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Needle-free Devices

How do you choose?

The design and functionality selection criteria for Needle-free Access Devices

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Who are the Global Opinion Leaders?

Global opinion leaders comprise statutory government agencies, clinical organisations, expert individuals and the authors of evidence-based research.

For needle-free devices this includes:

- Food and Drug Administration Agency (FDA)
- Center for Disease Control (CDC)
- Society of Healthcare Epidemiology of America (SHEA)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- The Infusion Nurses Society (INS)
- epic3
- **Dr William Jarvis:** Dr. Jarvis is a former president of SHEA, he is a former president of the association of Professional Infection Control and Epidemiology (APIC) research foundation board of directors. He previously served as acting director of the CDC's infection control program (now a Division of Health Quality Promotion) amongst other positions during his 23 years at the CDC. In addition he has written a number of articles dedicated to NLCs.
  - Health Care-Associated Bloodstream Infections Associated with Negative or Positive Pressure or Displacement Mechanical Valve Needleless Connectors. Clinical Infectious Disease, Volume 49, Issue 12 P. 1821-1827.
  - Choosing the Best Design for Intravenous Needleless Connectors to Prevent Bloodstream Infections. Infection Control Today 2010.

Dr William Jarvis

Flow Rates Characteristics

The flow rates required for needle-free devices in general clinical use is determined by many factors such as temperature, fluid viscosity, length of the IV circuit, gauge of the smallest restricting component etc. The one constant is the maximum capability of the IV pump, which drives the fluid through the IV circuit into the patient. The maximum flow rates achieved with standard IV pumps are:

- Syringe drivers (Level 10 @ 950mmHg) = 2200ml/hr or 36.7ml/min or 0.61ml/sec
- LVP (level 10 @ 950mmHg) = 1500ml/hr or 25.0ml/min or 0.42ml/sec

In some clinical situations where very high volume is given rapidly (such as theatres or dialysis) any needle-free device (except a specifically designed device with gravity flow rates exceeding 450ml/min) will hinder flow. CT injectors require both adequate flow rate and maximum pressure characteristics. Ensure your device meets the pressure capacity required for CT injections or a minimum of 350psi.

16 key criteria to choose a Needle-free Access Device

Design and functionality criteria for needle-free devices	Published evidence
Microbial Ingress Testing Data	A needle-free device that is supported by microbial ingress testing data. (1)
Split Septum vs Mechanical Valve Devices	A split-septum needle-free device is associated with a lower incidence of CRBSI compared to a Mechanical Valve (MV) needle-free connector. (2,3) This is significant because a mechanical valve device has one or more moving parts in the fluid pathway.
Septum Disinfection	A needle-free device with a smooth external septum surface with few, if any gaps, that can be more thoroughly disinfected. (4)
Biofilm Reduction	A tight seal between the septum and the needle-free device housing to reduce or eliminate space for contamination to occur and potential biofilm to develop.(4)
Direct, Straight Fluid Pathway	A needle-free device with a direct, straight fluid pathway that facilitates adequate flushing and reduces the internal surface for potential biofilm development. (3,4)
No Moving Parts within the Fluid Pathway	A needle-free device with the most direct and least tortuous fluid pathway, with preferably no moving parts to reduce the potential risk of CRBSIs. (4)
Lowest Dead Space	A needle-free device with little or no dead space in the fluid pathway minimises the surfaces that infusates can contaminate and where biofilm can develop. (4)
Standardised Clamping Sequence	Best practice specifies a needle-free device (neutral) that does not require a clamping sequence. Alternatively, use only one needle-free device type that requires a specific clamp-disconnection sequence (e.g. all negative pressure, all positive pressure) throughout the healthcare facility and ensure that all healthcare workers understand and are well trained in this clamp-disconnection sequence. (4)
Clear or Clearable	A transparent needle-free device is preferable to one that is opaque. (4)
Drug Loss Prevention	Adverse drug interaction with medical plastics is well documented. The material most frequently implicated with significant interactions is polyvinyl chloride (PVC). In the UK, syringe driver extension lines and IV catheters are made from plastics resistant to drug interactions, namely drug loss via Adsorption, Absorption and Permeation. (5-17). Select a device who's tubing is resistant to drug loss.
Overdose Prevention	The MHRA (MDA/2010/073) recommends the use of anti-reflux valves on multi-lumen extensions, to prevent infusions backtracking and the risk of subsequent drug overdose. (18)
Device Design	The MHRA (MDA/2008/016) – Application of a downstream clamp to an IV line/catheter during positive pressure technique (to maintain catheter patency) may result in a recessed septum in some brands of connector due to the negative pressure generated between it and the closed clamp. Swabbing of the connector in this condition may lead to inadequate decontamination. (19)
CRBSI Reduction	'The FDA has received three reports of death associated with BSI and positive displacement needleless connectors'. 'The Society for Healthcare Epidemiologists of America and Infectious Disease Society of America have recommended against using positive displacement needleless connectors'. (20)
Device Disinfection	epic3 recommends (IVAD 30) the use of 70% isopropyl alcohol with 2% chlorhexidine to clean needle-free devices. The recommendation relates specifically to active disinfection (wiping the hub) and it is categorised as a 'Class D/GPP' recommendation. (21) CDC guidelines recommends to 'scrub the hub' with 70% isopropyl alcohol. This is a microbiologically driven recommendation, given the evidence with regards to known contamination and effectiveness of cleansing.' (22)
Passive Disinfection	Passive disinfection has been shown to provide statistically better outcomes in clinical practice than active disinfection as it eliminates user variation by delivering consistent needle-free device disinfection. In the SHEA guidelines the section on 'special approaches to preventing CLABSI' recommends the use of "an antiseptic-containing hub/connector cap/port protector to cover connectors"(24) and is now recommended in guidelines published by the Infusion Nurses Society 2016 (INS) (25).
Compatibility with IV Connections	The percentage of pre-filled glass syringe accesses vs the number of accesses for normal plastic syringes and IV extension sets is less than 1% of all accesses, which occur per year. Consideration should be given to why neutral displacement needle-free devices are the dominant device in use within the UK and what clinical benefits would be lost by changing to a glass syringe compatible device on all types of IV catheter. (21,23)

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