

19 February 2019

Court ref: COR 2015 004647

Sanchia Nigli
Coroner's Registrar
Coroner's Court of Victoria
65 Kavanagh Street
Southbank 3006

Dear Sanchia

Re: Investigation into the death of Andrew O'Dwyer

On 16 November 2018, Safer Care Victoria (SCV) wrote a letter of response to the Coroner, as a result of the investigation into the exsanguination of Andrew O'Dwyer during home haemodialysis.

The Coroner's findings included the following recommendations relevant to SCV:

- *That Safer Care Victoria review the safety of haemodialysis machines used by home haemodialysis patients supported by Victorian public health services, with a particular focus on failsafe mechanisms and ways to avoid potentially dangerous short cuts when used in the home setting. (p19-20).*

In response to this recommendation, SCV held a risk analysis workshop on 21 November 2018 to identify risks and opportunities for improvement with haemodialysis machines used in the home setting. In order to provide diverse perspectives in the discussions, the workshop included consumers, nephrologists, renal nurses, industry representatives, the Therapeutic Goods Administration and Health Purchasing Victoria representatives, and technicians familiar with this equipment and patient experiences in a home setting. Following the workshop, a brief report addressing the safety of use of haemodialysis machines at home has been generated and accompanies this letter to the Coroner's Office.

Outcomes and planned actions from the workshop for the SCV Renal Clinical Network (RCN) include that:

- The RCN review protocols and procedures for home haemodialysis dialysis across Victorian healthcare services, with the aim of developing a standardised state-wide approach to the delivery of home haemodialysis;
- A copy of the final Risk Analysis Workshop Report will be sent to all stakeholders who participated in the workshop;
- A copy of this Risk Analysis Workshop Report will be sent to providers of home haemodialysis services in Victoria; Kidney Health Australia; and the Australian and New Zealand Society of Nephrology (ANZSN) Clinical Policy Advisory Committee and Dialysis Advisory Committee;
- Information and issues raised at the workshop will inform future discussions within the RCN and SCV, with the aim of improving the quality of care received by renal patients in Victoria.

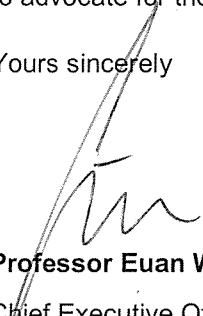
Key themes identified at the workshop include a desire for:

- Standardisation of home dialysis training protocols;

- Purpose built home machines with latest safety features which are easy to use;
- Regular assessment and reassessment of patients;
- Availability of respite;
- Shared learnings between services of near misses and events.

SCV, through the work of our Clinical Networks and our broader health service support functions, will continue to advocate for the safe care of all Victorian patients.

