PERGAMON

European Journal of Cancer 38 (2002) 764–772

European Journal of Cancer

www.ejconline.com

The implementation of guidelines and computerised forms improves the completeness of cancer pathology reporting. The CROPS project: a randomised controlled trial in pathology

L.K. Branston[a,*], S. Greening[a], R.G. Newcombe[b], R. Daoud[b], J.M. Abraham[c], F. Wood[d], N.S. Dallimore[e], J. Steward[f], C. Rogers[a], G.T. Williams[b]

[a]*Breast Test Wales, 18 Cathedral Road, Cardiff CF11 9LH, UK*
[b]*University of Wales College of Medicine, Heath Park, Cardiff CF14 4XN, UK*
[c]*Velindre Hospital, Whitchurch, Cardiff CF14 2TL, USA*
[d]*Cardiff School of Social Sciences, Cardiff University, Glamorgan Building, King Edward VII Avenue, Cardiff CF10 3AT, UK*
[e]*Llandough Hospital NHS Trust, Penarth, Cardiff, UK*
[f]*Wales Cancer Intelligence and Surveillance Unit, 14 Cathedral Road, Cardiff CF11 9LJ, UK*

Received 13 March 2001; received in revised form 26 May 2001; accepted 19 July 2001

Abstract

The aim of this study was to determine whether reporting guidelines and computerised form-based reports improve the completeness of histopathological cancer data available for patient management and population cancer registration and to evaluate the acceptability of the intervention. The study was a randomised controlled trial with a split unit design and stratified cluster randomisation. All 16 hospital pathology laboratories in Wales were randomly allocated to report either breast or colorectal resection specimens by computerised form or conventional free text. 1044 reports were analysed in the study arm, 998 in the control arm. Use of pre-defined forms led to a 28.4% (95% confidence interval (CI): 15.7–41.2%) increase in complete reporting of a minimum dataset required for cancer registration and a 24.5% (95% CI: 11.0–38.0%) increase in complete reporting of minimum data required for patient management. Form-based reporting was acceptable to pathologists and preferred by clinicians. In conclusion, guidelines and computerised forms significantly improve the quality of histopathology reporting.

Keywords: Pathology reporting; Guidelines; Computerisation

1. Introduction

Timely, complete and accurate pathology reports are fundamental to the provision of quality cancer services. Inconsistent pathology reporting, such that essential data items of therapeutic or prognostic relevance are sometimes missing, can lead to inconvenience for the patient and the clinician, delays in treatment, and inadequate or inappropriate postoperative therapy. Consequently, pathology reporting contributes to differences in standards of treatment between clinical teams. Previous audits carried out in Wales on breast and colorectal cancer histopathology reporting showed significant inter- and intra-hospital variation in the data items mentioned in reports, indicating scope for standardisation. For example, in 1991 only 55% of pathology reports on invasive breast cancer specimens contained information on histological grade [1] when there is strong evidence that grade predicts survival and response to chemotherapy [2–5]. In 1993, only 51.5% of rectal cancer reports contained a statement on the completeness of excision at the circumferential margin [6] when this predicts local recurrence and may indicate the need for post-operative radiotherapy [7]. There is evidence to show that the use of standardised pre-defined forms (as opposed to the use of free text) improves the quality and completeness of pathology reports [8,9].

* Corresponding author at: Wales Cancer Trials Network, Velindre Hospital, Whitchurch, Cardiff CF14 2TL, UK. Tel.: +44-29-2031-6228; fax: +44-29-2069-4179.
E-mail address: lucy.branston@velindre-tr.wales.nhs.uk (L.K. Branston).

0959-8049/02/$ - see front matter
PII: S0959-8049(01)00258-1

However, these studies have only been carried out in specialist teaching hospitals, and the generalisability of the findings to district hospital laboratories has not been investigated.

Histopathology data also form an important element of cancer registration and accurate, complete recording of pathology information contributes to the overall quality of a registry by facilitating high levels of ascertainment and satisfying national requirements for data completeness, including pathological staging. Currently data entry in most registries depends on the interpretation of free text pathology reports by trained coders. The reliability of coding is affected by the fact that pathology reports are actually intended for communication with clinicians making therapeutic decisions rather than clinical coders who work to objective rules. Free text pathology reports therefore raise data quality issues from a Registry perspective because they are not designed for cancer registration purposes. The potential for collecting histopathology data electronically and its direct transmission to the Cancer Registry in coded format, obviating the need for any interpretative stage, has been recognised for some time [10], but there has been little attempt at its implementation on a regional or national scale.

