

# Acute Kidney Injury Study

## Study protocol

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## Introduction

Acute kidney injury (AKI) can be defined as an acute rise in blood urea and serum creatinine levels due to a sudden decline in glomerular filtration rate. AKI can occur as an isolated problem, but it more commonly occurs secondary to a circulatory disturbance, for example, severe illness, sepsis, trauma or surgery. AKI is a life-threatening in patients undergoing both elective and emergency surgery, as well as those admitted to emergency medical units.

There is no universally accepted definition of AKI and it is, therefore, difficult to obtain accurate numbers and compare different studies. One of the largest studies in recent years, was a retrospective analysis of 41,972 patients admitted to 22 ICUs in UK and Germany between 1989 and 1998<sup>1</sup>. This study used the definitions of AKI proposed by Bellomo *et al*<sup>2</sup>. They found patients with acute renal injury (ARI), acute renal system failure syndrome (ARFS) and severe acute renal failure syndrome to have in-hospital mortality rates of 29.5%, 49.2% and 63.0% respectively; compared to 10.3% in patients without renal failure. A smaller 2002-03 UK-based study reported a one month mortality rate of 74% in patients who developed AKI in ICU<sup>3</sup>.

The number of finished consultant episodes (FCEs) in England for which AKI (ICD-10 code N17) is listed as the primary diagnosis has steadily increased over the last five financial years: rising from 10,085 FCEs in 2000-01 to 19,950 FCEs in 2004-05. Despite the rise in the number of FCEs over recent years, the number of patients with AKI as the primary cause of death has remained at approximately 470 deaths per annum.

At least some cases of both peri-operative and medical AKI are avoidable. Given the high mortality rate associated with AKI, it is important to identify those patients at risk; thereby allowing preventive measures to be commenced in a timely manner<sup>6</sup>. The National Service Framework for Renal Services emphasises the importance of pre-operative assessment and peri-operative management in the prevention of AKI and identifies prevention and management of AKI as a quality requirement<sup>7</sup>.

NCEPOD collects information from all National Health Service and Defence Secondary Care Agency hospitals in England, Wales and Northern Ireland, public hospitals in the Isle of Man and Guernsey and most independent hospitals. Participation in NCEPOD studies is mandatory.

As an independent confidential enquiry, NCEPOD has its own peer review process. This process entails a multidisciplinary group of clinicians, all of whom are directly involved with the care of patients with AKI, reviewing anonymised casenotes of patients identified during the study period.

## **Aims and Objectives**

### ***Overall Aim***

The primary aim of this study is to examine the process of care of all patients who die in hospital with acute kidney injury.

### ***Overall Objectives***

The objectives of this study are to evaluate care in the following areas:

- 1 Diagnosis and recognition of AKI
- 2 Recognition of risk factors associated with AKI
- 3 Prevention of AKI
- 4 Assessment of patients recognised as being in AKI
- 5 Management of established AKI
- 6 Recognition and management of complications of AKI
- 7 Organisational factors for hospitals

## **Method**

### ***Design***

Peer review will be undertaken to identify possible remediable factors in the organisation of care using the indicators identified above. Clinical and organisational questionnaires will also be used to obtain quantitative data and clinician views.

### ***Population***

Patients aged 16 years or over who have died with AKI.

### ***Exclusions***

Palliative care

Patients already on Renal Replacement Therapy

### ***Sample Size***

To be determined

### ***Sites***

All hospitals that treat patients with AKI in the National Health Service and Independent sector in England, Wales and Northern Ireland, and public hospitals in the Isle of Man, Jersey and Guernsey, will be included in the study.

### ***Timeframe***

The study period of data collection will be 6 calendar months between 1<sup>st</sup> October 2006 and 31<sup>st</sup> March 2007 inclusive.

### ***Case Identification***

Cases will be identified from ICD 10 codes for AKI as determined by the pilot study below.