Yours sincerely



Professor Euan Wallace

Chief Executive Officer

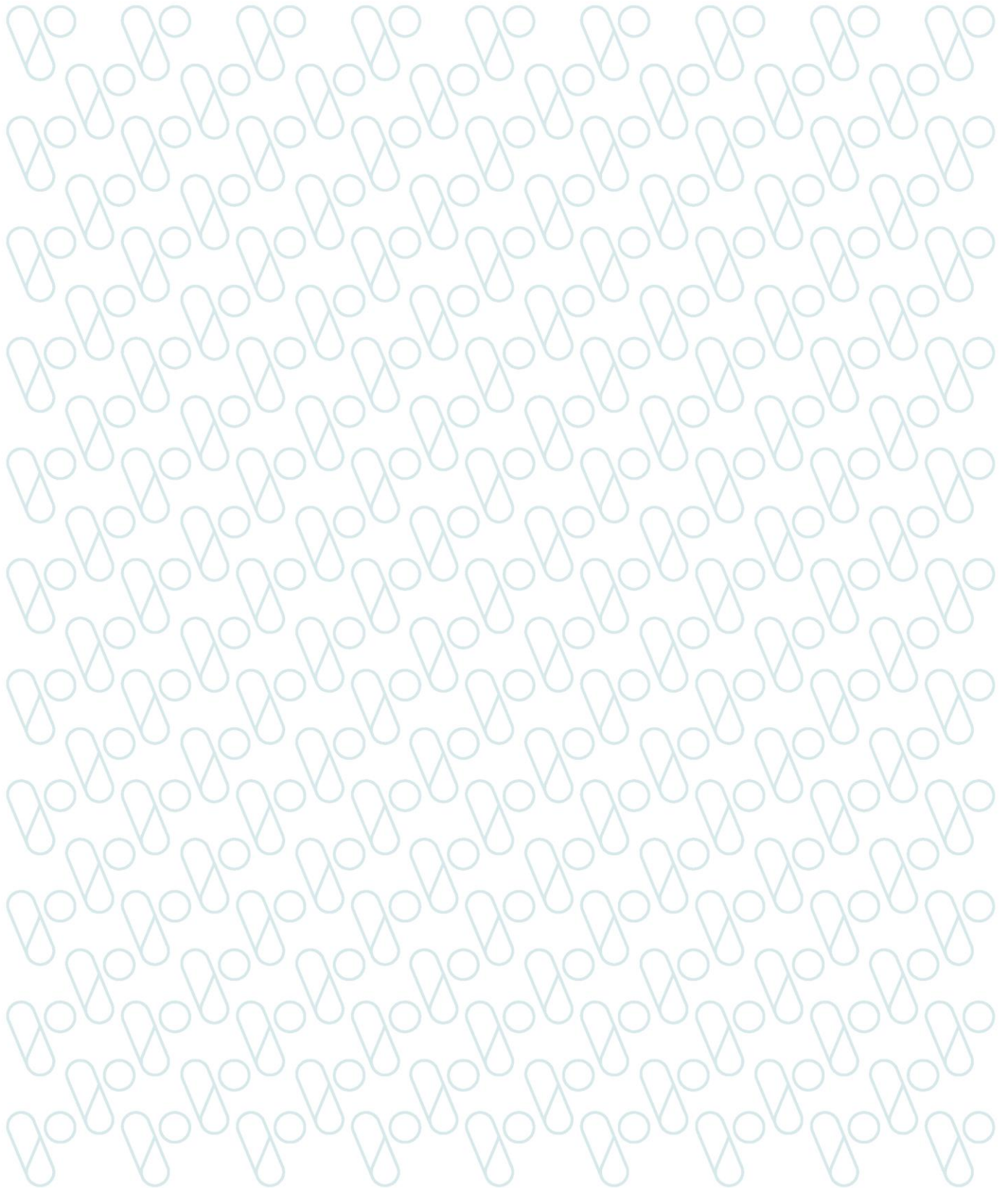
Safer Care Victoria

January 2019

Home haemodialysis risk analysis workshop

Summary document





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Summary

Home haemodialysis (HHD) enhances independence and quality of life for patients with end-stage kidney disease. It is associated with better overall outcomes than haemodialysis in-centre. About 10 per cent of Victorian dialysis patients are managed with HHD. However, after a case of fatal exsanguination (blood loss) in a HHD patient, the Victorian coroner recommended that Safer Care Victoria (SCV) review the safety of haemodialysis machines used by HHD patients and supported by Victorian public health services.

PROCESS

SCV held a half-day workshop in November 2018 to analyse the risks of using haemodialysis machines at home.

The workshop was attended by:

- consumers and a carer
- renal nurses
- nephrologists
- haemodialysis technicians
- representative from Therapeutic Goods Administration (TGA)
- representative from Health Purchasing Victoria (HPV)
- representatives from the major manufacturers of haemodialysis machines

Attendees represented metropolitan and regional health services.

We used a human factors approach to address the risk of exsanguination during home HHD, and to identify ways to prevent things going wrong or to reduce consequences if they do.

RESULTS AND OUTCOMES

Identified risks

We analysed the components of the HHD process as a sociotechnical system, and identified a wide range of factors contributing to what could go wrong and why. These included:

- patient factors
- machine factors
- patient and machine connection
- training
- staff and health services
- policies and procedures.

Opportunities for improvement

We identified a wide range of improvement opportunities, including those already in place and future aspirations, such as:

- improvements to machine design
- improved safety of connection and disconnection systems
- greater standardisation of training and procedures
- better assessments of patient physical and mental health
- improved systems of governance.

The output of the workshop will be used to help inform safety and quality improvements for Victorian HHD patients.

Workshop overview

PURPOSE

- To identify risks and opportunities for improvement for haemodialysis machines used in the home.
- To inform SCV's response to the Coroner's recommendation.

Coroner's recommendation

That Safer Care Victoria review the safety of haemodialysis machines used by home haemodialysis patients supported by Victorian public health services, with a particular focus on failsafe mechanisms and ways to avoid potentially dangerous short cuts when used in the home setting.

(Coroner's report: 6 September 2018 - COR 2015 004647)

SCOPE

In scope was:

- a holistic risk analysis of home haemodialysis focused on the risk of exsanguination during home haemodialysis
- a focus on the system supporting human-machine interaction
- identifying risks and opportunities for improvement.

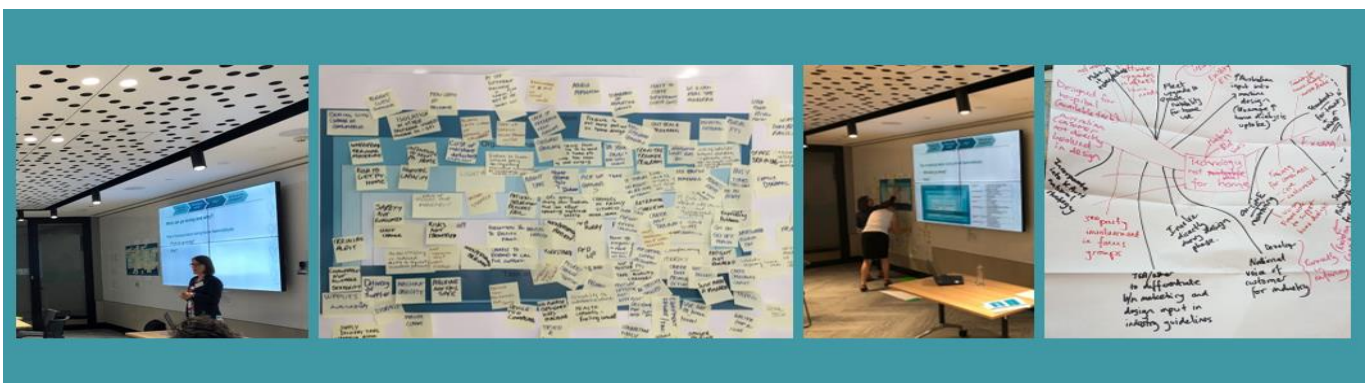
This overview document and a response to the coroner were developed following the workshop. Out of scope were any case specific elements or re-investigation of the case, usability assessment, risk analysis for a particular machine or brand, other types of dialysis, full systematic review, and implementation of any recommendations identified.

