# One-way valves and administration sets - a consultation document.

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## Background

In April 2016, a report was tabled at SALG (Safe Anaesthesia Liaison Group) regarding a patient who had a KCl infusion from a pumped giving set administered through a twin port connector on a central line. The other port had a gravity admin set connected with a bag of Hartmanns.

The patient went into sudden cardiac arrest, the suspected cause being hyperkalaemia (excess potassium) due to rapid infusion of potassium chloride.

The post incident investigation determined that at some stage the central line had been clamped, and during this period the pumped KCl followed the path of least resistance up the gravity set. The pump therefore did not alarm as no blockage was detected. The clamp was released after about 2.5 hours and it is thought that a bolus dose of the KCl was released into the patient centrally, which was sufficient to cause ventricular fibrillation (VF).

A discussion ensued about the role of one-way valves in administration sets to prevent retrograde flow. After the meeting, members of SALG had further discussions about whether International Standards for administration sets could help mitigate the risk of these incidents by providing a mechanical barrier to retrograde flow by default. It was noted that most gravity (manual) administration sets do not have anti-reflux valves attached.

Another issue arises with infusion sets used in volumetric infusion devices. By definition, these sets are used to deliver drugs where rate and volume need to be controlled, and sometimes this will mean very precise control is mandated, eg insulin-containing solutions, potassium containing solutions, fluids in patients where fluid balance is delicate and/or critical. If, upon removing the infusion set from the device it becomes (or can become) a gravity driven set, it is a case of 'fail dangerous'. One solution might be for infusion sets

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for volumetric devices to also incorporate a valve that prevents the set functioning as a gravity set, ie requires a higher opening pressure (a 'crack valve').

One of the members of SALG is also a member of the BSI committee which deals with administration sets and coordinated a series of email exchanges and a conference call between some SALG members and members of BSI committee CH/212 (the UK mirror committee for ISO/TC 76 Work Group 1- Transfusion, infusion and injection and blood processing equipment for medical and pharmaceutical use).

# Clinical Incidents - retrograde and free flow.

There have been a number of reported and unreported incidents where one-way valves may have reduced the risk to patients:

1. The risk of 'backtracking' of drugs into i.v. lines, with subsequent unintended flushing in of drugs has been the subject of an alert from the Medicines and Healthcare products Regulatory Agency[5]. This alert specifically highlights the problem arising when a multi-lumen connector is used, with the drug infused in one lumen backtracking into the other, rather than flowing forward into the patient. However, the problem can also occur without multi-lumen connectors being involved; an example would be a drug injected into the port of an i.v. cannula which is occluded distally (perhaps by thrombus) and so the injected drug backtracks into the giving set. If the cannula is later flushed and cleared, an unintended bolus of drug can be delivered. When this event is reported or referred to[6,7,8,9], it is often framed as being caused simply by residual unflushed drug in the cannula, but given the small volume of this and the magnitude of effect seen, it seems likely that the phenomenon of 'backtracking' may also be implicated.
2. There has been a reported incident in the UK where an administration set was placed in a pump in reverse formation, and lead to exsanguination of the patient. An alert clinician detected the presence of blood in the administration set.
3. One of the authors has observed a patient coming from a ward where the infusion set for a glucose-potassium-insulin infusion had been removed from its volumetric device, effectively converting it to a free running, gravity fed drip. This carried with it the significant risk of an unintended overdose of those potentially fatal drugs.

[5] MHRA, "Intravenous (IV) extension sets with multiple ports - risk of - Gov.uk." 20 Sep. 2010, https://www.gov.uk/drug-device-alerts/medical-device-alert-intravenous-iv-extension-sets-with-multiple-ports-risk-of-backtracking. Accessed 17 Jan. 2017.
[6] "Residual anaesthesia drugs in intravenous lines – a silent threat ...." 13 May. 2013, http://onlinelibrary.wiley.com/doi/10.1111/anae.12287/full. Accessed 17 Jan. 2017.
[7] "Residual anaesthesia drugs – silent threat ... - Wiley Online Library." http://onlinelibrary.wiley.com/doi/10.1111/anae.12370/full. Accessed 17 Jan. 2017.
[8] "Residual anaesthetic drugs in cannulae | Signal - Patient Safety." 27 Nov. 2009, http://www.nrls.npsa.nhs.uk/resources/?EntryId45=65333. Accessed 17 Jan. 2017.
[9] "Residual Anaesthetic Drugs in Cannulae and ... - NHS England." 14 Apr. 2014, https://www.england.nhs.uk/wp-content/uploads/2014/04/psa-residual-anaesthetic-drugs.pdf. Accessed 17 Jan. 2017.

4. Anaesthesia is often given by propofol infusion with a fluid infusion in parallel. This is deemed good practice to ensure that the vein is patent (if the fluid is running into the vein then the propofol is as well, and if the fluid stops then there is a risk the propofol is not getting to the parts it needs to reach). One of the authors knows of at least four cases in the last two years in their own hospital where the anaesthetist observed propofol being infused back up the fluid line, but the pressure alarms on the propofol pump did not activate. The patients were at risk of unintended awareness, and also of propofol overdose if the bolus was subsequently flushed. In all cases the anaesthetist incorrectly assumed that the device they had selected prevented backward flow in the IV line. It was only alertness of the individual anaesthetists combined with the clear visibility of propofol that prevented serious incidents.

