

**Yorkshire Cancer Research Network
Annual Report**

April 2003 – March 2004



**Mr C Button
Research Network
Manager, YCRN
Professor M Seymour
Clinical Lead, YCRN**

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Summary

- YCRN was identified in October 2001 and contracted from March 2002, covering a population of 2.6M with annual cancer incidence over 10,000. It embraces 7 Acute NHS Trusts and 17 Primary Care Trusts.
- From the outset, the YCRN has been closely integrated with the existing Cancer Network, Academic Units and Clinical Trial Unit
- YCRN is structured on a model of network-wide cancer site-specific portfolio coordinators working together with clinical research support staff at individual hospital locations, the whole supported by a core team for administration and education.
- YCRN currently wholly or partly employs 26 individuals (20.3 w.t.e.), over half of whom are research nurses. Over 80% of the total YCRN budget is spent on staff salaries.
- Recruitment to NCRN Portfolio trials within YCRN for 2001/2, 2002/3 and 2003/4 was 613, 826 and 1526 patients respectively. These figures represent 6.1%, 8.2% and 15.2% of the annual invasive cancer incidence.
- Plans for the current and future years are:
 - to maintain this high level of clinical research activity
 - to resolve service pressures arising from increased research activity
 - to improve and expand quality control in clinical research
 - to improve and expand the educational programme for research staff

1. Organisation and Development of Network

1.1 NCRN Appointments

YCRN was one of the second wave of NCRN networks, designated in October 2001. Our Strategic Outline Plan was agreed by the host institutions and signed off by NCRN and DoH in March 2002. Appointment of YCRN core staff started in October 2002, with the main clinical research portfolio coordinator posts coming on-line in January 2003. Additional clinical research nurses and other staff have been appointed throughout 2003-4, and are detailed in Appendix 1a.

1.2 Staff in Post

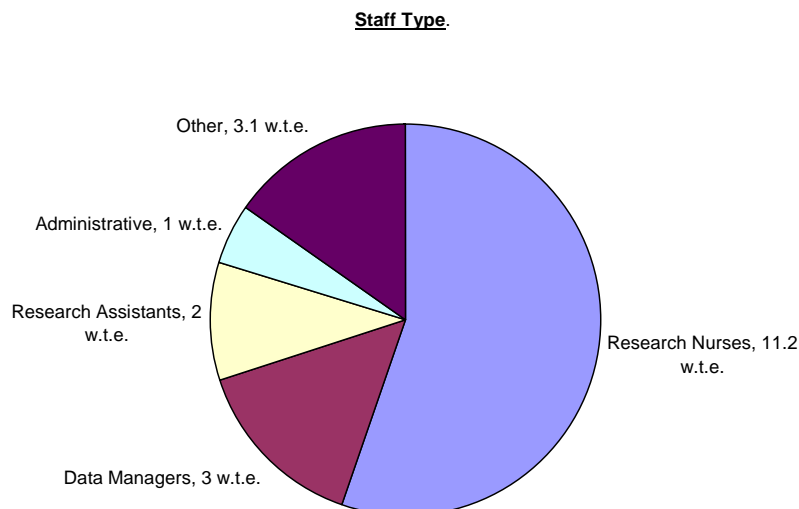
The YCRN now funds 20.3 whole time equivalent (w.t.e.) staff across the Network. This is a total of 23 individuals, all of whom support directly the set up and accrual of NCRN Portfolio trials. The YCRN also supports, financially, a further 3 posts within hospital service departments to indirectly support NCRN activity.

The total spend for staff in 2003/04 was £424,100. This was 79% of the annual YCRN expenditure.

See appendix 1b, Staff in Post

1.3 Overview of Network Staffing Profile

The pie chart below shows the proportion in terms of posts held, of appointments currently directly funded by the YCRN.



Of the 20.3 w.t.e. staff, 11.2 are research nurses. This is the largest group of individuals employed by the YCRN and reflects the ratio of research nurses to other staff across the whole Network. The remainder of staff groups comprise data

managers (3 w.t.e.), research assistants (2 w.t.e.), administrator (1 w.t.e.), Education & Information Manager (1 w.t.e.), IT Manager (1 w.t.e.), Network Manager (1 w.t.e.) and Research Clinical Lead (0.1 w.t.e.).

In addition to these 20.3 w.t.e. posts, three additional NHS posts receive some financial support from YCRN. These are a therapy radiographer, a pharmacy technician and a pathology technician.

Of the 11.2 w.t.e. research nurses, 8.2 w.t.e. have traditional roles, actively recruiting patients into clinical studies across a range of clinical trials with varying degrees of cancer site-specialisation and performing trial data capture. 7.2 w.t.e. of these posts are based predominantly at a single hospital site, but with scheduled time for network activities. In addition, 1 w.t.e. research nurse works across several Cancer Units supporting haematology trial activity.

3 w.t.e. research nurses, and the 3 w.t.e. data managers, act as portfolio coordinators for the whole Network, working with hospital site-based staff to improve clinical trials activity. Their current portfolios include colorectal, breast, lung, upper GI, urology, gynaecology, haematology, sarcoma, skin, head & neck, palliative and primary care. The remit of these individuals is to assist and lead the development of Network wide portfolios by promoting, educating, trouble shooting, supporting and completing regulatory paper work i.e. Ethics Committee and R&D applications.

2 w.t.e. research assistant posts have been created to promote new trials activity in specific areas of the NCRN portfolio. The first of these is in psychosocial oncology, reflecting a major interest and activity within the Yorkshire Network. The second, recently developed, will support the NCRN screening and genetics portfolio.

All the Trusts in the Network now have locally employed staff funded by the YCRN, along with regular input and support from YCRN Coordinating Centre staff. Throughout the development of the Network we have given a high priority to providing practical help (eg administrative and educational) for the pre-existing clinical research support staff, and integrating the new YCRN staff into the existing framework; we have also been careful that YCRN funding should be used to supplement, not replace, pre-existing research funding, where it existed.

Outstanding Vacancies

The YCRN has 2 outstanding vacancies:

- 1 w.t.e. Research Nurse, Mid Yorkshire NHS Trust. To be appointed in June 2004.
- 1 w.t.e. Research Assistant (genetics and screening trials), The Leeds Teaching Hospitals NHS Trust. To be appointed in July 2004.

Future Appointments

The YCRN Executive regularly review the need for additional posts. Currently we have identified the need, following implementation of the EU Directive in May 2004, for an additional administrator to act as a Regulatory Officer, supporting the existing administrator and portfolio coordinators.

Staff turnover

From the current 20.3 w.t.e. staff the YCRN has had 3 staff changes. 2 of these staff members, a research nurse and a data manager, left for alternative jobs within the NCRN and the final member of staff, a research nurse, left for a job not associated with research.

1.4 Training and Development

Up to May 2004, training and development for YCRN staff was coordinated and largely delivered by the Network Manager, with additional input from the Clinical Trials and Research Unit (CTRU), University of Leeds, with whom a formal training contract was agreed. From May 2004, this has been supplemented by the appointment of an Education & Information Manager.

1.4.1 Induction

The intensive 2 week induction as outlined in appendix 2, attachment A of the 2002/03 Annual Report continues to be the template for new staff induction. Only minor changes have been made to the programme to accommodate the training led by external staff and agencies. The appointment of The Education Manager will enable the YCRN to fully evaluate and alter accordingly the YCRN induction.

1.4.2 Training and Education Standard Operating Procedure (SOP)

YCRN has a commitment to implement the SOP, *'Performing and Documenting Clinical Team Training'* from the NCRN. Progress towards full implementation of this SOP is ongoing. We have however identified a need to revise certain aspects of the existing SOP and we are liaising with NCRN Training personnel to achieve this.

1.4.3 Local Training

The YCRN has provided a series of 14 sessions as a rolling programme of teaching and education, aimed at all the staff of the YCRN. These sessions have covered core topics relevant to the educational needs of the staff such as recruitment issues, research managers forum, NCRN activity updates, YCRN activity and trial updates, the role and effect of the trial coordinator in the network; quality of life issues and sessions looking at the work of particular trial portfolios. An analysis of all the courses provided has shown an overall satisfaction in the provision of educational needs as perceived by all the delegates. Feedback from all the sessions has been very good and suggests that the YCRN has been addressing the educational needs of the staff.

We are now working toward a further development of this programme. Appointment of a full time Education and Information Manager has been an important step, as it allows us to undertake educational and training needs assessments of all staff, and to develop educational activities in response to those needs.

1.4.4 Attendance on NCRN and Local Training Courses

See appendix 2a.

1.4.5 Other Network Training and Development Initiatives

In anticipation of the impact and significance of the E.U. Directive for all those involved in the promotion of clinical trials, but targeted mainly at Cancer Clinicians, the YCRN organised a series of three afternoon sessions led by Training Consultant, Teresa Fellows. The aim was to provide delegates with a clear understanding of the principles of ICP-GCP and the new E.U. clinical trials legislation. The sessions included a further study of other issues such as Consent, Safety Reporting, Data Protection, Patient Confidentiality and Recruitment. The sessions were well received. Feedback from the first 2 sessions can be found in appendix 2b.

We have developed a web forum as a platform for research initiatives with each site-specific tumour group. This forum will also be a potential training tool, and we plan to develop this over the coming 12 months.

1.5 Structures and Integration

The Research Network has its own reporting mechanisms. The YCRN Executive is a small group (as per Outline Plan Jan 2002) that meets at frequent intervals to discuss and resolve many ongoing issues. The YCRN Executive reports to the YCRN Management Board who oversee the general progress of the YCRN and approve any major strategic policy developments and funding decisions. The YCRN reporting structure is to be reviewed during the next 12 months. See Future Plans, section 7.

1.5.1 Service Network

The YCRN has a close working relationship with its service Network, the Yorkshire Cancer Network (YCN). Both the Lead Clinician and General Manager of the YCN sit on the YCRN Management Executive. The YCRN clinical lead sits on, and provides regular reports for, the YCN Management Board. See appendix 3 for YCN structure.

The YCRN has a presence at all of the Network Tumour Groups. These meetings are used primarily to feedback information about the National / Local trials portfolios; this includes trial accrual, promoting new trials and discussing common issues. Three of the tumour groups have research subgroups; these are breast, gynaecology and urology. All are now established groups that discuss the issues raised above but in greater depth. They also have a focus on the development of local research ideas.

It is becoming increasingly important that the YCRN links into the generic service network groups such as Cancer Drug Therapy, Imaging & Radiology, and Histopathology. These services are crucial to the success of clinical trials and the Network Groups provide a welcome single forum for ensuring service support when initiating new trials.

