

**USAGE OF NEEDLE-FREE CONNECTORS OVER THREE-
WAY STOPCOCKS FOR INFECTION CONTROL IN
HOSPITALS**

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Master of Business Administration (MBA)

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by

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2021

DECLARATION BY STUDENT

I hereby declare that this dissertation titled “**USAGE OF NEEDLE FREE CONNECTORS OVER THREE-WAY STOPCOCKS FOR INFECTION CONTROL IN HOSPITALS**” is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



Vedere Vinitha Reddy

Date: 01-07-2021

CERTIFICATE

This is to certify that **Vedere Vinitha Reddy** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed her/his internship at **PolyMedicure Ltd** during March 22, 2021, to June 19, 2021.

Place: Hyderabad

Date: 01-07-2021



(Regional business manager)

PolyMedicure Ltd.

CERTIFICATE

This is to certify that the dissertation titled “**USAGE OF NEEDLE FREE CONNECTORS OVER THREE-WAY STOPCOCKS FOR INFECTION CONTROL IN HOSPITALS**” is a record of the research work undertaken by **Vedre Vinitha Reddy** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Dr. Saurabh Kumar Banerjee

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ABSTRACT

Needle-free connectors (NFC) provide needle-free access at the hub end of the catheter for IV medication administration, fluid infusion, or withdrawal of blood samples or to connect administration sets to the intravascular catheters.

In NFCs, a syringe is inserted into the NFC and twisted or locked with a Luer lock for tight connection and the drug is administered. When the syringe is inserted into the NFC, the silicon layer goes down and provides a pathway for the fluid to pass and once the syringe is taken out from the NFC, the silicon layer goes back to the normal position closing the entry spot and thus helps in preventing the contamination and so, it is a closed system.

Three-way stopcocks consist of a valve or turning plug that controls the flow of fluid from a container through a tube. A 3WSC can be used on IV tubing to turn off one solution and turn on another. It is open to the air, without a membrane when the cover is not in place and so, it is called an open IV system.

When accessing the catheter site with three-way stopcocks, there is a Luer lock which can be a point of contamination as it is an open system. A needle-free connector is a closed system helping in infection control and preventing the HCW from needle stick injuries. A survey was conducted among the nurses to understand their awareness about NFC, preference, usage, risk, and limitations.

Even though NFCs are better in infection control and injury control, three-way stopcocks are most used including some limitations. Factors like pricing, market scenario, requirement, the quantity of fluid to be infused play a major role. Also, most of the nurses were aware of the product and they require product training to understand the benefits and usage of the product.

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V. VINITHA REDDY

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ABBREVIATIONS

NFC: Needle Free Connector

NSI: Needlestick injury

3WSC: Three-way Stopcock

HABSI: Hospital Acquired Blood Stream Infection

IV: Intravenous

CRBSI: Catheter-Related Blood Stream Infection

FDA: Food and Drug Administration

HCW: Health care workers

HBV: Hepatitis B Virus

HCV: Hepatitis C Virus

HIV: Human Immunodeficiency Virus

CDC: Centre for Disease Control and prevention

PEP: Post Exposure Prophylaxis

1. INTRODUCTION

NEEDLE-FREE CONNECTORS:

Needle-Free Connectors are important in vascular access, for both the patient's and the healthcare professional's safety. Needle-Free Connectors prevent healthcare workers' exposure to bloodborne pathogens by preventing needlestick injuries, whilst acting as a microbial barrier to protect the patient. The correct use of Needle-Free Connectors can reduce the risk of HABS (Hospital Acquired Blood Stream Infections)

Needle-free connectors (NFC) have a needle-free access at the end of the catheter for IV medication administration, fluid infusion, or withdrawal of blood samples or to connect the sets to the intravascular catheters. NFCs also have a split septum connectors and Luer activated metallic valves. The standard split septum connectors or negative reflux caps do not have internal mechanisms and are already pierced to allow access by a blunt cannula to open the fluid pathway for the IV fluid infusion and medication administration.



Figure 1.1: Different Needle-free connectors

Mechanical valves have an inner membrane or valve and require a Luer connector while flushing or administering IV fluids or medications. The syringe tip or the tip of the IV tubing is inserted straight into the cap without the need for a blunt needle. The design for the positive pressure valves is aimed at preventing retro-grade blood flow inside the catheter after the Luer is disconnected to prevent vein occlusions and to avoid catheter hub contamination and endoluminal microbial contamination.