We report here the findings of the Cancer Registration through On-line Pathology Systems (CROPS) project in Wales, UK. This project was funded in 1996 when the (then) Welsh Office of the UK Government was implementing an all Wales pathology computer system. This provided an opportunity to investigate the use of standardised computerised forms containing a set of specified data items, supplemented by written and on-screen guidelines, for reporting cancer specimens in all 16 hospitals in the Principality, and to consider the possibility of using electronic transfer of this standardised pathology data to the Cancer Registry.

2. Patients and methods

2.1. Project design

The project used a split unit design with stratified cluster randomisation by pathology laboratory. The 16 pathology laboratories, employing 39 consultant histopathologists and six registrars, in Wales were randomised into either the breast or the colorectal cancer reporting group. Laboratories were stratified according to workload, whether they reported breast screening programme specimens and the type of computer system they operated. In each hospital, the pathologists completed a computerised form for one cancer site (the test site), either breast or colorectal. Routine free text reports collected from the other cancer site at the same hospital acted as controls.

Data items were included on reporting forms on the basis of evidence for prognostic or therapeutic importance. Pre-existing UK national guidelines and forms were adapted for breast cancer reporting [11]. Guidelines and forms for colorectal reporting were drawn up by consensus by Welsh pathologists and were similar to those later issued by the Royal College of Pathologists [12]. The proposed guidelines for form reporting of the 'test' tumour site, which described and illustrated specimen handling, definitions of form data items, reporting software and local working practices, were then discussed with each pathologist individually. This was followed by open forum discussions with participating pathologists where the guidelines were finalised. No guidelines were provided to pathologists for reporting tumours of the control type.

2.2. Specific educational intervention

Each pathologist working in Wales was invited to a training day for the relevant 'test' cancer site at which the pathologist advisers to the project reinforced the definitions of data items in the guidelines. UK experts in breast and colorectal cancer from outside the Principality, (Professors C. Elston and P. Quirke) also held practical workshops to clarify difficult issues such as breast cancer grading and colorectal cancer specimen dissection, respectively.

2.3. Software development, installation and data collection

The two major providers of pathology computer systems to Welsh hospitals were commissioned to adapt their software to incorporate an extra CROPS reporting screen (Fig. 1 or Fig. 2) with coded fields. The coded fields were designed to capture all data items from CROPS report forms.

The CROPS reporting screen was triggered by the input of certain combinations of standardised topographic site codes (SNOP and SNOMED) codes for breast or colorectal cancer. Point of entry validation rules and on screen guideline help were embedded in the software and the coded fields were available for query, paper reporting and electronic download.

The software was piloted at two sites and revised accordingly. Seven of the 16 hospitals were unable to accept the software adaptations to their computer systems because their systems were incompatible or because they did not yet have the required upgrade to existing computer systems. The pathologists in these laboratories agreed to use paper forms identical to those on computer. Training was given at each hospital and a manual provided. The project researcher attended monthly all-Wales pathologist meetings in order to answer queries. An interim audit was held halfway

through the data collection period for breast and colorectal groups separately. Pathologists were given interim feedback on their individual reporting performance.

All sites submitted data for at least 9 months which were collected monthly and transferred to a database for analysis. Text reports for control specimens were interpreted onto equivalent forms, firstly by Cancer Registry coders, then by medically qualified Specialist Registrars in Oncology and Surgery, representing the clinical end users of the reports.

