What are the main risks for safety of renal patients?

Ensuring patient safety is a mandatory requirement of healthcare. The Francis1 and Berwick reports2 have given recommendations of priorities for safe clinical care. As patient safety is a multiprofessional responsibility, the strategy of what began as a Renal Association (RA) project is now being developed as a collaboration between the RA and the British Renal Society (BRS) as the RA/BRS Patient Safety Project.

Analysis of incidents and risks reported to the Patient Safety Project indicated that over half of incidents were due to failure of devices, mostly dialysis equipment or disposables. More than a third were as a result of technical failure or use error.3,4 Other incidents have led to the creation of guidelines, such as for venous needle dislodgement,3 and for haemolysis associated with sterilisation of water supplies.6 Renal patients can have multiple co-morbidities and are often seriously ill when admitted to hospital. If exposed to risks or patient safety incidents, their chances of survival might be compromised.

Objectives

To prioritise areas of the care of renal patients that might require particular attention to promote patient safety, data on incidents and risks available to the Patient Safety Project were analysed to determine the main risks for renal patients.

Methods

Analyses of three sources of data of incidents and risks in renal patients were undertaken. The first analysis was of incidents and risks which had been circulated by the Patient Safety Project to renal units over a seven-year period (2007–14). These incidents and risks had been reported to the project directly from renal units, or from the National Reporting and Learning System (NRLS), which is managed by NHS England, or from the Medicines and Healthcare Products Regulatory Agency (MHRA). These incidents and risks were reviewed to determine any themes of incidents.

Second, a survey was undertaken by emailing a questionnaire to all the senior nurses of renal units in the UK in September 2013. The objective was to determine what units considered to be the top patient safety risks for haemodialysis (HD) and peritoneal dialysis (PD). They were also asked what strategies they had implemented to prevent adverse events occurring. Responses were received from fifteen units.

Third, all incidents reported to the NRLS that resulted in death or severe harm to patients from April 2013 to March 2014 were reviewed. The causes that might have contributed to the incidents were categorised. The categorisation of incidents causing severe harm to patients or death, as distinct from lesser degrees of harm, was judged by the reporting healthcare worker.

Results

Reports of incidents and risks to the Patient Safety Project

Equipment or device failure, technical failure or use error of equipment, venous needle dislodgment, and haemolysis associated with sterilisation of water supplies have previously been highlighted, and all these issues have been publicised through the Patient Safety Project, together with sharing of experience and solutions. Some failures of dialysis disposables have been related to change in plastic composition or manufacturing faults. Failure of supply of dialysis disposables, either from loss of manufacturing capacity or failure of quality standards, has potentially put patients at risk.3,4

A prominent theme of risk to renal patients, identified from reports to the Patient Safety Project, is haemorrhage and infection related to HD access. Reports of haemorrhage incidents which have resulted in severe harm or death are shown in Box 1. Venous needle dislodgement5 is estimated to occur in one in 100,000 dialyses, but is undoubtedly rarely reported to the NRLS; however, it is an incident that occasionally can have a severe or fatal outcome.3,7 Bleeding has occurred from needling sites of arteriovenous (AV) fistulae in the community and can lead to fatal outcomes, and necrotic areas on fistulae are a potential cause of rupture, requiring urgent surgical intervention. Severe consequences or deaths have occurred due to delay in intervention or from inappropriate action in cases of severe haemorrhage from AV fistulae.

When femoral dialysis catheters are inadvertently pulled out, or become detached from the fixation wings, or if adequate haemostasis is not achieved following elective removal of a catheter, severe bleeding may be unrecognised by ward staff, and has had life-threatening or fatal consequences. Bleeding from the dialysis circuit has oc-
curred on commencing dialysis if connections with the dialyser have not been adequately tight-
ened, or if change in the plastic composition of the
connectors made tightening of the connector dif-
ficult at room temperature. Failure of the wash-
back procedure has also led to fatal blood loss.
Bacteraemia and endocarditis related to HD catheter infection remains a major risk for dialysis patients, and is also under-reported as an incident. There have been concerns that there is an in-
creased risk of infection related to buttonhole
needling,8,9 with recent reports of endocarditis
being reported to the Patient Safety Project.

