proforma-based reporting for a selection of common cancers.

Methods

The project was jointly initiated by the Royal College of Radiologists (RCR) and the National Cancer Intelligence Network (NCIN). The project was also designed in consultation with representatives from the Royal College of Physicians, Royal College of Surgeons of England, and the Royal College of Pathologists and thus a collaborative proposal was jointly funded by the Academy of Medical Royal Colleges and RCR.

This study did not require Research Ethics Committee (REC) approval as only anonymised patient data (MDT radiology reports) and NHS staff interview/questionnaires were used (23). The requirements of the Data Protection Act 1998 and the clinician's common law duty of confidentiality were met by the pre-anonymisation of all patient records by clinical care staff. Only centres that obtained written approval from the Trust Data Protection Officer (Caldicott Guardian) to release anonymised radiology reports to the CASPAR team for analysis were included. One centre did not obtain Caldicott agreement and was not included in the study.

Primary Objective

- To compare the minimum datasets of prognostically and therapeutically important staging data from radiology reports before and after adoption of proforma based reporting.

Secondary Objectives

- To determine:
  - how pilot centres implemented proforma reporting and any areas of difficulty.
  - the usefulness of support workshops and guidelines.

- the clinical impact of proformas from the radiology multidisciplinary team (MDT) lead and end-users (core MDT members).

The project was conducted in UK NHS hospitals by radiologists reporting newly diagnosed lung, prostate, endometrial, cervical, colon and rectal cancer working within their respective MDTs. Expressions of interest were sought from UK Radiology departments via the RCR website and an email invitation to all RCR Regional Chairs, the leads of all Special Interest Groups (SIG) and members of the NCIN Site Specific Clinical Reference Groups (SSCRG). Participating centres were selected by the CASPAR Steering Group to represent a spectrum of UK NHS hospitals, to maximise participation from the 2012 strategic health authority (SHA) regions, ensuring the ratio of non-teaching to teaching hospitals was weighted proportionately.

Based on the criteria above, 21 centres were selected to take part in the evaluation. Sample size estimate allowed for a 10-15% dropout rate.

A workshop was held to launch the project, this provided a project overview and demonstrated the six pilot proformas (lung, prostate, endometrial, cervical, rectal and colon) (Appendix 1). The pilot proformas were designed by the tumour site leads, with input and feedback from the relevant SIG and SSCRG. Breakout groups were held for each tumour site, where the individual proformas and guidance were explained in greater detail. Participants were requested to complete feedback forms. A follow-up teleconference held to answer remaining queries.

This was an interventional “before and after” study. In order to reduce the risk of bias in reporting standards pre-proforma introduction, reports were submitted from 3 months prior to and following the introduction of proforma reporting. To account for differences in the estimated cancer specific diagnosis rates between centres, the specific periods were modified for recruiting site and tumour type.

Pre-treatment MDT radiology cancer staging report staging for the six cancer types were eligible for inclusion. For pelvic malignancies, this included local staging pelvic MRI report and CT assessment for metastatic disease. For lung and colon cancers this included a CT report for

both primary and metastatic disease staging. Only tumour staging reports as documented by the radiologist (either MDM radiology report, report addendum following MDM or staging cancer report) were acceptable. Annotations made by the clinical teams or MDT co-ordinators during MDT discussions were not accepted. Imaging reports submitted not fulfilling the above criteria were excluded.

- **Cohort 1** (pre-proforma (free-text) reporting) - consecutive patients for whom a cancer staging radiology report was submitted prior to implementation of proforma reporting.
- **Cohort 2** (post-proforma reporting) - consecutive patients for whom a cancer staging radiology report was submitted following implementation of proforma reporting.

The radiology reports were completed by consultant radiologists. The study was non-blind, radiologists were aware of participation in the study in the pre- and post-proforma cohorts.

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 had used at least one proforma report for decision-making.

MDT Radiology reports and staff feedback questionnaires were collected between March 2012 and April 2013. The project was extended from the original 3 month pre- and 3 month post-proforma duration to allow for differences in the rates of cancer incidence and to allow time for implementation of proformas into the RIS systems.

The key minimum staging items considered essential to making clinical treatment decisions were defined by consultation with the NCIN SSCRGs comprising lead specialist multidisciplinary representatives. Cancer specific proforma report templates were produced to include these key data items considered clinically important for cancer treatment and prognosis (Appendix 2). These were approved by the respective UK specialist interest groups (SIG) and the NCIN SSCRGs. The completeness of reports was assessed using scoring/coding forms (designed by project leads) that listed the presence or absence of the pre-determined key staging data (Appendix 3). Staging items that were not applicable to a particular case were deducted from the 'total' count to produce a 'total needed' count.

All free text (pre-proforma) report scoring was carried out by experienced members of the project team. All proforma report scoring was carried out by an independent data analyst team and queries were referred to the project team.

Standardised questionnaires were used to solicit staff feedback on the usefulness of proformas in reporting imaging findings (radiologists) and facilitating clinical decision-making (end-users).

Data analysis

A project database was developed by the independent data analyst team. The database was checked by the independent data analyst team for completeness and checked against the data collection form, any missing data was identified and corrected as appropriate. A 10% sample of coded and source reports were sent to the independent data monitoring committee (DMC) to assess quality and fairness of coding of pre-proforma and proforma reports (Appendix 4). The DMC also checked that recruitment was adequate to meet the number needed based on the power calculations (table 1).

Statistical analysis for the primary endpoint

Hypothesis: the introduction of proforma reporting improved the completeness of reporting in the cancers tested by an expected 20% with an expected completeness rate pre-proforma of 50% (based on an internal audit). A difference in the percentage of completed data items between proforma and non-proforma reports of at least 20% following proforma introduction required a sample size of 124 cancer reports per cancer type prior to and after the introduction of proforma reporting, with 90% power and 5% significance.

Sample size calculations with variable proportion differences in completeness of reports to achieve at least 90% power and 5% significance were calculated as follows (table 1):

Table 1: Power calculations

Proportion difference	Power	Significance	Sample size needed
0.10	90%	5%	518
0.20	90%	5%	124
0.30	90%	5%	51

Thus, a total of 248 (124 free-text and 124 proforma) cancer reports per cancer type were required to show an increase of 20% completeness of reports between pre and post-intervention cohorts (24).

Primary objective

Differences in completeness of reporting of the predefined minimum staging data were calculated before and after proforma implementation. The data was analysed for the whole sample and stratified by tumour site and reporting hospital. The 95% confidence intervals for proportions of completed data items were calculated by the Method of Wilson (25). Differences in proportions of completed data items pre- and post-proforma reporting were calculated and confidence intervals for these differences calculated using Method 10 of Newcombe (26).

Secondary objective

A qualitative analysis through questionnaire responses was undertaken to evaluate the secondary objectives.

Results

The study flow and landmarks are summarised in figure 1. A total of 36 Radiology departments expressed an interest in taking part in the evaluation. Twenty-one centres attended the launch meeting workshop and enrolled to participate in the project.

Primary endpoint

Two centres (5 and 16) failed to supply any data, sixty-two pre-proforma and 3 proforma reports did not comply with the inclusion criteria, and were excluded.

Nineteen centres provided pre-proforma free text reports for inclusion in the study (table 2). Of these, four centres provided pre-proforma reports only (centres 6, 8, 14 and 21). In total 15 of the 19 centres provided both pre and post proforma reports for at least 2 tumour types (table 2). The total number of reports provided by cancer type is summarised in table 3.

The total number of pre-proforma reports for cervical and endometrial cancer and post-proforma reports for all of the tumour types was less than 124, meaning these were under-powered to detect a 20% difference. However, for all but cervical cancer post-proforma reports, there were greater than 51 reports meaning numbers were adequate to detect a 30% difference with 90% power.

Table 2 :Percentage of data fields completed by centre

Centre	PRE				POST				Proportion difference in completeness	95% Confidence Intervals
	Total number of reports	Number of data items completed	Total needed	Total % Completeness	Total number of reports	Number of data items completed	Total needed	Total % Completeness		
1	62	401	920	43.6%	34	312	440	70.9%	0.27	0.22-0.32
2	18	109	265	41.1%	30	390	433	90.1%	0.49	0.45-0.55
3	40	225	523	43.0%	18	226	240	94.2%	0.51	0.45-0.56
4	52	373	717	52.0%	52	672	718	93.6%	0.42	0.37-0.46
5	0	-	-	-	0	-	-	-	na	na
6	12	127	201	63.2%	0	-	-	-	na	na
7	84	516	1210	42.6%	45	559	702	79.6%	0.37	0.33-0.41
8	56	447	899	49.7%	0	-	-	-	na	na
9	32	268	508	52.8%	56	884	917	96.4%	0.44	0.39-0.48
10	20	126	295	42.7%	23	274	352	77.8%	0.35	0.28-0.42
11	57	495	836	59.2%	45	507	586	86.5%	0.27	0.23-0.32
12	41	317	602	52.7%	27	391	419	93.3%	0.41	0.36-0.45
13	43	347	600	57.8%	36	432	460	93.9%	0.36	0.31-0.40
14	45	252	648	38.9%	0	-	-	-	na	na
15	61	452	879	51.4%	44	440	550	80.0%	0.29	0.24-0.33
16	0	-	-	-	0	-	-	-	na	na
17	72	500	1053	47.5%	20	238	272	87.5%	0.40	0.35-0.45
18	36	224	519	43.2%	27	279	302	92.4%	0.49	0.44-0.54
19	14	69	186	37.1%	16	203	210	96.7%	0.60	0.52-0.66
20	20	106	281	37.7%	23	236	319	74.0%	0.36	0.29-0.43
21	22	232	328	70.7%	0	-	-	-	na	na
TOTAL	**787**	**5586**	**11470**	**48.7%**	**496**	**6043**	**6920**	**87.3%**	**0.39**	**0.37-0.40**

Table 3: Percentage of data fields completed by tumour type

	Lung Cancer		Prostate Cancer		Cervical Cancer		Endometrial Cancer		Colon Cancer		Rectal Cancer		Overall Cancer	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
No. of proformas	125	84	156	108	117	46	112	59	142	88	135	111	787	496
Staging item completed	1509	1236	885	871	918	596	823	921	707	1049	744	1370	5586	6043
Staging items needed	1969	1359	1944	1086	1877	720	2005	1059	1775	1132	1900	1564	11470	6920
AP totals	76.6%	90.9%	45.5%	80.2%	48.9%	82.8%	41.0%	87.0%	39.8%	92.7%	39.2%	87.6%	48.7%	87.3%
Proportion difference	0.14		0.35		0.34		0.46		0.53		0.48		0.39	
95% Confidence Intervals	0.12-0.17		0.30-0.37		0.30-0.37		0.43-0.49		0.50-0.55		0.46-0.51		0.37-0.40	
Mean completed	76.6%	90.9%	45.4%	80.1%	48.2%	82.4%	41.0%	87.0%	39.9%	92.7%	39.3%	87.5%	48.1%	86.9%
Median completed	76.5%	93.8%	41.7%	90.9%	47.1%	88.2%	44.1%	94.4%	38.5%	92.3%	40.0%	92.9%	46.2%	92.9%
St Dev	19.8%	10.4%	19.1%	23.4%	17.5%	15.7%	13.5%	13.7%	14.9%	8.8%	17.4%	14.7%	21.4%	9.3%
Min	25.0%	56.3%	0.0%	33.3%	11.8%	41.2%	0.0%	66.7%	7.7%	69.2%	0.0%	41.7%	0.0%	33.3%
Max	100.0%	100.0%	92.3%	100.0%	88.2%	100.0%	77.8%	100.0%	76.9%	100.0%	93.3%	100.0%	100.0%	100.0%
IQR 1	60.0%	87.5%	30.8%	63.6%	35.7%	70.6%	33.3%	72.2%	30.8%	84.6%	27.9%	78.6%	33.3%	78.6%
IQR 3	100.0%	100.0%	58.3%	100.0%	58.8%	94.1%	50.0%	100.0%	46.2%	100.0%	50.0%	100.0%	60.0%	100.0%