REPORTING FORM - BREAST CANCERS

Specimen no. _____ **Name** _____

Record only primary breast tumours - invasive or in situ
Values should be circled or ticked where boxes are present

Side: L R
A reporting form should be completed for each side

Tumour details:
In the case of multiple tumours record the tumour of highest grade.
Record microinvasion as the underlying carcinoma in situ.
Type :

Invasive			***In situ***		
❑	DUC	Invasive Ductal Carcinoma / No Specific Type	❑	N	None
			❑	DCIS	*In situ* Ductal Carcinoma
❑	LOB	Invasive Lobular Carcinoma	❑	LCIS	*In situ* Lobular Carcinoma
❑	MED	Invasive Medullary Carcinoma	❑	PAG	Paget's disease
❑	TUB	Invasive Tubular /Cribriform Carcinoma			
❑	MUC	Invasive Mucinous Carcinoma			
❑	MIX	Invasive Carcinoma Mixed - State which_____			
❑	OPC	Other Primary Carcinoma - State which_____			
❑	OMT	Other Malignant Tumour - State which_____			
❑	X	Not assessable			
❑	N	Not present			

Maximum diameter : whole tumour width ____ mm invasive width ____ mm

---

grade 1 2 3 X (not assessable)

---

multiple tumours Y N

---

microinvasion Y N P (Possible)

Lymph node details: number sampled ___ number containing tumour __

highest node involved Y N X (not known)

Excision margins : R reaches margin
U uncertain
C complete If C, state distance from margin __ mm

Vascular invasion : Y N

Breast Test Wales screening number (if available) _____

Fig. 1. Breast cancer reporting form.

2.4. Quantitative evaluation

A 2×2 split unit analysis [13] was used to quantify the percentage change in minimum dataset completeness of reports on resection specimens for laboratories *with*, versus those *without*, guidelines and forms for a particular cancer site. The evaluation included analysis of the completeness of individual data items, a minimum dataset based on UICC TNM recommendations for cancer registration [14] (Table 1) and also a minimum

REPORTING FORM - COLORECTAL CANCERS

Specimen No. _____ **Name** _____

Tumour Details:

Gross description:

Maximum tumour diameter _____cms

Distance to nearest margin _____cms

Rectal: Relation to peritoneal reflection : Above / aT / Below

AP resection: Distance from pectinate line : _____cms

Histology:

Type = Adenocarcinoma ? Y N If No, state_____

Predominant differentiation Poor / Other

Local invasion reaches S Submucosa

M Muscularis Propria

B Beyond Muscularis Propria

P Serosal surface or adjacent organs

If P, which organ?_____

Margins:

Tumour involvement of :

Doughnut Y N NA

End margin Y N

Rectal: Circumferential margin Y N If No, Distance _____mm

Metastatic Spread:

No.nodes examined _____

No.positive _____

Apical node +ve? Y N

Extramural vascular invasion? Y N

Background Bowel: ☐ Normal ☐ Familial adenomatous polyposis

☐ Adenoma ☐ Synchronous carcinoma

☐ Crohn's ☐ Ulcerative colitis

Pathological Staging:

Complete resection? Y N

TNM : T___ N___ M___

Dukes': ____

TNM Staging :

T1	Submucosa	N0	Node -ve	M1	Distant metastases present
T2	M Propria	N1	1-3 nodes +ve	MX	Distant metastases unknown
T3	Through M Propria	N2	4+ nodes +ve		
T4	Serosa or other organs	N3	Apical node +ve and/or +ve nodes around main vascular trunk		

Dukes':

A	Limited to muscle
B	Through muscle
C1	Node +ve (not apical)
C2	Apical node +ve

Fig. 2. Colorectal cancer reporting form.

Table 1
UICC TNM minimum data items recommended for cancer registration

Breast cancer	Colorectal cancer
Side	Tumour type
Tumour type—invasive	Tumour size
Tumour type—*in situ*	Tumour grade
Whole tumour width	Number of nodes positive
Invasive tumour width	Extramural vascular invasion
Tumour grade	pT and pN[a]
Number of nodes positive	
Vascular invasion	

UICC, International Union Against Cancer.
[a] All necessary items for pT and pN were included in the CROPS dataset for colorectal cancer.

Table 2
Minimum data items required for patient management

Breast cancer	Colorectal cancer
Side	Tumour type
Tumour type—invasive	Tumour size
Tumour type—*in situ*	Tumour grade
Whole tumour width	Number of nodes positive
Invasive tumour width	Extramural vascular invasion
Tumour grade	Circumferential margin involvement
Number of nodes positive	pT
Vascular invasion	pN
Lymph nodes sampled	
Highest node involved	
Excision margins	

dataset of items considered to be important for patient management and informing prognosis (Table 2). The analysis took into account the cluster randomised split-unit design and used weighting according to the numbers of specimens submitted to each laboratory.