Survey of renal unit senior nurse opinions on risks to renal patients

Fifty-three current patient safety issues in HD iden-
tified by the survey are summarised in Table 1. Vas-
cular access was considered a high-risk area, with 11 of the identified risks being in this category. Ve-
rous needle dislodgement was the most frequently
mentioned risk, with the units indicating that this
still occurred, although measures could be put into
place to ensure it did not lead to significant blood
loss. Other vascular access risks included haemor-
rhage from AV fistulae, and methicillin-sensitive
Staphylococcus aureus (MSSA) infections associated
with the buttonhole technique of needling of fist-
ulae and the use of tunnelled HD catheters.
The extracorporeal circuit was also considered a
high-risk area. Risks included loss of blood from the
circuit due to loose or disconnected connections,
clotting of the HD circuit and equipment failure. Er-
rors on programming the dialysis prescription, air
embolism and haemolysis were also mentioned.
Another risk identified was related to nursing
staff. This reiterated the risk related to monitoring
of the extracorporeal circuit and vascular access,
where lack of competence of inexperienced staff
and low staffing levels were considered to be risks.
Other safety issues raised by units included pa-
ient falls, aggression towards staff, reducing dial-
ysis time due to inflexible transport provision, and
medication errors.

Risks identified by renal nurses related to PD
were also analysed. Peritonitis continues to be
regarded as a risk (identified by seven units) with
some concerns expressed about encapsulating
sclerosing peritonitis. PD was considered to be a
safer treatment than HD, but two units raised the
risk of overfilling the peritoneal cavity with fluid
by automated peritoneal dialysis (APD) machines.
One unit raised the risk of patients being seen out
of hours by medical staff who do not have special-
ist renal experience, and where inappropriate
emergency medical treatment might put the pa-
tient at risk. This was raised in particular in relation
to PD, but is a risk for all dialysis treatments that
has been highlighted by Bray et al.10

In response to the question of what actions had
been taken to prevent adverse incidents, a wide
range of actions were identified, with a number of
units taking an approach of using more than one
intervention. Approaches shared that could re-
duce or prevent adverse incidents included chang-
ing procedures or service provision, retraining
staff, the use of new documentation or communica-
tion aids, implementing risk assessments of in-
dividual patients, auditing practice followed by
feedback of results to the team, and undertaking
root-cause analysis of critical incidents.
**NRLS reports of incidents causing death or severe harm**

An analysis of the causes of 99 incidents reported by renal units over a 12-month period to the NRLS database, which were categorised by the original reporter as causing severe harm or death, is shown in Table 2. A review of the clinical details supplied in ten of the reports did not suggest that those reports reflected true incidents. A few incidents had more than one cause, giving a total of 94 causes of the 89 incidents that resulted in severe harm or death. The analysis of these incidents is very dependent on the amount of information provided by the healthcare worker reporting the incident, and such an analysis inevitably has some limitations.

Six deaths from haemorrhage were reported, from fistulae, dialysis catheters and a renal biopsy. Incidents of infection were reported, though none were related to vascular access. Since the main reported incidents in hospitals are falls, it is not surprising that renal patients were susceptible to falls, of which five of the 25 reported were associated with the death of the patient. Fifteen pressure ulcers were reported.

Of particular concern is that the largest theme of incidents was related to failure of clinical management (n=38); the majority of such incidents were instances of delayed medical care by medical or nursing staff (n=23). A third of these delays were associated with the death of the patient. Other failure of management causes included medication errors and inappropriate treatment.

### Discussion

Approximately 10% of hospital patients experience some type of adverse event, of which half are preventable.11,12 The RA and the BRS, in their collaboration in developing the Patient Safety Project, are committed to working with all renal units to reduce risks and incidents. Continuing training ensures that use error is avoided.

A theme of haemorrhage related to vascular access is revealed from all three analyses: reports to the Patient Safety Project; the survey of renal nurses; and incidents reported to the NRLS.

The risk of venous needle dislodgement can be reduced by ensuring adequate taping technique,5 close supervision of restless or confused patients, and the use of blood detection devices6 or HD machines with sensors that respond to a fall in pressure and stop the blood pumps. Several training issues are identified by these incidents of haemorrhage, including management of femoral and internal jugular dialysis catheters, and HD techniques. Following guidelines and best clinical practice and taking preventive measures are essential.

There are unresolved issues about the potential benefits of the buttonhole-needling technique in extending the life of the fistula, which have to be balanced against the increased risk of infection.8 Training has been shown to reduce bacteraemia and complications of infection, such as endocarditis, as a result of buttonhole needling.9 The causes of loss of tissue viability over AV fistulae remain uncertain, but aneurismal fistulae, infection and cleaning solutions (chlorhexidine or alcohol) have been suggested by renal units as aetiological factors. Appropriate care of AV fistulae should also help to avoid skin necrosis and dislodged scabs in buttonhole needling sites. Hospital staff, particularly emergency department staff, as well as community healthcare workers, need training to understand their function.

