

1 STUDY PROTOCOL

Recommendations

Revise NCEPOD classification to include more specific definitions and guidelines, which are relevant across surgical specialities (NCEPOD responsibility).

Provide adequate information systems to record and review anaesthetic and surgical activity.

Ensure the correct ASA status is collected as it is an essential part of the patient assessment and record keeping.

Ensure that the information about hospital facilities is accurate in order to ensure that acute services are efficiently and safely managed.

INTRODUCTION

NCEPOD collected data on 72,343 surgical procedures performed in March and April 2002 and collected from 557 hospitals.

The study protocol was based on the first 'Who Operates When?' (WOW I) study undertaken in 1995/6 [3], which looked at the pattern of surgical activity during a randomised series of 24 hour periods which added up to one week's work for each participating hospital. In this first study, just over 53,000 cases were examined and over 5,000 cases performed out of hours were followed up in more detail.

Slight amendments were made to the method of data collection for this study. In particular, data was collected over a seven day period between 6th March and 16th April 2002. A week was randomly allocated to each participating hospital 3 weeks prior to the start of data collection, when they were sent all the necessary information to complete the exercise.

This was to ensure that data not routinely recorded could be collected specifically for the study and also to prevent any changes to the organisation of the theatre rota for that week.

In both studies, data were collected retrospectively via a self-completed questionnaire. For 'Who Operates When? II' (WOW II), the original data collection form was revised and additional fields e.g. 'ASA status' and 'specialty of consultant surgeon' were included (Appendix D).

DATA COLLECTION

In September 2001, chief executives of all relevant hospitals in England, Wales, Northern Ireland, the Isle of Man, Guernsey, Jersey, the Ministry of Defence and the independent sector were asked to identify a person to provide data on surgical procedures to NCEPOD. A letter was sent to Independent Hospitals asking them if they wished to participate.

Chief executives and local reporters of participating hospitals were given the opportunity to provide feedback on the proposed method and the draft questionnaire.

Each participating hospital was randomly assigned a seven day period within March or April 2002 during which to complete questionnaires on all surgical procedures. Data collection was planned to avoid public holidays.

NCEPOD informed the study contact of the relevant week, three weeks in advance of the date. If the contact was unavailable (e.g. on annual leave) they were asked to ensure that there was a replacement contact identified to NCEPOD. The study contact was sent a pack including questionnaires, notes about completion of the questionnaire, and definitions of terms used.

During the designated seven day period, surgeons, gynaecologists and dental surgeons were asked to complete a questionnaire for every theatre case or operative procedure performed within an operating theatre. Specific exclusions included procedures carried out in dental treatment rooms, X-ray rooms, obstetric delivery rooms or theatres, endoscopy rooms and A & E treatment rooms.

Out of hours cases

On receipt of the data, all procedures for which the 'start time of anaesthesia', or the 'start time of surgery', was between 18:00 and 07:59 on weekdays and all day on weekends were designated as 'out of hours' by NCEPOD. These were the time slots that had been designated 'out of hours' in WOW I and therefore for comparative purposes it was important to keep to these time slots. For each of these procedures, an out of hours questionnaire (Appendix D) was sent to the surgeon and anaesthetist involved in the procedure asking them to confirm or amend the starting time, and to state why the procedure was performed at that time.

General data questionnaire

An additional questionnaire requesting information about the facilities and organisational aspects of operating (Appendix D) was sent to the study contact for each participating hospital. They were asked to forward this questionnaire to an appropriate person for completion.

REPORTING

Hospitals were given the choice of returning the data on the questionnaires provided, or electronically using an Excel spreadsheet. Approximately 34% of the cases were submitted electronically.

Letters were sent to medical directors and study contacts two months after data collection reminding them that all outstanding data should be submitted.

All data from the completed questionnaires were input using scanning software. Following data quality checks, the data were imported into an Access database.

Unlike WOW I, OPCS codes were not allocated to each individual procedure as this was felt to be too time consuming and unnecessary for the data analysis. Where individual procedures/diagnoses have been identified for analysis, searching the text fields for relevant keywords has identified these.

DATA QUALITY AND VALIDATION

To ensure the completeness and quality of the data submitted to NCEPOD, a series of data quality and validation exercises were undertaken. NCEPOD staff liaised with the study contacts about omissions or queries in the data. Questionnaires with key fields missing were referred back to the clinician completing the questionnaire with a request that the information be provided. Furthermore, data validation checks were performed once the data had been imported into the database.

Poorly completed fields

The ASA status was missing in 33% of cases and the ASA was incorrectly assigned in a number of cases.