A total of 787 pre- and 496 post-proforma staging reports met inclusion criteria for analysis. The proportion of completed staging data from 787 pre-proforma staging cancer reports were 5586 of 11470 staging items (48.7%), compared with 6043 of 6943 staging items using proforma reports (87.3%). The improvement in cancer staging achieved by proforma reporting amounted to an absolute increase of 38.6% (95% CI: 37- 40%). Thus the overall improvement was significant and surpassed 30%, for which this study was powered. An improvement of greater than 30% with proforma reporting was seen for 12 of the 15 centres that submitted pre- and post-proforma reports (table 2).

An improvement in completeness was seen across all tumour types, and the improvement was greater than 30% for 4 of the 6 tumour types (table 3). For lung cancer however, the percentage improvement was 14% (95% CI 12 - 17%), this probably relates to the high percentage completeness of the pre-proforma lung cancer staging reports (76.6%). For cervical cancer the improvement in completeness was 34%, however the post-proforma group was underpowered (n= 46).

The distribution of elements of staging data by cancer site is summarised in Appendix 5 (tables 1-6). For lung cancer, two staging items (differentiation from consolidation and metastases) were less complete on the proforma reports compared to free-text reports, but the difference was small: 3% and 7% respectively. There were no other instances of a decrease in the completeness of staging items when proforma reports were compared with pre-proforma reporting.

For lung cancer staging, significant improvements in 2/17 minimum data cancer staging items were observed. There was a notable improvement in the documentation of endobronchial and pleural disease using proformas. Prostate proforma introduction saw 30% or greater improvement in 9/13 staging items – of particular clinical relevance was the improvement in documentation of local invasion and TNM stage. Proforma reporting of endometrial cancer produced a 30% or greater improvement in reporting of 12/18 staging items. The most striking improvements were in involvement of the serosa and pelvic organs, all crucial to surgical decision making and prognosis. For cervical cancer an improvement of greater than 30% was seen in 9/17 staging items following proforma reporting, however the post-proforma group was underpowered. One of the greatest improvements was for pelvic sidewall invasion, a predictor of pelvic nodal involvement. For rectal cancer staging proforma reports, improvements were seen in 13/15 staging items including extra-mural spread and extra-mural vascular invasion. Both are important prognostic markers and guide selection for

neo-adjuvant therapy. Marked improvement in 10/13 staging items was seen by the use of the colon cancer proforma reports. The greatest improvements were for peritoneal infiltration and resectability- both critical surgical determinants.

A wide range of percentage completeness in individual reports was seen, before and, to a lesser degree, after the introduction of proformas. For example, the range of completeness of lung cancer report was 25-100% (pre-proforma) and 56-100% (post-proforma) and for prostate was 0-92% (pre-proforma) and 33-100%(post-proforma). This probably, at least in part, reflects the difference in reporting style between individual radiologists. The effect of proforma reporting was not studied in individual radiologists. The range of percentage completeness reduced and the mean completeness increased for all cancer types after the introduction of the proforma. However, it is noted that even in the post-proforma-cohort, there were incomplete reports. It is unclear, without further assessment, the reasons for this. Possibilities include difficulties in using the proforma, inexperience or uncertainty in evaluating certain parameters or it could reflect limitation of the imaging modality.

Secondary endpoints

Some queries raised regarding the lung staging proforma were resolved by teleconference. For the remaining cancer specific workshops 100% of the attendees agreed that “the presentation given in this session was very clear” and 80-100% agreed that “[they can see how [they] can use this proforma in clinical practice”. There was an average of 67% agreement amongst the workshop attendees that “[they] feel confident to explain the use of this proforma to colleagues”.

During the study, six sites reported problems encountered with implementation of the proforma into their RIS systems. These included unavailability of the software upgrade within the project timeframe. For one site, the RIS system did not use voice recognition so paper versions of the template were manually completed.

Feedback was received from eleven of twenty-one centres participating in the launch meeting. All sites indicated moderate to strong agreement that the proformas were self-explanatory, included all key items and improved report quality. Feedback from those centres unable to submit proforma reports is summarised in table 4. Suggestions for improving proforma design included: mechanisms to document equivocal findings, reduce the time taken document negative findings and to include incidental findings. For three sites,

inability to engage colleagues and time pressure were cited as limiting factors and four sites indicated that lack of IT support from RIS suppliers resulted in failure to implement the proformas. Technical barriers to integration of proforma report templates into existing RIS is clearly an important obstacle to implementation.

Table 4: Summary of feedback from centres failing to submit completed cancer staging proformas

Proforma design
• Better section for documenting other findings (site 3). • An alternative approach might be to follow an algorithm only specifically mentioning positive findings as they are observed, rather than producing a report characterised by a long list of negative findings.(Site 17) • The proforma seemed to be designed for staging much more advanced disease than we are normally asked to scan. • Without nicely laid out proformas which can easily be completed, uptake and usage will generally be restricted. • Extra work to input pathology/histology and clinical information outside MDT. (Site 21) • Having transcribed the form into VR we had a difficulty for example with lymph nodes - if they were negative I had to manually select and delete all the individual nodes if I had said no to lymph node involvement. • Very comprehensive many more items included than normally explicitly mentioned in my usual reports. • Comprehensive but much more time consuming than our current (Site 17,21)
Support guidance
• More detailed guidance would have been helpful (4)
Ability to report equivocal findings
• Ability to state equivocal findings . Proforma doesn't work well in cases which are not definite cancers or where there is uncertainty. (Site 4,17,21). • Don't like the grade 1 to 5 for likelihood of prostate cancer as I don't think we can be that specific on MRI (site 21)
Importance of Proforma Reporting
• Although unable to implement the proforma this is considered it important to standardise the reporting of cancer without missing many important or relevant findings. In some respects they are a good template for primary reporting, not just for reviews. Proforma reporting in principle is a good idea (site 4,17) • The reporting format should be made available to RIS/PACS all over NHS and should be mandatory (site 4).
Constraints in implementing proforma due to work pressures
• Heavy workload. Have lost colleagues. Concerns over prescriptive proforma based reporting (site 3) • Cannot force colleague radiologists to do it (site 4) • One to one conversations and email reminders to colleagues. Most colleagues made one attempt to complete a proforma report and abandoned it due to the amount of time required compared to unstructured reporting. Not prepared to reconsider despite attempts to persuade them.(site 17)
RIS implementation problems
• RIS not supportive of proforma. We explored possibility of setting up a template, but given the potential difficulties, we went for a pragmatic solution of manually filling in proformas alongside radiology report. (Site3) • The forms had to be scanned on CRIS – not ideal. In support of the concept but the only way it can work is if it is tightly integrated into CRIS so the radiologist can electronically tick they boxes as images are reported. HSS have still not incorporated the proformas into CRIS for digital reporting; if they had, I feel we could all be persuaded to continue to use the proformas whenever possible/routinely. Early implementation in a PACS/CRIS friendly format is what I look forward to. Enthusiasm was very high in our department but the lack of integration into CRIS has meant that participation will not be ongoing until we can integrate. (site 4) • Sunquest RIS did not have ability for e-form, but we did put equivalent of proformas on VRS for endometrium, cervical and prostate. The RIS system was complicated and the reports produced were not user friendly. The report produced in our RIS system looked very cluttered found them very difficult to follow.(site 21)

End-user feedback was received from 35 MDT participants (across 7 centres), including surgeons, medical and clinical oncologists and CNSs (figure 2). Most respondents, 27/35 (77%), found proforma reports contributed positively to cancer staging, 27/35 (77%) and 28/35 (80%) agreed they improved MDT efficiency and data collection respectively. Interestingly 15/35 (43%) end-users felt that proforma reports had no impact on diagnosis, this maybe because diagnosis is often multifaceted i.e. also based on clinical examination and histological information. Feedback was received from 32 MDT lead radiologists (figure 3), 26/32 (81%) respondents found it a worthwhile exercise and 16/32 (50%) felt proforma reporting improved the quality of their reports, whereas 5/32 (16%) respondents did not feel it improved quality and 9/32 (34%) were neutral. Eighteen of 32 (56%) radiologists reported no technical difficulties completing the form. However, of 28 responses, the majority, 20/28 (71%) found proforma report took longer to complete than free-text reports (figure 4).

Discussion

Main findings

The study has shown that proforma based reporting was successfully implemented in 15 of the 21 centres with 1283 cancer staging reports submitted. The implementation resulted in a significant global improvement in the proportion of prognostic and therapeutically important cancer imaging features reported by radiologists – from 48.7% completeness using free text reports to 87.3% using proformas, showing an absolute overall improvement of 38.6% in staging completeness. Improvements were seen across all the cancer types and all 15 centres. Since the quality of this information drives preoperative cancer treatment decisions, this has profound implications for the quality of care in newly diagnosed cancer patients. Proforma reports also improved the consistency of completeness of cancer staging data.

Of the pre-proforma report cohort, lung cancer had the greatest completeness (75%). This was the only cancer type that did not have a greater than 30% improvement following proforma reporting. A possible explanation for this is that lung cancer is the commonest cancer in the UK, furthermore, the TNM staging system is very clear and comprehensive and is the only classification that is included in the core curriculum for radiology trainees(27). Thus most radiologists, whether they attend the MDT or not, will be familiar staging lung cancer and have a practised approach to reporting

Study feedback reflected high acceptability of structured reports. The clinical teams that make treatment decisions based on radiologic assessment of cancer found proforma reports helpful for treatment planning and MDM efficiency. A few centres reported inability to deploy the template proformas into RIS systems as a major barrier. The majority of radiologists considered proforma reporting more time consuming than free-text reporting. Highlighting once again 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. 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

Our audit has revealed that if pre-proforma reports had been used in MDMs they would not have met the national standards for MDM working. Thus, when staging items are missing on cancer staging reports, the radiologist taking the MDT must provide this information. The extra time taken to do this, which will be proportional to the amount of missing data, is rarely acknowledged.

