UK Kidney Association

Summary report and recommendations of Kidney Patient Safety Committee (KPSC) Working Group: review of risk associated with blood leaks from haemodialysis circuits and lines

Background

The Kidney Patient Safety Committee (KPSC) received correspondence from several units highlighting concerns about risk of blood leaks from lines and connections during haemodialysis treatment through a central venous catheter (CVC).

Blood leaks have the potential to cause significant harm to the patient involved. The KPSC set up a Working Group to explore renal unit experiences and practices and produce recommendations. This work took place from August 2019 - October 2020.

Method

The Working Group:

- Designed and circulated a survey (see Appendix 1) to all renal units in England, via the Association of Nephrology Nurses UK (ANNUK) and the Renal Association Clinical Director Network.
- Contacted the Medicines and Healthcare Products Regulatory Agency (MHRA) to understand national reporting practices (see Appendix 2)
- Contacted National Reporting and learning system (see Appendix 3)
- Sought and reviewed route cause analysis reviews and action plans from individual renal units

Results of Survey

Q) Renal Unit shared practice and experience

Has your kidney unit had any reported adverse incidents related to blood leaks on haemodialysis in patients with haemodialysis catheters (tunnelled/non-tunnelled)?

- 25 of 58 Renal Units reported 1 or more incidents (total = 30)
- 21 low harm
- 6 moderate harm
- 3 fatalities
- 33 no incidents

Key themes included:

- Intentional rounds using checklists and risk stratification of patients
- Confirmation of CVC connections by two healthcare professionals
- Ensuring connections visible at all times

Q) Do you use blood leak detectors or devices in your units? *(54 responses)*

- Practice varied
- External blood leak detectors used routinely in some centres and for selected patients in others.
- 26 of 54 Renal Units did not use blood leak sensors.

Q) Do you have a double checking system (2 person checking system) in place to check dialysis line connections at the beginning of dialysis and following flushing of the dialysis catheter during dialysis?

- Renal units use double-checking by 2 members of staff

Does your team undertake intentional (check) rounding on dialysis? (57 responses)

- Reporting this was standard practice on dialysis

Q) If your team undertakes intentional rounding (check) on dialysis, what are you checking for? (40 responses):

Components that were being checked included:

- CVC-to-line connections
- AVF-to-line connections
- Blood pump speeds
- Arterial and venous pressure
- Ultrafiltration rate/total volume
- Heparin dose
- Observations (BP, heart rate)
- Some teams provided the frequency of checks made: for example every 30-60 minutes.

Q) What do you think the key considerations are to prevent the risk of blood leaks during haemodialysis in patients dialysing using a CVC?

Key themes included:

- Importance of patient and staff education related to potential leaks/blood loss
- Re-training and competency checks related to potential leaks/blood loss during dialysis
- Procedures and competencies in place to manage disconnection of lines from CVC/AVF
- review of connections at start of treatment and regularly throughout by 2 members of staff
- If patient is self-caring, both patient and nurse/carer to check connections at start of treatment and regularly throughout
- Haemodialysis operator should confirm that line is appropriately primed with fluid before connecting CVC
- Minimise interruptions when staff are undertaking routine checks
- Ensure lines and connections are visible
- Avoid red or dark-coloured blankets in Renal Units
- Complete checklist review during treatment and document
- Identify high-risk patients and monitor appropriately
- Identify high-risk accommodation, for example lack of visibility and monitor appropriately
- Competent staff to investigate and respond to machine alarms appropriately

Conclusion

Our survey suggests that serious harm related to blood leaks during haemodialysis in association with CVC and disconnection is rare. It is possible that under-reporting of near miss events and recall

bias have skewed responses. Practice varies across Renal Units, but measures to reduce risk are commonly used.

