Improving patient safety and avoiding incidents in renal units

Patient safety is a priority in health care and is the responsibility of all renal staff. Paul Rylance looks at how health professionals and NHS trusts can implement and share information that has developed from the findings of the Renal Association Patient Safety Project. The objectives of the project were to formulate and share solutions to clinical incidents and risk-prone situations.

Abstract
The Renal Association Patient Safety Project has identified that renal patients have been exposed to incidents and risks from failure of dialysis equipment or disposables, or from use error. Blood loss on haemodialysis, particularly from venous needle dislodgement, as well as haemolysis associated with haemodialysis, are risks for potential fatal outcomes. Solutions to these incidents and risks have been formulated and circulated, and guidelines for water treatment quality have been developed. Renal patients are susceptible to infection and also are at risk when admitted as acutely ill. Attention to the influence of ‘human factors’ on safety of renal patient care should be emphasised, especially in communication, handover and team-working. Incident reporting through hospital reporting systems within a ‘no blame’ culture is essential in order to learn from incidents. Incidents and risks related to medical devices should also be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA). Sharing of incidents, risks, solutions and best practice can be rapidly achieved through the Renal Association Patient Safety Project and is being further developed in a multidisciplinary approach through collaboration with the British Renal Society and the Association of Renal Technologists.

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Patient safety is an essential priority for all health professionals in the NHS (Department of Health (DH), 2006a). Data from the National Patient Safety Agency (NPSA) (2013a) indicates that over 1 million patient safety incidents are reported each year. Around 10% of patients in hospital experience some type of adverse event, of which half are preventable (Vincent et al, 2001). Approximately 12 000 deaths in hospital each year can be attributed to problems in care (Hogan et al, 2012), which equates to around 70 potentially avoidable deaths in an average NHS acute trust. The potential outstanding litigation costs related to adverse events is estimated at £22 billion (NHS Litigation Authority, 2013).

Much can be learnt from the Francis (2013) report, where ‘recommendations require every single person serving patients to contribute to a safer, committed and compassionate and caring service’. The recommendations from Francis (2013) with regard to nursing could be summarised into three categories: caring, training and leadership. This builds on previous recommendations by the NPSA (2004) on the seven steps to patient safety:

- Build a safety culture
- Lead and support staff
- Integrate a risk management activity
- Promote reporting
- Involve and communicate with patients and the public
- Learn and share safety lessons
- Implement solutions to prevent harm.

The Berwick report, from the National Advisory Group on the Safety of Patients in England, highlights strategies that should be employed in all NHS organisations (DH, 2013). The DH (2012) has published a list of 25 ‘never events’—events that should never happen in health care. At least half of these never events are particularly relevant to the care of renal patients.

Incidents in renal units
An analysis of NPSA data from 2008 estimates that at least 725 incidents a year occur in renal units in England and Wales that result in death, potential death, severe harm or moderate harm (Rylance, 2008). It is likely that there is at least one death per renal unit each year, though this is likely to be a significant underestimate.

Renal patients are likely to be particularly at risk of complications through being elderly, having associated comorbidities, and being at risk of infection through being immunocompromised from renal failure or immunosuppression. For patients on dialysis, there is the exposure to risk from invasive procedures and from dialysis. Renal patients are admitted to hospital when acutely ill, and so improving safety involves being aware of potential risks as well as focusing on delivering safe general clinical practice, as well as ensuring safe management of their renal conditions.
Incidents related to medical devices

There are approximately 120,000 medical devices in the UK market and possibly 200,000 throughout the European Union. The cost of UK devices in 2011 was approximately £12 billion, which was the same as the UK drugs budget of approximately £11.5 billion. There are 13,000 incidents a year in the NHS related to medical devices, and 60% of these incidents are related to a failure of use of devices (Medicines and Healthcare Products Regulatory Agency (MHRA), 2013). The failure of medical devices has been highlighted in the medical and national press recently by the safety issues related to Poly Implant Prothèse (PIP) breast implants and metal-on-metal hip prostheses (McCulloch, 2012). Renal units are major users of medical devices, which includes not only equipment, but also disposables. Any incidents related to medical devices should be reported to the MHRA (MHRA, 2011).