Proforma reports also provide an educational resource, especially for radiologists and trainees who do not regularly attend the relevant cancer MDM and so may not appreciate the staging items pertinent to clinical decision making.

Progress in cancer treatment has been paralleled by developments in imaging technology that enable more accurate and detailed radiological evaluation. Despite the increase in the complexity and amount of information that needs to be interpreted and conveyed by the radiologist, the reporting style has largely remained unchanged from its' original free prose format. Whilst the deficiencies in some reports may be rectified upon MDM review, this is not a reliable or efficient method and is inconsistently documented. Currently, only clinical T, N and M data are recorded for the cancer registries. Consequently, it may not always be possible to determine the basis on which treatment decisions for patients were made.

Strengths and weaknesses in relation to other studies

Previous studies have highlighted deficiencies in cancer staging information from free-text reporting for various cancer types (28,29). Furthermore, studies have shown structured reports to improve completeness and clarity (13–19,30–32). A study of radiological assessment of pancreatic cancer, showed proforma reporting improved assessment of resectability and confidence in treatment decisions (29).

The management options in cancer treatment are ever increasing, and there is now an established evidence base for the selective use of preoperative treatment to improve outcomes in many cancers(21). However, there remain wide variations in cancer care and outcomes in the UK, as demonstrated for lung cancer management in a recent large UK study (33). Radiology proforma reporting could improve cancer staging data available for national cancer statistics, which in turn could be used to identify the causes of variation in cancer care.

The pathology model has shown that a structured report template provides an effective conduit for capturing and storing data, which in turn is easier to extract and view (14,34). Structured radiology cancer reporting provides high-quality and more complete information that is more conducive to data gathering. With the increasing emphasis on healthcare systems to demonstrate regular and robust quality assessment followed by improvement, the structured format is well suited to audit and research. It also facilitates the development of 'bioregistries' and tumour databanks.

Strengths and weaknesses of this study

A limitation of this study was that, despite extending the period for report submission, the post-proforma cohort was underpowered across all tumour types and the pre-proforma cohort was underpowered for cervical and endometrial cancers to detect a difference in completeness of 20%. However, the improvement was in fact greater than 30% across four cancer types (prostate, endometrial, colon and rectal) and overall. and this study was adequately powered to detect this. Thus, given the scale of the improvements we observed across these common cancer types, the sample size was in fact too large and we had effectively overpowered the study for the primary endpoint. Despite prolonging the study, the post-proforma cervical cancer cohort was underpowered to detect a 30% improvement. This is a likely a reflection the relatively lower incidence of cervical cancer.

There was a higher than expected drop-out rate, of the 21 centres that enrolled to participate in the study and attended the launch, only 15 sites provided reports for the post-proforma cohort. Feedback indicates that the major barriers to proforma implementation were technical difficulties with integration into RIS and poor uptake by reporting radiologists. Before widespread roll-out can even be considered, the technical difficulties with integration of proforma templates into IT systems will need to be addressed by commercial RIS providers. They will need to ensure there is an effective user-template interface so that using proformas in regular reporting practise is easy and efficient.

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.

A further limitation of our study is that whilst improving the content and quality of the report through measuring completeness, 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 proforma reports have already been shown to be prognostically crucial and have already been validated against survival outcomes(2). The point we are making is that if the information is not even present on the reports, then the prognostic information to optimise treatment is not available.

The implementation of the structured reporting template was a non-blinded intervention, thus the degree of report completeness, including in the pre-proforma cohort, may have been inflated by the process of this as an audited measure (a Hawthorne effect). Although, this could in itself be an argument for introducing standardised proforma reporting in radiology as a nationally audited quality measure of excellence in cancer care.

Implications for doctors and policy makers

We believe minimum dataset cancer staging radiology reports, like pathology minimum dataset reports, should be a mandatory standard for patients with newly diagnosed cancers. This model of proforma reporting is amenable to modifications, and could be expanded to other cancer types, developed with the input of relevant specialists. In the future, the aim should be toward developing evidence based validated reporting templates with a

standardised structure and content including expert consensus agreed essential reporting elements.

Structured proforma reporting clearly improves the information available that is needed for patient care. To facilitate proforma template implementation and utilisation on a national scale, support through education, training,and IT infrastructure improvements will be needed. This will require collaboration between RIS providers and the RCR. Manufacturers need to improve functionality to enable easier integration of proforma report templates into RIS/ IT systems to ensure that proforma reporting can be implemented efficiently without becoming burdensome or time consuming for radiologists.

Sufficient resource will be necessary to test and maintain radiologists' competence in such a crucial component of cancer care to safeguard the consistency of standards. Measuring the quality and accuracy of radiology reports against pathology (where available) and outcomes will contribute to this.

Unanswered questions for future research

A well designed radiology cancer staging proforma should include staging items which have already been established to be of prognostic significance. The next step would be to assess the accuracy of individual reports and whether this translates into enhanced patient outcomes. One way to do this would be to determine whether radiological assessments of individual radiologists are of sufficient quality and consistency, and these could be measured against outcome. Furthermore, analysis of the data retrieved from radiology proformas may help us better understand the differences in regional variations in cancer outcomes.

Contributorship statement:

APat contributed to data analysis and interpretation. She drafted and finalised the manuscript. AR designed, developed and finalised the study. She contributed to design of the work and acquisition of data. She read and approved the final manuscript. AG designed, developed and finalised the study. He read and approved the final manuscript. FG designed, developed and finalised the study. He read and approved the final manuscript. SW designed, developed and finalised the study. She contributed to acquisition and interpretation of data. She read and approved the final manuscript. SG contributed to design of the work and developed and finalised the study. She read and approved the final manuscript. DB designed, developed and finalised the study. He read and approved the final manuscript. CA contributed to design of the work, developed and finalised the study. She read and approved the final manuscript. APad contributed to design of the work and acquisition of the data. He read and approved the final manuscript. BC contributed to design of the work and data acquisition. He read and approved the final manuscript. PC developed and finalised the study. He contributed to analysis and interpretation of data. He read and approved the final manuscript. MP contributed to design of the work and developed and finalised the study. He read and approved the final manuscript. GB (PI) conceived, designed, developed and finalised the study. She was involved in data analysis and interpretation. She drafted, read and approved the final manuscript.

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Competing interests statement:

There are no declarations o§f competing interest. All authors have completed and signed the ICMJE form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Data sharing statement:

All data that has been used and analysed for this study has been made available in this publication. There is no outstanding data or results/analysis for later publication.

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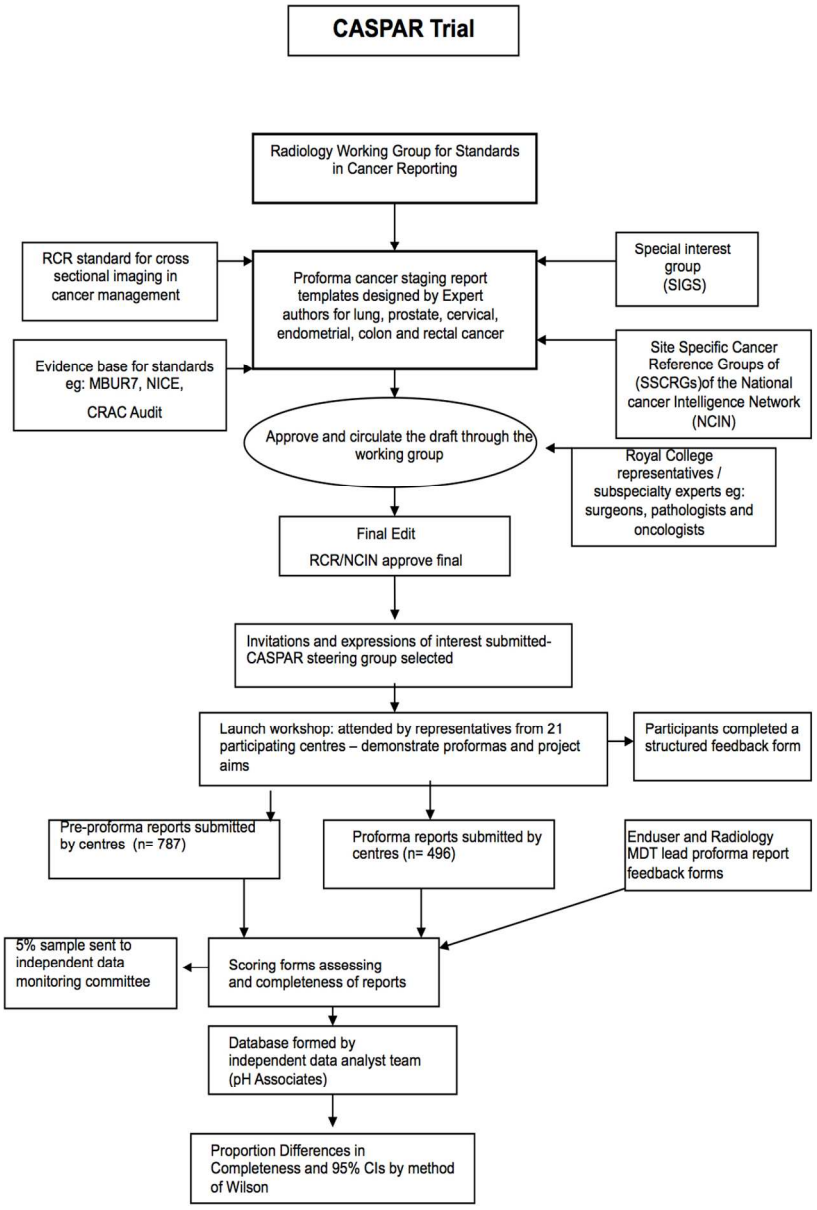
Figure legends:

Figure 1: Study flow and landmarks

Figure 2: MDT End-user rating of impact of proforma reporting

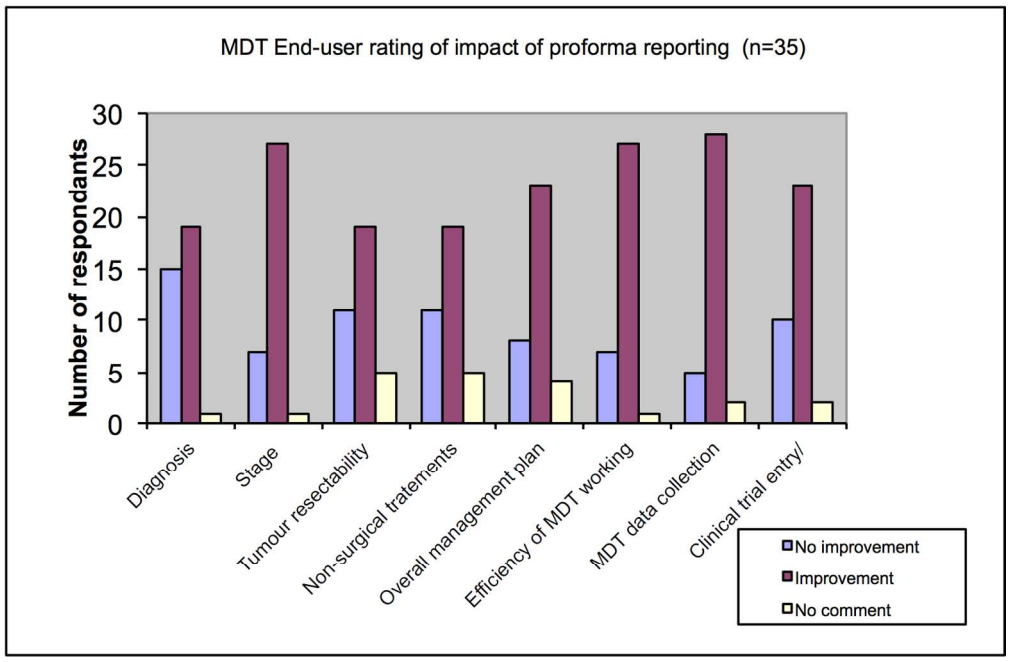
Figure 3: MDT Lead radiologist's rating of proforma reporting