Certain fields on the questionnaires were particularly poorly completed despite detailed definitions being provided (Appendix D). The ASA status of the patient was missing in 33% of all questionnaires returned. Furthermore, we are concerned over the inappropriate assignment of ASA status. 35 cases were reportedly ASA 6 which designates 'a declared brain-dead patient whose organs are being removed for donor purposes', however on detailed investigation only four procedures warranted this status.

Grade of senior anaesthetist and specialty of consultant surgeon in charge were also poorly completed (11% and 13% missing respectively).

NCEPOD classification of operations

NCEPOD classifications are not being consistently recorded.

Inconsistencies were also identified in how hospitals assign NCEPOD classifications (emergency, urgent, scheduled, elective). For example, three apparently similar cases of forearm fractures in eight year-olds were classified as emergency, urgent and scheduled.

NCEPOD therefore undertook a small qualitative investigation via telephone interview of 15 hospitals,

in conjunction with the Audit Commission, in order to determine how classifications of urgency of operations were assigned for the WOW II study.

Our findings suggest that discrepancies exist in how NCEPOD classifications are assigned between specialties and hospitals. Many use a different means of classifying urgency e.g. urgent and routine or emergency and elective.

Although most hospitals that were contacted felt that it would be beneficial to use NCEPOD classifications, most had no procedures in place for classifying and recording urgency and timing of operations, and no monitoring systems in place to determine why and when operations were done at inappropriate times. Two hospitals that were contacted did however indicate that the introduction of NCEPOD classifications had reduced the incidence of operations at inappropriate times.

Interviewees expressed a need for definitive guidelines on assigning NCEPOD classification of operations, particularly with regard to appropriate times for operations and clear definitions of emergency and urgent.

Validation of general data questionnaire

In order to attempt to validate the data returned regarding hospital facilities, the NCEPOD clinical co-ordinators visited 27 hospitals, selected at random. We are grateful to all the staff who took time out of their busy programmes to meet the clinical co-ordinators and show them round their hospital facilities.

Twelve data fields were reviewed, to assess the accuracy of data returns.

In most fields, data returns were judged to be accurate. However, in certain fields the data was inaccurate, or had been missing in the original return, but was easily identifiable by the clinical co-ordinators (Table 1.1).

Table 1.1		Results of validation of general data questionnaire		
Question	Correct	Incorrect	Not recorded	
Number of surgical theatres (excluding maternity)	13	8	6	
Daytime trauma sessions available and staffed	20	1	6	
How many trauma session per week?	10	7	7	
Daytime emergency sessions available and staffed	21	0	6	
How many emergency sessions per week?	6	10	7	
Is the recovery area available & staffed 24 hrs/day all week?	16	5	6	
If 'no' to above, who would normally recover patients out of hours?	6	0	6	
For each recovery bed/trolley space is there a pulse oximeter?	18	2	7	
For each recovery bed/trolley space is there an ECG monitor?	17	2	8	
Is there a nominated arbitrator to decide clinical priorities?	16	4	7	
If 'yes' to above what is the person's professional background?	5	2	8	
Does the theatre IT system record grades of anaesthetists and surgeons present?	12	6	9	
Total (%) out of 290 possible correct responses	160 (55)	47 (16)	83 (29)	

Number of theatres

The greatest discrepancy was from a hospital which actually had 20 theatres but had reported only 13. Many of the inaccuracies related to only one or two theatres, and there was considerable confusion about whether maternity theatres should have been included or not. Discrepancies arising from the inclusion or exclusion of maternity theatres have been treated as correct in the above table.

Daytime trauma sessions staffed

The one incorrect response to this question had indicated that there were no daytime trauma lists, however the clinical co-ordinator established that daytime trauma lists were available.

How many trauma sessions per week?

Three hospitals indicated that they had no trauma lists, and therefore no response was required from them in this field. There should therefore have been 24 correct responses.

Daytime emergency sessions staffed

The clinical co-ordinators commented that in six hospitals, the trauma and emergency lists were timetabled to be staffed by SpR or SHO surgeons and/or anaesthetists. One hospital had introduced five daytime emergency sessions since completing the WOW II return.

How many emergency sessions per week?

Four hospitals indicated that there were no daytime emergency lists, and therefore no response was required from them in this field. There should therefore have been 23 correct responses.

Two hospitals indicated that the number of weekly emergency sessions available had been reduced to accommodate waiting list pressures on elective work.

Is the recovery area available and staffed by dedicated recovery staff, 24 hours a day, 7 days a week?

There were 12 hospitals which either answered 'no' or did not have staffed recovery available 24 hours/day.

For each bed/trolley space is there a pulse oximeter? For each bed/trolley space is there an ECG monitor?