2.5. Qualitative evaluation

At the end of the project, an independent researcher evaluated the impact of computerised form reporting on pathologists' practice using face to face semi-structured interviews lasting between 15 and 90 min. Interviews covered pathologists' opinions on the dataset and guidelines, reactions to the introduction of form-based reporting, appraisal of the training and support offered during the trial and general issues relating to their role in multi-disciplinary teams and overall workload. The project researcher also interviewed a surgeon from a relevant speciality from each of the participating hospitals, who had been in receipt of the computer-generated pathology reports.

3. Results

2042 reports from 16 hospitals were available for analysis (Table 3). For breast cancer, there were 602 reports in the study arm and 539 in the control arm. For colorectal cancer, there were 442 and 459, respectively. A thorough search of hospital databases for all possible specimens identified that 680 specimens had not received a form report in the study arm. Over half 376 of these missing study reports were either breast core biopsies or colorectal biopsies of less than 5 mm which could not provide clinical staging information and were excluded from the trial. This left the figure for large resection specimens that should have been included in the study arm, but did not receive a form report at 304 (8% of all reports produced during the study period). This figure is relatively high and supports Cancer Registry practice of backing up electronic data capture with other methods of case ascertainment.

3.1. Quantitative analysis of dataset completeness

The results are summarised in Tables 4–6. Using the completion of the essential Cancer Registry items in Table 1 as the standard, the intervention resulted in a 28.4% (95% confidence interval (CI): 15.7–41.2%) improvement in data completeness when compared with

Table 3
Accounting for all pathology reports in the trial

	Total breast and colorectal specimens reported during study period	CROPS form/control report missing	Total analysed	Number of biopsy reports excluded from analysis	Reports available for analysis	Control reports interpreted by specialist registrars and included in final analysis
Breast control	918	(40)[a]	878	258	620	539
Colorectal control	772	(66)[a]	706	223	483	459
Breast study	1239	340	899	297	602	602
Colorectal study	823	340	483	41	442	442
Totals	3752	786	2966	819[b]	2147	2042[c]

[a] Control reports were identified on audit that had been missed due to coding, human and computing errors.
[b] Biopsy reports were excluded, as they do not contain adequate information for clinical staging.
[c] 105 control reports were not reviewed by specialist registrars due to human error (mislaid reports).

Table 4
Effect of intervention on overall percentages satisfactorily completed for breast and colorectal tumours compared with Cancer Registry coder control arm interpretation of Cancer Registry minimum dataset

	Intervention breast/ colorectal (%)	Coder control breast/ colorectal (%)	Estimate (%)	95% confidence interval (CI)	*P* value
Whole form	72.8/49.8	28.8/7.0	39.4	27.6–51.3	<0.0001
Cancer registry dataset (Table 1)	82.6/68.8	42.9/43.6	28.4	15.7–41.2	<0.0001

Cancer Registry coders' interpretation of free text reports (Table 4). Using the completion of the clinically relevant data items in Table 2 as the standard, the intervention resulted in a 24.5% (95% CI: 11.0–38.0%) improvement when compared with the interpretation of the free text reports by medically qualified registrars (Table 5). When all the data items on the forms are included in the analysis, this improvement increased to 39.4 and 29.3%, respectively (Tables 4 and 5).

Table 6 shows that the effect of the intervention on individual data items varied greatly. The greatest effect in breast cancer was on the recording of tumour size, tumour grade and margin involvement and in colorectal cancer on tumour grade, extra-mural vascular invasion and the involvement of circumferential margins.

3.2. Qualitative analysis

3.2.1. Pathologist interviews

Interviews were held with 33 histopathologists in the 16 hospitals. These highlighted that different methods of CROPS data entry that had been adopted, from on-screen computer entry by pathologists or their secretaries, to completion of paper forms (the latter necessitated by difficulties in incorporating the CROPS screen into some hospitals' systems). CROPS forms were almost universally thought to be quick and easy to complete and the datasets were considered to include the essential data items, whilst not being unrealistic or over-complicated. Some commented that it took time to adapt to 'negative reporting' when certain pathological

Table 5
Effect of intervention on overall percentages satisfactorily completed for breast and colorectal tumours compared with medically qualified registrar control arm interpretation of patient management dataset