METHOD

We used a human factors approach for the workshop. It aimed to understand factors affecting patients, staff and the technology at the core of the issue, along with all the elements of the wider home haemodialysis system and how they interact (**Figure 1**).

Posters of this system figure were placed on the walls, and attendees were invited to attach thoughts, topics and discussion points using sticky notes. (**Figure 2**).

For feedback on this method, see page 17.



Attendees were divided into two separate groups, with those from the same service put in to different groups where possible. Each of the two groups included a balanced mix of skill sets. The groups worked through the following questions and then reported back to each other:

1. What and who is in the 'home haemodialysis system'?
2. Risk of exsanguination during home haemodialysis: What can go wrong and why?
3. Opportunities for improvement:
 - What do we currently have in place to prevent things from going wrong or to minimise harm?
 - Importantly, what else can we aspire to do?

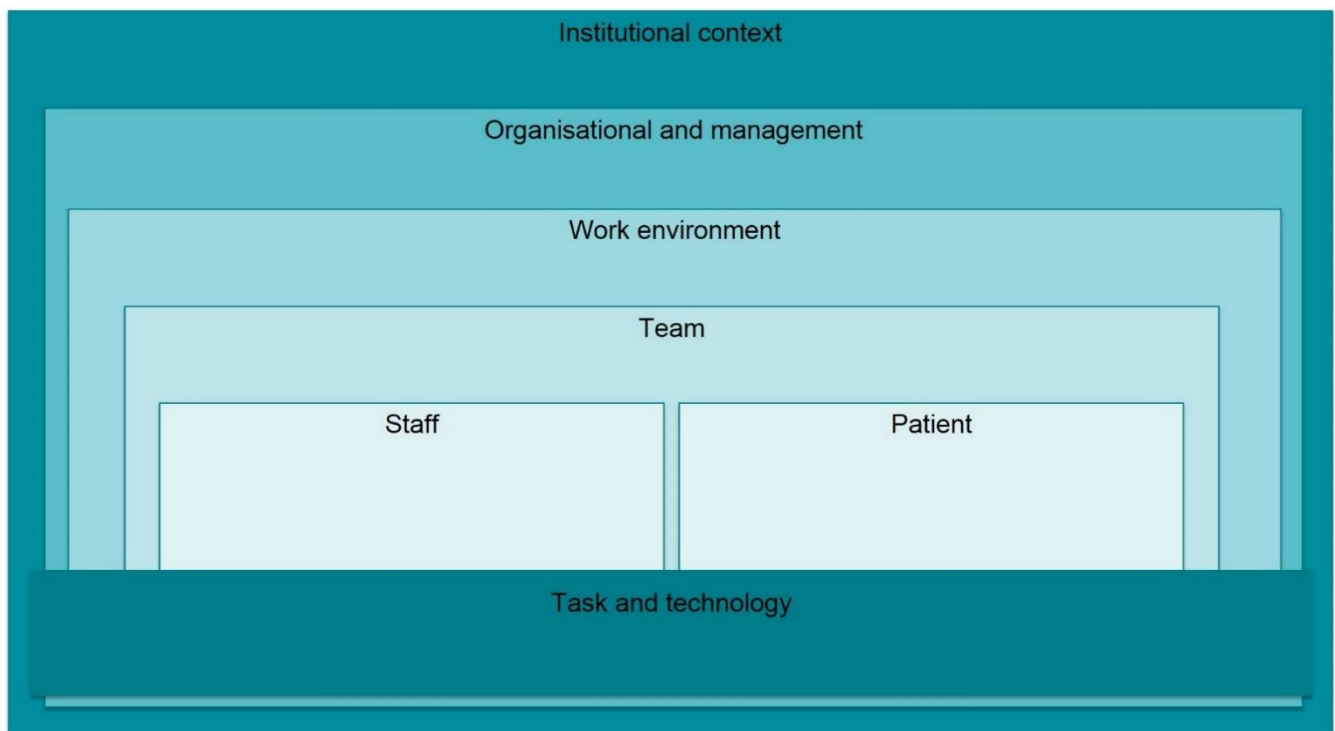
The two groups identified overlapping and unique insights.

The following pages summarise the information gathered during the workshop through a structured discussion.

This only represents the view of the workshop attendees and may therefore be incomplete or include opinions that are not held by other stakeholders.

The draft summary report was circulated to the workshop attendees with feedback incorporated into the final draft.

Figure 1. The different layers considered as part of the 'HHD system', which was provided as a basis for discussion at the workshop