Two hospitals used systems which allowed continuous monitoring including the transfer from theatre to recovery. Three hospitals indicated that there were several different types of equipment in use, which meant that BP cuffs, ECG and pulse oximeter leads were incompatible between monitors in theatre and recovery. It was stated in one hospital that the reason for this was failure by managers to take account of clinical advice about compatibility in favour of cost constraints, during the procurement process. One unit had recently upgraded its recovery monitoring equipment, but the opportunity to incorporate facilities to print off continuous monitoring had been lost, because of a lack of modest funding.

Is there a nominated arbitrator to decide clinical priorities? If 'yes', what is that person's background?

There were only 15 hospitals which indicated that they had an arbitrator. There should therefore be 15 correct responses.

Does the information acquired by the operating theatres about the case also record the grades of all anaesthetists and surgeons present?

Several systems recorded the names of surgeons and anaesthetists, but did not have the facility to record their grades. In some cases, it was possible to link back to a clinician's profile in order to establish the grade of clinician.

Implications for theatre management of incorrect facility information

The data validation exercise for the hospital facility questionnaire demonstrates serious weaknesses in the ability of hospitals to provide fairly simple levels of information about their surgical services.

It is particularly worrying that information, requested from medical directors is inaccurate with regard to basic information such as the number of operating theatres within a hospital.

This begs the question, how can managers plan and deliver an efficient acute surgical service, if they are unaware of the physical resources such as operating theatres, which are available to them?

This exercise also demonstrated a number of other weaknesses, particularly in relation to the incompatibility of monitoring equipment between theatres and recovery. This could significantly degrade the efficiency and safety of patient monitoring between theatres and recovery.

There are inaccuracies in reporting the number of trauma and emergency lists available. Clinical co-ordinators were told that in a number of cases these lists are timetabled to be staffed by unsupervised trainees; this is unacceptable practice.

DATA ANALYSIS

The data were aggregated and anonymised so that individual patients, hospitals and clinicians could not be identified.

Advisory groups

An expert group of advisors was invited to take part in two multidisciplinary advisory groups, where the aggregated data was presented for discussion. The advisors were selected from nominations provided by professional bodies and included surgeons, anaesthetists, nurses, theatre managers and senior hospital management.

The NCEPOD clinical co-ordinators, who directed the discussion around key issues surrounding the data, chaired these meetings. The objective of this expert group was to review the data, identify areas of suboptimal care and provide an overall assessment of the quality of care.

NCEPOD is extremely grateful to the advisors who attended meetings and who provided valuable advice and commentary on the data.

PARTICIPATION

Data were received from 557 hospitals. 205 NHS Trusts, representing 448 NHS hospitals, and 109 independent hospitals submitted data (Table 1.2). Non-participating NHS hospitals are those that are known to have surgical activity and therefore should have responded. The non-participating independent hospitals are those that subscribe to the Enquiry but did not return data.

	Did not participate	Participated (%)	Total
NHS hospitals	33	448 (93)	481
Independent hospitals	51	109 (63)	160
Total	84	557 (87)	641

Participation among NHS hospitals was high with 93% of all appropriate hospitals submitting data. It is not possible to make a direct comparison of the participation rate because the method of determining eligible hospitals was not reported in WOW I.

Reasons for non-participation

NHS hospitals

Of the non-participating NHS hospitals, five were minor surgical units that did not perform any operations during the study week. Other reasons cited for non-participation included administrative difficulties such as “questionnaires lost” and “local reporter unavailable”. One Trust, comprising four hospitals, stated that “we started data collection but did not submit the data because the quality of the questionnaires returned was so poor”. Despite contacting the medical directors and local reporters with information about the study several times prior to data collection, one hospital reported not knowing about the study. One Trust submitted data after the cut-off date.

Independent hospitals

One large independent group informed NCEPOD before the study started that they were not willing to participate and this accounts for the majority (38)

of non-participating hospitals in the independent sector. Other reasons included “very few procedures, therefore decline to take part”, and “no key co-ordinator available”.

Out of hours and general data questionnaire response rates

The response rate for the out of hours questionnaire was approximately 65%. This was slightly disappointing as it was felt that these questionnaires provided valuable information for validating and categorising true out of hours procedures.

71% of participating hospitals (395/557) submitted general data questionnaires. The lack of complete facility information for certain hospitals caused some difficulties when comparing surgical activity and resources.

FEEDBACK

Trusts that participated in the study were sent comparative data showing their performance against other Trusts in the same cluster (e.g. Large acute outside London, Acute specialist) [4] *vide infra* Table 2.1 in Chapter 2. Performance was analysed using three of the key performance indicators proposed by the NHS Modernisation Agency in Step Guide to Improving Operating Theatre Performance [1] and one determined by NCEPOD.