1.5.2 Network Hospitals and Staff

YCN comprises a single comprehensive Cancer Centre based within the Leeds Teaching Hospitals Trust (on 3 main hospital sites) plus six Cancer Unit Hospital Trusts (on 10 main hospital sites). Leeds Cancer Centre and Bradford Royal Infirmary, are also jointly host to an NTRAC Centre and to the Cancer Research UK Clinical Centre in Leeds. These bring considerable clinical and laboratory expertise and resources, which enhance the clinical trials activity for the Network as a whole.

The Cancer Units have defined referral pathways for each cancer type, and some have designated Centre status for intermediate cancers (eg Upper GI and Urology), in accordance with Improving Outcomes Guidance. All referrals for radiotherapy are made to the Cancer Centre, along with some of the intermediate cancer and all rare cancer referrals.

The Clinical Trial Coordinators are providing a vital link in identifying and improving pathways for clinical trial activity. These pathways and improved lines of communication enhance and speed up both staff working lives and patient journey times.

Communication across such a large Network is vital. All of the YCRN Coordinating Centre Staff visit all active units regularly, offering support and advice as well as acting as communication channels. Within the YCRN Coordinating Centre there is a weekly team brief which allows information to be shared about individual units; this ensures that relevant information is fed to the units and allows information return to the YCRN. The YCRN has taken this one step further and has a quarterly meeting to discuss individual units performance. The pilot of these meetings was successful in that it allowed the YCRN to ascertain and consider each Unit's strengths and weaknesses.

1.5.3 Multidisciplinary Team (MDT) Meetings

The MDT Meetings are important for encouraging research activity, raising awareness of trials and identifying patients suitable for trial recruitment. Representation at MDTs across the Network is inconsistent. The nature of MDTs varies from one Trust / disease site to another. Research nurses and data managers attend MDTs where they feel they can effectively contribute, but sometimes feel that due to a lack of inclusion within these meetings, their attendance has not been as worthwhile as it could and should be.

Standards at MDTs are increasing with the commitment of the YCN to MDT Coordinator training and development.

1.5.4 NCRI Clinical Studies Groups

The NCRI Clinical Studies Groups (CSGs) provide the primary route through which new ideas for clinical trials are developed. At present there are 20 NCRI CSGs. The full list can be found at <http://www.ncrn.org.uk/Csg/index.htm>

The Network has strong representation within these national groups. Of the 20 groups, Yorkshire Cancer Network is represented at 17, by 25 individuals.

2 Accrual

Accrual into the NCRN Portfolio of studies continues to increase. From the baseline year 2001/02 to the last complete year of records 2003/04 there has been a 149% increase in trial accrual. In real terms this has gone from 613 patients recruited in 2001/02 to 826 and 1526 in successive years. This represents over the same period 6.1%, 8.2% and 15.2% of newly incident cancer patients entered in to NCRN Portfolio studies.

15.2% of newly incident cancer patients entered into NCRN Portfolio studies in 2003/04 compares very favourably with our unofficial target of 10% set in the previous annual report.

2.1 Overall Accrual into NCRN Portfolio Studies

In the period April 2003 – March 2004, the Network saw a further 700 patients entered into NCRN Portfolio trials compared with 2002/03 total. Significant increases have been recorded across the whole Network with every Acute Hospital Trust showing an increase. These range in percentage terms from a 24% increase at Bradford Hospitals NHS Trust to a 700% increase at Harrogate Healthcare NHS Trust. The Leeds Teaching Hospitals NHS Trust increase was 77%. Particular increases were seen, across the Network, in breast, melanoma, upper GI and miscellaneous trials.

For Hospital Trust breakdown see appendix 4, Annual Accrual for The Yorkshire Cancer Research Network.

2.2 Accrual by Cancer Site into NCRN Portfolio Studies

Breast cancer remains the largest single recruiting disease site with 295 patients, a rise of 103 from last year. This is closely followed by melanoma with a recruitment total of 219, after minimal activity in previous years. The remaining sites in the portfolio consolidated last year's increases. There are small recruitment decreases in both colorectal and urology portfolios; these are likely due to the changes in their respective portfolios, i.e. large trials closing after reaching accrual targets.

The local adoption of 2 psychosocial trials onto the NCRN Portfolio has made the biggest single difference to the portfolio. There were no psychosocial trials in last year's portfolio. The inclusion this year has seen the Network's accrual figures enhanced by a further 300.

See appendix 5, Accrual by Cancer Site into NCRN Portfolio Studies

2.3 Monthly Accrual into NCRN Portfolio Studies

Appendix 6 shows monthly recruitment for April 2002 – March 2004. The graph depicts a typical pattern of recruitment taking into consideration seasonal variations. It is clear from the graph that there is a steady increase over the period shown. The comparison made in last year's annual report was a mean monthly accrual figure showing the 2001/02 figure of 51 per month and for 2002/03 a figure of 69 per month; this has increased to 127 per month for 2003/04.

2.4 Monthly Accrual into NCRN Portfolio Studies by Hospital Trusts

- The Leeds Teaching Hospitals NHS Trust (Cancer Centre) continues to be responsible for more than half of the Network's trial recruitment: 54% in 2003/04. Most of these patients are recruited at the three main hospitals, Cookridge Hospital, Leeds General Infirmary and St James University Hospital. The Trust also has the largest clinical trial workforce, with 25 research nurses and data management staff. The mean monthly accrual for 2003/04 is 69, a rise of 30 from last year and a rise of 43 from the baseline. The portfolio is strong across the whole range of cancers.

Credit for this activity also needs to be given to all hospitals within the Network as the recruitment total for this Trust includes inward referrals from all units. Inward referrals are mainly for trials involving rare or intermediate cancers, trials including radiotherapy or complex therapy trials not suitable for the Cancer Units. Current NCRN accrual data relate to the hospital of randomisation/registration, which is sometimes different from where the referral originated, or where the treatment takes place. We have therefore developed a more sophisticated database for local use in future years.

- Airedale NHS Trust's main strength continues to be the breast and colorectal portfolios. We have seen particularly high recruitment this year, partly because of a locally adopted study of the effect of accessibility to cancer services from rural areas, which recruited 117 patients.

The research is coordinated through a model unique in our Network. Nursing staff from the chemotherapy unit work with disease specific patients. They coordinate and give the care to all patients within their allocated disease site; this includes both trial and non-trial patients. This model is to be reviewed during the next 6 months.

The mean monthly accrual has risen from 5 patients in 2001/02 to 7.5 in 2002/03 and 16 in 2003/04.

- Bradford Hospitals NHS Trust portfolio contains breast, colorectal, gynaecology, haematology, lung, melanoma and upper GI studies. The strongest of these continues to be the common cancer sites of breast and colorectal. This year Bradford has contributed 40% of the Network's accrual into the gynaecology trials portfolio. Trial accrual continues its steady increase. Two new academic medical oncology appointments within the past year are beginning to be reflected in further expansion of the research portfolio in this Trust.

The mean monthly accrual has risen from 5 in 2001/02 to 5.75 in 2002/03 to 6.5 in 2003/04.

- Calderdale and Huddersfield NHS Trust recruits well into breast and colorectal studies. They also contribute to haematology, lung, melanoma and upper GI studies. The addition of a further Medical Oncologist in 2002/03 has helped double annual accrual.

The mean monthly accrual remained static at 4.5 for 2001/02 and 2002/03 but has risen to 10 in 2003/04.

- Harrogate Healthcare NHS Trust and York Health Services NHS Trust. From a low starting-point in 2001, both these Trusts have now developed significant clinical trials activity in portfolios which include trials for breast, colorectal, haematology, lung, melanoma, prostate and upper GI cancer. Each Trust now has an established full time equivalent research nurse and a joint Medical Oncology appointment.

The mean monthly accrual was only 3.5 in 2001/02 and 3 in 2002/03, but has now leapt to 10.8 in 2003/04.

- Mid Yorkshire NHS Trust comprises hospitals in Dewsbury, Wakefield and Pontefract. This Trust has particular strengths in haematological and urological research, with representation on NCRI CSGs for both. The appointment of 2 w.t.e. research nurses in July 2003 enabled the portfolio to develop further, and the Trust now also participates strongly in breast, colorectal, lung and melanoma studies.

The mean monthly accrual has risen from 5 in 2001/02 to 7.5 in 2002/03 to 13 in 2003/04.

See appendix 7, Monthly Accrual by NCRN Portfolio Studies by Hospital Trust

2.5 Plans for Maintaining Accrual

Accrual for 2003/04 was 15.2% of newly incident cancer patients entered into clinical trials. Of these, 11.3% were trials in the National NCRN portfolio, with the remaining 3.9% contributed by locally adopted NCRN studies. The latter group included two large psychosocial / quality of life studies. The Network has however seen a steady increase into all the common and intermediate cancer sites in virtually all Trusts.

The very rapid rate of increase in YCRN's activity over the past 3 years is gratifying. However, for the future we anticipate some levelling-off and will be happy to maintain or modestly increase current activity. There are several reasons for this, including the increase in complexity of trials following introduction of the EU Directive, and pressure on the treatment delivery and support services. For example, pharmacy, radiology, pathology and other support services, whilst generally supportive of our efforts, find it difficult to keep pace with increased demands as trials activity expands. We must also recognise that whilst YCRN funding has supplemented the clinical research support staff, a high proportion of NCRN Trial activity is still undertaken by non-YCRN-funded research nurses and clinical staff.

With this in mind, YCRN expects to see recruitment level over the coming 12 months between 12 - 15%. Over the coming year the YCRN will investigate the effect that this increase in accrual has had across the Network in terms of the implications of follow-up whilst ensuring the ability to maintain a similar level of recruitment. There is room for improvement although probably not much beyond the 15% accrual, unless current working systems are changed both on the ground at research nurse / data management level and at the regulatory level with Research & Development.

There is still some work continuing to improve recruitment in the common cancer sites, particularly in lung studies, but the YCRN will shift its emphasis during the next year to support intermediate and rarer cancers.

3 Local Portfolio of NCRN Studies

3.1 Current Local Portfolio

The local portfolio continues to expand. It covers all the common, intermediate and rare cancers with the exception of Head and Neck.

3.2 Adoption

The YCRN has submitted 10 trials for adoption onto the local NCRN Portfolio. Five of these have been adopted, 4 onto the local NCRN Portfolio and 1 as a nationwide study. Four were deferred until further information has been collected; 1 was not adopted. The list of trials adopted is available from the YCRN.