Figure 4: Radiologists' feedback on time taken to complete proforma reports



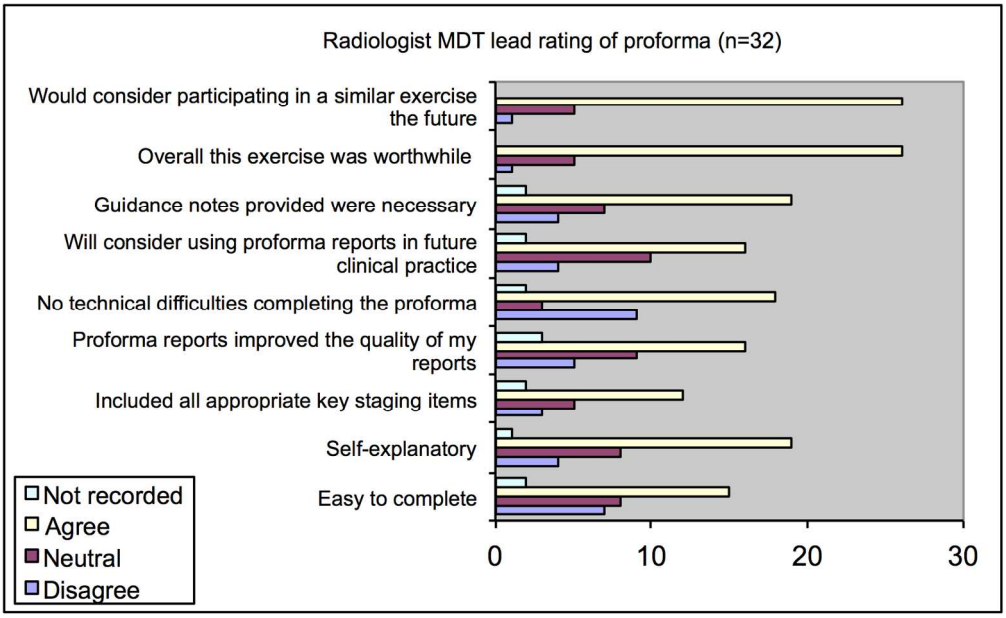
Study flow and landmarks

99x146mm (300 x 300 DPI)



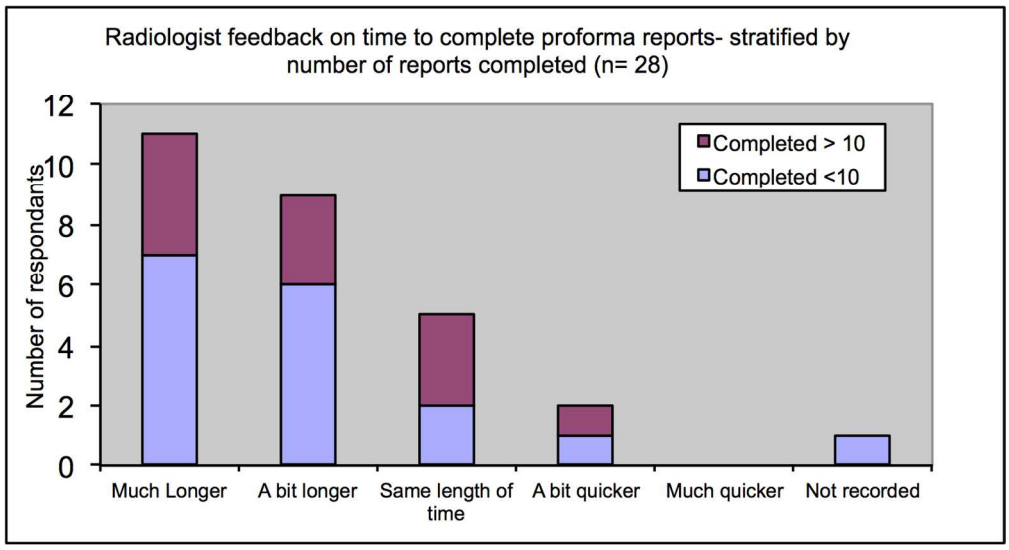
MDT End-user rating of impact of proforma reporting

153x99mm (300 x 300 DPI)



MDT Lead radiologists' rating of proforma reporting

153x93mm (300 x 300 DPI)



Radiologists feedback on time taken to complete proforma reports

142x76mm (300 x 300 DPI)

Lung proforma

Patient Name: _____ **Patient No:** _____ **Date of Birth:** _____

REPORTING PRO FORMA FOR CT STAGING: LUNG CANCER

(SECTIONS SHOWN IN BLUE ARE OPTIONAL)

TUMOUR

Primary tumour: ☐ solid ☐ part solid / part GG ☐ entirely GG

☐ cavitating ☐ necrotic

☐ spiculated ☐ irregular ☐ lobulated

☐ air bronchograms

Located in: ☐ RUL apical seg ☐ RUL anterior seg ☐ RUL posterior seg

☐ RML medial seg ☐ RML lateral seg

☐ RLL apical basal seg ☐ RLL ant basal seg

☐ RLL lateral basal seg ☐ RLL posterior basal seg ☐ RLL medial basal seg

☐ LUL apicoposterior seg ☐ LUL anterior seg ☐ Lingula

☐ LLL apicobasal seg ☐ LLL anterior basal seg

☐ LLL lateral basal seg ☐ LLL posterior basal seg

Tumour dimensions: _____ x _____ x _____ mm

Tumour difficult to differentiate from adjacent consolidation ☐

Endobronchial disease: Present/absent ☐ Trachea ☐ main bronchus ☐ lobar ☐ segmental ☐ subsegmental

Tumour locally invades: ☐ visceral pleura

☐ parietal pleura

☐ mediastinal fat

☐ mediastinal structures - ☐ SVC/Aorta/Oesophagus/Heart/Trachea

☐ diaphragm

☐ rib(s)

☐ vertebral body/ies ☐ One ☐ More than one

☐ neural foramina/spinal canal

☐ into pleural apex, involving vessel(s)/nerves

☐ main bronchus within 2cm of carina

Distal lung/lobar atelectasis : ☐ present lung/lobe ☐ absent lung/lobe

Other features:_____

Change from previous imaging: _____

Potential for percutaneous lung biopsy: ☐ yes ☐ no

Distance from pleura ____ cm
Cross fissure/bulla ☐ yes ☐ no

REGIONAL LYMPH NODES Nodes > 10mm short axis diameter

Ipsilateral bronchial or hilar LN:	☐ None	☐ present _____ mm	
Ipsilateral mediastinal or Subcarinal LN:	☐ None	☐ present _____ mm	
Contralateral mediastinal or Hilar, supraclavicular or scalene LN:	☐ None	☐ present _____ mm	
Other distant LN:	☐ None	☐ present _____ mm	

Site _____

METASTATIC DISEASE

Metastatic disease in liver: ☐ no evidence ☐ indeterminate ☐ definite evidence

Incidental note: ☐ cysts ☐ haemangioma

☐ equivocal low density lesion

☐ for characterisation by MRI

☐ for characterisation by US

☐ requires follow up

☐ unlikely to represent metastatic disease

Pulmonary nodule(s): ☐ No CT evidence

☐ CT evidence ☐ Ipsilateral ☐ Contralateral

☐ Indeterminate solitary nodule requires follow up Size _____ mm

☐ Indeterminate multiple nodules require follow up. Number _____

Lymphangitis carcinomatosis: ☐ Possible ☐ Definite

☐ Unilobar ☐ Multilobar

Other Details _____

Adrenal metastatic disease: ☐ no evidence

☐ definite metastases

☐ definite adenomas

☐ equivocal lesion requires other investigation

Bone metastatic disease: ☐ no evidence

☐ CT evidence

☐ equivocal – requires further investigation

Cerebral metastatic disease: ☐ no evidence

☐ CT evidence

☐ not assessed

Pleural disease	☐ Present	☐ Absent	
	☐ Ipsilateral	☐ Contralateral	☐ Bilateral
	☐ Effusion	☐ Thickening	☐ Nodule(s)
Pericardial effusion	☐ present	☐ absent	
Other sites of metastases:	☐ no evidence		
	☐ CT evidence		
	_____		

SUMMARY

Overall stage T _____ N _____ M _____

Discussion points for imaging case:

Prostate proforma

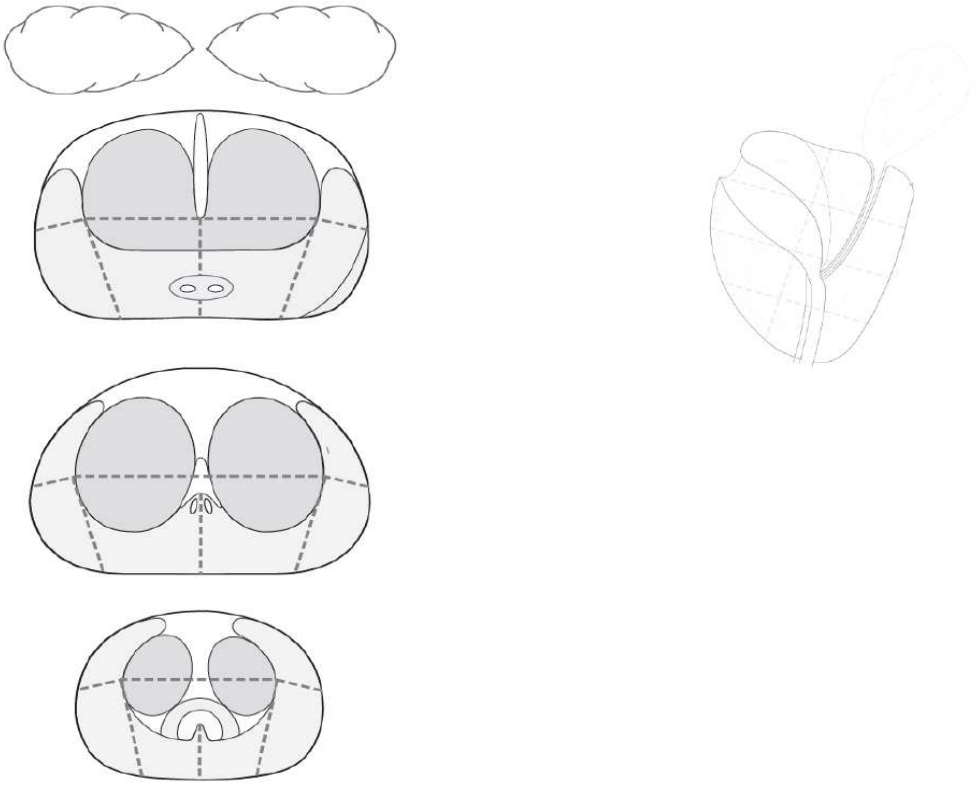
Hospital Name

REPORTING PROFORMA FOR STAGING PROSTATE CANCER *(SECTIONS SHOWN IN BLUE ARE OPTIONAL)*

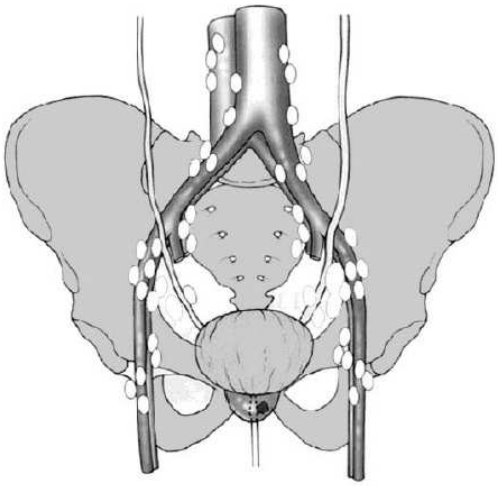
Patient label

Surname		**Forenames**		**Birth date**				
Hospital		**Hospital no**		**NHS no**				
Examination date		**MDT date**		**Consultant**				
Clinical stage		**PSA/date**		**TRUS date**	**Lt**		**Rt**	
Treatments received								
Examinations dates	**MRI**	**US**	**CT**	**Bone scan**		**Other (specify)**		
Prostate gland dimensions (XYZ)				Volume (ml)				
BPH	None □	Mild □	Moderate □	Marked □				

Lesion locations & ECE (upto 3 lesions; including index cancer; lesion size; probability of clinically significant cancer 1-5 (Clinically significant disease - highly unlikely (1) ↔ clinically significant disease - unlikely (2) ↔ indeterminate ↔ clinically significant cancer likely (4) ↔ clinically significant disease - highly likely (5))



Organ confined	Yes	□	Indeterminate	□	No	□		
Beyond prostate (state side)	Yes	□	Indeterminate	□	No	□	Bilateral	□
Into seminal vesicle(s) (state side)	Yes	□	Indeterminate	□	No	□	Bilateral	□
Into bladder neck	Yes	□	Indeterminate	□	No	□		
Fixed or into adjacent organs or pelvic wall.	Yes	□	Indeterminate	□	No	□	Specify:	
Neurovascular bundle invasion	Yes	□	Indeterminate	□	No	□	Bilateral	□

Nodal status (draw sites of positive nodes	**Node positive**	□		Number (positive nodes/total)	
	Node negative	□		Right side	Left side
	Indeterminate	□		Maximum short axis dimension mm	Maximum short axis dimension mm

Metastases	Yes □	Indeterminate □	No □	Locations

TNM stage	**N**	**M**
□ Tx (cannot be assessed; should not be used for uncertainty in other T categories) □ T1 (invisible by imaging) □ T2a (tumour involves one half of one lobe or less) □ T2a (tumour involves more than one half of one lobe but not both lobes) □ T2c (bilateral disease) □ T3a (EPE; unilateral or bilateral) □ T3b (SV positive; unilateral or bilateral) □ T4 (other organs involved)	□ Nx □ N0 □ N1	□ Mx (cannot be assessed) □ M0 (No distant metastasis) □ M1 (Distant metastasis) □ M1a (Non regional node(s)) □ M1b (Bones) □ M1c (Other site(s) with or without bone disease When more than one site of metastasis, the most advanced category is used. M1c is most advanced.

Additional comments
Recommendations of further imaging CT □ MRI □ PET-CT □ Bone scan □

Signature …… **Date**……..

Radiologist Name:

Cervical proforma

REPORTING PROFORMA FOR MRI STAGING IN PRIMARY CERVICAL CANCER

(SECTIONS SHOWN IN BLUE ARE OPTIONAL)

Surname…… Forenames…… Date of birth……

Hospital…… Hospital no……

Pre MRI clinical information (if available)

Previous biopsy No biopsy ☐

Yes ☐ Date: _____ Cone ☐ LLEZT ☐

Type: squamous carcinoma ☐ adenosquamous carcinoma ☐ adenocarcinoma ☐

neuroendocrine carcinoma ☐ other ☐ specify……

Differentiation: well/grade 1 ☐ moderate/grade 2 ☐ poor/grade 3 ☐

not applicable ☐

Description of uterus

Dimensions of uterus: length…….mm transverse……...mm anteroposterior…….mm

Cervix:

No tumour seen ☐

Maximum dimensions of tumour:……....mm x .....……mm x.....……mm

Tumour volume: **(V=d1×d2×d3×π/6).** .....

Position of cervical tumour: anterior ☐ posterior ☐ right ☐ left ☐ circumferential ☐

Morphology: ectocervix/exophytic ☐ endocervix ☐ barrel-shaped ☐

Depth of transverse invasion:

Confined to cervix ☐ Deep stromal invasion ☐

Parametrial invasion Rt ☐ Parametrial invasion Lt ☐

Anterior paracervical invasion ☐ Posterior paracervical invasion ☐

Vagina Vaginal involvement Yes ☐ No ☐

Anterior fornix involved ☐ Posterior fornix involved ☐

Lower third of vagina involved ☐

Pelvic side-wall Involved No ☐ Yes ☐

Side of involvement: Right ☐ Left ☐

Depth of involvement: Visceral ☐ Muscle ☐ Bone ☐
Hydronephrosis No ☐ Right ☐ Left ☐

Bladder	No involvement ☐ Serosal invasion ☐ Muscle invasion ☐ Mucosal invasion☐
Rectum	No involvement ☐ Serosal invasion ☐ Muscle invasion ☐ Mucosal invasion☐
Ascites	No ☐ small volume ☐ moderate volume ☐ large volume ☐

Nodes

Pelvis:	Suspicious node >10mm SA	yes ☐	no ☐
	Suspicious node <10 mm SA	yes ☐	no ☐
	Necrosis ☐ Extra-nodal spread ☐		
Para-aortic	Suspicious node > 10mm SA	yes ☐	no ☐
	Suspicious node <10 mm SA	yes ☐	no ☐
	Necrosis ☐ Extra-nodal spread ☐		

Position of suspicious nodes:

Along external iliac vessels	Rt short axis .....mm	Lt short axis .....mm
Obturator fossa	Rt short axis .....mm	Lt short axis .....mm
Common iliac	Rt short axis .....mm	Lt short axis .....mm
Left para-aortic	Short axis .....mm	
Aorto-caval	Short axis .....mm	
Other	.....	

Other tissues and organs:	Normal	Abnormal (describe)
Endometrium	☐	.....
Myometrium	☐	.....
Right adnexum	☐	.....
Left adnexum	☐	.....
Kidneys	☐	.....
Liver	☐	.....
Lungs	☐	

Provisional radiological FIGO stage*……

iTNM stage: iT……iN……iM…….

Further recommendation/comments

: ……

Need for: CT chest/abdomen ☐ No ☐ Yes Already available ☐

PET/CT ☐ No ☐ Yes Already available ☐

Signature of Radiologist: …….. Date……..

Endometrial proforma

REPORTING PROFORMA: MRI STAGING IN PRIMARY ENDOMETRIAL CANCER

(SECTIONS SHOWN IN BLUE ARE OPTIONAL)

Surname…… Forenames…… Date of birth……
Hospital…… Hospital no……..

Pre MRI clinical information (if available)

Previous biopsy No biopsy ☐ Yes ☐ Date: _____

Type: endometriod adenocarcinoma ☐
adenosquamous carcinoma ☐
Serous papillary carcinoma ☐ Clear cell carcinoma ☐
Mixed Mullerian Tumour ☐ other ☐ specify……

Differentiation: well/grade 1 ☐ moderate/grade 2 ☐ poor/grade 3 ☐
not available/applicable ☐

Description of uterus

Dimensions of uterus: length…….mm transverse……mm anteroposterior…….mm
Endometrial thickness: ……mm
Maximum dimensions of tumour:……..mm x ……mm x……mm
Maximum depth of myometrial invasion Less than 50% ☐ Greater than 50% ☐
Position of tumour (predominant) fundal ☐ mid uterine body ☐ lower uterine body ☐
Position of maximum myometrial invasion ……

Benign myometrial pathology: No ☐ Adenomyosis ☐ Bulky fibroids ☐

Uterine serosal involvement No ☐ Yes ☐

Cervix: No invasion ☐ Stromal invasion ☐ Parametrial invasion ☐

Ovarian involvement No ☐ Right ovarian involvement ☐ Left ovarian involvement ☐

Peritoneal involvement No ☐ Pelvic peritoneal deposits ☐ Abdominal peritoneal deposits ☐

Vagina Vaginal involvement No ☐ Upper third ☐ Middle third ☐Lower third ☐

Bladder	No involvement ☐ Serosal invasion ☐ Muscle invasion ☐ Mucosal invasion☐
Rectum	No involvement ☐ Serosal invasion ☐ Muscle invasion ☐ Mucosal invasion☐
Hydronephrosis	No ☐ Right ☐ Left ☐
Ascites	No ☐ small volume ☐ moderate volume ☐ large volume ☐

Nodes

Pelvis:	Suspicious node >10mm SA	yes ☐	no ☐
	Suspicious node <10 mm SA	yes ☐	no ☐
	Necrosis ☐ Extra-nodal spread ☐		
Para-aortic	Suspicious node > 10mm SA	yes ☐	no ☐
	Suspicious node <10 mm SA	yes ☐	no ☐
	Necrosis ☐ Extra-nodal spread ☐		

Position of suspicious nodes:

Along external iliac vessels	Rt short axis .....mm	Lt short axis .....mm
Obturator fossa	Rt short axis .....mm	Lt short axis .....mm
Common iliac	Rt short axis .....mm	Lt short axis .....mm
Left para-aortic	Short axis .....mm	
Aorto-caval	Short axis .....mm	
Other	.....	

Other tissues and organs:	Normal	Abnormal (describe)
Liver	☐	.....
Kidneys	☐	.....
Lungs	☐	.....
Other.....	☐	.....

Radiological FIGO stage.....

iTNM stage: iT.....iN.....iM.....

Further recommendation/ Comments

: .....

