2. Method

Study aim

The aim of the study was to review the care of medical patients referred for Level 3 care rather than the intensive care practice.

In *Comprehensive Critical Care* [10], the Department of Health recommended that the division into intensive care and high dependency care based on individual units be replaced by a classification that focused on the level of care that individual patients need, regardless of location:

Level 0	Patients whose needs can be met through normal ward care in an acute hospital.
Level 1	Patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with additional advice and support from the critical care team.
Level 2	Patients requiring more detailed observation or intervention including support for a single failing organ system or postoperative care and those “stepping down” from higher levels of care.
Level 3	Patients requiring advanced respiratory support alone, or basic respiratory support together with support of at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

Medical intensive care patients were defined as those referred to intensive care by a physician and, if they survived, were subsequently discharged to the care of a physician.

Data collection

Data collection took place for one month from 1st June until 30th June 2003. All patients 16 years and over admitted to a general ICU during this time were included. Patients were not included if they were admitted to a specialty specific intensive care unit such as cardiac or neurosurgical, and patients were also excluded if they were classified as Level 3 but not admitted to an ICU.

To identify appropriate patients, all participating ICUs were asked to flag each admission to the ICU during the study period. Each flagged patient was then monitored until one of the following triggers occurred:

- The patient died on the ICU - in which case extracts of the casenotes were requested, to be reviewed by an NCEPOD advisor.
- The patient was transferred to another Level 3 care facility, either within the same hospital or another hospital.
- The patient was downgraded to Level 2 care.
- The patient was discharged from the ICU.
- The patient was still alive in ICU 30 days after admission and still classified as Level 3.

Following one of the above events, clinical questionnaires were sent to the two relevant clinicians. The physician referring the patient to ICU completed one questionnaire; this questionnaire related to the pre-admission aspects of patient care. The intensive care consultant to whom the patient was referred on the ICU completed a second questionnaire; this questionnaire related to the post admission aspects of patient care and, if applicable, discharge from Level 3 care. Blank questionnaires were distributed by the NCEPOD local reporter, or an alternative contact within the ICU.

If a patient was admitted to an ICU following transfer from another hospital, data were collected only from the intensive care consultant in the admitting ICU. This was because it was not possible to match the casenotes from different hospitals.

Hospital participation

The study aimed to include general ICUs in all hospitals in England, Wales, Northern Ireland, Guernsey, the Isle of Man, and the Defence Secondary Care Agency and those hospitals in the independent sector that participate in the work of NCEPOD. All primary care trusts, community hospitals and specialist centres were excluded from the study.

For each participating hospital, an organisational questionnaire relating to the ICU and provision of outreach services was sent to the hospital's medical director for completion.

Copies of all three questionnaires can be found in Appendix 3.

Sample size

The sample size estimated for this study was 6,000 patients. This sample size was based on the number of available general ICU beds [11] multiplied by 7 as an estimate of bed occupancy per month.
It was expected that 20-30% of the admitted patients would die on the ICU during the study period[12]. This sample also included patients that had been re-admitted to the ICU for Level 3 care within the one month study period.

Quality & validation

The data from all questionnaires received were electronically scanned into a preset database.
Prior to any analysis taking place, the data were cleaned to ensure that there were no duplicate records and that erroneous data had not been entered during the scanning procedure. Where data from paired questionnaires did not match, e.g. date of outcome, then the local reporter was contacted to confirm the correct details. Following this, any fields that contained spurious data that could not be validated were removed.

All information that might identify a patient, hospital or clinician was removed from the questionnaires and the photocopied extracts of the casenotes, before any clinician, including the NCEPOD clinical co-ordinators, advisors or expert group, saw them.

Data analysis

All data were analysed using Microsoft Access and Excel by the staff at NCEPOD. Quantitative analysis of the data from all questionnaires was performed along with further qualitative analysis following review of the casenotes of the deceased patients by an advisory group. Where tables indicate 'not answered' this means that no information was provided for this particular analysis. Where 'insufficient data' is indicated this means that the advisors could not make a decision based on the information available. Where 'unknown' is shown in tables this is the box ticked by the hospital clinician completing the questionnaire.

Advisor groups

A multidisciplinary group of advisors were recruited to review the questionnaires and associated casenotes of the patients that died on the ICU. The groups of advisors comprised of intensive care physicians, general physicians, nurses and pathologists.

For each case reviewed, the advisor completed a separate questionnaire, the questionnaire assessment form (QAF), which is shown in Appendix 3. This allowed both quantitative and qualitative analysis of the advisor's opinion.

Expert review

An independent group of experts comprising intensive care physicians, general physicians and a nurse reviewed the combined analysis of the data; both from the questionnaires and the extra information from the advisory groups. This group determined the key factors that are presented in this report.