3.3 R&D Approval

As last years report states, R&D remains a stumbling block in developing the trial portfolio in many Trusts. Each individual Trust has different R&D forms to complete, some with many additional forms which consider issues such as data protection, risk assessment and health and safety. The R&D forms and additional assessments require several individual's signatures, often lengthening the approval period.

The YCRN keeps a record of all trials that are submitted to R&D, but only where YCRN staff deal with any of the regulatory paperwork. These show a mean time to approval across the Network of 70 days with a range of 6 days (Study 14¹; Leeds TH NHS Trust) to 233 days (ICON 5²; Airedale NHS Trust). The table below shows mean, range and number of R&D submission for individual Trusts within the Network:

	Mean time to decision (days)	Range (days)	Number of R&D submissions
York	28	6-159	19
Leeds	30	6-69	22
Calderdale & Huddersfield	38	12-88	10
Mid Yorks	74	10-146	13
Harrogate	94	42-188	10
Airedale	128	54-233	6
Bradford	133	85-180	2

YCRN R&D submission to decision details

York R&D have managed to keep their decision time low, and despite the range, the average time does reflect the speed with which the Trust R&D Department handles its R&D submissions. This has been achieved by the R&D lead, Cancer Management Team and relevant clinicians meeting and agreeing a complete portfolio prior to any LREC/ R&D submissions. Harrogate R&D was taken on by York NHS Trust R&D on 1st April 2004.

¹ Study 14 - A Phase II/III Randomised, Double Blind, Placebo Controlled Trial of Gemcitabine/ Carboplatin with or without Thalidomide in Advanced Non-Small Cell Lung Cancer .

² ICON 5 - An international, 5-arm randomised trial of paclitaxel and carboplatin v triplet or sequential doublet combinations in patients with epithelial ovarian or primary peritoneal carcinoma.

Currently Bradford is reviewing the way in which new trials are processed through the Trust. It is likely that individual trials will be approved at management meetings, which will include all disciplines involved in the trial. This should reduce the time in gaining future R&D approval.

3.4 Ethics Approval

The approval process for ethics has gone through a gradual change over the last year, necessitated by the implications of the EU Directive, resulting in a reduction in approval times.

YCRN records show a mean time to approval across the Network of 45 days, with a range of 5 days (MS-01³; Leeds East LREC) to 120 days (Myeloma IX⁴; Airedale NHS Trust LREC). The table below shows mean, range and number of Ethics submission for individual Trusts within the Network:

	Mean time to decision (days)	Range (days)	Number of LREC submissions
Leeds West	16	5-26	14
York	30	10-77	18
Leeds East	30	6-74	13
Harrogate	34	10-82	13
Calderdale & Huddersfield	41	19-76	9
Mid Yorks	62	15-119	19
Airedale	67	33-120	10
Bradford	67	57-77	2

YCRN LREC submission to decision details

The OREC Manager for Northern and Yorkshire, Amanda Hunn, has become an essential contact for the YCRN and has helped resolve several minor issues that the Network has had with Local Ethics Committees.

3.5 Strategy for Developing Local NCRN Portfolio

The YCRN will continue to work with individual units / clinicians and groups where possible to develop the local portfolio. There will be a greater emphasis on feedback and disseminating information about new trials to the Network Tumour Groups. Research is on the agenda of most of the Tumour Groups and is gradually becoming a part of the generic Network Service Groups e.g. Cancer Drug Therapy and Imaging. The YCRN will continue to raise the profile of research both within these groups and across other disciplines in the Network.

The common cancer site tumour groups are relatively well established, and we will continue to support and develop them. However the emphasis, as already stated in section 2.5, will be to increase activity in the intermediate and rarer cancers, such as gynaecology, head & neck, sarcoma, brain, upper GI, testis and bladder.

³ MS-01 - A randomised controlled trial of active symptom control with or without chemotherapy in the treatment of patients with malignant pleural mesothelioma

⁴ Myeloma IX - Myelomatosis therapy trial for patients of all ages. A randomised trial comparing second generation vs third generation bisphosphonates, induction chemotherapy regimens (CVAD vs CTD, and MP vs CTDa) and thalidomide maintenance vs no maintenance therapy.

4. Consumer Involvement

The YCRN is working with the newly established Network Consumer Group. There is much enthusiasm to develop a sub research group to look at all aspects of research and not just that falling within the remit of the YCRN. The YCRN has played a key role in the initial discussions and will maintain that contact and offer any assistance, support or leadership needed to sustain the current momentum.

The YCRN involves consumers in many aspects of its training; individuals have spoken at sessions and conferences held by the YCRN; the YCRN Education programme is open to, and indeed taken up by, a variety of consumers.

The YCRN has constructive contact with the excellent YCN User Facilitator and User/Consumer Group Co-Chairs.

5. Examples of Activities / Initiatives developed in the Network that have been Particularly Effective

The large majority of YCRN activity has conformed to our original planned model of network-wide cancer site-specific portfolio coordinators working with location-specific research support staff. In a few instances we have found it helpful to develop in new ways in response to local opportunities. For example:

- Haematology research. The clinical service and research activity in haematology is more widely dispersed than in many solid tumours, but is also more difficult to support with cancer unit research nurses. We have appointed a roving haematology research nurse who supports trial recruitment and data collection at many sites in the Network, with a high degree of flexibility, in terms of both time and location. The haematology portfolio across the Cancer Units has increased as a direct result of this support.
- Colorectal surgery. A local issue for our Network is that the Cancer Centre is large and split onto three sites. Colorectal surgery and non-surgical oncology are based at different sites, and we have appointed a research nurse with a particular remit to bridge these sites and coordinate activity for trials involving a surgical element.
- Psychosocial Oncology. Within our network the Cancer Centre has a strong academic psychosocial oncology programme. We have worked with the academic unit to identify psychosocial trials suitable for dissemination across the network, and adoption into the local NCRN Portfolio. To support this development, we have funded a research assistant in psychosocial oncology.
- Relationship with CTRU. The Leeds University Clinical Trials and Research Unit is one of the NCRN accredited cancer trials units. From the start of YCRN we have had a formal relationship with this unit, accessing their expertise for education of our staff and support for new trial development within the Network Tumour Groups.
- Web forum. We developed a web forum primarily to facilitate research idea development in the Network Tumour Groups. In the past year we have, however, used this facility to create a national upper GI research nurse forum.

6. Finance

The YCRN budget for 2003/04 was £601,600. The total expenditure for the same period was £544,100. Staff costs in the year accounted for £424,100. The YCRN carries forward a cumulative underspend, from the start of the YCRN, of £364,500 into 2004/05. This underspend was earmarked early in 2003/04 for 6 short-term posts around the network. These are now in post and that underspend will disappear by the end of the 2006/07 financial year.

7. Future Plans

7.1 Management Structure

The YCRN management structure as outlined in section 1.5 was effective for establishing our research network, but because of the need to include a very large number of stakeholders in the management board, this group is too large to meet frequently. We are therefore exploring a change in structure, to use the main Cancer Network Management Board (which meets quarterly) as the ratifying committee for decision made in the Research Network Executive. At the same time, the Executive will be expanded to increase stakeholder representation on that group.

7.2 Intermediate and Rare Cancer Trials

As stated in section 3.5, more emphasis will be placed on intermediate and rare cancer trials. The Network Manager and trial coordinator will allocate more time to set up and promote trials in gynaecology, head & neck, sarcoma, brain, upper GI, testis and bladder.

7.3 Standard Operating Procedures

Several operational policies have already been developed and are in use throughout the Network, including SOPs for Ethics and R&D submissions, and maintaining site files.

Now, in response to NCRN standards and the EU Directive, we are expanding our SOPs to cover every aspect of clinical research activity, record-keeping and audit. We intend to take the lead nationally in producing and implementing workable high quality standards.

7.4 Education Accreditation

We are currently seeking accreditation for our education programme from the University of Leeds and The Royal College of Nursing.

Negotiations with the University of Leeds and John Moore's University, Liverpool are in progress to assess the feasibility of delivering the modules of the widely recognised Clinical Trials Certificate at the YCRN in Leeds.

7.5 R&D Forum

The R&D approval process is the principal cause of delays in initiating trials across the Network. We have therefore proposed convening an R&D Forum, in which R&D managers from each Trust in the Network will consider common issues and individual trials. This proposal has gained support from several R&D Managers, and we plan to develop this initiative in the coming year.

