# Pathology and Diagnostics

The current pre-analytics crises or challenges presently facing the industry.

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## Key Speakers

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Director of the Healthcare Associated Infection Program

**Kathryn Duesman**
Vice President Clinical Affairs, Retractable Technologies

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# The following information offers expert insights into the current challenges facing the Pathology and Diagnostic sector.

What are the current pre-analytics crises or challenges presently facing the industry?

Currently there exists a two-fold problem:

- A post-COVID upsurge in sampling which is applying substantial pressure on sampling facilities,
- a supply chain efficiency and delivery due the rapid increase in demand for items such as blood tubes and needles; and
- exponential pressure is exhibited in terms of raw material supply, manufacturing of products, and transportation around the globe.

The two expert speakers on these issues are:

**Doctor Susan Jain**, Director of the Healthcare Associated Infection Program and, **Kathryn Duesman**, Vice President Clinical Affairs, Retractable Technologies.

# Current Pre-Analytics Challenges

## Doctor Susan Jain

Doctor Susan Jain

Doctor Jain is a Principal Adviser for infection prevention and control, a graduate from the University of New South Wales and holds a Master of Nursing from the University of Wollongong. Doctor Jain heads up the COVID-19 response lead, is Director of the Healthcare Associated Infection Program, and has a Doctorate in transmission-based precautions.

(Disclaimer, Doctor Jain does not work for or endorse any products listed or mentioned in the following, or has received any fees or payments for her academic opinion). The topic for the following information is infection prevention and control and blood collection procedures. The processes and steps described are beneficial to the prevention infection of when undertaking the phlebotomy procedure.

### Why is infection prevention and control so paramount during blood collection?

- Main concern is the direct interaction of pathogens into patients' bloodstream where infection prevention and control has not been conducted properly during phlebotomy.
- The National Health and Medical Research and Australian Commission states that effective infection prevention and control practices reduce risk of infection transmission between patients, health workers and healthcare environment due to needle stick injury and other sharps injuries to patients.
- In the public or private sector, infection prevention and control is the cornerstone of patient and health worker safety.
- When performing a procedure such as phlebotomy transmission base and standard precautions must be followed.

### What are standard precautions?

- Hand hygiene is a primary factor.
- Patient skin cleaning is important for skin antisepsis.
- Sterile single-use collection sample device and safety engineered device.

### Hand Hygiene Procedures

- **Alcohol-based:** Use an adequate alcohol-based hand rub amount to cover both hands.
- **Hand washing:** vigorous washing with soap and water, using the 'through method' shown on step-by-step hand washing diagrams, performed according to World Health Organization's hand hygiene standard.
- **Gloves:** Mandatory when performing a phlebotomy procedure, but it's not recommended to apply an alcohol rub onto the gloves as the integrity will be damaged by the alcohol content.

### PPE Items

- Other personal protective equipment, including masks, mainly provide a variety of barriers that are used alone or in combination to protect the mixed membrane i.e. eyes, skin, nose.
- In order to be effective, close attention is being paid to PPE for clinicians working hospitals, pathology collection departments and in laboratories.

Fit must be suitable and the correct size, and any reusable item must be thoroughly cleaned. Donning PPE procedure is as follows:

- firstly, perform hand hygiene,
- only after that don a gown or an apron,
- place a mask, then eye protection if required; and

- before performing the procedure, gloves must be worn, to avoid contaminating gloves during the procedure.

The site of the procedure, or the key part where the procedure is being performed informs the type of PPE to be worn. It's crucial to remember:

- face touching must be avoided that when wearing PPE,
- cross-contamination occurs in the eyes, nose and mouth membrane which are all high-risk areas for infections; and
- masks must not be worn around the neck or under the chin, and must not be adjusted or touched once donned and the nominated procedure begun.

At the commencement of blood collection:

- cease touching or adjusting any PPE.
- Gloves must also be changed when visibly contaminated and changed between each patient,
- if gloves do become contaminated, they should be removed,
- hands washed and a fresh pair worn; and
- surface touching should also be limited and if something is touched, repeat the recommendation.

During the last two years of Covid, specified correct mask wearing recommendations are:

- Masks should not put that around the neck, forehead or under the nose.
- Crisscrossing loops should also be avoided as a space is immediately created for particles to enter and contaminate the mucus membrane.
- Tie loose mask loops underneath chin and keep the nose and mouth covered.