In NFCs, a syringe is inserted into the NFC and twisted or locked with a Luer lock for tight connection and the drug is administered. When the syringe is inserted into the NFC, the silicon layer goes down and provides a pathway for the fluid to pass and once the syringe is taken out from the NFC, the silicon layer goes back to the normal position closing the entry spot and thus helps in preventing the contamination and so, it is considered to be a closed system.



Figure 1.2: Pathway for fluid to pass when the syringe is connected

Based on their inner membrane function mechanical valves are classified as negative, neutral, and positive displacement types.

Negative displacement NFCs allow blood reflux or backflow into a vascular access device lumen when disconnected due to movement of valve mechanism or removal of the syringe or set. With negative displacement mechanical valves, the Luer caps must be clamped before emptying or removing the syringe or tubing set to prevent blood from backing up into the catheter.

Positive displacement NFCs allow a small amount of fluid to be held in the device upon set or syringe disconnection, this fluid is pushed through the catheter lumen to clear any blood that refluxed into the lumen. the positive displacement valves, have a fluid reservoir that creates a positive displacement movement or pressure and should not be clamped when disconnecting the syringe or IV administration sets.

Neutral displacement NFCs contain an internal mechanism designed to prevent blood reflux into the catheter lumen upon connection or disconnection. There is no displacement of fluid for neutral displacement valves into the catheter when connecting or disconnecting the syringe or tubing, and their use requires no change in clamping practices.

THREE-WAY STOPCOCKS:

Three-way stopcocks consist of a valve or rotating plug that controls the flow of fluid from a container through a tube. A Three-way stopcock can be used on IV tubing to turn off one solution and turn on another one. It is open to the air, without a membrane when the cover is not in place and so, it is called an open IV system.



Figure 1.3: Three-way stopcocks

NEEDLESTICK INJURIES AND INFECTIONS:

To prevent accidental needle stick injuries and to comply with Occupational Safety and health administration regulations and the needle stick safety and prevention act, various designs for safety devices have been developed. Also, considerable increases in CRBSI have been reported since NFCs came into the market. As a result, infection control practices involving these devices were brought into focus, leading to decreased infection risks. Negative displacement NFCs were introduced to decrease the risk of needle use with these devices. Also, to decrease IV line occlusions and CRBSI risks, positive displacement NFCs were introduced, resulting in fewer CRBSI outbreaks being associated with these NFCs.

Eventually, the FDA required US manufacturers of positive displacement NFCs to provide evidence showing that their devices were associated with risk factors of CRBSI in comparison with negative displacement NFCs.

Needlestick injuries (NSIs) as defined as the injuries caused by hypodermic needles, blood collection needles, intravenous (IV) stylets, and needles used to connect parts of IV delivery systems. NSIs are common and to an extent inevitable in healthcare workers (HCWs) during the execution of their patient care services. When there is a breakage in the skin due to cuts or needle injury, it may lead to contamination into the blood or into the blood fluids, called as percutaneous exposure. Mucocutaneous exposure occurs when body fluids encounter open wounds, nonintact skin such as those found in eczema, or mucous membranes such as the mouth and eyes.

Health care workers or HCWs are also exposed to droplets or the splashes of urine, blood, and saliva. Percutaneous injury and splashes of fluids are the source of exposure to blood-borne pathogens such as HBV, HCV, and HIV for HCWs and responsible for a significant proportion of infections in this group.

It has been estimated by the CDC that every year more than 3 million HCWs are exposed to blood and body fluids through a sharp needle injury in the US alone with an annual estimated 6 million NSIs. Due to NSIs, the risk of infections ranges from as low as 0.2–0.5% for HIV to as high as 3–10% for HCV and 40% for HBV. Although, contaminated needles and other contaminated sharps should not be bent, recapped, or removed, many studies have revealed that recapping being still prevalent among HCWs.

Many studies are indicating that the prevalence of NSI and the risk factors associated differ among different HCW groups such as doctors and nurses depending on the place of studies like teaching institutes, hospitals, and corporate setups. Occupational exposures are common in the developing world, and it is believed that 45–70% of these injuries are not reported.

Unreported needlestick injuries are a serious problem and stop injured HCWs from receiving postexposure prophylaxis against HIV, which is shown to be 80% effective in preventing HIV infection in these subjects. There are limited comprehensive data from India on this aspect. This study was conducted to know the prevalence of Needlestick injuries and factors responsible for Needlestick injuries and to understand the postexposure measures taken by the Healthcare workers in India.