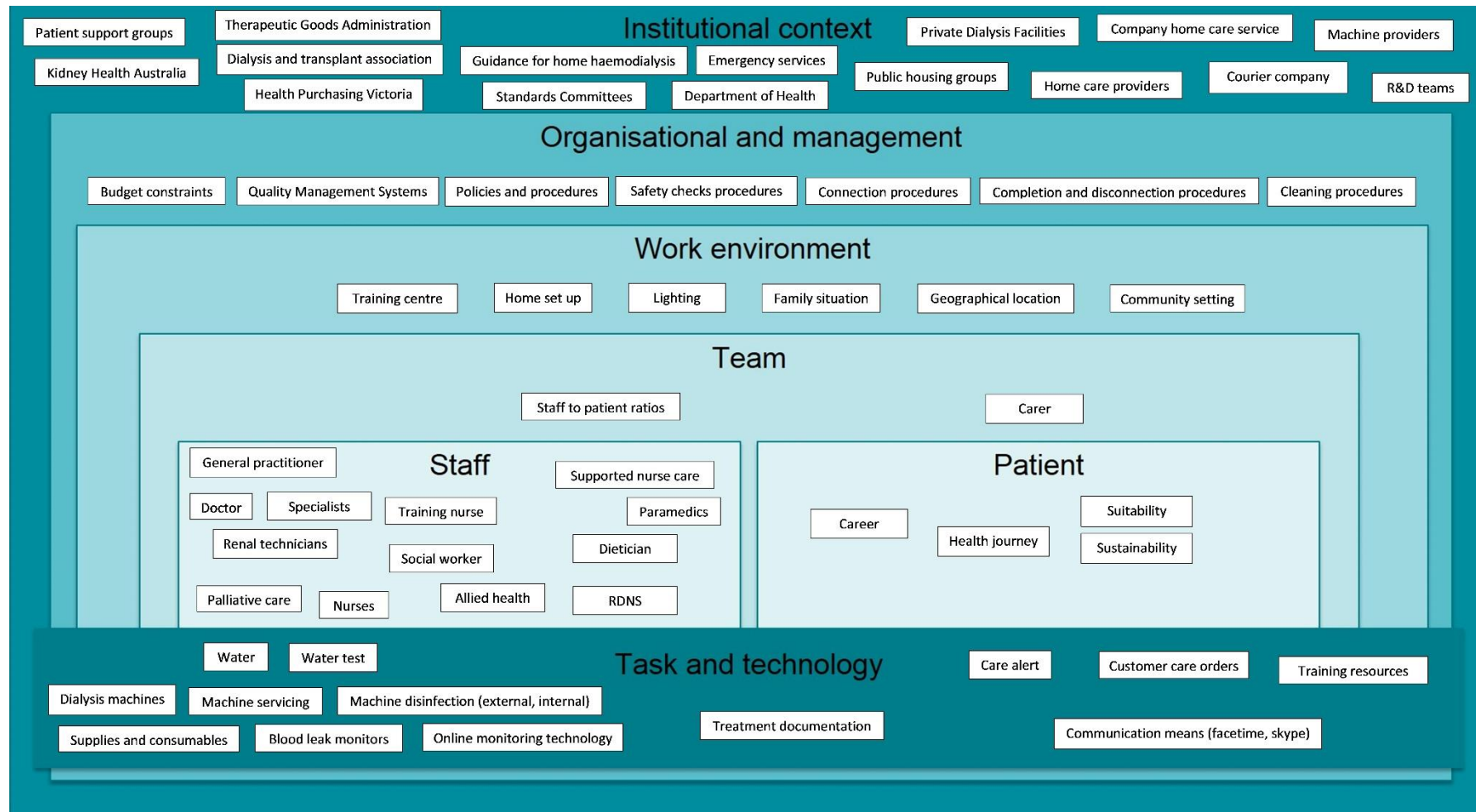


SUMMARY

1. What is the 'home haemodialysis system'?

Attendees considered who and what exists in the HHD system. This helped set the scene for the rest of the workshop to ensure a focus on the larger system rather than focusing on the machine, staff or patient only.

Figure 2. Components of the home haemodialysis system, as identified by the workshop attendees



2. Risk of exsanguination during home haemodialysis: What can go wrong and why?

Attendees identified possible factors contributing to the risk of exsanguination during HHD. The factors identified across the two groups were combined, themed and are summarised below.

Theme	What could go wrong and why?		
Patient Carer	<p>CAPABILITY</p> <ul style="list-style-type: none"> ● Low literacy ● Limited experience ● Low level of competence ● Device seems too technical or complicated 	<p>MENTAL STATE</p> <ul style="list-style-type: none"> ● Made a mistake ● In a hurry ● Not engaged ● Complacent ● Not seeking help ● Distraction ● Fed up ● Tired ● Chronic fatigue ● Mental health issues 	<p>CHANGES</p> <ul style="list-style-type: none"> ● Eyesight ● Unwell, fever ● Mental and physical health changes ● Prescription medication affecting operating machine ● ageing <p>SOCIAL ENVIRONMENT</p> <ul style="list-style-type: none"> ● Dialysis alone ● Patient and family not motivated ● Changes in family situation ● Competing personal demands
Staff	<p>RESOURCE MANAGEMENT</p> <ul style="list-style-type: none"> ● Staff changes ● Under staffed ● Insufficient role clarity, e.g. technicians versus nurses ● Staff to patient ratios, centre/service specific ● Lack of after-hours clinical or technical support 		<p>MULTI-DISCIPLINARY</p> <p>Uncertainty when to get social worker involved (assessment)</p>

Theme	What could go wrong and why?	
Location	<p>COMMUNITY BARRIERS</p> <p>Outreach programs needed</p>	<p>GEOGRAPHICAL BARRIERS</p> <ul style="list-style-type: none"> ● Variation of accessible services, e.g. water, power ● Regional: may need to ship in water ● Reduced access to health services and support ● Lack of satellite dialysis availability – patients who are no longer suitable for HHD
Machine	<p>VARIATION</p> <ul style="list-style-type: none"> ● Variations in machine design cause confusion ● Older machines in use ● Multiple generations of machines in circulation 	<p>INFREQUENT EVENTS</p> <p>Infrequent events/failures (power off) – patient doesn't know what to do or forgets - needs manual</p>
	<p>COMPLEXITY</p> <p>New safety features make the machine more complex</p>	<p>FAULT RECTIFICATION</p> <ul style="list-style-type: none"> ● Can forget how to rectify fault over time ● Technician unavailable/unable to respond to call for support ● Home dialysis preparation visits are generally Monday to Friday - some after-hours support available
	<p>RISK ASSESSMENT</p> <ul style="list-style-type: none"> ● Safety not sufficiently evaluated ● Not all risks are identified 	
	<p>FAULTS/FAILSAFE</p> <ul style="list-style-type: none"> ● Equipment failure or fault ● Machine is not failsafe 	
		<p>DESIGN FOR HOME USE</p> <ul style="list-style-type: none"> ● Machines not purposely designed for home – tried and failed to date ● HHD market is too small for manufacturers to invest in specific machine development ● Home machines do not have same safety features as in-centre due to footprint of machines
		<p>USER INPUT IN DESIGN</p> <ul style="list-style-type: none"> ● User is not the purchaser ● Misconception patients are not allowed to be directly consulted by manufacturer (can be consulted via focus groups) ● Design informed by clinicians ● Trials are done in centre dialysis not HHD