There is a correct way to remove PPE using a sequence; information which can be easily sourced using the Clinical Excellence Commissions website in New South Wales.

- PPE gloves should be removed first, then hand hygiene and then gown or apron.
- Hands must be cleaned to avoid touching contaminated items.
- When eye protection is finally removed, hands must be cleaned first.
- Hands must be cleaned before finally removing the mask, by loosening the loops from the back, leaning slightly forward and depositing the item straight away into a general waste bin and hands cleaned afterward.

This is the recommended sequence for removing PPE. Standard precautions and transmission-based precautions are practised and are effective in preventing the three types of transmission-based infections: **contact, droplet and airborne**.

In the case of droplet precautions:

- Initial hand cleaning is required and then the collection room prepared.
- When in extreme close contact with the patient and surroundings, don an apron or a gown.
- Hands must be cleaned before injecting the patient, or don pair of gloves.
- Avoid touching door handles – which are high traffic transmission areas.

In the case of droplet precautions:

- the mucus membrane must be protected above the neck area.
- Wear a full-face shield, gown and a surgical mask.
- The remaining choice of PPE will depend upon the procedure, e.g. in phlebotomy, gloves must be worn immediately before inserting the needle.

"Main concern is the direct interaction of pathogens into patients' bloodstream where infection prevention and control has not been conducted properly during phlebotomy."

Current Pre-Analytics Challenges continued

In cases of airborne precaution:

- a P2 or N95 respirator is required.
- Remaining PPE will depend upon the patient's condition, e.g. eye protection if the patient is COVID-19 positive.
- Conduct a fit check when wearing a respirator.

There are two types of testing for COVID in New South Wales, qualitative and quantitative, using the same machine to measure pathogen particles

## In a quantitative fit test:

- the individual is required to wear a respirator mask rather than a surgical mask.
- In a room a particle generator generates particles inside and then particles outside.
- A number is calculated for the outside measurement, divided by the inside measurement and a percentage is given for the distance required for pathogen protection.
- The aim of this method is to measure the effectiveness of a given mask seal.

## Phlebotomy infection control safety

- All veins and arteries are highways to the heart and when they are punctured no pathogens or micro-organisms should be introduced into that vein. When the subject technique is practised correctly, the sterility of the equipment is maintained as are the key parts during the procedure. This will help protect the patient by minimising the risk of contamination on the key side - the side that is introduced near or into, and where the patients must be protected from developing infection. Bacteraemia or any bloodstream infection is a genuine risk, so it is important that a septic technique is practised while performing the procedure.

Shop safety refers to safe blood sampling equipment of high quality, and in regard to phlebotomy, a needle and syringe is used to withdraw various amounts of blood.

- Single use needles should be used for each patient and placed as a single unit into a sharps container immediately after use. Westlab promotes a safety engineer device suitable for these procedures and there many other products like this available in the market. A responsible approach is to ask for the manufacturer's recommendations when using safety engineer devices. Healthcare workers need to be trained in activating the safety mechanisms for effective application and appropriate use.

There are numerous studies available which promotes the use of safety engineered devices;

- 22 of these studies support their use in a systematic review.
- The Australian Commission on Safety and Quality in Healthcare, states that there are broad range of devices available with different safety aspects.
- The use of device is being practised in the US, France, Spain and the European Union, where use has shown a significant reduction in the rate of incidents of needle stick injuries.
- Due to the results, the Commission and other countries promote the use of a safety engineered device for the protection of healthcare workers while they're performing a procedure involving a needle.

Sharps disposal is an integral part of the safety process. The Work, Health and Safety Act and legislation states that sharps must be safely disposed. Australian guidelines on infection prevention and control also state that shafts must not be passed directly from hand to hand, and handling is kept to a minimum.

- There should be no recapping, bending, or breaking after use.
- Single use sharps must be immediately disposed into an approved sharps container.
- They should not be over 3/4 full, and depending on state or local health guidelines, be disposed into a proper sharps-container with the single-hand technique.

## What is the best way to practice the safest phlebotomy method?

- The World Health Organization endorses modern hand hygiene, and recommends a step-by-step process of how to best perform phlebotomy has been developed. This paper is available for viewing and contains 11 steps which mainly reviews the use of PPE, protecting the skin, protecting the hands and safe procedure performance. Included are healthcare worker and patient safety aspects. These precautions prevent the spread of spread of micro-organisms - specifically bloodborne viruses

## Standard precautions include:

- cleaning and disinfection;
- reusable trays and tourniquets must be cleaned and disinfected.
- Effective cleaning can be achieved in one step using a neutral detergent and disinfectant inone clean.
- Combined products must be registered with the Therapeutic Goods Administration Act, so that the product can be used safely, and that the disinfection micro-organism will kill the macro-organism.