Renal inpatient care

Safer care for patients when admitted to hospital should be facilitated by maintaining specialised renal wards with renal medical and nursing expertise. Managing renal patients on outlying wards should be avoided when at all possible. When this is not possible, it is essential that training and protocols are available for non-renal staff. Continuity of patient care needs to be maintained, which is increasingly difficult with shift working, and in these circumstances clear communication and handover is important. Ensuring the effectiveness of early-warning scoring alerts is essential.

In an analysis of hospital deaths in acute and general hospitals undertaken by the NPSA (2007), three key issues were identified. Firstly, some patients who died did not have observations; secondly, the deterioration shown by observations was not recognised; and thirdly, there was a delay in receiving medical attention. It systems that highlight patients with high early-warning scores, ensure that deterioration of patients is recognised, and critical care outreach teams can support ward staff in monitoring high-risk patients. The demand on health professionals is continually increasing, and staffing levels and working practices need constant review. Guidelines for the management of acutely ill patients are available, for example, from the National Institute for Health and Care Excellence (NICE) (2007), which helps to focus attention on the clinical needs of renal patients when acutely ill.

Renal Association Patient Safety Project

There is an obligation for health professionals to report incidents that have occurred that put patients at risk. Reporting should be in the context of a ‘no blame’ culture so that health professionals can learn from adverse incidents. Professional accountability in health care is essential, but health professionals have to be confident that reported incidents and risks are reviewed and discussed in hospital trusts, with the clear objective of learning from them rather than to apportion blame. All renal staff should participate in the clinical governance process. 'Straw polls' conducted by the author at multidisciplinary renal meetings indicated that a relatively small proportion of renal staff regularly attend clinical governance meetings. Incidents reported through hospital reporting systems are fed into the National Reporting and Learning System database (NRLS), originally devised by the NPSA (2013a), but recently taken over by NHS England.

The Renal Association Patient Safety Project was commenced in 2007, initially in collaboration with the NPSA, but more recently with the support of the Renal Association. The objectives were to formulate and share solutions to clinical incidents and risk-prone situations. Incidents and risks identified by the renal unit, the NRLS database and
the MHRA are communicated to the project lead (PBR). These incidents and risks are then circulated to the renal unit clinical directors and lead nurses by email. Shared experiences and solutions are collated by the project lead and re-circulated to renal units. In addition, national safety reports and guidelines have been circulated to renal units (Figure 1).
Between June 2007 and October 2012 (65 months), 101 incidents, risks, alerts and reports were circulated. Of these, 57 were related to equipment failure, mostly dialysis machines and disposables, and 36 were due to technical failure or use error. In addition, there were other incidents related to medication or infection.

Blood loss incidents
The Renal Association Patient Safety Project was instituted as a result of a fatal incident of a dislodged venous fistula needle during haemodialysis, leading to significant blood loss. A survey of renal units estimated that approximately 100 episodes of venous needle dislodgments occur in the UK each year, though this is likely to be an underestimate. Of these episodes, 6.4% resulted in moderate or severe harm, resulting, for example, in hospital admission, but no other deaths were reported other than the original index case. This would give an incidence of approximately one venous needle dislodgement per 100,000 dialyses (NHS Purchasing and Supply Agency, 2009).
A positive outcome of the analysis of this problem was that it resulted in recommendations being developed by the European Dialysis and Transplant Nurses Association/European Renal Care Association (EDTNA/ERCA) for care of venous needles and how to minimise the risks of venous needle dislodgement (Van Waeleghem et al, 2008). A blood loss detector, giving an audible warning, became commercially available. A report was produced in conjunction with the Centre for Evidence-based Prescribing (CEP), which concluded that this detector could not be justified for universal use for dialysis patients on the
grounds of cost, but could be indicated for high-risk patients, such as patients receiving haemodialysis at home, or in isolation rooms, and restless patients (NHS Purchasing and Supply Agency, 2009).