	Intervention breast/ colorectal (%)	Registrar control breast/ colorectal (%)	Estimate (%)	95% confidence interval (CI)	*P* value
Whole form	72.8/49.8	42.7/13.3	29.3	15.0–43.7%	<0.0001
Patient management dataset (Table 2)	81.4/67.6	53.4/40.7	24.5	11.0–38.0%	<0.001

Table 6
Effect of intervention on proportions satisfactorily completed for items applicable to breast and colorectal tumours separately, compared with medically qualified registrar control arm

Reported item	Estimate (%)	95% confidence interval (CI)	*P* value
Breast			
Tumour type—invasive	1.0	−0.7–2.6%	0.25
Maximum width of tumour	11.4	−13.5–36.2%	0.37
Tumour grade	10.2	−1.2–21.5%	0.022
Excision margins	10.9	1.5–20.2%	<0.0001
Lymph nodes sampled	−1.1[a]	−4.3–2.0%	0.48
Lymph nodes positive	−3.1[a]	_[b]	
Colorectal			
Circumferential margins	36.8	10.0–63.6%	0.002
Maximum width of tumour	4.1	0.3–7.8%	0.007
Tumour grade	9.9	1.9–17.9%	0.015
Lymph nodes sampled	7.1	−1.5–15.7%	0.10
Lymph nodes positive	1.9	−1.6–5.5%	0.29
Extramural vascular invasion	17.5	1.0–33.9%	0.037
Tumour type—invasive	−0.2[a]	−1.5–1.0%	0.71

[a] A negative value indicates that, if anything, the intervention resulted in less good completeness rather than better.
[b] Owing to 100% completeness in one part of the data, the confidence interval could not be calculated.

features were not present, but this was made quicker by using tick boxes. A few pathologists chose to write free text reports in addition to completing and issuing form reports, and stated that they used the forms as a checklist when writing text reports. Eight respondents volunteered that form-based reporting could satisfactorily replace text reporting, particularly if requested by local surgeons. 24 pathologists supported an extension of predefined form reporting to other cancer sites. The main limitation of the forms was lack of flexibility in describing the rarer complex specimens. This could be partly resolved by provision of free text fields. The written guidelines were considered to be valuable for clarifying complicated data items with diagrams, and were used regularly.

Nearly all interviewees were satisfied with the training and advice received. 24/39 (62%) consultant pathologists attended the training days and some reported an improvement in their gross specimen handling practice or were examining more tissue blocks as a result of the guidelines and training.

3.2.2. Surgeon interviews

Surgeons' responses indicated they clearly favoured form reporting, but had concerns that the pathologists should be comfortable with the format and content. Several highlighted the value of forms in ensuring consistency of reporting formats and in finding quickly and unambiguously the information needed for patient management.

4. Discussion

In this paper, we have described the first use of a randomised controlled trial to investigate an intervention in the process of pathology reporting. The results show that a package of guidelines and computerised forms made a significant impact on the completeness of data available, both to the clinicians treating the patients and to the Cancer Registry, compared with interpretation of free text reports by medical staff and Cancer Registry coders, respectively. Furthermore, the benefit has been clearly demonstrated across all of the hospital laboratories in a European health region with a total population of some 2.93 million, rather than in a single teaching institution where specialist pathologists might be especially motivated.

We chose to use 'minimum' data requirements as the gold standard for the main analysis. Other published recommendations, such as those from the Association of Directors of Anatomic and Surgical Pathology [15,16], are recognised as requiring more comprehensive reporting than the CROPS study. Tables 4 and 5 show that when the maximum number of data items on the CROPS forms are included in the analysis, the beneficial effect of computerised reporting is even greater. This is not surprising since individual pathologists' perceptions of the importance of items that are not regarded as essential, and hence their inclusion of them in free text reports, is likely to vary.

Table 6 indicates that the effect of the intervention on different data items varied considerably. Some items, for example lymph node status in breast cancer, have always been well reported in free text reports and there was little room for improvement. Others, such as excision margin involvement in both tumour types, the histological grade of a breast tumour, and the recording of extramural vascular invasion in colorectal tumours, have not been so consistently reported and the effect of the intervention was highly significant. This may be related to the fact that the importance of some of these items, notably circumferential margin involvement in rectal cancer, has only been appreciated relatively recently [7].