Specific methods for enhanced cleaning:

- Start from high to low in the work environment, starting from outside, inside and from clean to dirty, and extend to an S shape.
- Cleaning steps should be applied to the items, turns, day or tracing used and blood collection trolleys, and ensure that used gloves do not contaminate the trolley.
- After completion, remove gloves, clean hands, and come to the trolley with clean hands to maintain cleanliness.

Studies show that phlebotomy can create an environment for bloodborne viruses and also multidrug resistant organisms like MRSA. These can hover over trolleys; therefore, a clean trolley is essential to avoid this risk. It must be kept as clean as possible and if touched with contaminated hands, it must be wiped clean. In the case that a patient is under specific transmission-based precautions, use PPE appropriately and use safety engineer devices whenever available with education to backup on appropriate use.

“Studies show that phlebotomy can create an environment for bloodborne viruses and also multidrug resistant organisms like MRSA.”

# Minimising needlestick injuries

## Kathryn Duesman

**Catherine Duesman**
Vice President Clinical Affairs, Retractable Technologies

Ms Duesman is actively involved in needle safety and focuses on critical points in the prevention of needle stick injury. Retractable Technologies manufactures safety devices, and the following topic specifically concerns vanishing point blood collection sets.

Retractable Technologies as a company was established in 1994, with an initial launch product known as the vanish point syringe, developed with grants from the United States National Institute of Health. Corporate headquarters is located in Texas in the United States. Manufacturing and warehousing operate in the United States and Texas, as well as contract manufacturers located in China.

### The product goal:

- Minimise needle stick injuries, as factually there exist more than 20 bloodborne pathogens that can be transmitted from contaminated needles or sharps.
- These include: HIV, Hepatitis B and Hepatitis C, and the general the risk for seroconversion.

### How does an Injury occur?

- With a device that is visibly contaminated with the source patient's blood;
- or, is an injury involving a needle placed in the source – the patient's artery.
- Injuries occur during phlebotomy because of the hollow bore - a blood filled needle, and are among the highest risks for transmitting bloodborne pathogens.
- According to data sourced from the United States, there are reports of over 300,000 sharps injuries every year which include not only hospitals but non-hospital settings.

In urgent care settings:

- Breakdown of results show a count of over 800 sharps injuries per day and almost 40 sharps injuries an hour.
- In the United States, it is the Occupational Safety and Health Administration that mandates safety for employees, and their bloodborne pathogen standard is regulated and mandated for safe product use in the United States.
- These regulations call for an engineered control which is built into the device as the primary means to eliminate or minimise worker exposure to bloodborne pathogens.

Retractable Technologies products and in particular, vanish point products have several advantages:

- An integrated needle stick prevention mechanism is a needle safety device is actually built into the product itself.
- As it can be activated using one hand is key to an effective safety procedure.
- Vanish point products allow for pre-removal activation by activating the safety mechanism before removal from the patient; this action virtually eliminates exposure to the contaminated needle thereby effectively reducing the risk of needle stick.
- Once the safety mechanism is activated, the needle automatically retracts directly from the patient's vein and the tubing is clamped, reducing the risk of blood exposure, allowing for very safe and efficient disposal.

Retractable Technologies produces thin-walled needles which improve blood flow, and also make all vanished point products. These are not made with any natural rubber, latex, PVC or DEHP, and the blood collection sets may be used for short term infusion for up to two hours. Pre-removal activation is key to safety precaution, as studies have shown that the majority of needle stick injuries occur within seconds after a needle has been removed from the patient.

In phlebotomy this is a key contribution to needle stick injury as:

- when patients assume the blood collection process is over, tend to move or bend their arm or move generally.
- By activating the safety mechanism before removal from the patient, exposure to the contaminated is virtually eliminated.