Theme	What could go wrong and why?		
Connections and consumables	<p>CHANGE IN CONSUMABLES</p> <ul style="list-style-type: none"> Budget cuts/changes Price of consumables has been driven down and resulted in changes to suppliers, e.g. blood lines Dealing with change of consumables May meet standard but there is a scale of what is acceptable (parts, needles) 	<p>PATIENT NEEDS</p> <p>Consumables not suitable for all dexterity levels, e.g. small clamps, Luer lock sticky</p> <p>DESIGN</p> <ul style="list-style-type: none"> Non-standard lines Design of lines is machine specific Manufacturers validate their blood lines on their machines 	<p>SUPPLIES AND STOCK</p> <ul style="list-style-type: none"> Issues with supply delivery: delivery times, changing drivers, not rotating stock Supply availability varies Storage may vary Things may fall out when opening a pack –need to grab another one, which requires stock and good quality control during packing
Patient and machine connection during home haemodialysis	<p>CONNECTING</p> <ul style="list-style-type: none"> Connecting on and off is a busy time (critical time) Tricky process Relies on patient/carer vigilance Overloaded, a lot going on Danger period when lines are disconnected 	<p>CONNECTION ISSUES</p> <ul style="list-style-type: none"> Systemic leak Needle can come out Needles are inflexible Market viability limits needle design Limited choice of tape Tape quality changes Skin integrity issues Inadequate taping Overlock not tight enough Disconnection (direct/indirect) Protocols non-standard Training/compliance variation Bleeding from fistula Self-harm 	<p>MACHINE SENSORS</p> <ul style="list-style-type: none"> Machine does not 'know' if it is connected to patient Pressure sensors not always sufficiently sensitive: distal to patient and line design variation Can disable the blood detector or forget to put it in Machine can start without blood detector in place <p>OTHER SENSORS</p> <ul style="list-style-type: none"> Not all use moisture detectors Some moisture detectors not purpose designed (design for bed wetting) High cost of moisture detectors (are disposable)

Theme	What could go wrong and why?		
Suitability assessment	<p>SUITABILITY</p> <p>Inadequate minimum specifications lead to variable assessment of patients for suitability</p>	<p>FLAGS FOR CHANGES</p> <p>Patient needs to be very capable to do HHD - this can change over time and may not be picked up as there is no regular reassessment/review</p>	
Training	<p>STANDARDISATION</p> <ul style="list-style-type: none"> ● No standardised formal training program for HHD leads to variable unit policy and oversight ● Individual training program, different per centre ● Variation in standards of training. No central standards in training ● Variation in re-training and annual competence (patients and staff) 	<p>QUALITY</p> <ul style="list-style-type: none"> ● Inexperienced trainer ● Inappropriate training materials ● Exsanguination minimally covered in training 	<p>LONG TERM CAPABILITY</p> <ul style="list-style-type: none"> ● Over time people forget what was learned in training ● Informal communication between patients ● If things go right, we don't reassess or retrain patients ● Should do retraining and checking routinely
		<p>EXPOSURE</p> <p>Patient will see different machines, different nurses and different strategies (may be short cuts) when in acute settings, then they may try these at home</p>	<p>CARER TRAINING</p> <p>Carer is not always trained but will start doing priming and setting up, not always disclosed/discussed, there are carer emergency charts</p>

Theme	What could go wrong and why?		
Policies and procedures	<p>VARIATION</p> <p>There is some general guidance, but variation exists between health services policies and procedures (lack of standardisation)</p>	<p>STANDARDS</p> <p>International Organisation for Standardisation (ISO) standards for HHD mainly consider electrical safety, etc but not human factors or consumables (for example)</p>	
Picking up changes	<p>CHANGES</p> <p>Changes not picked up</p>	<p>MONITORING/ASSESSMENT</p> <ul style="list-style-type: none"> ● No routine monitoring ● Lack of regular home assessment ● Understaffing – reduced ability to regularly reassess patients ● No formal policy in place regarding mandated reassessment of patient competency ● Patients may refuse home visits ● Patients may fail to attend clinic and then is not reassessed regularly 	<p>REAL-TIME MONITORING</p> <ul style="list-style-type: none"> ● Real-time monitoring not available in Australia ● Would patient want real-time monitoring (privacy vs risk)? <p>HOME VISITS</p> <ul style="list-style-type: none"> ● Home visits during day, see how they perform during day (not night) ● Penalty rates if visiting at night ● Often on best behaviour <p>DISCONTINUING HOME DIALYSIS</p> <p>Patient may refuse to get off home haemodialysis (if found to be no longer suitable) and technicians may have to go in and remove machine (conflict)</p>
	<p>DIALYSIS SETTING</p> <ul style="list-style-type: none"> ● Home alone while on dialysis ● Night time dialysis higher risk of problems unnoticed 		
	<p>KNOWING WHAT GOES ON</p> <ul style="list-style-type: none"> ● Patients don't always express problems ● Not knowing what goes on ● On your own, not seen a nurse for a while 		

Theme

What could go wrong and why?