Pathologists knew that their written reports would be checked and included in the study and this might suggest that the effect of the intervention was underestimated in this trial. Indeed, had the trial failed to show a difference and shown a high level of completeness in both arms of the study, this would have been an important possible explanation. However, the low levels of overall completeness, in both the intervention and the control arms, suggest that the lack of blinding did not grossly distort pathologists' practice. Such non-blinding was unavoidable given that we had to gain pathologists' consent to take part in the trial.

It is not possible to evaluate the differential contributions made by each of the three main components of the intervention package—training, forms and guidelines—on the outcome. While it is likely that the enforced use of forms had the greatest impact on ensuring that every report contained a statement on each data item, it is likely that the elements of training and providing reporting guidelines contributed to the accuracy, precision and overall quality of these data items. The availability of comprehensive on-screen guidelines that provide full and careful definitions of the various data items through a 'Help' key is likely to be an important element in the successful implementation of similar systems in the future.

Despite the perceived advantages of undertaking this project in parallel with the implementation of an all-Wales laboratory computing system, we experienced a number of practical difficulties with information technology that meant that seven of the laboratories were unable to make use of on-screen forms, having to use paper forms instead. We have learned a number of lessons for the widespread implementation of computerised form reporting in the future. There must be strong and consistent interaction between the laboratories and the software providers at all stages of the development. The software systems developed must be

sufficiently flexible, versatile and user-friendly to allow their implementation in laboratories of differing size and complexity, to cope with the different requirements of forms for the different tumour sites, and to allow their review and modification in response to new knowledge.

Interviews demonstrated enthusiastic support for form reporting from surgeons, who cited their readability in particular. Not all pathologists felt so comfortable, however, their main concern being the constraint on the freedom to write specimen-specific reports. Future developments should look carefully at addressing this. We consider that there should always be room for adding a free text component to the form, in order that pathologists can describe properly the complex specimen, the special situation that 'does not fit' and the truly unusual observation that may lead to new insights into the understanding of cancer and its treatment.

The introduction of form-based reporting appears to have been acceptable to the professions involved, and the system described represents a reasonable prototype for further development. There has been interest in adapting the CROPS model in other UK registries and electronic capture of pathology data fields is a key element of the English Cancer Information Strategy. In Wales, the results of the trial have been reported to a group that is reviewing cancer information systems in the Principality. We hope the lessons learnt from this trial about the value of actively collecting data with online pre-defined forms and reporting guidelines will inform future information developments, as most systems currently attempt to capture data passively by retrospective downloads from hospital databases. Resolving queries about incomplete and inconclusive reports downloaded in this way can prove difficult for Cancer Registries.

Pathology data are widely recognised as a crucial component of complete and accurate cancer registration data. Histological verification is a quality indicator for 74% of Cancer Registries in the EU [17] and 57% of European Registries receive computerised inputs [17]. Many European registries can accept pathology data in electronic text format [18], but we are not aware of the electronic transfer of pre-defined forms elsewhere in Europe, although there may be developments in this direction in North America (Ontario) [18]. With adequate investment in pathology and Cancer Registry information systems and ongoing consultation between cancer clinicians, pathologists and Cancer Registries, we suggest that the CROPS model could have a significant impact on the quality of cancer data available at both the clinical and population levels.