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NCRN Appointments

Hospitals covered by post (base hosp first)	Post Title	Post Category	Tumor Site 1	Tumor Site 2	Tumor Site 3	Tumor Site 4	Tumor Site 5	Grade	WTE	Contract Length (mts)	Surname	Forename	Salutation	Start Date	End Date	Comments
CKH, Network	Administrator	AD	N/A					A&C4	1.0	36	Lloyd	Jan	Ms	7-Oct-2002		
CKH, Network	Clinical Lead for Research	CL	N/A						0.1	60	Seymour	Matt	Dr	15-Oct-2001		
CKH, Network	Database Manager	DM	N/A					A&C6	1.0	36	Oates	Leigh	Mr	14-Oct-2002		
CKH, Network	Data Manager	DM	LJUNG					A&C5	1.0	36	Tetlow	Michelle	Ms	6-Jan-2003		
CKH, Network	Data Manager	DM	COLO					A&C5	1.0	36	Chauhan-Lall	Nina	Ms	6-Jan-2003	28-Nov-03	Moved to Birmingham
CKH, Network	Data Manager	DM	BR					A&C5	1.0	36	Roworth	Wendy	Ms	6-Jan-2003		
CKH, Network	Research Network Manage	MG	N/A					SM8	1.0	60	Button	Christopher	Mr	8-Feb-2002		
CKH, Network	Research Nurse	RN	UR	GY				F	1.0	36	Hughes	Jane	Ms	6-Jan-2003		
CKH, Network	Research Nurse	RN	GI	HN	MEL			F	1.0	36	Sleigh	Carole	Ms	13-Jan-2003		
CKH, Network,+(all Network Hospices)	Research Nurse	RN	HAEM	SAR	PC	PAL		F	1.0	36	Wright	Helen	Ms	6-Jan-2003	04-Jan-04	Promotion to SPIRIT Post
AGH	Research Nurse	RN	ALL					F	0.5	36	Henry	Aiden	Mr	1-Dec-2002		
BRI	Research Nurse	RN	ALL					F	0.5	12	Kay	Annie	Mrs	1-Dec-2003		
C&H	Research Nurse	RN	ALL					F	1.0	36	Bamford	Linda	Ms	1-Jul-2002		
HDH	Research Nurse	RN	ALL					F	0.6	36	Webb	Marion	Ms	4-Nov-2002		
MYT	Research Nurse	RN	ALL					F	1.0	36	Timbs	Fiona	Ms	7-Jul-2003	30/04/2004	
YDH	Research Nurse	RN	ALL					F	0.5	36	Campbell	Hilary	Ms	1-Mar-2003		
CKH, Network	Research Nurse	RN	HAEM					F	1.0	24	Allen	Majorie	Mrs	1-Dec-2003		
SJUH, CKH	Research Nurse	RN	ALL					H	0.6	36	Rodwell	Sue	Mrs	15-Oct-2002	17/05/2004	
SJUH, CKH	Research Nurse	RN	UR	MEL				F	1.0	36	Sugden	Jo	Ms	3-Nov-2003		
CKH, LTH	Research Nurse	RN						F	1.0	12	Wright	Nancy	Ms	15-Sep-2003		Surgical Post - no category
SJUH	Research Nurse	RN	PAED					F	0.5	12	Marshall	Sandra	Ms	5-Jan-2004		
SJUH	Research Nurse	RN	PAED					F	0.5	12	Goran	Camilla	Ms	5-Jan-2004		
SJUH	Research Assistant	RA						F	1.0	24	Winterbottom	Anna	Ms	8-Sep-2003		Psychosocial Post - no category
CKH, Network	T & E Manager	TM	N/A					SM9	1.0	36	VACANT			1-Feb-2003	17/05/2004	post filled
CKH, Network	Data Manager	DM	COLO					A&C5	1.0	24	VACANT			1-Dec-2003	12/04/2004	post filled
CKH, Network	Research Nurse	RN	HAEM	SAR	PC	PAL		F	1.0	24	VACANT			5-Jan-2004	12/04/2004	post filled
CKH, Network	T & E Manager	TM	N/A					SM9	1.0	24	Maher	Paul	Mr	17-May-2004		
CKH, Network	Data Manager	DM	COLO					A&C5	1.0	24	Harbron	Joanne	Miss	12-Apr-2004		
CKH, Network	Research Nurse	RN	HAEM					F	1.0	24	Woolley	Sharon	Miss	12-Apr-2004		
MYT	Research Nurse	RN	ALL					F	1.0	24	VACANT			1-May-2004		
SJUH, CKH	Research Nurse	RN	ALL					H	0.6	24	VACANT			18-May-2004		
YDH	Clinical Research Officer	CRO	UR	HAEM	GI			CRO	0.5	24	Taylor	Carol	Ms	1-Jun-2004		CRO post & grade - no category

Appendix 1a

Staff In Post

Title	Salutation	Forename	Surname	WTE
Adminstrator	Ms	Jan	Lloyd	1
Clinical Lead for Research	Dr	Matt	Seymour	0.1
Database Manager	Mr	Leigh	Oates	1
Data Manager	Ms	Michelle	Tetlow	1
Data Manager	Ms	Wendy	Roworth	1
Research Network Manager	Mr	Christopher	Button	1
Research Nurse	Ms	Jane	Hughes	1
Research Nurse	Ms	Carole	Sleigh	1
Research Nurse	Mrs	Majorie	Allen	1
Research Nurse	Ms	Linda	Bamford	1
Research Nurse	Mr	Aiden	Henry	0.5
Research Nurse	Mrs	Annie	Kay	0.5
Research Nurse	Ms	Marion	Webb	0.6
Research Nurse	Ms	Fiona	Timbs	1
Research Nurse	Ms	Hilary	Campbell	0.5
Research Nurse	Mrs	Sue	Rodwell	0.6
Research Nurse	Ms	Jo	Sugden	1
Research Nurse	Ms	Nancy	Wright	1
Research Nurse	Ms	Sandra	Marshall	0.5
Research Nurse	Ms	Camilla	Goran	0.5
Research Assistant	Ms	Anna	Winterbottom	1
Education & Information Manager	Mr	Paul	Maher	1
Data Manager	Miss	Joanne	Harbron	1
Research Nurse	Miss	Sharon	Woolley	1
Clinical Research Officer	Ms	Carol	Taylor	0.5

Yorkshire

Attendees on NCRN and non-NCRN courses between 1/4/2003 and 31/3/2004

Delegate	Course(s) Attended
Marjorie Allen	Research Methodology (19/01/2004 - 19/01/2004) Intro to GCP and EU Directive (27/01/2004 - 27/01/2004)
Sr Heidi Aram	BODMA NCRN Conference (08/09/2003 - 09/09/2003)
Maxine Armitage	Advanced ICH GCP (29/10/2003 - 29/10/2003)
Louise Arnold	ICH GCP (13/08/2003) Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Sr Linda Bamford	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Poster Exhibition (08/09/2003 - 08/09/2003)
Andrew Barker	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Cathy Bartle	ICH Good Clinical Practice (GCP) (11/12/2003 - 11/12/2003)
Richard Benton	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Heather Berry	Advanced ICH GCP (29/10/2003 - 29/10/2003)
Carol Bilbrough	Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Kathryn Black	Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Jenny Boards	Advanced ICH GCP (29/10/2003 - 29/10/2003)
David Buchanon	Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Catherine Burton	ICH GCP (13/08/2003) Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Mr Christopher Button	Training Link meeting (10/07/2003 - 10/07/2003) National Briefing (23/10/2003 - 23/10/2003) NTL Forum (26/11/2003 - 26/11/2003) RNM Professional Development Programme (09/12/2003 - 10/12/2003) Advanced GCP and EU Directive (13/01/2004 - 13/01/2004)
Hilary Campbell	Cancer Clinical Trial Induction Course (22/09/2003 - 25/09/2003)
Mr Mikhail Cannon	BODMA NCRN Conference (08/09/2003 - 09/09/2003)
Gail Castle	ICH Good Clinical Practice (GCP) (13/08/2003 - 13/08/2003)
Alison Chatten	Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Nina Chauhan-Lall	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Research Methodology (23/10/2003 - 23/10/2003) Advanced ICH GCP (29/10/2003 - 29/10/2003) Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003) Cancer Policy & Politics (02/12/2003)
Helen Dalton	ICH Good Clinical Practice (GCP) (13/08/2003 - 13/08/2003)
Michelle East	ICH Good Clinical Practice (GCP) (11/12/2003 - 11/12/2003)
Janice Farish	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Advanced ICH GCP (29/10/2003 - 29/10/2003) Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Amanda Forsyth	Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003)
Rebecca Foster	ICH Good Clinical Practice (GCP) (13/08/2003 - 13/08/2003) BODMA NCRN Conference (08/09/2003 - 09/09/2003)

	<i>Advanced GCP & EU Directive (05/02/2004)</i>
Janet Hale	Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Fiona Halstead	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Sr Denise Hancock	BODMA NCRN Conference (08/09/2003 - 09/09/2003)
Aidan Henry	Advanced ICH GCP (29/10/2003 - 29/10/2003)
Stephanie Hession	<i>ICH GCP (13/08/2003)</i> Intro to GCP and EU Directive (27/01/2004 - 27/01/2004)
Jane Hughes	BODMA NCRN Conference (08/09/2003 - 09/09/2003) ICH Good Clinical Practice (22/01/03) Cancer Policy and Politics (04/03.02) Advanced ICH GCP (29/10/2003 - 29/10/2003) Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003) Leo Training Course (20/04/04)
Ms Alison Jenkins	Advanced ICH GCP (29/10/2003 - 29/10/2003)
Anne Kay	Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003)
Jan Lloyd	ICH- GCP and EU Directive (19/05/04) Effective Minute taking 23/09/03)
Leigh Oates	Introduction to Cancer (27/02/03) Remarc – Dreamweaver MX Advanced (18/06/03) BSc (Hons) Business Information Technology (01/10/03)
Mrs Sarah Pashley	ICH Good Clinical Practice (GCP) (13/08/2003 - 13/08/2003) Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Maggie Peat	ICHGCP Paediatrics (07/10/2003 - 07/10/2003) Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003)
Suzanne Rogerson	ICH Good Clinical Practice (GCP) (11/12/2003 - 11/12/2003)
Wendy Roworth	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Research Methodology (23/10/2003 - 23/10/2003) Advanced ICH GCP (29/10/2003 - 29/10/2003) Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003)
Dr Matt Seymour	National Briefing (23/10/2003 - 23/10/2003)
Alison Shaw	Advanced ICH GCP (29/10/2003 - 29/10/2003)
Carol Sleigh	Research Methodology (22/07/2003 - 22/07/2003) ICH Good Clinical Practice (GCP) (13/08/2003 - 13/08/2003) BODMA NCRN Conference (08/09/2003 - 09/09/2003) Poster Exhibition (08/09/2003 - 08/09/2003) Advanced ICH GCP (29/10/2003 - 29/10/2003) Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003) Cancer Policy and Politics (Module 1 04/03/03) Cancer Clinical Trial Introduction Course (22/07/03) LEO Training Programme (20/04/04) Dialogue Data Star (18/3/04)
Carol Sleigh (Continued)	
Joanne Sugden	ICH Good Clinical Practice (GCP) (11/12/2003 - 11/12/2003)
Michelle Tetlow	Research Methodology (23/04/2003 - 23/04/2003) ICH Good Clinical Practice (GCP) (14/05/2003 - 14/05/2003) Advanced ICH GCP (29/10/2003 - 29/10/2003)
Ruth Thorpe	Advanced GCP and EU Directive (15/01/2004 - 15/01/2004)
Fiona Timbs	ICH Good Clinical Practice (GCP) (13/08/2003 - 13/08/2003)

Appendix 2a

	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Marion Webb	NCRN BODMA interest in (08/09/2003 - 08/09/2003)
Rachel Wharam	<i>Research Methodology & Terminology (19/01/2004)</i> Intro to GCP and EU Directive (27/01/2004 - 27/01/2004)
Marie Wild	<i>Cancer Policy & Politics (02/12/2003)</i> Advanced GCP and EU Directive (05/02/2004 - 05/02/2004)
Helen Wright	BODMA NCRN Conference (08/09/2003 - 09/09/2003) Advanced ICH GCP (29/10/2003 - 29/10/2003)
Nancy Wright	Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003)
Helen Wright	Developing Practice Based on Users Experiences (20/11/2003 - 20/11/2003)

Teresa Fellows Feedback Analysis

Course: ICH-GCP and the EU Directive.