A more recent type of blood loss detector not only triggers an alarm at the dialysis machine, but also stops the blood pump immediately and activates a venous clamp. In addition, venous access monitoring technology has been developed that allows detection of sudden small drops in venous pressure, even when the venous pressure does not exceed the lower alarm limit. This type of technology increases the probability of early detection of venous needle dislodgement.

Renal unit staff also need to be aware of other occurrences of blood loss, such as inadequate tightening of the connector between the dialyser and the lines, particularly if the dialysis machine is behind the patient and not fully in view. There is a risk of exsanguination during a washback procedure if the process is not carried out correctly. Bleeding can occur from fistula needling sites and from removal of femoral dialysis lines.

**Equipment and device failure and use error**

Failure of dialysis equipment and devices may be due to manufacturing faults. Incidents identified through the Patient Safety Project have included cracking of plastic dialysis components, alterations in the cuff manufacture of percutaneous haemodialysis lines, resulting in dialysis catheters falling out, and failure of safety for haemodialysis needles.

While technical failures of dialysis machines have been reported, use errors of haemodialysis machines have also occurred as a result of errors of programming, particularly when dialysis staff are unfamiliar with certain types of machines. This emphasises the importance of training for new dialysis staff and those transferring from other units that use different manufacturer’s equipment.

There have been two significant occurrences with failure of supply of dialysis disposables. Firstly, there was concern about endotoxin levels in peritoneal dialysis fluid and, secondly, a breakdown of supply of haemofiltration disposables as a result of an earthquake destroying the manufacturing plant. This raises the potential risk of contracting with a single supplier.

**Haemolysis associated with haemodialysis**

An incident occurred in a renal unit where five dialysis patients were admitted with chest pain, pancreatitis, unexpected anaemia and hyperkalaemia. This was due to haemolysis. One patient with a previous cardiovascular history died (National Patient Safety Agency, 2008). The origin of this was that silver-stabilised hydrogen peroxide used for sterilisation of the hospital water supply reached the dialysis unit water supply. Although the hydrogen peroxide was in low concentrations in the hospital water supply, as a result of the large volume of water used by the unit water treatment plant, the accumulative amount of hydrogen peroxide overwhelmed the carbon filters and reached the patients, causing haemolysis. The same problem was reported in the community when chloramine was used by a water company to sterilise the supply. This affected patients in satellite units and patients on home haemodialysis (NPSA, 2013b).

There have been additional reports of haemolysis associated with dialysis unrelated to water sterilisation. Over a 9-month period, 14 cases were recorded in one area (NPSA, 2013b). The cause of this remains unknown, but is thought to have been related to kinking of an unsupported dialysis line into the arterial port of the dialyser. However, other cases of haemolysis, not due to dialysis line kinking, have subsequently occurred, which have remained unexplained. Haemolysis is a potential source of significant morbidity and mortality, and could go unrecognised. Renal unit staff need to be aware that, when laboratories report blood samples as being haemolysed, there may also be the possibility of haemodialysis-related haemolysis rather than resulting from in vitro haemolysis during blood sampling.

**Renal unit water treatment plants**

A national survey of renal units was performed by Gerard Boyle (2013) around the issue of water supply and sterilisation techniques. This survey showed that only 27% of renal units had a direct feed from the water company mains. The 73% of units that have a water supply from a holding tank require additional sterilisation of the hospital water supply to be undertaken. In addition, 47% of renal units had water plants over 10 years old. The survey identified that there has been no consensus of protocol for sterilising or testing water supplies. It also highlighted lack of communication between estates departments and renal units when water sterilisation was being undertaken. Due to these findings a guideline has been developed by UK Renal Association and the Association of Renal Technologists (2012).