Health service

CAPACITY TO DIALYSE IN CENTRE

Hospital does not have sufficient capacity (maximum patient numbers) to accommodate large number of patients coming in for dialysis

HOSPITAL INTERACTION

- Hospital at capacity
- Pressure from in-centre dialysis to send unwell patients home too soon (i.e. post-surgery)
- Rush and incentivised to get patient home
- Low knowledge in emergency department about renal needs
- Pressure to put more patients on HDD

Connecting with and learning from others

INTEGRATION

- Isolation from other health professionals
- Lack of understanding of dialysis by others, e.g. general practitioners

VARIATION

- State to state different machines, consumables and processes
- Different hospitals have different machines, consumables and processes

LEARNING

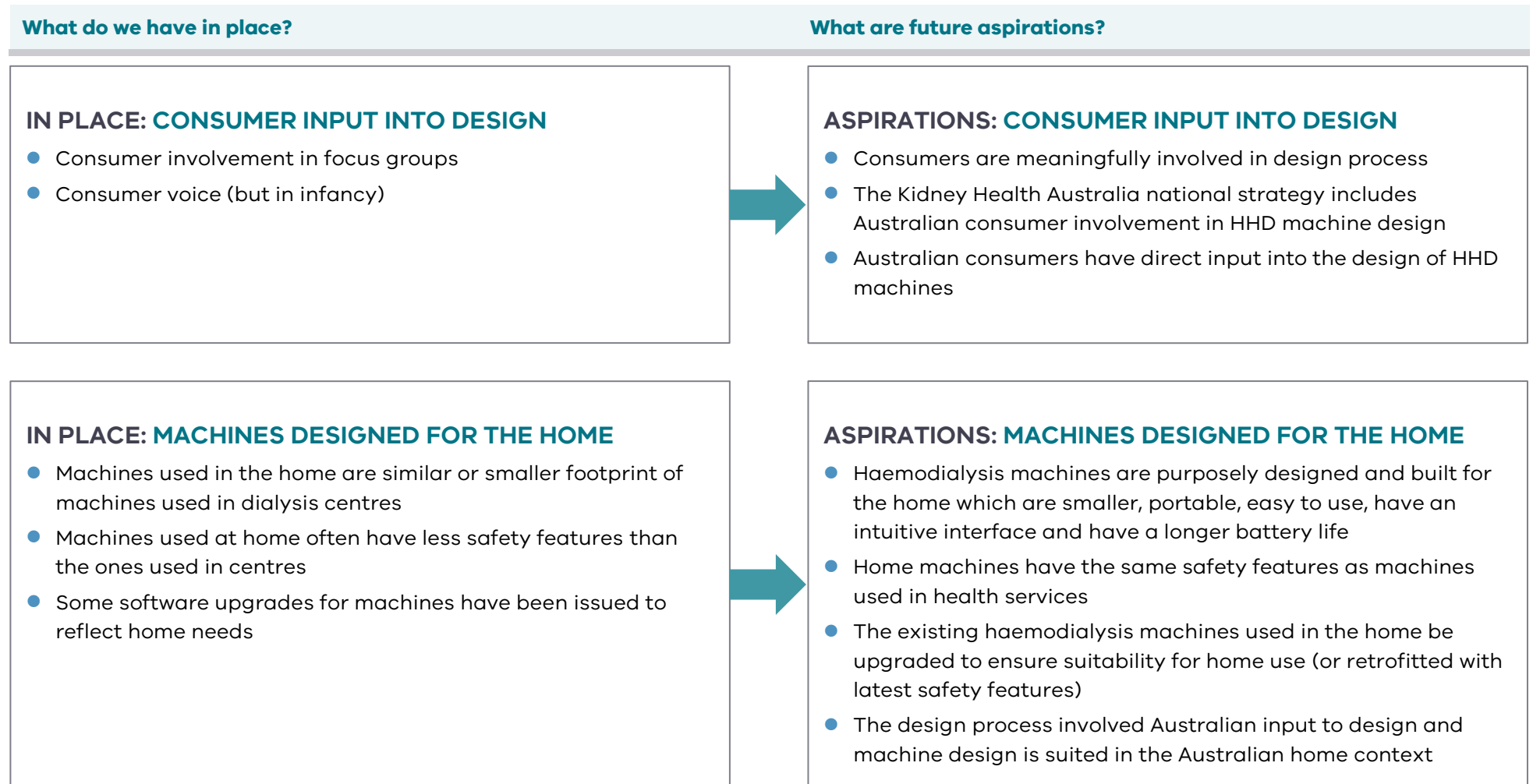
- Lack of sharing issues/problems noted across health services and states
- Blame game instead of learning opportunity

CORONER

- Lack of feedback from coroner
- Lack of standard reporting to and from coroner
- Need for closure and grieving for staff and patients

3. Opportunities for improvement: what do we currently have in place to prevent things from going wrong or to minimise harm and, importantly, what else can we aspire to do?

Attendees identified strategies to reduce the risk of exsanguination and whether these strategies were already in place or were future aspirations. The insights identified across the two groups were combined, themed and are summarised below.



What do we have in place?

IN PLACE: CHANGES TO MACHINE

- Some health services send group SMS to patients once they are informed of changes by the manufacturer or supplier, or have identified a problem
- An overhaul of machines and supplies when there is a manufacturer or supplier change at a health service



What are future aspirations?