Dates: 19-05-04 & 26-05-04

Number returned: 40

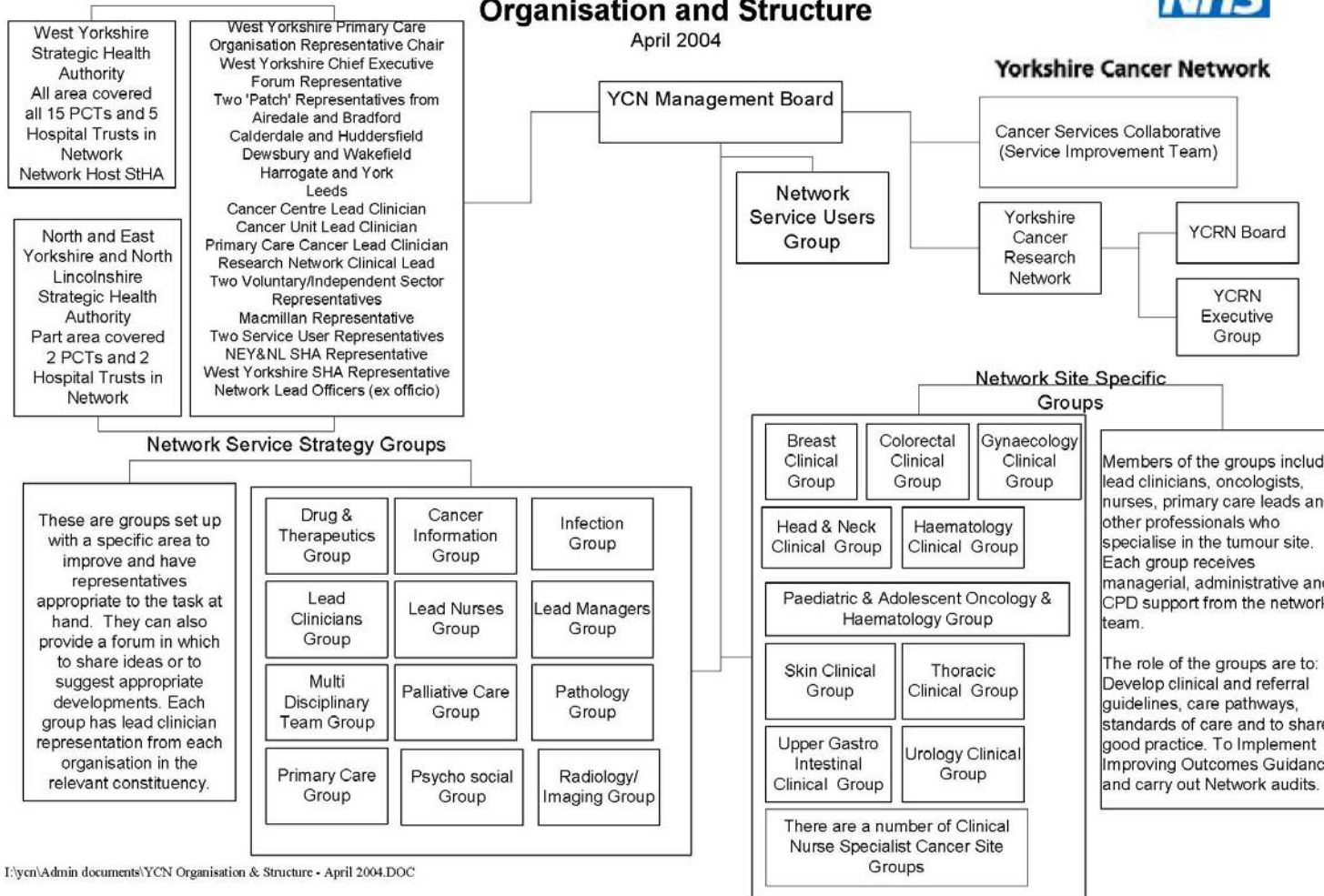
<i>Question</i>	<i>% Yes</i>	<i>% No</i>	<i>Comments made</i>
Were your personal objectives met?	98	2	<ul style="list-style-type: none"> -I felt I was obligated to come. -Mainly wanted info on EU directive. -Some not really relevant to me, consent etc, but very useful to get the whole picture. -Some aspects were good but I suspect this is not training. -Case studies would have been good. -Good but would have responded better to an 'on-your-side' approach.
Was anything missing from the course?	14	86	<ul style="list-style-type: none"> -As a pharmacist the most important areas for me were the EU directive rather than the rest. Nothing I noticed! -Too many abbreviations- needed full names more often. -As a pharmacist a bit more specific about labelling and packaging would have been helpful. -More floor participation. -I wouldn't know if there was! -Time was needed for more experience to be gained. -How can we proceed in the context of a busy practice? -Lots of abbreviations in written papers. -Perhaps a little more emphasis on the research management approval process as this is often forgotten. -Minor point; work with R and D departments to determine process e.g. some need COREC part D others not.
Would you recommend this course to others	96	4	<ul style="list-style-type: none"> -Key points summarised very well. -Improved clarity on the area. -To those involved in clinical trials. -Maybe a little less material; possibly remove data protection

<p>Overall course score (1=poor, 5=excellent)</p>	<p>1=7% 2=2% 3=4% 4=44% 5=39%</p> <p>No response=4%</p>	<ul style="list-style-type: none"> -This is a dry subject that was very well delivered. -Went through things a little too quickly but I still kept up! -Kept me interested. -Went through things very quickly but clear and not too difficult to keep up. -Could benefit from more focussing on target audience, e.g. cancer research here. -Fair. -Pace was very fast and I am a good listener having sat through thousands of lectures. Vast amount of material. -Need more specific approach to academic, non-drug company research. -Very long! -Not sure the consent issues were clear. -Informative and enjoyable
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Organisation and Structure

April 2004



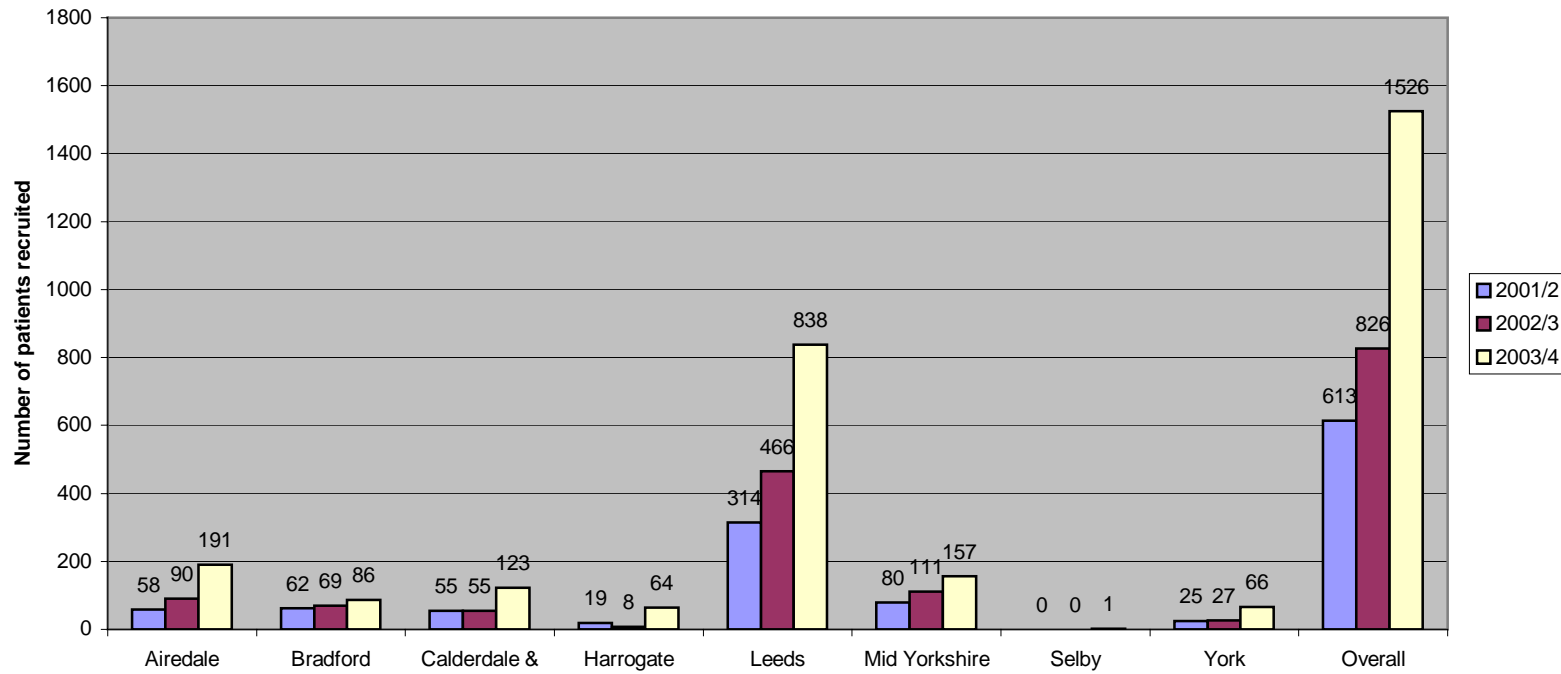
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2. Accrual

2.1 Overall Accrual into NCRN Portfolio Studies

	Airedale	Bradford	Calderdale & Huddersfield	Harrogate	Leeds	Mid Yorkshire	Selby	York	Overall
2001/2	58	62	55	19	314	80	0	25	613
2002/3	90	69	55	8	466	111	0	27	826
2003/4	191	86	123	64	838	157	1	66	1526