All vanish point Retractable devices feature an automated retraction, and studies show that products with automatic or even semi-automatic mechanisms are associated with the lowest needle stick instance. Any product with automatic or semi-automatic mechanisms is 10 times less likely to be associated with needle injury as opposed to fully manual devices. There have also been some very good studies that have shown that retractable devices in particular are much more effective than manually activated devices. For instance:

- One study reported an 88% reduction in reported needle stick injuries following the implementation of a retractable device. Vanish point blood collection sets have a very clear body and that is key to successful blood draws, the clear body aids good visualization of blood return.
- Colour coding has been applied to the side and is actually the trigger, and additional colour coding for the needle gauge. For example, a 21-gauge needle that's attached to the product has built-in finger grips for ease of handling; when the trigger is fully depressed the needle automatically retracts directly from the patient and is completely encased inside. The body and tubing is clamped off, reducing the risk of exposure to blood. The tubing is 178 millimetres and 305 millimetre in length and is a kink resistant.

Usage Description:

- When using a tube holder during blood collection, it needs to thread onto the lure adapter while ensuring that it stays tightly connected. If using a syringe, the adapter can be removed; or if the presentation does not require a lure adapter, the lower cap can be removed and syringe firmly attached. When drawing blood using a syringe, this method ensures that blood is transferred to the appropriate specimen container according to institutional protocol.

Design benefits:

- To minimise any kind of risk when using a vanish point, it is oriented with the bevel up so that a vena puncture can be performed typically as one would following an aseptic technique. When observing for blood return, the clear body gives excellent visualisation. To verify that vein entry has been achieved, once blood is flowing into the first tube, the tourniquet can be released.
- The design of the product means that the tube falls naturally to the left, reducing the need for pressure, and the tubing can then drape naturally. While the blood is drawing it is necessary to avoid pressure on the trigger prior to actually activating the retraction mechanism.

When blood collection is complete:

- Use gauze or cotton gently placed on the site.
- Do not apply pressure to the site while the needle is still in the patient's vein as this can cause discomfort for the patient, and as there is a stainless-steel needle in that vein, it could also cause some damage.
- Lightly place gauze on the side, and use a squeezing motion to apply pressure directly to the colour coded trigger, the needle retraction will be activated, and should be done while the needle is in the vein. That way, it comes directly from the vein and becomes encapsulated in the device. It is then totally encapsulated inside the device and the tubing which moves over, is now clamped off.

"Any product with automatic or semi-automatic mechanisms is 10 times less likely to be associated with needle injury as opposed to fully manual devices."

Minimising needle stick injuries continued

Benefits in a difficult draw:

- e.g. in neonatal or geriatric patients; where it is required to harvest the blood in the tubing.
- Pull the trigger back to its preactivation position which will unseal the tubing and allow the syringe to harvest the blood in the tubing.
- This action will not cause the needle to be exposed in any way, the needle is safely retracted, and blood can be drawn out by sealing that tubing.

Exposure prevention:

- The fact that this seals off the tubing really prevents potential drips or leaks that can happen with blood drawing procedures, and expose clinicians to blood and contaminate surfaces.
- The product can be disposed in an appropriate sharps container.
- A good aspect of this product is the built-in stabilising arms as opposed to the wings that are typically used and the efficient, compact design falls very well into a sharps container.
- Previous blood collection sets, often referred to butterflies, can be challenging to drop into a sharps container as they are lightweight and the wings can catch.
- A compact design that actually drops efficiently into a sharps container means that the needle is completely encapsulated and stays safe throughout disposal once it's been activated.
- The product is also totally non-reusable, with zero needle exposure so there is no chance of salvage and reuse.
- If the product is being applied in a short-term infusion, which is defined as up to two hours, the luer adapter or the lower cap can be removed.
- The product can be attached to IV tubing or a syringe and includes a priming volume, and be set to the tubing in accordance with the chosen protocol.
- There are available sizes for priming volumes, for both the 178-millimetre tubing, as well as the 305-millimetre tubing. All of the needles are 19 millimetres long, the usual standard for blood collection sets, and there are three different gauges, 21, 23 and 25, and each are all thin-walled needles.
- To really maximize blood flow, they are available with both Luer adapters attached, and without Luer adapters.
- An imminent release is a product where it is actually packaged with the tube holder attached. When opening the package, the tube holders already there, there's no attachment necessary. With the lower cap, if it is going to be attached to the syringe, the cap is removed, or with a Luer adapter a tube holder can be attached.