### Table 2. Renal incident reports to NRLS resulting in severe harm or death: April 2013–March 2014

<table>
<thead>
<tr>
<th>Themes of incidents based on clinician review of free text</th>
<th>Total</th>
<th>Reported as causing severe harm</th>
<th>Reported as causing death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management failure</td>
<td>38</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Delayed medical or nursing care</td>
<td>23</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Delayed transfer</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Inappropriate treatment</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Medication</td>
<td>7</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Transplant work-up</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Treatment documentation</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Falls</td>
<td>25</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>15</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Infections</td>
<td>7</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>MRSA</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Norovirus</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Clostridium difficile</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Unspecified</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Fistula</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Dialysis catheter</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Renal biopsy</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Venous thromboembolism</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Breach of confidentiality</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Consent/mental capacity</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL INCIDENTS</strong></td>
<td><strong>94</strong></td>
<td><strong>66</strong></td>
<td><strong>28</strong></td>
</tr>
</tbody>
</table>

This table was based on review by a clinician of free text data from the NRLS from England and Wales. Date of reporting April 2013–March 2014; degree of harm reported = severe harm or death; specialty = renal. Some incidents described multiple problems and are therefore counted more than once in the table.

MRSA = methicillin-resistant *Staphylococcus aureus*; NRLS = National Reporting and Learning System.
ensure that haemorrhage from fistulae or dialysis catheters is dealt with promptly and appropriately.

Excessive use of temporary or tunnelled dialysis catheters will always increase the risk of infection, but this can be reduced by following guidelines to prevent infection. 14 Thus, ensuring achievement of the RA standards for the proportion of patients with AV fistulae is essential.

Infection remains a risk for renal patients who are immunocompromised by uraemia or immunosuppressive drugs. Inadequate monitoring of patients on immunosuppressive drugs and failure to use prophylactic antibiotics, when indicated, might result in life-threatening infection.

In addition, renal patients are commonly comorbid and elderly. They are just as susceptible to falls and pressure ulcers as any elderly or comorbid patient, if not more so. Medication errors can have severe or even fatal consequences. Delay of, or inappropriate, treatment should be avoided, since this is a major factor in the mortality of patients. 14

Analysis of the NRSL database has its limitations. There is undoubtedly under-reporting of incidents by healthcare staff, and analysis of the incidents reported is often limited by the lack of clinic detail supplied. Incidents resulting in severe harm or death are usually low-frequency, high-impact events. Analysis of all incidents, including those with a less serious outcome, will give a different pattern of high-frequency, low-impact incidents, which should trigger other preventive actions. Nevertheless, this analysis has provided helpful indicators to where action needs to be taken. This emphasises the importance of reporting all incidents to the NRSL, and maintaining a system of review of incidents in the context of a ‘no blame’ culture. Incidents related to devices should always be reported to the MHRA as well.

These results are consistent with the analysis by Bray et al, 16 who identified themes that emerged from case record review of factors that did, or may have, contributed to patient death: lack of recognition and timely management of hyperkalaemia; unsafe prescribing of drugs with altered pharmacokinetics in end-stage renal disease; lack of out-of-hours care, in that specialist staff are not on site 24/7; failure to prevent and manage infection; unsafe maintenance of vascular access.

Conclusion

All renal unit staff should maintain vigilance in preventing haemorrhagic and infective incidents related to vascular access. The renal community should continue to work with the dialysis industry to prevent device failure, and there have recently been discussions with the Department of Health to formulate national supply disruption guidelines. Training should be enhanced to avoid use error of equipment. 3 Early recognition of deterioration through early-warning scores, and avoiding delay in patients receiving medical or nursing care, will help to prevent management failure. 14 Strategies to prevent falls and pressure ulcers need to be reinforced. Future development of the RA/BR S Patient Safety Project should facilitate not only focused attention on risks to patients, but also sharing of best practice, to change outcomes and make renal units and wards safer places for care of patients. 11

Declaration of interest

The authors have not declared any conflict of interest.

Acknowledgments

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References


Key points

- Patient safety is one of the main challenges for the renal team.
- Analyses by the Patient Safety Project identified the main aetiology of risks to patients being related to haemorrhage and infection from vascular access.
- More general causes of incidents, particularly falls and pressure ulcers, also compromise renal patient safety.
- A common risk identified is failure of patient management, particularly delay in receiving medical or nursing care. Renal units therefore need to focus on maintaining standards of care.

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