An NCEPOD Local Reporter in each hospital will be asked to identify all patients that died regardless of disease type or disorder between 1<sup>st</sup> October 2006 and 31<sup>st</sup> March 2007 inclusive and input that data into the spreadsheet provided by NCEPOD.

Once NCEPOD has the above information, a matching exercise will then take place to identify all patients that died with AKI.

Once patients who have died with AKI have been identified, a questionnaire will be sent to the clinical responsible for the patient at time of death. Casenote extracts will also be requested. The questionnaires and associated casenote extracts will then be reviewed by a multidisciplinary group of clinicians and aggregated data analysed quantitatively.

### ***Data Collection***

Two questionnaires will be used in this study:

- Organisational Questionnaire

For the purpose of this study, 'organisation' will be defined as a hospital/centre not a Trust. This will give a clearer picture of the facilities and care received by the patient at that particular site rather than by the Trust as a whole. An organisational questionnaire will be sent to the NCEPOD Local Reporter/study contact for each site. The questionnaire is designed to collect data on topics such as hospital/site facilities, staff numbers and clinical protocols.

- Clinician Questionnaire

A questionnaire will be sent to the clinician responsible for the patient at the time of death.

### ***Pilot Study – case identification***

The aim of the pilot was to determine whether patients were accurately coded for AKI (ICD10 codes N17 – N20) in order to determine if ICD10 coding could be used to obtain a true representative sample of patients that die in hospital from AKI.

Casenotes from the Emergency Admissions study were used to assess this.

The emergency admissions (EA) study included all adult medical and surgical patients who were admitted to hospital as an emergency admission, and met one of the following criteria:

- Died on or before midnight on day 7 (the first day of admission being recorded as Day 1); **or**
- Were transferred to adult critical care on or before midnight on day 7; **or**

- Were discharged on or before midnight on day 7 and subsequently died in the community within 7 days of discharge.

The above was collected retrospectively for one week in February 2005.

Over 1200 sets of casenotes were included in the EA study, of which approximately 70% met the first criteria, i.e. died within 7 days of admission. This group of patients were used to pilot case identification for the AKI study.

Twenty patients from the above EA group were coded for N17 – N20. The casenotes for all of these patients were assessed by experts to confirm the clinical indication of AKI. Additionally, a selection of cases coded for sepsis (A41) and 50 random (non N17 – N20 ICD10) cases were assessed to determine the incidence of AKI in these patients.

It was found that all of the cases coded for N17-N20 were indicative of AKI. In addition a significant number of patients coded for sepsis showed signs of AKI (7/20) or it was not possible to rule AKI out (10/20). The incidence of AKI in the random group was very low. The expert group therefore felt that it would be appropriate to initially, just include cases coded for AKI (i.e. N17-N20). If it is found that this does not yield a large enough sample size, additional cases coded for sepsis will be included.

## **Analysis and Review of Data**

### ***Advisors***

A multidisciplinary advisory group will review the data collected and provide expert opinion on the process of care and management of patients with AKI.

All identifiable information will be removed prior to review by the advisors, i.e. all data will be anonymised (see below).

### ***Confidentiality and Data Protection***

Once the data have been extracted by the NCEPOD researchers, the questionnaires and case notes will be anonymised to remove patient, clinician and hospital identifiers prior to review by the Advisory Group.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 60 approval has been obtained to perform this study without obtaining patient consent.

Approval for the study methods of all NCEPOD studies is granted by the Patient Information Advisory Group (PIAG) during an annual review.

### ***Dissemination***

On completion of the study a report will be published and widely disseminated.

## **Timescale**

<b>Main Event</b>	<b>Date</b>
<i>Pilot</i>	<i>1st October 2007 – 31st October 2007</i>
<i>Data collection</i>	<i>February 2008 – July 2008</i>
<i>Advisory Groups</i>	<i>May 2008 – January 2009</i>
<i>Data Analysis</i>	<i>February - March 2009</i>
<i>Publish Report</i>	<i>Summer 2009</i>

## **References**

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