ASPIRATIONS: CHANGES TO MACHINE

- Health services and patients receive timely information from the manufacturers and suppliers about upcoming changes
- Manufacturer and supplier changes in health services are gradual to allow adjustment and training

IN PLACE: SAFETY DEVICES IF DISCONNECTED

- Blood detectors
- Older machines have the same alarm tone for critical and non-critical alarms. Newer in-centre machines have different tones for critical and non-critical alarms
- One machine currently on the market has a dynamic pressure detector that can stop the machine
- One machine currently on the market has a wetness detector that can stop the machine
- In some countries, there has been experience with real-time monitoring of HHD patients where a failed attempt to contact a patient, could be followed up by calling an ambulance



ASPIRATIONS: SAFETY DEVICES IF DISCONNECTED

- Mandatory use of leak detectors and failsafe mechanisms that will stop the machine if leak detected or if detector not in place
- Wetness detectors are cheaper, easier, better, purpose-designed and mandated
- All machines have dynamic pressure detectors that can stop the machine if a problem is detected
- All machines have alarms designed using good design principles (including better able to be distinguished, response requirement etc), made easier to distinguish critical and non-critical alarms, and alarms that cannot be easily overridden
- Machines 'know' whether connections are successful
- All machines have air detectors
- All machines have blood detectors (used while running on) which will turn machine off when blood detected, and cannot be bypassed or overridden
- Real-time and/or remote monitoring is available to all HHD patients and help is dispatched if patients cannot be contacted

What do we have in place?

IN PLACE: CONNECTING MACHINE AND PATIENT

- Needle and taping has remained the same for a long period of time
- Taping – Chevron technique
- TEGO connector
- Before-treatment checklists (not always used)
- Some newer machines in dialysis centres have a cartridge/cassette approach to assembling lines which requires less dexterity and connection steps
- National safety standards for line connections (*added due to feedback)



What are future aspirations?

ASPIRATIONS: CONNECTING MACHINE AND PATIENT

- Patients are connected to the lines using a connector that does not dislodge easily
- If patients are using a needle to connect to the lines, better tape is available to prevent disconnection
- All machines use a cartridge/cassette system with all lines pre-assembled to connect lines and the machine
- Programs are available to have nurses roam a region (home visits) and help patients connecting on and off to the machine.
- Consumables and parts are compatible with a range of dexterity levels for patients
- Lines and consumables are not machine specific
- Improved adherence to national safety standards on line connections
- Improved safety standards for machine and tubing connections

IN PLACE: TRAINING

- Training for patients (core, customised)
- Training for HHD nurses and technicians
- Training audit
- Train the trainer program
- One-on-one training
- Decisions about training are made within each health service



ASPIRATIONS: TRAINING

- Standards for training and trainers that maintain adherence to standard operating procedures and protocols
- Core safety training is standardised across machines and manufacturers
- Training and manuals have key information sheets for patients to quickly find important information
- Support material is available for infrequent emergency situations for patients and carers
- Training resources are adapted for easy use and training in the home
- Technicians and patients are regularly recertified
- After hours clinical and technical support available to all patients at all times

What do we have in place?

IN PLACE: PICKING UP CHANGES IN PATIENT PHYSICAL AND MENTAL HEALTH

- Home visits (but is variable)
- Patients attend health service at regular intervals (attendance variable)
- Referral process to escalate concerns (is informal and ad hoc)
- Some experience overseas with real-time remote monitoring – where a failed attempt to contact a patient can be followed up by calling an ambulance



What are future aspirations?

ASPIRATIONS: PICKING UP CHANGES IN PATIENT PHYSICAL AND MENTAL HEALTH

- Patient 'issues' are well researched
- Evidence based and standardised patient suitability assessment process
- Evidence based understanding of risk of solo dialysis
- Assessment of patient capability and understanding
- Establish competence for HHD
- Regular assessment and reassessment of patient and carers, including psychosocial factors
- Staff are equipped to assess mental health status
- Mental health assessment tools are integrated
- Re-assessment is conducted at regular intervals
- Multi-disciplinary decision-making tools are available to support assessment and process (team approach)
- Patients are actively engaged in ongoing evaluation of suitability
- Patients receive training to recognise changes early
- Fatigue risk assessment for patients and carers
- Clear guidelines for patients, co-designed with patients
- Routine monitoring
- Non-punitive near miss reporting system for health services
- Formal referral process to escalate concerns in place
- Trigger or mechanism for respite (day or night)
- Availability of option to dialyse in a centre for respite (day/night)
- Staff are supported to have difficult conversation with patient about changes to treatment
- Real-time and/or remote monitoring is available to all HHD patients and help is dispatched if patients cannot be contacted

What do we have in place?

IN PLACE: GUIDANCE AND GOVERNANCE

- General guidance (but variation is wide)
- Minimum specification (prospective)
- Victorian framework to support HHD
- Standards consider electrical safety
- Funding model: home dialysis grant uncapped
- TGA approved products
- HPV mandate approved purchasing list
- Department of Health and Human Services: Targets, funding, KPIs



What are future aspirations?

ASPIRATIONS: GUIDANCE AND GOVERNANCE

- Resolution and publication of standards for home - ISO registration
- Further specification (retrospective)
- Statewide policy/procedure for HHD
- Standards consider human factors and consumables
- Regulatory changes or equipment changes to be gradual, if safe to do so, to enable adaption and training of staff and patients

IN PLACE: LEARNING

- Learning happens within health services
- Coroner cases provide learning opportunities across health services



ASPIRATIONS: LEARNING

- Health services and states share experiences and are learning from each other from near misses to serious events
- Increased co-operation and communication between the TGA and other agencies (e.g. SCV) regarding the reporting and review of adverse events involving haemodialysis machines

Next steps

SCV's Renal Clinical Network will review protocols and procedures for HHD dialysis across Victorian healthcare services, with the aim of developing a standardised statewide approach to the delivery of HHD.