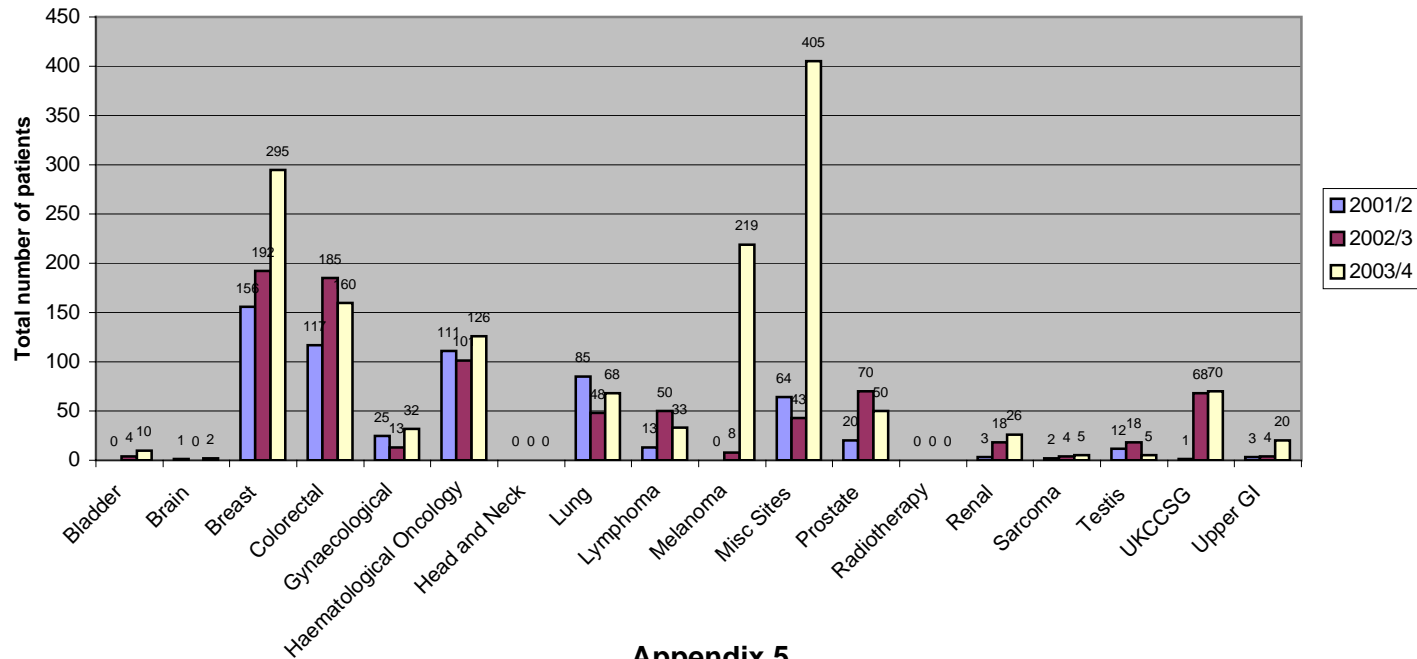
Annual Accrual
for Yorkshire Cancer Research Network (by Trust)



2.2 Accrual by cancer site into NCRN Portfolio studies

	Bladder	Brain	Breast	Colorectal	Gynaecological	Haematological Oncology	Head and Neck	Lung	Lymphoma	Melanoma	Misc Sites	Prostate	Radiotherapy	Renal	Sarcoma	Testis	UKCCSG	Upper GI
2001/2	0	1	156	117	25	111	0	85	13	0	64	20	0	3	2	12	1	3
2002/3	4	0	192	185	13	101	0	48	50	8	43	70	0	18	4	18	68	4
2003/4	10	2	295	160	32	126	0	68	33	219	405	50	0	26	5	5	70	20

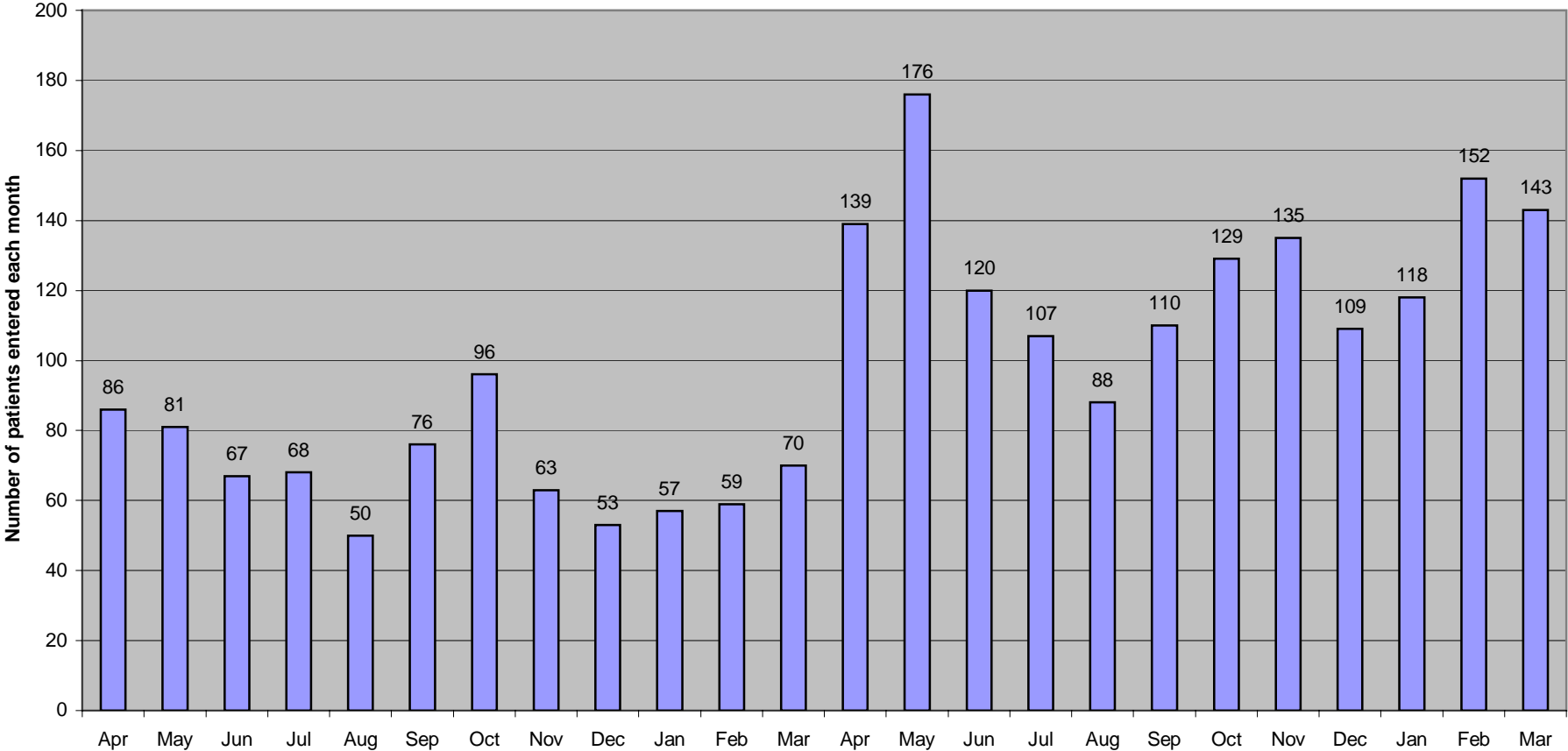
Annual Accrual by Cancer Site for Yorkshire Cancer Research Network



2.3 Monthly Accrual into NCRN Portfolio studies for the Network

Year	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	86	81	67	68	50	76	96	63	53	57	59	70
2003/4	139	176	120	107	88	110	129	135	109	118	152	143

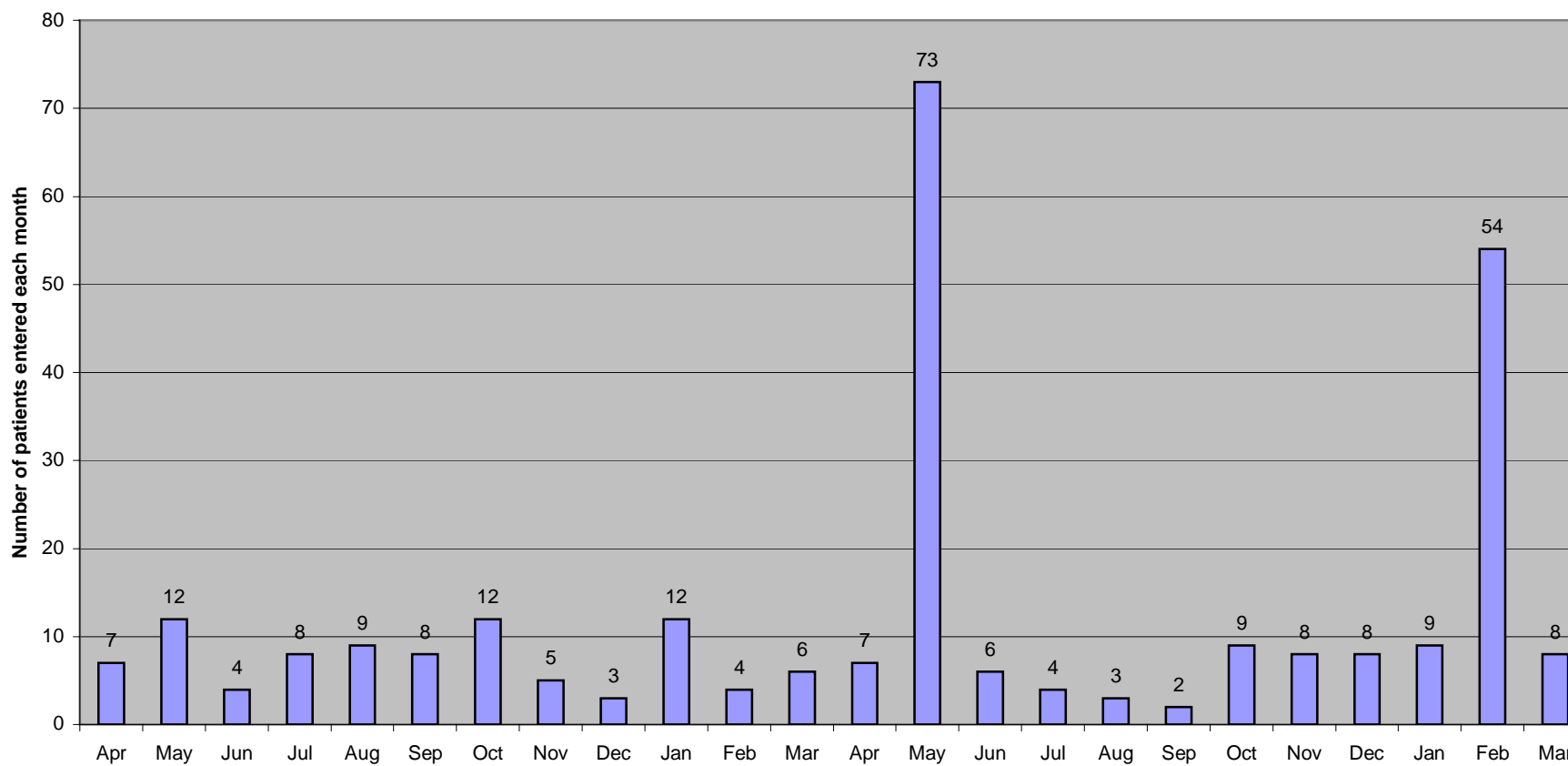
Monthly Accrual for Yorkshire Cancer Research Network (Years 2 and 3)