Vanish point trigger design:

- reduces that risk of accidental activation with a simple squeezing motion, which means the device is not tipping up and down and is much more deliberate.
- Lowers risk of accidentally being activated during the procedure. In addition, activation of the vanish point product automatically clamps the tubing, and reduces the risk of blood leakage or exposure.
- Tubing of the IV product is not clamped, so there is no risk that blood can leak – risking exposure.
- Usual product tubing is made with PVC, whereas the vanish point product is not made with any PVC; a poly vinyl chloride which has a very high chlorine content.
- PVC disposed devices are a major source of dioxin and hydrochloric acid that can be released during incineration at the point of disposal or after disposal with toxic Dioxin.

# Conclusion and Westlab Profile

Ted Fowler and Neha Patil

## Conclusion – Ted Fowler

These are staggering statistics around the current needle stick injury crisis, and an innovative solution from Retractable Technologies. Neha Patil from Westlab offers an overview on just how the company is supporting and alleviating current supply pressures and what we can offer.

## Westlab Profile – Neha Patil

**Westlab has been operating since 1993 and is a major supplier to the education, research, university, industry, healthcare and pathology market. Westlab is unique in offering a 360-degree solution to the industry. The company provides complete laboratory solutions where any laboratory environment can be efficiently designed, furnished and equipped; as well as offering an ongoing supply of consumables and related services. Westlab thinks about infection control in all aspects of its services, whether it be safety, engineered medical devices or designing a touchless laboratory.**

**Westlab has partnered with world leading brands such as Retractable Technologies, and the products mentioned today, including vanished point blood collection sets as well as easy point needles, are available through Westlab. We also are a distributor for the Disera VacuSera range of blood collection tubes as well as accessories.**

**We also bring into Australia our urine collection system and some of the products that we might have touched on today, which is the disposable tourniquets, are available through us. Personal protection equipment including our face shields have been quite popular over the past two years and is one of our best-selling products and an Australian made product. [Contact us on health@westlab.com and we will answer any inquiries as soon as possible]**

# Q&A

## Doctor Susan Jain and Kathryn Duesman

### Question: Doctor Susan Jain.

**Could you comment on disposable versus reusable equipment? Perhaps PPE or any equipment for that matter in the collection centre?**

From an infection prevention and control point of view, we will definitely recommend single use items that can be disposed of after use. In last three years we have learned that we have used an extensive amount of PPE, which generates a lot of plastic and consequently waste.

So, when considering the environmental impact and sustainability, we would say that reusable items definitely have a place for reuse after cleaning. So, my message is that especially with tourniquets, the single use item with which I was involved, was that it wasn't easy to tie and use. It's a bit tricky and sometimes can be flimsy. Sometimes the skin can be caught up, so make sure that it is applied correctly. Factoring in reusable ones probably would be easy to do, but then you need to clean it in between patient use. With sharps containers for example, there are some products which can be reused from a landfill and from a waste point of view, reusable ones definitely take priority,

But depending upon your resources the expense, single use ones are best. So, both have a role in reuse. Depending upon your facility and your local needs, you need to choose a position in disposable and reusable products.

### Question: Kathryn Duesman.

**Regarding needle stick injuries and the staggering statistics around those, what are the actual risks associated with it? If somebody does get a needle stick injury, what is the potential outcome?**

The outcome would be exposure to bloodborne pathogens which differs with the different pathogens in terms of the risk of actual SERO conversion. But as I mentioned, that risk is appreciably higher when you have a hollow bore, as in a blood-filled needle - a needle that has just been used to access a vein or an artery. So obviously we've had some horrible cases in the United States, where people have actually contracted not only HIV but Hepatitis C as well. And some of those cases were not just the device that the clinician was using, but a device that had been disposed of previously and was protruding out of the top of the sharps container where there was no source patient that could be found. So, the risks are very high in terms of how serious they can be.

Luckily the sera conversion rate for example, in HIV and sustained by a needle stick injury is relatively low. The usual procedure after any type of exposure, is obviously to test the source patient. But if it's high risk or they cannot identify the source patient, e.g., for HIV, they would begin post-exposure prophylaxis, which is quite serious and goes on for some time and includes significant testing. Obviously, and I I'm sure it's the case in Australia, most healthcare workers are immunised for Hepatitis B, which is extremely helpful, but as I'm sure everyone knows, there is no vaccine for Hepatitis C.

One of the greatest risks that is posed to clinicians is exposure to hepatitis. Because of the rights that we have, there are well over 4,000,000 people estimated to have Hepatitis C in the United States and because many can be asymptomatic, they may not even know. So, the fact is that exposure to a bloodborne pathogen is definitely a risk, and the real key is prevention, and there are some really good safety devices to prevent that.

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