Need for CT chest/abdomen ☐ No ☐ Yes Already available ☐

Signature of Radiologist: ..... Date.....

Rectal proforma

REPORTING PRO FORMA FOR RECTAL CANCER

(SECTIONS SHOWN IN BLUE ARE OPTIONAL)

Patient Name:_____ **Patient No:**_____ **Date of Birth:**_____

Primary tumour: ☐ Annular ☐ Semi-annular ☐ Ulcerating ☐ Polypoidal ☐ Mucinous ☐ Not seen
Height from anal verge: _____ mm

Distal edge lies: ____mm ☐ Above puborectalis sling ☐ At puborectalis sling ☐ below puborectalis sling

Extends craniocaudally over: _____ mm
Lies: ☐ Above the peritoneal reflection ☐ Below the peritoneal reflection ☐ At the peritoneal reflection

Invading edge of tumour: From _____ O'clock To _____ O'clock

Muscularis propria: ☐ Confined to ☐ Extends through

Extramural spread: _____ mm

T stage: ☐ T1 ☐ T2 ☐ T3a ☐ T3b ☐ T3c ☐ T3d ☐T4 visceral ☐T4 peritoneal

For low rectal tumours at or below the puborectalis sling
☐ Submucosal layer/part thickness of muscularis propria : intersphincteric plane/mesorectal plane is safe intersphincteric APE or ultra low TME possible, CRM is safe
☐ Full thickness of muscularis propria : intersphincteric plane/mesorectal plane is **unsafe**, Extralevator APE.
☐ Into intersphincteric plane : intersphincteric plane/mesorectal plane is **unsafe**, for extralevator APE.
☐ Into External sphincter : intersphincteric plane/mesorectal plane is **unsafe**.
☐ Beyond External sphincter into ischiorectal tissue : intersphincteric plane / mesorectal plane is **unsafe**.

Free Text Additional comments:

Lymph nodes:
☐ None ☐ Only benign reactive ☐ Present number _____ mixed signal/irregular border

Extramural venous invasion: ☐ No evidence ☐ Evidence
☐ Small ☐ Medium ☐ Large

Closest circumferential resection margin: _____ O'clock
The closest CRM is from ☐ Direct spread of tumour ☐ Extramural venous invasion ☐ Tumour deposit

Minimum tumour distance to mesorectal fascia: _____mm ☐ CRM clear ☐ CRM involved

Peritoneal deposits: ☐ No evidence ☐ Evidence

Pelvic side wall lymph nodes: ☐ None ☐ Benign ☐ Malignant mixed signal/irreg border

Location: Obturator fossa ☐ R ☐L . External Iliac Nodes☐ R ☐L. Inf Hypogastric ☐ R ☐L

Summary: MRI Overall stage: T _____ N _____ M_____

☐ CRM clear ☐ CRM involved ☐ EMVI positive ☐ EMVI negative

☐ No adverse features eligible for primary surgery ☐ Poor prognosis safe margins for preoperative therapy

☐ Poor prognosis unsafe margins eligible for preoperative chemoradiotherapy

Post Treatment Assessment MRI Rectal Cancer

☐ The treated tumour: shows no fibrosis,TRG5

☐ Less than <25% fibrosis, predominant tumour signal, TRG4

☐ 50% tumour/fibrosis, TRG 3

☐>75% fibrosis, minimal tumour signal intensity,TRG2

☐low signal fibrosis only no intermediate tumour signal TRG1

Height from anal verge:_____ mm

Treated tumour distal edge is: ____mm ☐Above puborectalis sling ☐ At puborectalis sling ☐ below PR sling

Extends craniocaudally over: _____ mm

Lies: ☐ Above the peritoneal reflection ☐ Below the peritoneal reflection ☐ At the peritoneal reflection

Invading edge of treated tumour: From _____ O'clock To _____ O'clock

Tumour signal is ☐ Confined to ☐ Extends through the muscularis propria.

Fibrotic signal is ☐ Confined to ☐ Extends through muscularis propria.

Extramural spread: _____ mm for tumour signal _____ for fibrotic stroma _____

yMR T stage: ☐ T1 ☐ T2 ☐ T3a ☐ T3b ☐ T3c ☐ T3d ☐T4 visceral ☐T4 peritoneal

For low rectal tumours at or below the puborectalis sling tumour signal/fibrosis extends into

☐ Submucosal layer/part thickness of muscularis propria : intersphincteric plane/mesorectal plane is safe intersphincteric APE or ultra low TME possible, CRM is safe

☐ Full thickness of muscularis propria : intersphincteric plane/mesorectal plane is **unsafe**, Extralevator APE.

☐ Into intersphincteric plane : intersphincteric plane/mesorectal plane is **unsafe**, for extralevator APE.

☐ Into External sphincter : intersphincteric plane/mesorectal plane is **unsafe**.

☐ Beyond External sphincter into ischiorectal tissue : intersphincteric plane / mesorectal plane is **unsafe**.

Free Text Additional comments:

Lymph nodes:

☐ None ☐ Only benign reactive ☐ Present number _____ mixed signal/irregular border

Extramural venous invasion: ☐ No evidence ☐ Evidence
☐ Small ☐ Medium ☐ Large

Closest circumferential resection margin: _____ O'clock
Closest CRM is from ☐ Direct spread of tumour ☐ Extramural venous invasion ☐ Tumour deposit

Minimum tumour distance to mesorectal fascia: _____mm ☐ CRM clear ☐ CRM involved

Peritoneal deposits: ☐ No evidence ☐ Evidence

Pelvic side wall lymph nodes: ☐ None ☐ Benign ☐ Malignant
Location: Obturator fossa ☐ R ☐L . External Iliac Nodes☐ R ☐L. Inf Hypogastric ☐ R ☐L

Summary: y MRI Overall stage ymrT _____ ymr N _____ M_____ , TRG _____

☐ CRM clear ☐ CRM fibrosis only ☐ CRM involved
☐ EMVI positive ☐ EMVI negative
☐ Good prognosis, CRM clear, TRG 1-3, EMVI –ve ☐ Poor prognosis

Colon proforma

REPORTING PRO FORMA FOR COLON CANCER

(SECTIONS SHOWN IN BLUE ARE OPTIONAL)

Patient Name:_____ Patient No:_____ Date of Birth:_____

Primary tumour: ☐ Annular ☐ Ulcerating ☐ Polypoidal ☐ Villous ☐ Eroding
☐ Mucinous ☐ Not easily shown

Located in colon: ☐ Caecum ☐ Ascending ☐ Hepatic flexure ☐ Transverse ☐ Descending
☐ Sigmoid ☐ Rectum ☐ Has been demonstrated on MRI scan, pls see report

Advancing edge tumour (border): ☐ Mesenteric ☐ Peritoneal ☐ N/A

To bowel wall: ☐ Confined ☐ Extends through
Peritoneal infiltration: ☐ No evidence ☐ Evidence
Tumour extension: ☐ <5mm ☐ >5mm Tumour
Diameter: _____ mm Tumour Thickness:_____ mm

Lymph nodes in colonic mesentery: ☐ Benign ☐ Reactive ☐ Malignant

Extramural venous invasion: ☐ No evidence ☐ Evidence

Peritoneal disease: ☐ Absent ☐ Present

Retroperitoneal lymphadenopathy: ☐ Absent ☐ Present

Incidental note: ☐ Intra-abdominal pathology ☐ Pelvic pathology

Metastatic disease in liver: ☐ No evidence ☐ Evidence Details:
☐ Segmental sparing ☐ No segmental sparing

Incidental note: ☐ Cysts ☐ Haemangioma ☐ Equivocal low density lesion
☐ For characterisation by MRI ☐ Follow-up
☐ Unlikely to represent metastatic disease

Pulmonary metastatic disease:	☐ No CT evidence	☐ CT evidence
Details:		

Summary:	Overall stage:	T _____	N _____	
	☐ Resectable	☐ Irresectable	☐ EMVI positive	☐ EMVI negative
	☐ M0	☐ M1	☐ Good prognosis	☐ Poor prognosis
Discussion points for imaging case:				
Radiologically Eligible for :				

Appendix 2

Lung

Proforma Staging Item	Clinical Strategy
Tumour morphology	Baseline for future response assessment
Tumour location	Biopsy target Resectability/ surgical planning Radiotherapy planning
Tumour dimensions	Surgical planning- parenchyma sparing vs lobectomy Adjuvant chemotherapy selection (T2-3, and >4cm (NICE)) Baseline for future treatment response assessment
Differentiation from consolidation	Surgical planning- segmentectomy vs lobectomy Radiotherapy planning
Endobronchial disease	Guide biopsy Radiotherapy/ surgical planning Need for stenting
Tumour locally invades	Operability Surgical planning- en bloc resection Radiotherapy planning Anticipate complications Specialist referral
Distal lung/ lobe atelectasis	Radiotherapy planning Surgical planning
Regional lymph nodes	Operability vs chemotherapy Radiotherapy planning Biopsy approach
Metastatic disease liver	Operability Chemotherapy
Pulmonary nodules	Operability (if in same lobe) Chemotherapy (different lobe to primary)
Adrenal metastatic disease	Surgical planning (if solitary metastasis) Chemotherapy (if multifocal metastasis)
Bone metastatic disease	Need for MRI Chemotherapy Radiotherapy
Cerebral metastatic disease	Surgical resection Radiotherapy planning Need for urgent intervention e.g. decompression in hydrocephalus, steroids for oedema
Pleural disease	Operability Surgical planning Need for drainage
Pericardial effusion	Operability
Other sites of disease	Operability Systemic disease- chemotherapy
Overall stage	Prognosis and risk stratification

Appendix 2

Prostate

Staging item	Clinical Strategy
Gland dimensions/ volume	Calculate PSA/ml enabling risk stratification- active surveillance vs treatment
Lesion location	EBRT/ brachytherapy planning
Organ confined	Radical surgical resection
Extending beyond the prostate	Surgical planning or radiotherapy
Extending into seminal vesicles	Surgical planning
Extending into bladder neck	Operability
Fixed or into adjacent pelvic organs/ wall	Inoperable Radiotherapy planning
Neurovascular bundle	Nerve-sparing surgery possible
Pelvic nodes	Surgical and radiotherapy planning
Nodes benign or malignant	Surgical and radiotherapy planning
Anatomic location if positive	Need for and extent of lymphadenectomy
TNM staging	

Appendix 2

Endometrial cancer

Staging Item	Clinical strategy
Size of uterus	
Endometrial thickness	Diagnosis
Tumour dimensions	
Depth of myometrial invasion	Surgical approach- radical, cytoreductive or palliative Correlates with risk of lymph node involvement- need for lymphadenectomy 5 year prognostic factor
Benign myometrial pathology	
Uterine serosal involvement	Stage III disease Surgical approach- radical, cytoreductive or palliative
Cervix involvement	Surgical approach- radical, cytoreductive or palliative Predictor of lymph node involvement and extra-uterine disease
Ovarian involvement	Surgical approach- radical, cytoreductive or palliative
Peritoneal involvement	Systemic therapeutic approach
Rectum involvement	Need for posterior exenteration
Hydronephrosis	Need for urgent urinary tract decompression Surgical planning - anterior exenteration
Ascites	Risk peritoneal disease
Pelvic nodes	lymphadenectomy
Para-aortic nodes	Para-aortic lymphadenectomy
FIGO stage	Prognostic stratification
TNM stage	Prognostic stratification