Acknowledgements

This research was funded by a grant from the Wales Office of Research and Development for Health and Social Care, with additional support from the Royal College of Pathologists Audit Office, the Welsh Cancer Intelligence and Surveillance Unit and Breast Test Wales — the Welsh breast screening programme. This project could not have been completed without collaboration and data collection by histopathologists in Wales: Dr M. Appleton; Dr R. Attanoos; Dr A.H. Burdge; Dr S. Burroughs; Dr T. Caslin; Dr C. Champ; Dr A. Dalton; Dr A. Dawson; Dr R.B. Denholm; Dr S.D. Dojcinov; Dr A.G. Douglas Jones; Dr R.W. Fortt; Dr A.R. Gibbs; Dr J. Gough; Dr A.P. Griffiths; Dr D.F.R. Griffiths; Dr S. Howell; Dr M. Hughes; Dr S.M. Ismail; Dr R.J. Kellett; Dr P. Laidler; Dr P. Matthews; Dr G. Melville-Jones; Dr J.K. Murphy; Dr L.A. Murray; Dr N. Nind; Dr C. O'Brien; Dr E.W. Owen; Dr D. Pace; Dr S. Polacarz; Dr A.M. Rashid; Dr A.M. Rees; Dr B. Rodgers; Dr P.W.B. Scott; Dr C.G.B. Simpson; Dr D. Stock; Dr M. Sweerts; Dr I. Thompson; Dr A. Verghese; Dr N. Ward; Dr D.M. Wayte; Dr W. Williams; Dr R.B. Williams; Dr S. Williams; Dr N. Williams and the clinical coders at WCISU: Judith Andrews, Linda Baumber, Nan Germain, Joy McRae and Linda Morgan. Dr Elizabeth Roberts, Dr Mary Cotter and Mr Graham Davies were former members of the CROPS steering group and made significant contributions to study design and funding. We also acknowledge the valuable help of Professors C. Elston and P. Quirke for providing the CROPS training sessions.

References

1. Roberts RE. *The Annual Report of the Director of Breast Test Wales 1995/6*. Cardiff, Welsh Breast Screening Centre, 1997.
2. Fisher ER, Sass R, Fisher B. Pathologic findings from the National Surgical Adjuvant Project for Breast Cancers. Discriminants for tenth year treatment failure. *Cancer* 1984, **53**(Suppl.), 712–723.
3. Early Breast Cancer Trialists' Collaborative Group. Systemic treatment of early breast cancer by hormonal, cytotoxic or immune therapy. *Lancet* 1992, **339**, 1–15, 71–85.
4. Pinder SE, Murray S, Ellis IO, *et al*.. The importance of the histologic grade of invasive breast carcinoma and response to chemotherapy. *Cancer* 1998, **83**, 1529–1539.
5. Stotter A. A prognostic table to guide practitioners advising patients on adjuvant systemic therapy in early breast cancer. *Eur J Surg Onc* 1999, **25**, 341–343.
6. Bull AD, Biffin AHB, Mella J, *et al*.. Colorectal cancer pathology reporting: a regional audit. *J Clin Pathol* 1997, **50**, 138–142.
7. Adam IJ, Mohamdee MO, Martin IG, *et al*.. Role of circumferential margin involvement in the local recurrence of rectal cancer. *Lancet* 1994, **344**, 707–711.
8. Cross SS, Feeley KM, Angel CA. The effect of four interventions on the informational content of histopathology reports of resected colorectal carcinomas. *J Clin Pathol* 1998, **51**, 481–482.
9. Rigby K, Brown SR, Lakin G, Balsitis M, Hosie KB. The use of a proforma improves colorectal cancer reporting. *Ann R Coll Surg Engl* 1999, **81**, 401–403.
10. Working Group of the Registrar General's Medical Advisory Committee. *Review of the National Cancer Registration System*. London, OPCS, 1990.

11. National Coordinating Group for Breast Screening Pathology. *Pathology Reporting in Breast Cancer Screening*. Publication No. 3. London, National Health Service Breast Screening Programme, 1995.
12. Quirke P, Williams GT. *Minimum Dataset for Colorectal Cancer Histopathology Reports*. London, Royal College of Pathologists, 1998.
13. Donner A, Birkett N, Buck C. Randomization by cluster. Sample size requirements and analysis. *Am J Epidemiol* 1981, **114**, 906–914.
14. Sobin LH, Wittekind CH, eds. *UICC: TNM Classification of Malignant Tumors,* 5th edn. New York, John Wiley, 1997.
15. Association of Directors of Anatomic and Surgical Pathology. Recommendations for the reporting of resected large intestinal carcinomas. *Hum Pathol* 1996, **27**, 5–8.
16. Association of Directors of Anatomic and Surgical Pathology. Recommendations for the reporting of breast carcinoma. *Hum Pathol* 1996, **27**, 220–224.
17. Storm H, Clemmensen I, Black R. *Survey of Cancer Registries in the European Union*. Lyon, IARC, 1998.
18. Black RJ, Simonato L, Storm HH, Demarét E, *et al*., eds. *Automated Data Collection in Cancer Registration*. *IARC Technical Reports No*. *32*. Lyon, IARC, 1998.