The key performance indicators used were:

- Elective theatre performance: Number of day cases as % of all operations performed.
- Emergency theatre performance: Number of emergency theatre sessions each week. (NCEPOD performance indicator).
- Emergency operations out of hours:
 - Number of operations in categories NCEPOD 2,3 & 4 between midnight and 8am.
 - Total anaesthetic plus operating time in categories NCEPOD 2,3 & 4 between midnight and 8am.

(NCEPOD 2 = Urgent, NCEPOD 3 = Scheduled, NCEPOD 4 = Elective).

This was the first time NCEPOD provided feedback to participating Trusts. The response was positive and it is hoped that this feedback process will become part of future studies where appropriate.

Further feedback on the quality of data submitted by each hospital will be sent to medical directors at the time of publication of the report.

OVERVIEW OF DATA

The total number of operations reported to NCEPOD for this study was 72,831 of which 488 were excluded as they did not fall within the sampling frame e.g. obstetric cases. Therefore, the total number of cases on which this study is based is 72,343, with just over 13% being identified as out of hours (9457/72,343). A breakdown of cases is shown in Figures 1.1-1.3.

The additional 18,181 cases reported in this study compared to WOW I are, we believe, a result of NHS participation becoming mandatory (several NHS hospitals declined to participate in WOW I), and more independent hospitals participating in the Enquiry as a whole.

Fig 1.1 Admission type by hospital type

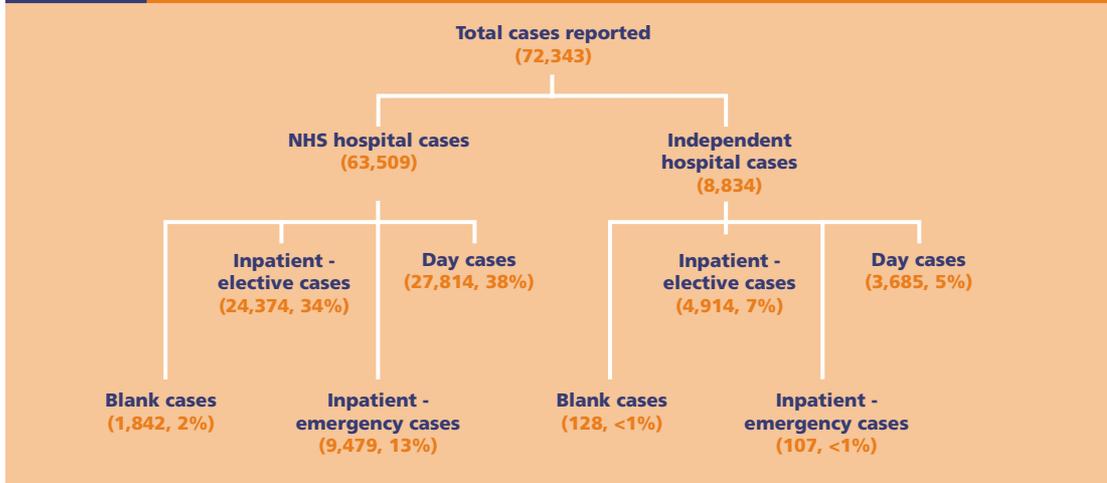


Fig 1.2 Classification of theatre case

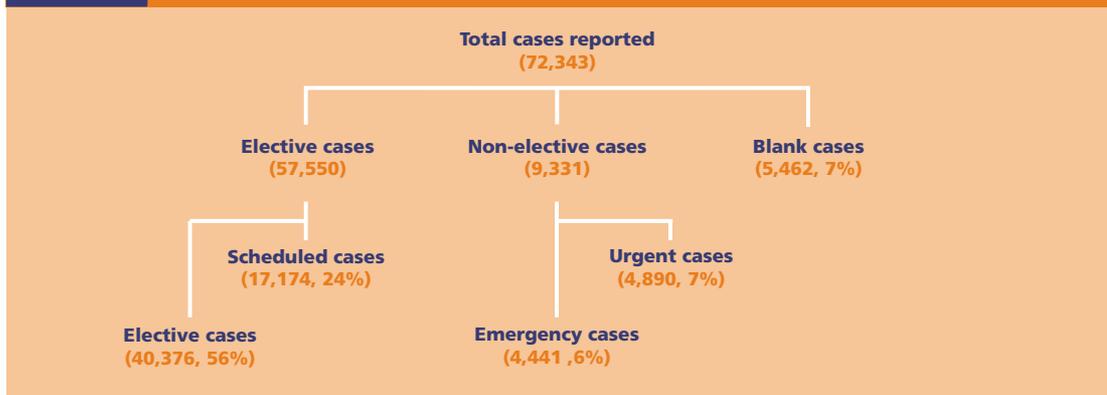


Fig 1.3 Classification of theatre case by hospital type