Recommendations

1. Routinely identify high-risk patients at each treatment through use of a checklist including patient and accommodation factors. This risk assessment should be added to haemodialysis team safety huddles and handovers.
2. Routine line connection checking at the start and throughout dialysis by two healthcare professionals where staffing permits. Individual practice for home dialysis patients should be considered during their training and reviewed.
3. Ensure visibility of the CVC and connections at all times. Avoid dark or red blankets.
4. Respond to and investigate machine alarms promptly and only if competent to do so
5. Consider the use of external blood leak sensors for high-risk patients and high-risk accommodation areas
6. Highlight the importance of suitable clothing to allow easy access to CVC and line connections
7. Annual skills/competency assessment of staff, patients and carers
8. Emphasise the importance of reporting all incidents, including near-misses, via local and national incident reporting systems (Datix or similar)

Working group members

Dr Catriona Shaw, Consultant Nephrologist, Kings College Hospital, London (Working Group Chair)
Dr Katy Jones, Consultant Nephrologist, Newcastle upon Tyne (Kidney Patient Safety Committee Co-chair)
Dr Pete Thomson, Consultant Nephrologist, Queen Elizabeth University Hospital, Glasgow
Dr Roopa Prabhakar, Senior Medical Device Specialist; Devices Safety & Surveillance, MHRA Devices
Mr Gerry Boyle, Section Manager, Renal Services Dumfries & Galloway Royal Infirmary, Dumfries
Ms Helen Cronin, Haemodialysis Matron, King's College Hospital, London
Ms Helen Spooner, Nurse Consultant Renal Services, New Cross Hospital, Wolverhampton
Ms Melanie Withero, Quality Improvement & Patient Safety Manager Transplant, Renal & Urology Guy's and St Thomas' Hospital, London
Ms Amy Robinson, Renal Association Secretariat
Ms Sarah Crimp, Renal Association Secretariat
Dr Oshorenua Aiyegbusi, Specialty Trainee in Nephrology, Queen Elizabeth University Hospital, Glasgow

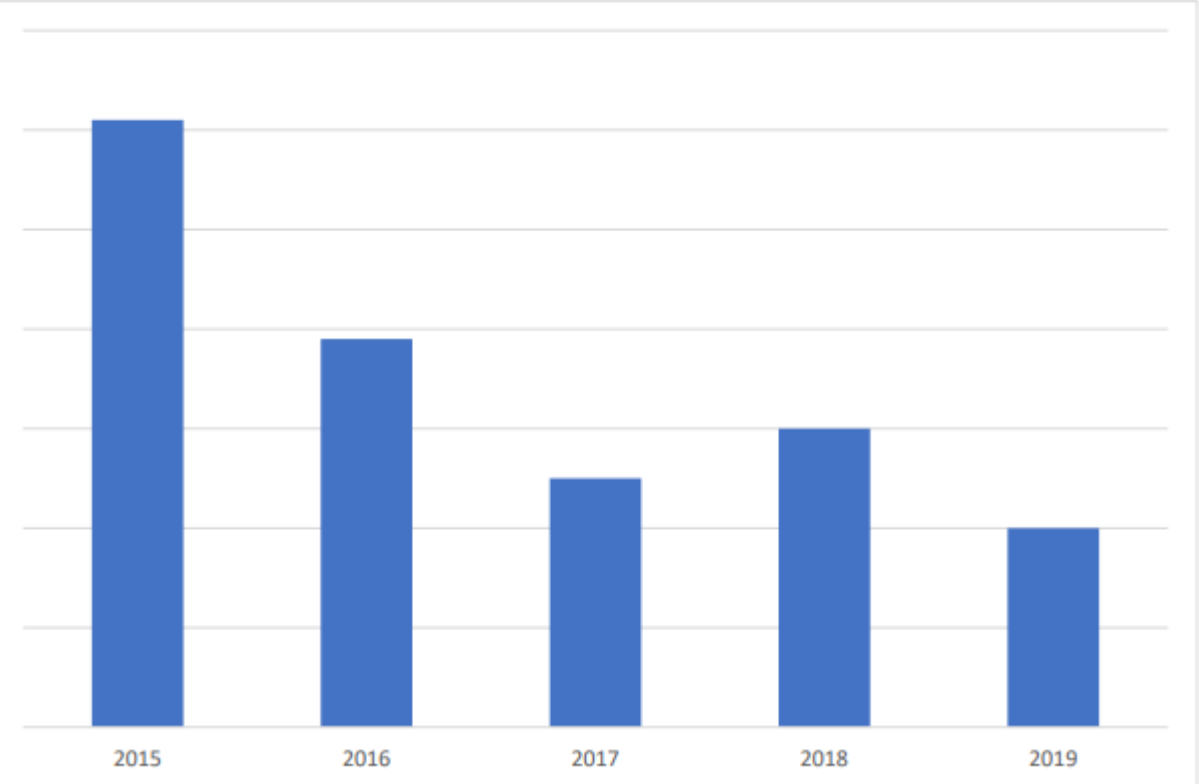
Appendix 1

The survey asked the following questions:

- Has your kidney unit had any reported adverse incidents related to blood leaks on haemodialysis in patients with haemodialysis catheters (tunnelled/non-tunnelled)
- If yes (to question 1) would you be willing to share your action plans/key learning points- if yes please enter here
- Do you use blood leak detectors or devices in your units (for example red sense or other device)?
- Do you have a double checking system (2 person checking system) in place to check dialysis line connections at the beginning of dialysis and following flushing of the dialysis catheter during dialysis?
- Does your team undertake intentional (check) rounding on dialysis?
- If you answered yes to question 5, what are you checking?
- What do you think the key considerations are to prevent the risk of blood leaks on haemodialysis in patients using a dialysis catheter?

Appendix 2

This data illustrates the number of dialysis bloodline leaks between 2015 – 2019 inclusive logged on MHRA's AI database.



There appears to be a general downward trend in reports received over this five year period.

The database includes reports from a number of sources, primarily manufacturers and Healthcare Professional user reports. Healthcare user reports in the UK are submitted voluntarily. Manufacturers are legally obliged to report any fatalities, serious injuries and potential for serious injury linked to their devices. In addition to this, manufacturers have a legal requirement to notify MHRA of any field corrective safety actions taking place in the UK.

Other sources of reports include other devolved administrations, National Competent Authorities etc.

UK Kidney Association

Appendix 3

Adverse Events from Haemodialysis Line Leak

Oshorenua Aiyegbusi, Peter Thomson,
Glasgow Renal & Transplant Unit,
For the Kidney Patient Safety Committee Haemodialysis Line Leaks Working Group

Introduction

Bleeding from dialysis vascular access is uncommon and death as a result from these bleeds rare. Reported incidence rates are less than 1 for every 1000 patient-years on dialysis.[1] However, when these incidents occur the consequences may be catastrophic.

The Kidney Patient Safety Committee had received correspondence from several renal units highlighting concern regarding possible risk of catheter related leaks on haemodialysis.

The aim of this analysis of data from the national reporting learning system was to assess the frequency of reported incidents of blood leaks related to haemodialysis extracorporeal circuits /haemodialysis lines.

This data will help inform feedback and recommendations to the UK renal community regarding best practice to reduce risk of haemodialysis line leaks

Aim

The primary aim is to assess the frequency of reported incidents of blood leaks related to haemodialysis extracorporeal circuits/haemodialysis lines, in order to identify potential opportunities for quality improvement.

Methods

The NRLS is a dynamic reporting system that captures data on patient safety in England and Wales. It is a voluntary system to which NHS Trusts submit data on patient safety related incidents.

A data request was submitted to the NRLS (appendix 2). Data was requested for the time period 1.4.2016-31.03.2019.

Both quantitative and descriptive data are presented. Descriptive data were produced from free text responses in the reported cases. The qualitative data was reviewed by a single person to identify the nature and frequency of recurring themes. Descriptive data analysis was undertaken for 'moderate harm and above' category.

All data were analysed using Microsoft excel.

Results

896 incidents were reported on the NRLS between 1/04/16 to 31/03/19. A total of 48/896 (5.4%) incidents were reported as 'moderate harm and above'; 232/896 (25.9%) 'low' harm; and 616/896 (68.8%) incidents reported as 'no' harm.

In this analysis, 248 cases were reviewed. All 48 cases from the 'moderate harm and above' category, as well as 100 from each of the 'low' and 'no' harm categories.