2.4 Monthly Accrual into NCRN Portfolio studies by Hospital

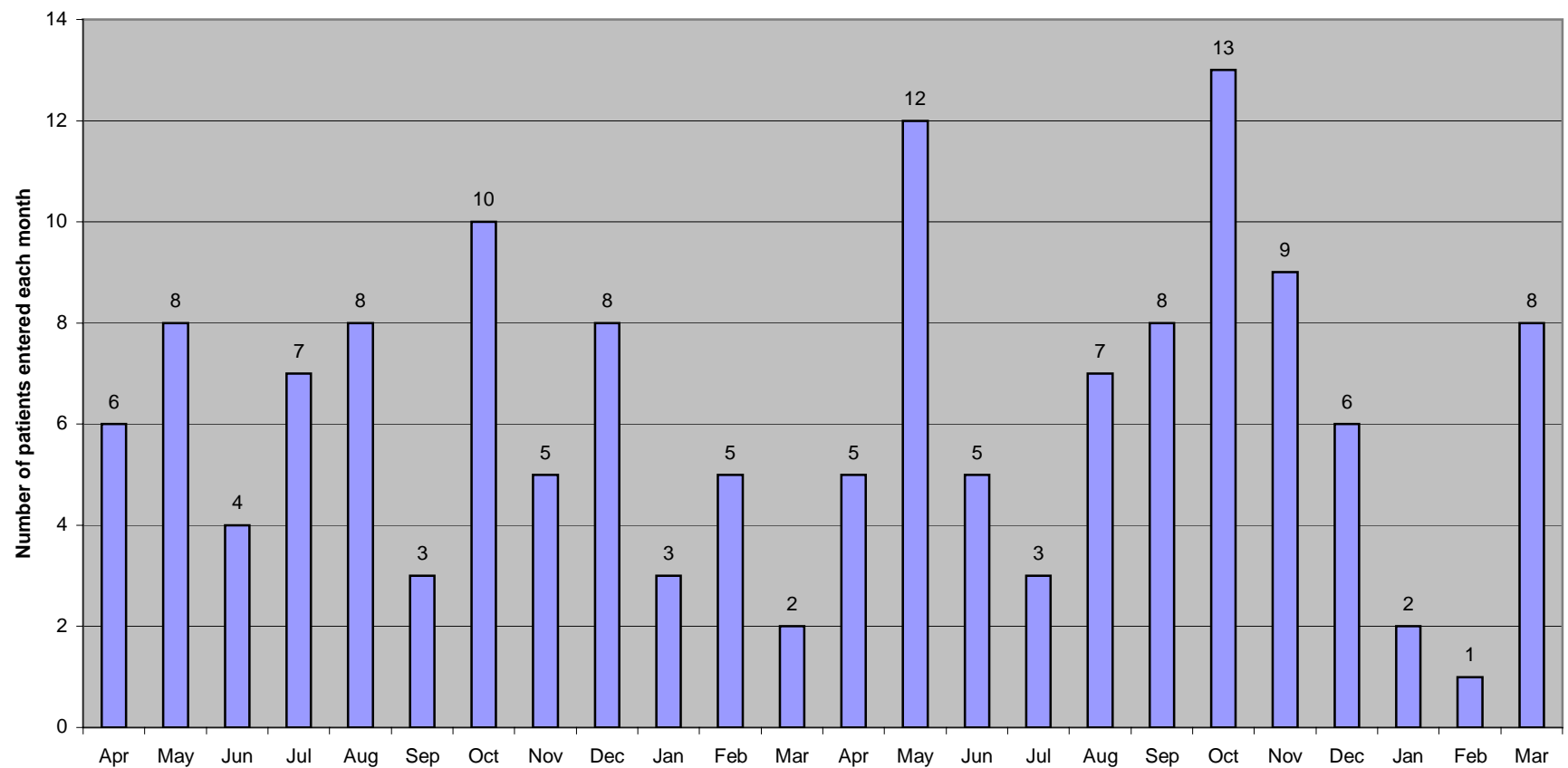
Airedale General Hospital	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	7	12	4	8	9	8	12	5	3	12	4	6
2003/4	7	73	6	4	3	2	9	8	8	9	54	8

Monthly Accrual for Airedale Hospital NHS Trust (Years 2 and 3)



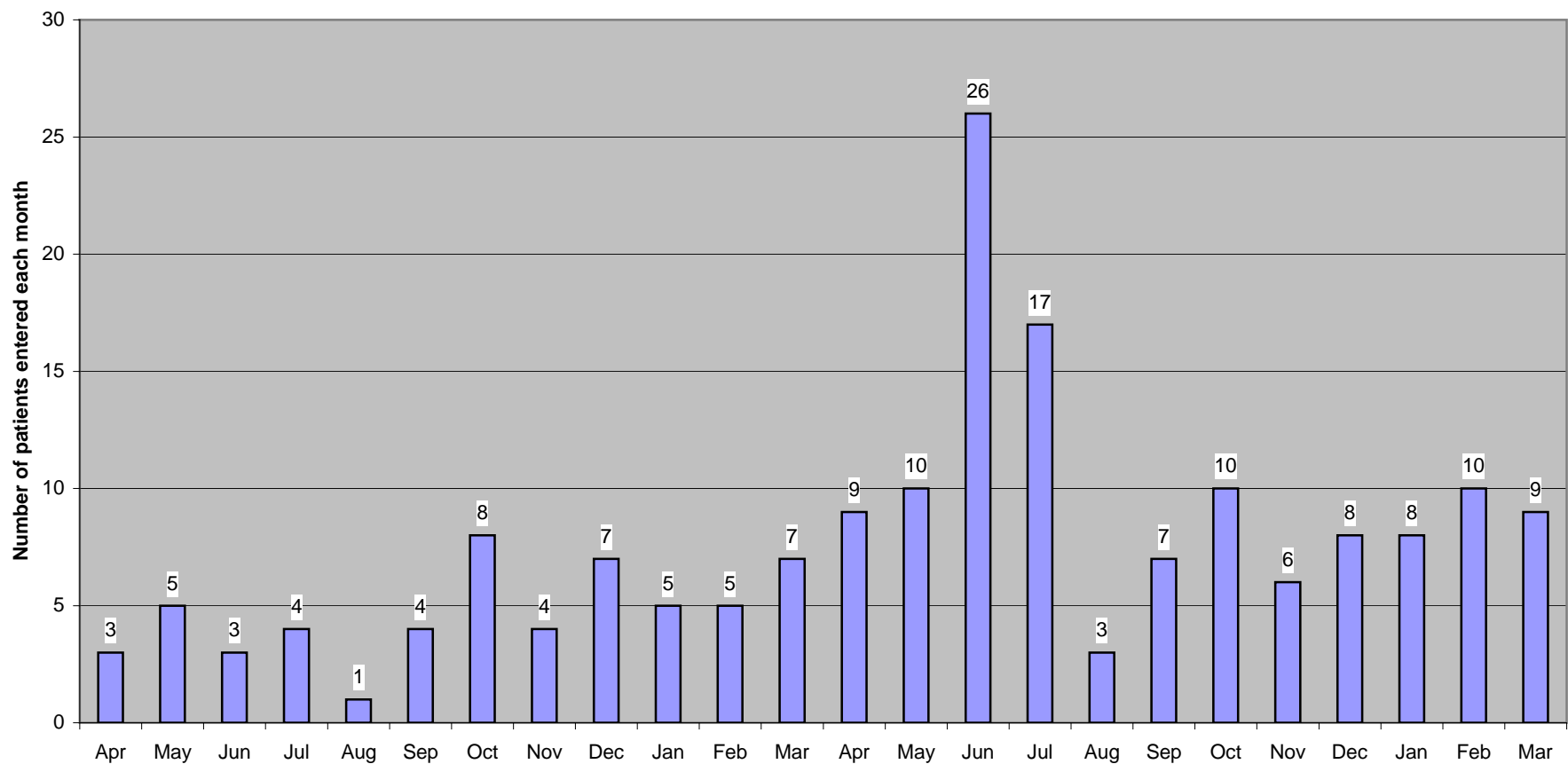
Bradford Hospitals NHS Trust	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	6	8	4	7	8	3	10	5	8	3	5	2
2003/4	5	12	5	3	7	8	13	9	6	2	1	8

Monthly Accrual for Bradford Hospitals NHS Trust (Years 2 and 3)



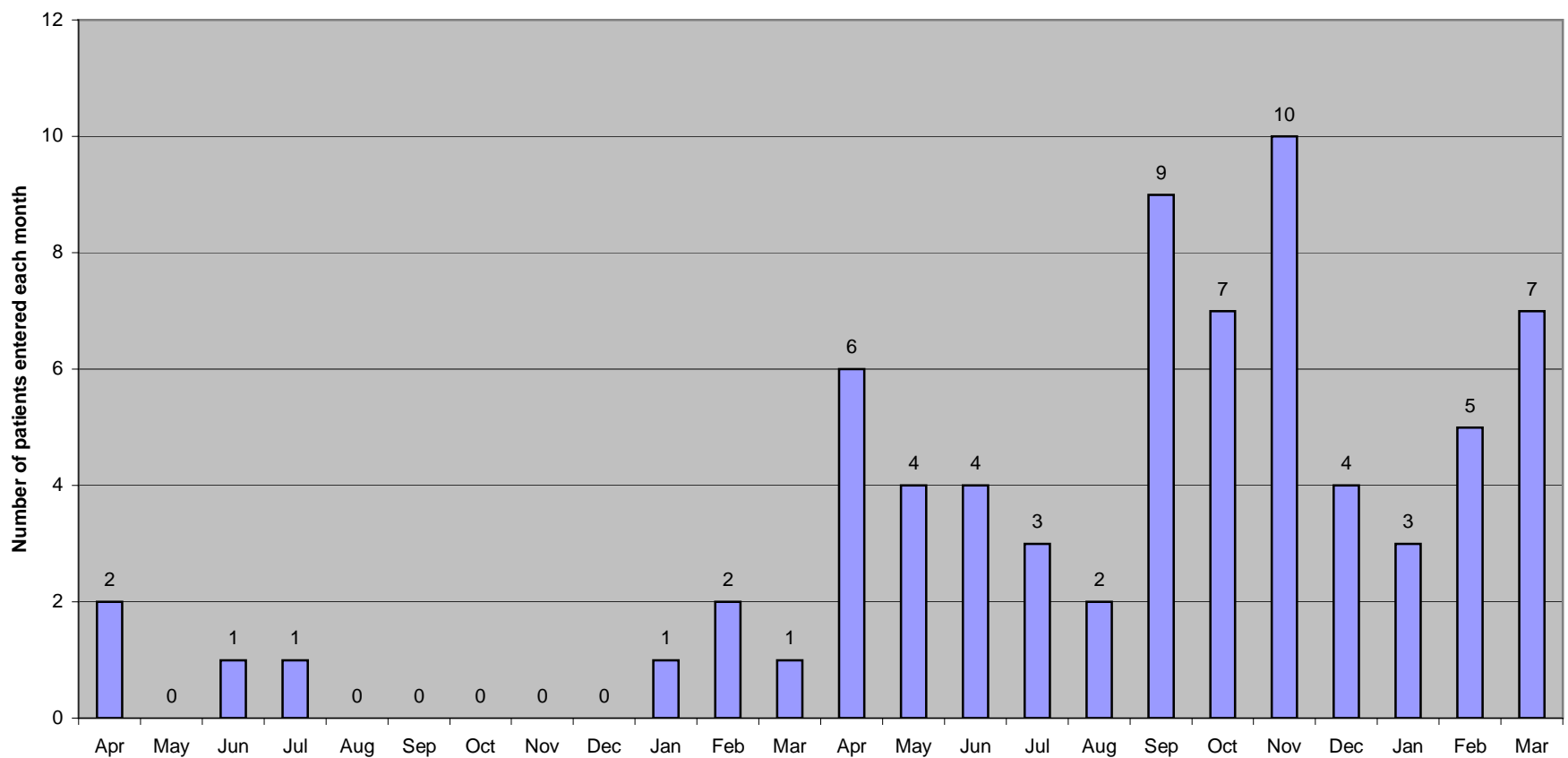
Calderdale & Huddersfield	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	3	5	3	4	1	4	8	4	7	5	5	7
2003/4	9	10	26	17	3	7	10	6	8	8	10	9

