THE NBOCAP BOWEL CANCER PROSPECTUS

Proposal for ensuring that outcomes data are available so that patients can be informed about risk

Background

The primary aim of the national audit of bowel cancer is to ensure the highest standards of care for all patients treated for this condition.

NBOCAP is a unique opportunity to develop a high quality clinical database, which will provide a model that allows risk-estimation for individual patients, and a risk-adjusted comparison of hospitals with a group mean. The benefit of audit is mainly achieved by clinicians being aware of the quality of care they provide compared with nationally established standards. This will encourage self-regulation and development by each centre of strategies to improve their own outcomes, regardless of their position in relation to the national standards. We firmly believe that this will occur in the majority of centres without the need for external intervention.

Accurate information, based on local data, provides the basis for clinicians to discuss the benefits and risks of treatment with individual patients so that informed clinical decisions can be made i.e. truly informed patient consent.

A national audit in the future would also mean that patients could be confident that the centre in which they were being treated was comparing its outcomes with the average of other centres, that it was subject to external reviews, and that its clinical outcomes fell within safe limits. Units providing care, falling outside nationally agreed standards, would be identified and appropriate measures taken to address the problem.

These benefits can only be achieved if the data collected is complete, accurate and risk-adjusted, and that conclusions are drawn only after careful statistical analysis.

Data available to patients must be statistically analysed and presented in a way that is clear and understandable to avoid the danger of over simplistic comparisons which may

cause unnecessary worry to patients and do more harm than good. It is also unfair and demoralising for clinical units to be incorrectly labelled, when this is largely due to differences in case-mix. If this is allowed to happen, there will be perverse incentives for the collection of inaccurate data, which may provide the basis for setting falsely-high, unachievable standards from which poor clinical decisions may be made.

For these reasons we believe that the results of the audit project should remain confidential until the data is sufficiently robust so that both the profession and patients can be fully confident of the analysis.

This may be achieved in 2006, by which time it will be necessary to devise means by which information may be released to the general public in a clear and unambiguous format.

Proposed future strategy for making data from the ACPGBI national audit available to the general public

Stage 1: The Audit

Audit will occur on a yearly basis from April 1st to March 31st. It is estimated that processing the data will take between 6 and 12 months which means that the data will not be available for feedback to local clinicians for at least a year after the end of the period of collection. We hope this will be improved as the audit becomes web-based.

At the end of the year, after appropriate professional statistical advice, the NBOCAP Committee, together with the Public and Patients Sub-Committee, will discuss the results. Clinical units (not individual surgeons) that lie outside an established standard of a surrogate marker of the quality of care, for example, postoperative mortality, will be identified. As the audit matures, it is hoped that other surrogate markers of high quality of care such as colostomy rates, anastomotic leak rates, local recurrence from rectal cancer and 5-year survival will also be measured.

It will be necessary to establish thresholds of care that will trigger the need for clinical units to carry out a formal enquiry. It is expected that all units, when they know their results,

regardless of their status in relation to the national mean, will want to conduct in-house reviews to improve the standard of the care they provide. However, units falling outside the nationally defined threshold will be subject to a more formal process.

It has been suggested that the threshold, for the risk-adjusted, postoperative, mortality rate, requiring formal review, should be two standard deviations from that of the national average. Therefore, if the risk-adjusted postoperative mortality rate for elective colon cancer were 4%, the mechanism for triggering external review would be 8%.

This is an arbitrary decision and is for discussion, but some threshold for triggering an external review needs to be established for each of the surrogate markers of quality of care.

Stage 2: Check on the accuracy of the data by the local unit

The process of collecting audit data is subject to potentially serious errors. It is crucially important therefore that, once a clinical unit has been identified and informed through their lead clinician as falling outside the established threshold, that the unit is given time to check the results and for these to be re-analysed. The letter informing the unit of their outlying status will include a strong recommendation that they should share this information with their Chief Executive, who will be reassured that they are checking the accuracy of their data before concluding that they are truly outside the previously-established standard. It is suggested that this should be done within a one-month period, and this is also for discussion.

Stage 3: Local review of cause of outlier status

If, after a month, it is established that the data submitted, which has determined their outlying status, is complete and accurate, then a review of all the postoperative deaths in that year should be made, to determine the cause for each death, and whether this might have been avoided by for example, better selection, pre-operative preparation, a different surgical technique or better postoperative care in a High Dependency Unit or Intensive Care Unit. If a cause can be identified, this needs to be officially discussed with the Chief Executive and the unit's local Clinical Governance Committee.

Stage 4: Plan to correct deficiencies causing the unit to be outside the established standard

After the identification of the deficiencies causing the informal review have been identified, plans will be made to correct the deficiency and the results carefully monitored, over the next year, to establish movement to within the threshold standard.

If a centre identified in stage 3 shows that the submitted data has been inaccurate, this will be re-checked by NBOCAP and, if the unit's outcomes now come below the threshold triggering a formal review, the unit will be monitored for a further year to establish that their results continue to be below the threshold for a formal review.

Stage 5: Data available to general public on a need-to-know basis

Once the outlying unit's data has been confirmed as accurate, then the data from the year's national audit will be made available to the general public in an anonymous form on the NBOCAP website together with links to the Healthcare Commission and the National Health Service Information Authority.

It will be clear that certain treatment units lie outside an established national standard, and the website will make it clear that it is possible for patients and GPs to find out their own centre's results by contacting their local Trust through the Chief Executive and the Clinical Audit Committee.

This means that information about an individual unit's outcomes will be available to patients and GPs on a need-to-know basis. Outlying units should be able to tell patients and GPs that problem areas have been identified and corrected so that their results will move back within acceptable limits.