Incidents per year

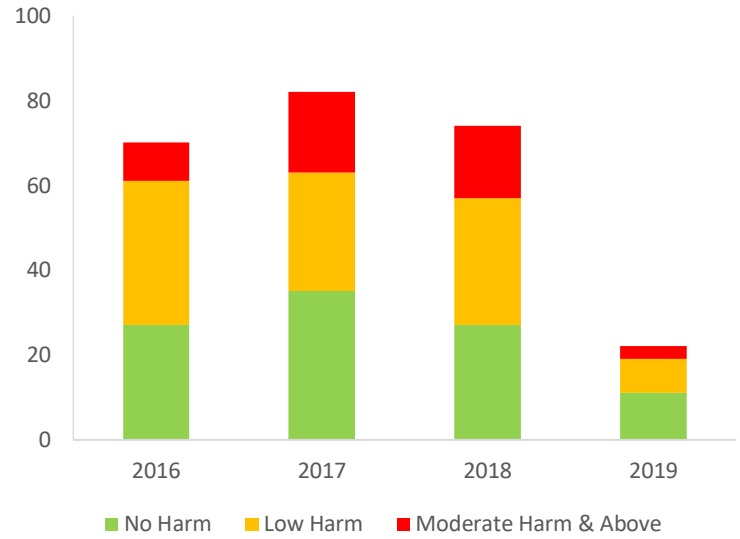


Figure 1 – Counts of NRLS reports on haemodialysis access adverse events 01/04/2016 to 31/03/2019 (note data do not cover the full calendar year of 2016 or 2019)

	No Harm **n = 100**	**Low Harm** **n = 100**	**Moderate Harm & Above** **n = 48**
Age range (years)			
≤ 1	4	2	1
>1 -4	1	0	1
5-11	0	1	0
18-35	4	5	0
36-55	29	27	12
56-75	31	32	22
>75	20	23	9
not stated	11	10	3
Gender (%)			
Female	21 (21.0)	27 (27.0)	18 (37.5)
Male	45 (45.0)	41 (41.0)	18 (37.5)
Not stated	34 (34.0)	32 (32.0)	12 (25.0)
Location (%)			
In-patient	50 (50.0)	57 (57.0)	31 (64.6)
Out-patient	20(20.0)	21 (21.0)	8 (16.7)
Other	30 (30.0)	22 (22.0)	9 (18.8)

Table 1 – Demographics of the NRLS cohort.

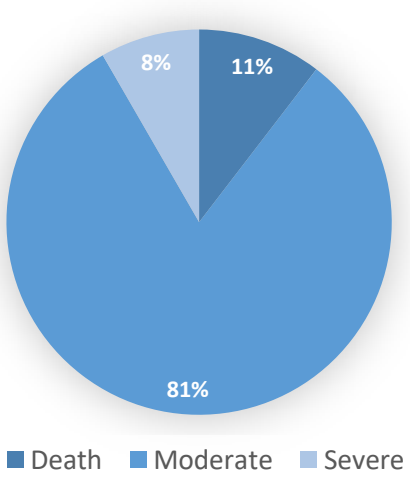


Figure 2 - Incidents reported as "moderate and above" in detail

	Line	Tub	Connect
No harm (n= 100)	76	5	19
Low harm (n=100)	80	6	14
Moderate Harm & above (n=48)	42	1	5

Table 2 – Reported events in relation to haemodialysis line connection/circuits.

	No Harm **n = 95**	**Low Harm** **n = 97**	**Moderate Harm & Above** **n = 46**
Age range (years)			
18-35	4	5	0
36-55	29	27	12
56-75	31	32	22
>75	20	23	9
not stated	11	10	3
Gender (%)			
Female	20 (21.1)	26 (26.8)	18 (39.1)
Male	44 (46.3)	39 (40.2)	16 (34.8)
Not stated	31 (32.6)	32 (33.0)	12 (26.1)

Location (%)			
In-patient	47 (49.5)	55 (57.0)	29 (63.0)
Out-patient	19(20.0)	20 (21.0)	8 (17.4)
Other	29 (30.5)	22 (22.0)	9 (19.6)

Table 3 – Demographics of the Adult cases (Age>18 years) in NRLS cohort

Review of cases resulting in Death

5/896 (0.6%) NRLS haemodialysis access incidents were associated with subsequent death. 3 deaths were related to infection (1 from line sepsis). 2 deaths (0.23% of NLRS reported events) were directly linked to vascular access haemorrhage.

In the first case of death related to vascular access haemorrhage, a non-tunnelled central venous catheter was required to facilitate dialysis due to PD peritonitis. Initial two attempts at inserting catheter was unsuccessful. Eventually, catheter was inserted by senior medical member of team. 14 hours later, the patient had a cardio-respiratory arrest with return of spontaneous circulation after about 25 minutes. Clinical deterioration was attributed to sepsis. Given significant co-morbidities and guarded prognosis, the patient was kept comfortable. Post mortem review however deemed likely cause of death was due to retroperitoneal haematoma as a complication of line insertion.