Appendix 2

Cervical cancer

Staging item	Clinical strategy
Tumour size	Chemoradiotherapy for bulky tumours Radiotherapy planning Uterus preserving surgery Predictive of lymph node involvement
Tumour position	Surgical planning Trachelectomy planning
Morphology	
Depth of invasion	Radical surgery possible or not- parametrial invasion
Vaginal involvement	Surgical planning CRT planning
PSW involvement	Need for lymphadenectomy in early tumours
Hydronephrosis	Intervention to decompress
Bladder involvement	CRT planning
Rectum involvement	CRT planning
Ascites	Distant metastases
Pelvic nodes	Precludes radical surgery- CRT or debulking and CRT Radiotherapy field
Paraaortic nodes	Metastatic disease
Endometrium	Feasibility of fertility preserving surgery- trachelectomy Predicting risk of nodal metastases
Myometrium	Fertility preserving surgery- trachelectomy Predicting risk of nodal metastases
Adenexae	Surgical planning
TNM	Prognostic stratification
FIGO	Prognostic stratification

Appendix 2

Rectal Cancer

Staging item	Clinical Strategy
Tumour morphology	Prognosis and baseline for tumour response
Height from anal verge	Surgical and radiotherapy planning
Distal edge to PS sling	Surgical planning- organ/ sphincter preservation
Muscularis propria breach	Neoadjuvant treatment decision T1- local excision
Depth of extramural spread	Selective use of chemotherapy/ radiotherapy/ CRT
T sub stage	Prognostic
Description of low rectal tumour	Surgical and radiotherapy planning Treatment intent?
Extra-mural venous invasion	Neoadjuvant treatment decision
Site of closest CRM	Surgical and radiotherapy planning
Tumour distance to mesorectal fascia	Surgical and radiotherapy planning
Peritoneal deposits	Surgical and radiotherapy planning Radicality of neoadjuvant treatment
PSW lymph nodes stated and characterised	Surgical and radiotherapy targeting Neoadjuvant treatment selection
MRI overall T sub stage and N stage	Prognosis and risk stratification
CRM clear or involved	Surgical and radiotherapy planning TME or beyond TME surgery Neoadjuvant treatment selection
EMVI positive/ negative	Neoadjuvant and adjuvant treatment decisions Prognostic indicator

Appendix 2

Colon cancer

Staging item	Clinical strategy
Location in colon	Surgical planning
Advancing edge	Surgical planning
Confined to bowel wall	Neoadjuvant treatment vs primary surgery
Peritoneal infiltration	Surgical planning, neoadjuvant and adjuvant treatment decisions
Tumour extramural extension distance	Surgical planning
Tumour diameter/thickness	Surgical planning
Peritoneal disease	Neoadjuvant treatment
Retroperitoneal lymphadenopathy	Surgical planning Neoadjuvant and adjuvant treatment decisions
Hepatic metastatic disease	Surgical planning- operable? Neoadjuvant adjuvant treatment decisions treatment
Pulmonary metastatic disease	Neoadjuvant treatment Operability Surgical adjuvant treatment decisions planning
	Prognosis and risk stratification
Resectable/ irresectable	Operable vs inoperable
M0/M1	Neoadjuvant and adjuvant treatment decisions. Palliative treatment selection

Lung coding form

PROFORMA REPORT LUNG SITE No. …… REPORT No. ……..

	Data field	
1	Tumour morphology	
2	Tumour location	
3	Tumour dimensions	
4	Differentiation from local consolidation	
5	Endobronchial disease	
6	Tumour locally invades	
7	Distal lung/lobe atelectasis	
8	Regional lymph nodes	
9	Metastatic disease - liver	
10	Pulmonary nodules	
11	Adrenal metastatic disease	
12	Bone metastatic disease	
13	Cerebral metastatic disease	
14	Pleural disease	
15	Pericardial effusion	
16	Other sites of metastases	
17	Overall stage	

Prostate coding form

PROFORMA REPORT PROSTATE SITE No ..... REPORT No. .....

	Data field	
1	Prostate gland dimensions/volume	
2	BPH	
3	Lesion location	
4	Organ confined	
5	Extending beyond prostate	
6	Extending into seminal vesicles	
7	Extending into bladder neck	
8	Fixed or into adjacent organs or pelvic wall	
9	Neurovascular bundle	
10	Pelvic nodes	
11	Stated whether nodes benign or malignant	
12	Anatomic location (stated if positive)	
13	TNM staging	

Cervical coding form

PROFORMA REPORT CERVICAL SITE No. …… REPORT No. ……

	Data field	
1	Tumour size	
2	Tumour position	
3	Morphology	
4	Depth of invasion	
5	Vaginal involvement	
6	Pelvic side wall involvement	
7	Hydronephrosis	
8	Bladder involvement	
9	Rectum involvement	
10	Ascites	
11	Pelvic nodes	
12	Para-aortic nodes	
13	Endometrium	
14	Myometrium	
15	Right & left adnexae	
16	FIGO stage	
17	iTNM stage	

Endometrial coding form

PROFORMA REPORT ENDOMETRIAL SITE No. …… REPORT No. ……..

	Data field	
1	Size of uterus	
2	Endometrial thickness	
3	Tumour dimensions	
4	Depth of myometrial invasion	
5	Benign myometrial pathology	
6	Uterine serosal involvement	
7	Cervix	
8	Ovarian involvement	
9	Peritoneal involvement	
10	Vaginal involvement	
11	Bladder involvement	
12	Rectum involvement	
13	Hydronephrosis	
14	Ascites	
15	Pelvic nodes	
16	Para-aortic nodes	
17	FIGO stage	
18	iTNM stage	

Colon coding form

PROFORMA REPORT COLON SITE No. …… REPORT No. …….

	Data field	
1	Location in colon	
2	Advancing edge tumour	
3	Bowel wall confined or not	
4	Peritoneal infiltration	
5	Tumour extension	
6	Tumour diameter/thickness	
7	Peritoneal disease	
8	Retroperitoneal lymphadenopathy	
9	Metastatic disease in liver	
10	Pulmonary metastatic disease	
11	Overall stage T sub stage& N stage	
12	Resectable/irresectable	
13	M0/M1	

Rectal coding form

PROFORMA REPORT RECTAL SITE No. …… REPORT No. …….

	Data field	
1	Tumour morphology	
2	Height from anal verge	
3	Distal edge to PR sling	
4	Muscularis propria breached	
5	Extramural spread depth given	
6	T sub-stage	
7	Description low rectal tumours	
8	Extramural venous invasion	
9	Site of closest CRM	
10	Tumour distance to mesorectal fascia	
11	Peritoneal deposits	
12	Pelvic side wall lymph nodes stated & characteristics	
13	MRI overall stage T sub stage, N stage	
14	CRM clear/involved	
15	EMVI positive/negative	

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Appendix 5 Table 1 Percentage completeness for each predetermined data item - LUNG

	PRE						POST						Proportion difference	
	yes	no	n/a	total	total needed	% complete	yes	no	n/a	total	total needed	% complete		95% CI
Tumour morphology	82	41	2	125	123	67%	76	8	0	84	84	90%	0.24	0.13-0.34
Tumour location	99	24	2	125	123	80%	82	2	0	84	84	98%	0.17	0.9-0.25
Tumour dimensions	114	9	2	125	123	93%	80	0	4	84	80	100%	0.07	0.02-0.13
Differentiation from local consolidation	68	27	30	125	95	72%	22	10	52	84	32	69%	-0.03	-0.22-0.14
Endobronchial disease	69	50	6	125	119	58%	78	6	0	84	84	93%	0.35	0.24-0.45
Tumour locally invades	97	24	4	125	121	80%	68	16	0	84	84	81%	0.01	-0.11-0.11
Distal lung/lobe atelectasis	70	51	4	125	121	58%	69	14	1	84	83	83%	0.25	0.13-0.36
Regional lymph nodes	117	8	0	125	125	94%	84	0	0	84	84	100%	0.06	0.01-0.12
Metastatic disease - liver	118	6	1	125	124	95%	83	1	0	84	84	99%	0.04	-0.02-0.09
Pulmonary nodules	114	11	0	125	125	91%	79	5	0	84	84	94%	0.03	-0.05-0.10
Adrenal metastatic disease	114	10	1	125	124	92%	83	1	0	84	84	99%	0.07	0.0-0.13
Bone metastatic disease	107	17	1	125	124	86%	81	3	0	84	84	96%	0.10	0.02-0.18
Cerebral metastatic disease	5	24	96	125	29	17%	60	12	12	84	72	83%	0.66	0.46-0.78
Pleural disease	86	39	0	125	125	69%	82	2	0	84	84	98%	0.29	0.19-0.38
Pericardial effusion	67	58	0	125	125	54%	61	23	0	84	84	73%	0.19	0.06-0.31
Other sites of metastates	101	17	7	125	118	86%	66	18	0	84	84	79%	-0.07	-0.18-0.04
Overall stage	81	44	0	125	125	65%	82	2	0	84	84	98%	0.33	0.23-0.42
Overall total	1509	460	156	2125	1969	77%	1236	123	69	1428	1359	91%	0.14	0.12-0.17

Appendix 5 Table 2 Percentage completeness for each predetermined data item - PROSTATE

	PRE						POST						Proportion difference	
	yes	no	n/a	total	total needed	% complete	yes	no	n/a	total	total needed	% complete	%	95% CI
Prostate gland dimensions/volume	29	127	0	156	156	19%	86	22	0	108	108	80%	0.61	0.50-0.69
BPH	32	124	0	156	156	21%	73	35	0	108	108	68%	0.47	0.35-0.57
Lesion location	114	42	0	156	156	73%	87	2	19	108	89	98%	0.25	0.16-0.32
Organ confined	106	50	0	156	156	68%	71	17	20	108	88	81%	0.13	0.01-0.23
Extending beyond prostate	101	55	0	156	156	65%	61	27	20	108	88	69%	0.05	-0.08-0.16
Extending into seminal vesicles	96	60	0	156	156	62%	85	4	19	108	89	96%	0.34	0.24-0.42
Extending into bladder neck	16	140	0	156	156	10%	57	31	20	108	88	65%	0.55	0.43-0.64
Fixed or into adjacent organs or pelvic wall	15	141	0	156	156	10%	57	31	20	108	88	65%	0.55	0.43-0.65
Neuorvascular bundle	25	131	0	156	156	16%	62	26	20	108	88	70%	0.54	0.42-0.64
Pelvic nodes	146	10	0	156	156	94%	105	3	0	108	108	97%	0.04	-0.02-0.09
Nodes benign or malignant	97	49	10	156	146	66%	13	5	90	108	18	72%	0.06	-0.18-0.23
Anatomic location if positive	37	45	74	156	82	45%	14	4	90	108	18	78%	0.33	0.07-0.49
TNM staging	71	85	0	156	156	46%	100	8	0	108	108	93%	0.47	0.37-0.56
Overall total	885	1059	84	2028	1944	46%	871	215	318	1404	1086	80%	0.35	0.31-0.38