If outside bodies wish to collect data from all units and create League Tables and star rating of individual units, this will be possible. However NBOCAP, supported by the Healthcare Commission and the National Health Service Information Authority, should formally discourage this activity, as this is likely to do more harm than good.

Summary

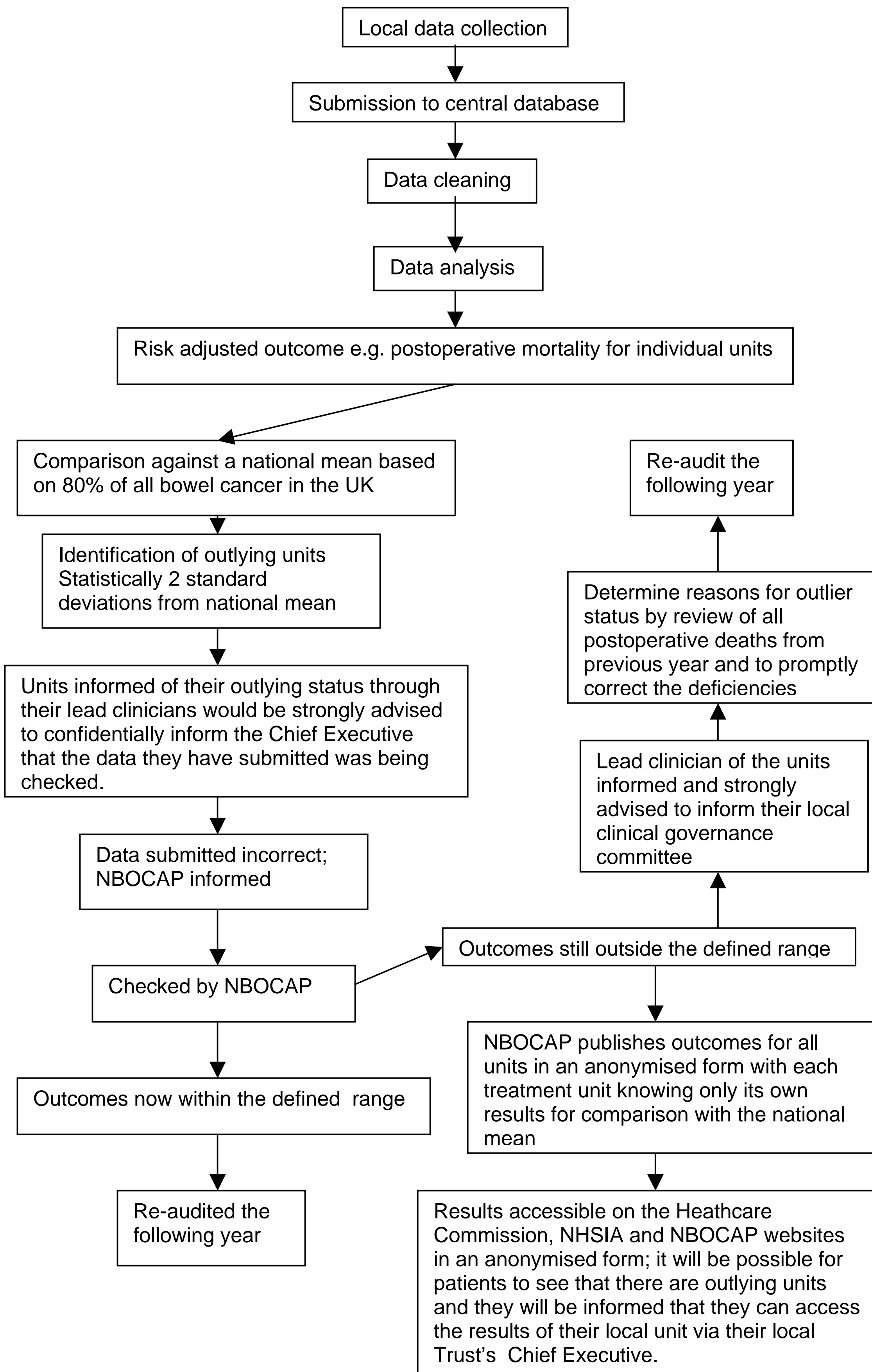
It was agreed that anonymised results of the NBOCAP should be published soon after it is established that the data submitted by outlying units was a true reflection of the quality of care that they were providing.

At this time, the information would be in the public domain with access to individual unit's status through Trust Chief Executives and Clinical Governance Committees.

Patients, who may only be able to get treatment from their local centre, could be reassured that the unit providing their care fell within the nationally established standard or, if not, that appropriate measures had been taken to ensure that their local unit would achieve the desired standards in the future.

It is felt that this algorithm of dealing with the data should not be susceptible to legal challenges, and this is being checked both by NHSIA and the Patient and Public Committee of NBOCAP. It is important that the release of information about the outlying status of individual units by NBOCAP should not be vulnerable to legal challenges. This will be achieved by NBOCAP maintaining confidentiality of the data so that outlier status of any individual units identified by NBOCAP will only be revealed directly to the individual units and the responsibility for correcting any deficiencies in the quality of care provided by the unit will be entirely the responsibility of the individual unit, the Local Clinical Governance Committee and the Chief Executive. NBOCAP's role in the national audit of bowel cancer will be entirely as a facilitator to enable individual clinical units to know their clinical risk-adjusted outcomes for comparison with national standards. It is firmly believed that this will encourage self-regulation and enhance the quality of care for all treatment units, regardless of their relationship to the national standards.

Algorithm of national audit of bowel cancer (NBOCAP)



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