Information and issues raised at the workshop will inform future discussions within the clinical network and SCV, with the aim of improving the quality of care received by renal patients in Victoria. These include a desire for:

- standardising home dialysis training protocols
- purpose built home machines with latest safety features which are easy to use
- regular assessment and reassessment of patients
- availability of respite
- shared learnings between services.

SCV's Renal Clinical Network Governance Committee will review the findings and consider implications for the network.

Distribution

This report will be sent to:

- the Coroner as a follow up to SCV's response letter
- all stakeholders who participated in the workshop, including consumers and clinicians, HPV, the TGA and two major manufacturers of haemodialysis machines in Australia
- providers of HHD services in Victoria
- Kidney Health Australia
- the Australian and New Zealand Society of Nephrology (ANZSN) Clinical Policy Advisory Committee and Dialysis Advisory Committee.

Acknowledgements

This document was prepared by Miranda Cornelissen, Maree Branagan, Peter Mount, Nathan Farrow and Gemma Ricketson.

Appendix: Feedback

The workshop used a human factors approach which is a new process for SCV. Participants in the workshop were asked to provide feedback on the summary document, their involvement in the workshop and learnings from the day. The following questions were provided in a survey sent to each participant:

1. Does the attached document accurately reflect your input and discussion on the day?

If not, please reference the element which you believe is not an accurate reflection of what was said on the day and suggest what you believe it should be. (Please note this document is an overview of all participants' input and only reflects the discussion on the day)

2. What were the main learnings you took away from the workshop?

3. Have the learnings resulted in any changes you are proposing or have already made?

If yes, please describe these so that we can showcase this feedback in the report.

4. How did you find the workshop process using a human factors and systems lens on the problem, and using the facilitated discussions to identify risks and opportunities for improvement for home haemodialysis?

The overall feedback indicated that it was a productive and positive experience. Some comments received are grouped into themes on the following pages.

LEARNINGS

"The workshop created an opportunity to reflect on the multifaceted structure that is set up to send people home on dialysis. As a result of the many people and institutions involved, we inherently get multiple layers of policies and procedures that often don't intersect. There is certainly room for improvement from all the stakeholders if a unified approach is developed. From a technical point of view, I was unaware of a machine on the market with 'integrated' wet sensors and dynamic pressure sensors. The problem of needle dislodgement has been known for a very long time. Good to see a design team is now looking at it. This should be fast tracked to all available machines on the market as well as further safety features to protect the home patient. Input from all stakeholders to the design process would be a valuable thing. At least supplying a wish list."

"Not having a clinical background, a key learning was the significant number of potential contributing factors that could lead to exsanguination. I was surprised that there was not greater standardisation across health services or training resources available."

"Need for standardised training of all staff. Zero tolerance of shortcuts and modifications."

"The importance of sharing experiences and learning from each other. Consideration for standardisation of policies and procedures across the state."

"Opportunities for risk reduction regarding exsanguination in HHD."

"Complexity of system and process."

"The need for improved communication and support with regard to provision of Home haemodialysis (HHD) to enable learning from each other and industry signals to produce innovation to enhance safety."

CHANGES PROPOSED OR MADE

"Review of a patient's techniques and re-education for HHD was arranged for a consumer at the workshop by a nurse at his centre (which hadn't been done recently)."

"Increase in communication to patients around safely dialysing at home and being vigilant when setting up machines."

"Company staff informed. Training is already scripted." (manufacturer representative)

"Awaiting final report to enable local consideration and prioritisation of recommendations."

"I will report back to our global team some of the suggested improvements needed." (manufacturer representative)

COMMENTS ON WORKSHOP PROCESS

"I found the interactive workshop with many people from all areas across home haemodialysis to be very beneficial in understanding what can go wrong, why and ways that it can be improved upon using a collaborative approach. An excellent idea that hopefully should see this area improves to the benefit of not only the patient's safety but the ease of care in the home setting."

"It was very well run and demanded participation and thought-provoking solutions. Looking at the issue from many angles."

"Enjoyed the process, was very logical and effective in working through potential issues and opportunities for improvement."

"First time at this type of workshop. It flowed well. We seemed a little short of time, which was probably inevitable. Having an array of stakeholders was good. The home dialysis structure was well fleshed out. A lot of the discussion was probably broader than the immediate problem of exsanguination (again, probably inevitable) but to place the problem in the bigger picture highlights the pathways we need to navigate to address even simple issues. The process also highlighted the necessity of a two-way involvement between patient and the haemodialysis system. Risks and opportunity for improvement were highlighted and discussed but the big gap is how to facilitate those discussions into productive outcomes across a broad national organisation. The dissemination of information gathered will be an important part of the process to make sure all stakeholders are involved and aware of problems in the world of home haemodialysis. Sharing of information (good and bad) is a key factor."

"I thought the workshop was excellent and the volume of information collected in a 4-hour session was accurate and impressive. There needs to be more group activities like this. This is just the start of the conversation and more work groups like this should be encouraged to lead a change in making dialysis and equipment optimal for patient safety."

"This was an appropriate setting and structure, hopefully there will be future opportunities to develop guidelines and standardisation for home units."