In the second case of death related to vascular access haemorrhage, post mortem results revealed death was due to a bleed into the pericardial sac via erosion of wire stent in SVC into the aorta. The stent had been placed to relieve SVC obstruction caused by central venous stenosis from previous haemodialysis catheter. This is a recognised complication of stent insertion (patient consented for this risk at time of placement). Monitoring of stent is not required nationally therefore no missed opportunity identified.

Review of cases resulting in 'moderate-severe' harm

44/896 (4.9%) NRLS haemodialysis access incidents led to 'moderate-severe' harm with 4/896 (0.45%) described as severe harm. In the incidents leading to severe harm, 2 were associated with line sepsis and the other two cases (0.23% of NLRS incidents) related to bleeding complications. Both cases leading to haemorrhagic complications occurred in hospital and involved the cardiac arrest team. One case led to ICU admission following a hyperkaliaemic cardiac arrest; it is unclear if this was a direct consequence of bleeding. The second incident was a direct consequence of line leak. The venous line of TCVC was disconnected from the venous lumen leading to significant blood loss. As a result, the patient had haemodynamic compromise however improved with resuscitation utilising blood products.

Within the moderate harm category 10/40 incidents related to line infection, and 25/40 related to haemodialysis blood loss events. 47.5% (19/40) were haemorrhage leak due to CVC versus 15% (6/40) involving AVF and/or grafts. Of these, 2 cases required intervention (CT angiogram). The remaining 5 cases were other medical complications (hypoglycaemia, pressure ulcers, gentamicin induced vestibulotoxicity, PD fluid leak and spontaneous bleeding into knee joint on background of thrombocytopenia).

Haemodialysis line circuits and reported harm

Table 2 gives an overall summary of reported cases in relation to haemodialysis line connection. This may not reflect the actual number events leading from line leaks when descriptive data is appraised. For example, the fatal case leading to death is reported under 'line' however the patient died as a consequence of line erosion not haemorrhage line leak. For this reason, we have presented descriptive data following review of cases in 'moderate harm & above' category.

29/896 (3.3%) of NLRS events reported as 'moderate harm and above' due to bleeding complications. 19/896 (2.1%) directly consequence of haemorrhage line leak.

Notes with regard to future review

The NRLS dataset contains a mixture of adverse events related to haemodialysis access adverse events. Identifying those events that relate to haemodialysis blood losses can only be done manually at present, due to the free text nature of the source data entry. This free text recording of the data led to some potentially useful elements of interest either being difficult to find or missing. These include details on the type and site of the vascular access, anticoagulation and antiplatelet exposure, and concurrent pathologies such as frailty, delirium, agitation or cognitive impairment.

Conclusions

Fatal blood loss events occurred in 2/896 (0.2%) of NLRS reported events. Severe blood loss occurred in 2/896 (0.2%) of NLRS reported events. Moderate harm events from haemodialysis blood loss accounted for 25/896 (2.8%) of NLRS reported events. The majority of events were recorded as occurring in an in-patient environment.

The age and gender split across the severity of events appears similar, however additional data on prescribed medication, comorbidity, frailty and cognition at the time of the events are poorly captured.

The similarity in demographics across event severity groups, and the 'pyramidal' distribution of event numbers, from relatively high numbers of low severity events, through to relatively low numbers of severe/fatal events is of interest. This suggests that the most severe/fatal events arise as a function of how many events are occurring overall. As such reducing the overall numbers of events per se, may lead to a reduction in the frequency of severe or life threatening events.

Details on the narrative surrounding events are relatively scarce, and are provided in a non-standardised way, making objective assessment for common features between incidents challenging.

The NLRS data suggest stable levels of event reporting in 2017 and 2018.

References

1. Jose, Matthew D et al. *Fatal Dialysis Vascular Access Haemorrhage. American Journal of Kidney Diseases, 2017 Volume 70, Issue 4, 570 - 575*

Appendices

Appendix 1 – Glossary

AVF	Arteriovenous fistula
CT	Computed tomography
CVC	Central venous catheter
ICU	Intensive care unit
PD	Peritoneal dialysis
SVC	Superior venous cava
TCVC	Tunnelled central venous catheter

Appendix 2 – Search terms to generate NRLS data

Combination of words used below:
dialys OR filtrat OR extracorpo OR circuit
AND
Line OR tub OR catheter OR connect
AND
Leak OR bleed OR blood OR bled OR haemorrhage OR exsanguin OR haemoly