There are also concerns about how users know what the functionality is to be expected of a particular device attached to the end of an administration set. For example, some needle-free connectors (NFCs - used for two-way access to the venous system - sampling and injecting/infusion) look very similar to anti-reflux devices once out of the packaging. An NFC attached to a cannula is sometimes confused with a one-way valve by clinicians not involved in the original setup of the cannula, who therefore assume that retrograde flow is not possible. Thus there are risks related to mis-identification of devices, especially where the device itself has no clear functional markings.

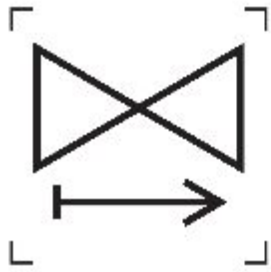
Finally, we suspect that there is confusion over the terminology used, such as '*check*', '*anti-syphon/anti-free-flow*', '*non-return*' and '*anti-reflux*' valves. A SALG document on TIVA [10] notes that:

> "*One-way valve = anti-reflux valve, check valve, non-return valve*"

A number of publications[11] help clarify the use of anti-syphon and anti-reflux valves in particular.

# Current Solutions

ISO have a symbol for one-way valves:

| | | |
|---|---|---|
| 5.6.6  | One-way valve | Indicates a medical device with a valve that allows flow in only one direction. |

[10] "SAFE ANAESTHESIA LIAISON GROUP Guaranteeing Drug Delivery in Total Intravenous Anaesthesia - AAGBI." https://www.aagbi.org/sites/default/files/tiva_info.pdf. Accessed 17 Jan. 2017.

[11] "The safe use of infusion devices - CEACCP - Oxford Journals." http://ceaccp.oxfordjournals.org/content/4/3/81.full. Accessed 17 Jan. 2017.

ISO also have a standard for 'check valves' : ISO 8536-12:2007 - *Infusion equipment for medical use -- Part 12: Check valves*, and whilst this includes performance requirements, it does not include a definition of a check valve or how it may be used.

# Proposed Actions

We believe that there are a number of ways we can mitigate the risks to patients. These range from short term / relatively easily achieved initiatives to longer term such as revising global medical device manufacturing standards.

1. Identify and agree a common nomenclature for the various types of valves and NFCs.
2. Raise awareness and education of clinicians so that they understand the role of one-way valves and other devices on the patient-proximal end of a giving set. This could include journal articles, patient safety alerts, and newsletter items.
3. Raise awareness and involvement of procurement and industry so that they understand the potential safety issues associated with the use of administration sets in the current diverse range of clinical settings and scenarios. Furthermore that they are primed and receptive to the changes that may be necessary to device specific ISO standards and their compliance, including appropriate labelling and marking when producing and acquiring devices.
4. Require clearer labeling on devices themselves[12] so that when packaging has been disposed of, their identity and expected functionality is still clear to the clinician. This would involve amendments to standards (for example, ISO 8536-12:2007 - *Infusion equipment for medical use -- Part 12: Check valves*) and liaison with manufacturers, possibly through BAREMA. This could include the use of the ISO one-way valve symbol.
5. Put forward a proposal to ISO TC76 WG1 to amend some of their medical device standards (for example ISO 8536-4:2010 - *Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed*, ISO 8536-8:2015 - *Infusion equipment for medical use -- Part 8: Infusion sets for single use with pressure infusion apparatus*, and ISO 8536-5:2004 - *Infusion equipment for medical use -- Part 5: Burette infusion sets for single use, gravity feed*) to include a mandatory one-way/anti-reflux valve.
6. Put forward a proposal to ISO to include an anti-free-flow valve on pumped sets to prevent them entering a free-flow infusion state when disconnected from the pump.
7. Request any National Guidelines[13] to be amended appropriately to caution against use of systems which can lead to retrograde flow.

There are a number of issues to be examined further if mandatory valves were to be considered, which may require testing. For example:

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[12] We accept that this may be difficult for small devices, but the use of symbols and codes may offer a solution.

[13] "Standards for infusion therapy - Royal College of Nursing." https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2016/december/005704.pdf. Accessed 17 Jan. 2017.

- would blood transfusion sets require the valves, and if so would they affect blood component quality (e.g. red cell haemolysis and activation of platelets and clotting factors) ?
- Would universal anti-reflux valves affect flow rates on standard gravity sets, and could they cause backpressure on pumped sets which may trigger an alarm[14] ?

*The purpose of this briefing is therefore to ask the clinical and medical device community whether they foresee any adverse consequences of the addition of a valve to administration sets which would outweigh the risk mitigation of unintended bolus and free flow.*

## Specific Questions:

1. Would you anticipate any adverse consequences from adding **one-way/anti-reflux valves** to **gravity IV infusion** administration sets ?
2. Would you anticipate any adverse consequences from adding **one-way/anti-reflux valves** to **pumped IV infusion** administration sets ?
3. Would you anticipate any adverse consequences from adding **anti free-flow valves** to **pumped IV infusion** administration sets ?
4. Would you anticipate any adverse consequences from adding **one-way/anti-reflux valves** to **blood transfusion** sets ?
5. Are you aware of any Professional or National Guidelines which should be amended to include advice on prevention of retrograde flow followed by unintended bolus ?
6. Do you have any suggestions as to how to investigate and/or avoid these potential adverse consequences?

Please send your responses to: oneway.valves.consultation@gmail.com

## Useful resources:

- AMS descriptors of different types of valves
- BBraun OEM list of valves

[14] "Arrangements of the intravenous parallel infusions with anti -reflux valves decreasing occlusion alarm delay - NCBI." 28 Apr. 2014, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4028558/. Accessed 17 Jan. 2017.