Monthly Accrual for Calderdale & Huddersfield NHS Trust (Years 2 and 3)



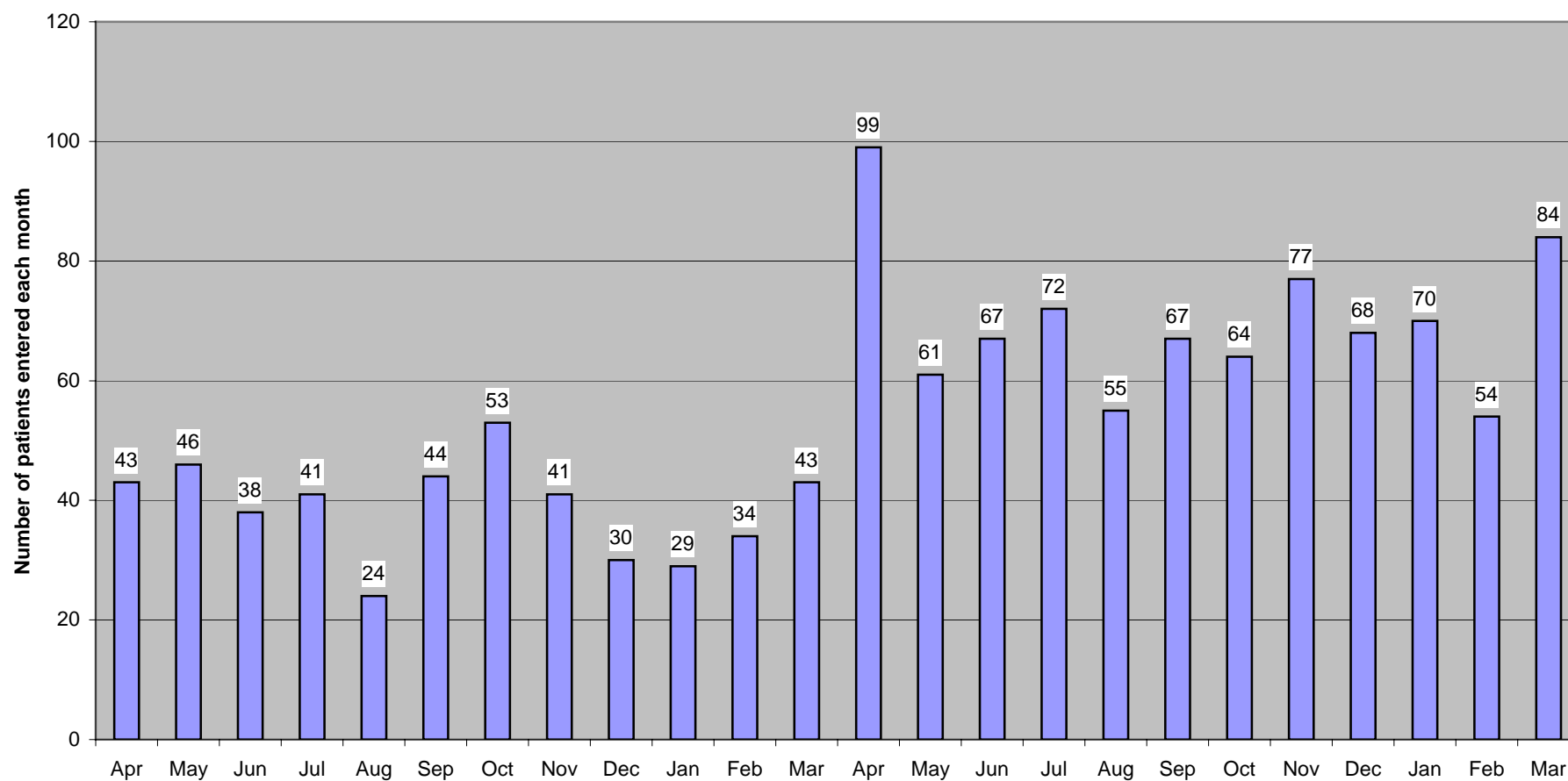
Harrogate District Hospital	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	2	0	1	1	0	0	0	0	0	1	2	1
2003/4	6	4	4	3	2	9	7	10	4	3	5	7

Monthly Accrual for Harrogate Health Care NHS Trust (Years 2 and 3)



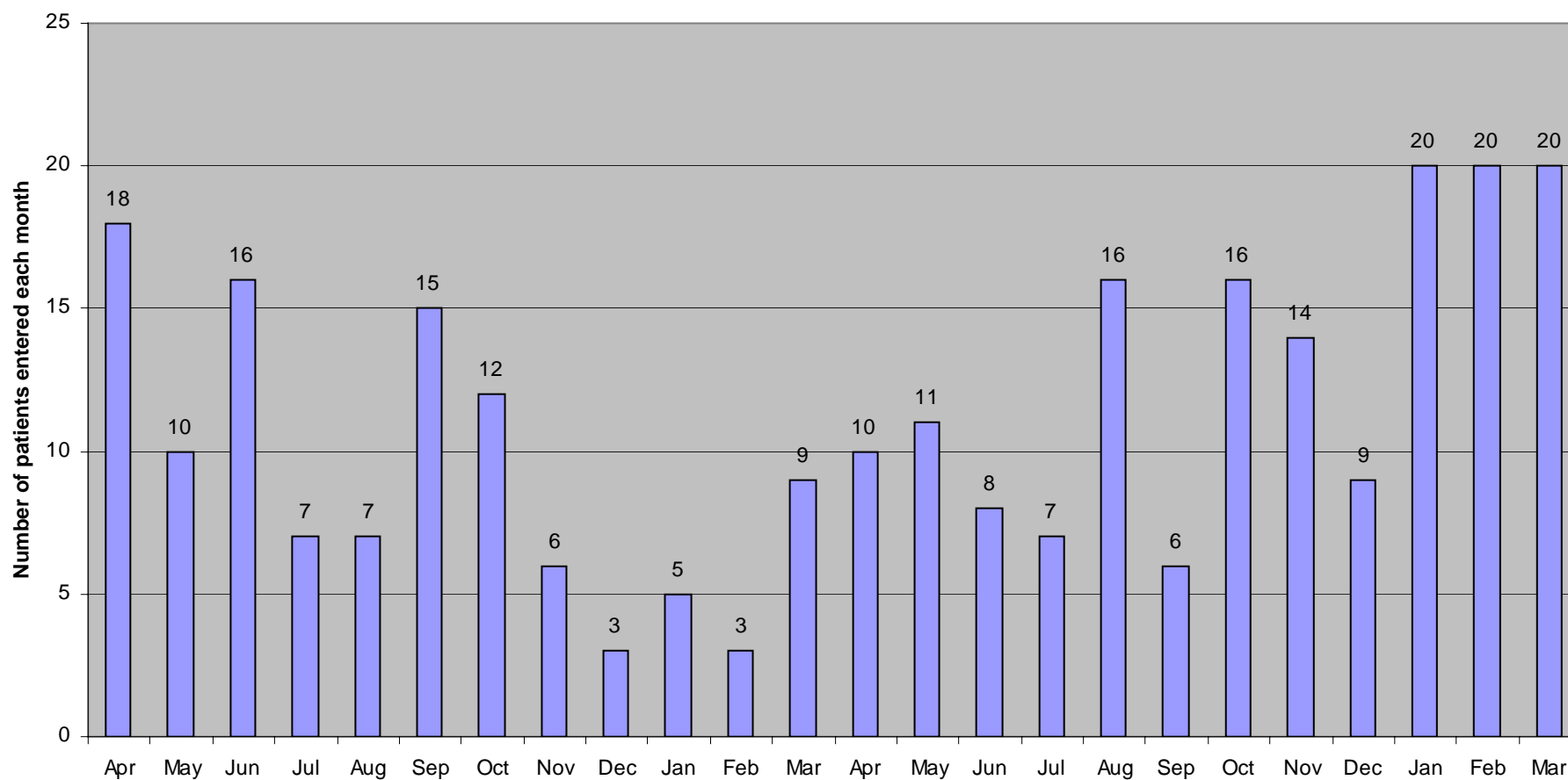
Leeds	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	43	46	38	41	24	44	53	41	30	29	34	43
2003/4	99	61	67	72	55	67	64	77	68	70	54	84

Monthly Accrual for Leeds Teaching Hospitals NHS Trust (Years 2 and 3)



Mid Yorkshire	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	18	10	16	7	7	15	12	6	3	5	3	9
2003/4	10	11	8	7	16	6	16	14	9	20	20	20

Monthly Accrual for Mid Yorkshire NHS Trust (Years 2 and 3)



York District Hospital	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
2002/3	7	1	1	0	1	2	1	2	2	2	6	2
2003/4	3	3	4	1	1	11	8	9	6	6	7	7

Monthly Accrual for York District Hospital (Years 2 and 3)