**Health-care-associated infection and dialysis quality standards**

Health-care-associated infections are a significant risk for renal patients. Dialysis catheter infections can be reduced by improving arteriovenous fistula rates, together with emphasis on training, catheter care bundles, bacterial surveillance and policies of line removal (DH, 2006b).
Precipitous commencement of dialysis is associated with increased mortality. There has been an improvement in the incidence of late presentation (less than 90 days) for commencement of dialysis from 23.9% of patients in 2006 to 19.6% in 2011. However, late presentation ranges from 9.1–35.1% across UK renal units, which indicates that there is still variability in detection and referral of patients approaching end-stage renal failure (UK Renal Registry, 2012).

A recent analysis of patients treated with renal replacement therapy in Scotland (Bray et al, 2013) indicated themes that emerged from case record review of factors that were identified that did or may have contributed to patient death. These were:

- Recognition and timely management of hyperkalaemia
- Safe prescribing of drugs with altered pharmacokinetics in end-stage renal failure
- Lack of out-of-hours care, in that specialist staff are not on site 24/7
- Prevention and management of infection
- Safe maintenance of vascular access.

The cause of these factors was a result of failure of organisational, environmental, technical and human factors. A report from the Clinical Human Factors Group (2013) said that:

*Human factors are all the people issues—how we see, hear, think and function physically—as well as the interrelationship of people and their environment and to each other which need to be considered to optimise performance and assure safety. In health care, these range from the design of tools such as medical devices, to services and systems as well as the working environment and working practices such as rotas, roles, team behaviours and so on.‘

Human factors are increasingly being recognised as a cause or contribution to failure of safe care.

**Strategies to reduce risks to renal patients**

Pippias and Tomson (2013) suggest ways to ensure patient safety in chronic kidney disease, such as:

- The need for quality improvement techniques
- Encouraging junior doctors to call for senior help
- Nurses challenging doctors when they are concerned that a patient is at risk
- Patients being empowered to be part of their care
- Interventions to improve team work
- Implementing a ‘safety culture’
- Standardisation of care with protocols and clinical practice guidelines.

Patient safety is the responsibility of all renal health professionals and renal units should ensure that it is a priority. Incident reporting with a ‘no blame culture’ is essential to identify risks, and the sharing of solutions will facilitate dissemination of best practice. All units should ensure that training and continuing professional development (CPD) is available for all renal health professionals, together with all being actively involved in audit and clinical governance. The Renal Association Patient Safety Project has developed a collaborative approach to renal patient safety through liaison between the Renal Association, British Renal Society and the Association of Renal Technologists. Working with the NHS England Medical Safety Expert Panel, the Royal College of Physicians Patient Safety Committee, and the MHRA will also help to set standards, monitor incidents and facilitate dissemination of best practice. The Berwick report (DH, 2013) sets out the principles of safe patient care as:

- Place the quality of patient care, especially patient safety, above all other aims.
- Engage, empower, and hear patients and carers at all times
- Foster wholeheartedly the growth and development of all staff, including their ability and support to improve the processes in which they work
- Embrace transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.

**Conclusion**

Improving patient safety for renal patients is a challenge for the multidisciplinary renal team, whether it be on the haemodialysis unit, on the ward, in the outpatients department or in the community. Staff need to ensure delivery of the highest quality standards of care, since quality care will be safer care, and that in itself will enhance patient experience and quality of life. Maintaining the enthusiasm of renal staff to provide high-quality care in an increasingly pressured NHS requires everyone to work together, support each other and to provide CPD and training. If

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**Key points**

- Patient safety is the responsibility of all health professionals
- Incident reporting in a ‘no blame’ culture is essential to learn from adverse events
- Incidents on renal units are most commonly related to dialysis equipment and disposables or their use
- Sharing incidents and risks through the Renal Association Patient Safety Project allows rapid sharing of experience and formulating solutions
- Incidents related to medical devices should be reported to the Medicines and Healthcare Products Regulatory Agency

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adverse events occur, then these must be formally reported through hospital reporting systems, so that staff can positively learn from these incidents, formulate solutions and, most importantly, share good practice and, where necessary, develop new national guidelines.

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