Appendix 5 Table 3 Percentage completeness for each predetermined data item - CERVICAL

	PRE						POST						Proportion difference	
	yes	no	n/a	total	total needed	% complete	yes	no	n/a	total	total needed	% complete		95% CI
Tumour size	70	17	30	117	87	80%	29	2	15	47	31	94%	0.13	0.03-0.24
Tumour position	44	43	30	117	87	51%	29	2	15	47	31	94%	0.43	0.25-0.54
Morphology	31	56	30	117	87	36%	26	5	15	47	31	84%	0.48	0.29-0.61
Depth of invasion	68	49	0	117	117	58%	27	4	15	47	31	87%	0.29	0.11-0.41
Vaginal involvement	53	64	0	117	117	45%	44	2	0	46	46	96%	0.50	0.37-0.60
Pelvic side wall involvement	33	84	0	117	117	28%	45	1	0	46	46	98%	0.70	0.60-0.77
Hydronephrosis	66	51	0	117	117	56%	30	16	0	46	46	65%	0.09	-0.08-0.24
Bladder involvement	43	74	0	117	117	37%	46	0	0	46	46	100%	0.63	0.51-0.71
Rectum involvement	38	79	0	117	117	32%	46	0	0	46	46	100%	0.68	0.56-0.75
Ascites	34	83	0	117	117	29%	33	13	0	46	46	72%	0.43	0.26-0.56
Pelvic nodes	111	6	0	117	117	95%	45	1	0	46	46	98%	0.03	-0.07-0.09
Para-aortic nodes	93	24	0	117	117	79%	39	7	0	46	46	85%	0.05	-0.09-0.17
Endometrium	39	78	0	117	117	33%	30	16	0	46	46	65%	0.32	0.13-0.46
Myometrium	45	72	0	117	117	38%	29	17	0	46	46	63%	0.25	0.08-0.40
Right & left adnexae	74	43	0	117	117	63%	33	13	0	46	46	72%	0.08	-0.08-0.23
FIGO stage	63	43	11	117	106	59%	34	10	2	46	44	77%	0.18	0.01-0.32
iTNM stage	13	93	11	117	106	12%	31	15	0	46	46	67%	0.55	0.39-0.68
Overall total	918	959	112	1989	1877	49%	596	124	62	782	720	83%	0.34	0.30-0.37

Appendix 5 Table 4 Percentage completeness for each predetermined data item - ENDOMETRIAL

	PRE						POST						Proportion difference	
	yes	no	n/a	total	total needed	% complete	yes	no	n/a	total	total needed	% complete		95% CI
Size of uterus	48	64	0	112	112	43%	59	0	0	59	59	100%	0.57	0.46-0.66
Endometrial thickness	31	81	0	112	112	28%	56	2	1	59	58	97%	0.69	0.57-0.77
Tumour dimensions	55	53	4	112	108	51%	57	0	2	59	57	100%	0.49	0.38-0.58
Depth of myometrial invasion	84	25	3	112	109	77%	59	0	0	59	59	100%	0.23	0.14-0.32
Benign myometrial pathology	28	84	0	112	112	25%	35	24	0	59	59	59%	0.34	0.19-0.48
Uterine serosal involvement	29	83	0	112	112	26%	57	2	0	59	59	97%	0.71	0.59-0.78
Cervix	64	48	0	112	112	57%	59	0	0	59	59	100%	0.43	0.32-0.52
Ovarian involvement	75	37	0	112	112	67%	55	4	0	59	59	93%	0.26	0.14-0.36
Peritoneal involvement	23	89	0	112	112	21%	34	25	0	59	59	58%	0.37	0.22-0.50
Vaginal involvement	9	103	0	112	112	8%	59	0	0	59	59	100%	0.92	0.83-0.96
Bladder involvement	8	104	0	112	112	7%	59	0	0	59	59	100%	0.93	0.84-0.96
Rectum involvement	4	108	0	112	112	4%	59	0	0	59	59	100%	0.96	0.88-0.99
Hydronephrosis	29	83	0	112	112	26%	33	26	0	59	59	56%	0.30	0.15-0.44
Ascites	48	64	0	112	112	43%	34	25	0	59	59	58%	0.15	-0.01-0.29
Pelvic nodes	107	5	0	112	112	96%	59	0	0	59	59	100%	0.04	-0.02-0.10
Para-aortic nodes	85	25	2	112	110	77%	58	1	0	59	59	98%	0.21	0.11-0.30
FIGO stage	82	29	1	112	111	74%	58	1	0	59	59	98%	0.24	0.14-0.33
iTNM stage	14	97	1	112	111	13%	31	28	0	59	59	53%	0.40	0.25-0.53
Overall total	823	1182	11	2016	2005	41%	921	138	3	1062	1059	87%	0.46	0.43-0.49

Appendix 5 Table 5 Percentage completeness for each predetermined data item - COLON

	PRE						POST						Proportion difference	
	yes	no	n/a	total	total needed	% complete	yes	no	n/a	total	total needed	% complete		95% CI
Location in colon	124	16	2	142	140	89%	85	1	2	88	86	99%	0.10	0.04-0.17
Advancing edge tumour	5	124	13	142	129	4%	83	2	3	88	85	98%	0.94	0.86-0.97
Bowel wall confined or not	59	71	12	142	130	45%	83	3	2	88	86	97%	0.51	0.41-0.60
Peritoneal infiltration	15	115	12	142	130	12%	80	7	1	88	87	92%	0.80	0.70-0.86
Tumour extension distance	33	96	13	142	129	26%	62	24	2	88	86	72%	0.47	0.33-0.57
Tumour diameter/thickness	19	112	11	142	131	15%	68	18	2	88	86	79%	0.65	0.52-0.73
Peritoneal disease	13	129	0	142	142	9%	83	5	0	88	88	94%	0.85	0.76-0.90
Retroperitoneal lymphadenopathy	87	55	0	142	142	61%	85	3	0	88	88	97%	0.35	0.26-0.44
Metastatic disease in liver	134	8	0	142	142	94%	87	1	0	88	88	99%	0.04	-0.01-0.10
Pulmonary metastatic disease	123	13	6	142	136	90%	84	4	0	88	88	95%	0.05	-0.03-0.12
T substage & N stage	37	103	2	142	140	26%	88	0	0	88	88	100%	0.74	0.65-0.80
Resectable irresectable	0	142	0	142	142	0%	73	15	0	88	88	83%	0.83	0.73-0.89
M0/M1	58	84	0	142	142	41%	88	0	0	88	88	100%	0.59	0.50-0.67
Overall total	707	1068	71	1846	1775	40%	1049	83	12	1144	1132	93%	0.53	0.50-0.55

Appendix 5 Table 6 Percentage completeness for each predetermined data item - RECTAL

	PRE						POST						Proportion difference	
	yes	no	n/a	total	total needed	% complete	yes	no	n/a	total	total needed	% complete		95% CI
Tumour morphology stated	51	83	1	135	134	38%	108	1	2	111	109	99%	0.61	0.52-0.69
Height from anal verge	79	56	0	135	135	59%	109	0	2	111	109	100%	0.41	0.33-0.50
Distal edge to PR sling	31	104	0	135	135	23%	102	7	2	111	109	94%	0.71	0.61-0.78
Muscularis propria breached	123	12	0	135	135	91%	104	6	1	111	110	95%	0.03	-0.04-0.10
Extramural spread depth given	34	81	20	135	115	30%	86	23	2	111	109	79%	0.49	0.37-0.59
T sub stage	64	70	1	135	134	48%	96	15	0	111	111	86%	0.39	0.27-0.48
Description low rectal tumours	19	45	71	135	64	30%	15	14	82	111	29	52%	0.22	0.09-0.42
Extramural invasion	45	90	0	135	135	33%	102	8	1	111	110	93%	0.59	0.49-0.68
Site of closest CRM	46	77	12	135	123	37%	79	29	3	111	108	73%	0.36	0.23-0.47
Tumour distance to CRM	30	91	14	135	121	25%	65	40	6	111	105	62%	0.37	0.24-0.48
Peritoneal deposits	5	127	3	135	132	4%	92	19	0	111	111	83%	0.79	0.70-0.85
Pelvic side wall lymph nodes stated and characterised	46	88	1	135	134	34%	107	4	0	111	111	96%	0.62	0.52-0.70
T substage N stage	80	55	0	135	135	59%	109	2	0	111	111	98%	0.39	0.30-0.47
CRM clear/involved	56	77	2	135	133	42%	98	13	0	111	111	88%	0.46	0.35-0.56
EMVI positive/negative	35	100	0	135	135	26%	98	13	0	111	111	88%	0.62	0.51-0.71
Overall total	744	1156	125	2025	1900	39%	1370	194	101	1665	1564	88%	0.48	0.46-0.51

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
Introduction	*Why did you start?*
3. Problem Description	Nature and significance of the local problem
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies

5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work
6. Specific aims	Purpose of the project and of this report
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest
Results	*What did you find?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data
Discussion	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project

15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps
Other information	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting

Table 2. Glossary of key terms used in SQUIRE 2.0. This Glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They may, and often do, have different meanings in other disciplines, situations, and settings.

Assumptions
Reasons for choosing the activities and tools used to bring about changes in healthcare services at the system level.

Context
Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the interpretation of these factors ("sense-making") by the healthcare delivery professionals, patients, and caregivers that can affect the effectiveness and generalizability of intervention(s).

Ethical aspects
The value of system-level initiatives relative to their potential for harm, burden, and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and value of healthcare services include opportunity costs, invasion of privacy, and staff distress resulting from disclosure of poor performance.

Generalizability
The likelihood that the intervention(s) in a particular report would produce similar results in other settings, situations, or environments (also referred to as external validity).

Healthcare improvement
Any systematic effort intended to raise the quality, safety, and value of healthcare services, usually done at the system level. We encourage the use of this phrase rather than "quality improvement," which often refers to more narrowly defined approaches.

Inferences
The meaning of findings or data, as interpreted by the stakeholders in healthcare services – improvers, healthcare delivery professionals, and/or patients and families

Initiative
A broad term that can refer to organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, planning, execution, and assessment)

Internal validity
Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular healthcare system.

Intervention(s)
The specific activities and tools introduced into a healthcare system with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a system's performance.

Opportunity costs

Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative

Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential

Process
The routines and other activities through which healthcare services are delivered

Rationale
Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

Systems
The interrelated structures, people, processes, and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

Theory or theories
Any "reason-giving" account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to be explicit and well-founded about any informal and formal theory (or theories) that are used.