2. LITERATURE REVIEW

- Victor D Rosenthal, Sep 2019, Impact of needle-free connectors compared with 3-way stopcocks on catheter-related bloodstream infection rates: A meta-analysis. Needle-free connectors (NFCs) were introduced to eliminate the use of needles in intravascular catheters, and their newest generations were designed to improve patient safety and reduce catheter-related bloodstream infection (CRBSI) risks.
- Jun Oto, Hiroshi Morimatsu, et al, November 2007, Comparison of contamination between conventional three-way stopcocks and needleless injection device: A randomized control trial. Intraluminal contamination of catheter hubs has been recognized as the most frequent cause of catheter-related bloodstream infections.
- Victor Daniel Rosenthal, November 2020, Clinical impact of needle-free connector design: A systematic review of the literature. The objective of this systematic review is to analyze types of needle-free connectors and open systems and their effects on central line-associated bloodstream infection rates and other adverse outcomes through a research protocol consistent with the Preferred Reporting Items for Systematic Reviews' recommendations.
- Victor Daniel Rosenthal, Farokh Earch Udwadia, et al; 2015, Clinical impact and cost-effectiveness of split-septum and single-use prefilled flushing device vs 3-way stopcock on the central line-associated bloodstream infection rates in India: a randomized clinical trial conducted by the International Nosocomial Infection Control Consortium. Three-way stopcocks are open systems used on intravenous tubing. The split septum is a closed system with the pre-pierced septum. Single-use prefilled flushing devices carry a lower risk of contamination than standard intravenous flushing.
- Tuba Sengul, Betul Guven, Ayse Ferda Ocakci, Nurten Kaya, October 2019, Connectors as a risk factor for blood-associated infections (three-way stopcocks and needle-free connectors); A randomized experimental study. Microorganisms causing catheter-related bloodstream infections colonize intravenous catheters particularly connectors mounted to catheters. This study aimed to examine the colonization in 3-way stopcock connectors and needleless connectors that integrated into central, port, and peripheral venous catheters.
- Juan C.Yébenes, MateuSerra-Prat, December 2008, Clinical use of dis-infectable needle-free connectors, In the United States, the Food and Drug Administration required health care services to adopt needle-free devices to prevent health care workers' exposure to bloodborne pathogens resulting from needlestick injuries, and several systems of dis-infectable needle-free connectors (DNC) were introduced.

- Evonne Curran, September 2016, Needleless connectors: the vascular access catheter's microbial gatekeeper. Needleless connectors (NCs) are essential devices that connect to the end of vascular catheters and enable catheter access for infusion and aspiration.
- SP Jadhav and PA Jategaonkar, March 2014, Three-way stopcock, an effective air-tight connector for laparoscopic gas insufflation. Laparoscopic cannula leads to frequent disconnection of gas inflow tubing with resultant loss of pneumoperitoneum amounting to rising frustration and chaos in the surgical team. To encounter this problem we have been using the three-way stopcock with spin-lock, which fits snugly to both the trocar and tubing nozzle.
- Andrew D Milne, September 2013, Complete Obstruction to flow in the three-way stopcock due to a manufacturing defect. Recently, when preparing our heated intravenous sets for intraoperative use, we detected a series of defective three-way stopcocks that caused complete obstruction to flow. Our typical heated fluid line setup includes a three-way stopcock placed between a set of heated tubing and a 30-in tubing extension connected to an intravenous cannula.
- Ozaki Masayuki, November 2002, A Rapid infusion system using a three-way stopcock with two no return valves. Injecting manually with a syringe has been used to start rapid infusion for sudden massive bleeding. We present a useful method using a three-way stopcock with two non-return valves for rapid infusion. In this method, we connected two no-return valves to both sides of a three-way stopcock.

3. METHODOLOGY

- **Research instrument:** The instrument is a questionnaire checklist to gather the required data. The draft of the questionnaire is based on readings, previous studies, and professional literature. In the preparation of the instrument, the requirements in designing good data collection will be considered.
- **Research questions**
How are needle-free connectors effective than three-way stopcocks?
What is the scenario in the market for three-way stopcocks and needle-free connectors?
- **Research objectives**
To understand the usage of NFCs and three-way stopcocks.
To find the effects and benefits of NFCs over three-way stopcocks.
- **Collection of data:** Data was collected via the questionnaire from the respondents with their consent. The respondents are people from the medical industry and people with little or more exposure to nursing education and practice.
- **Questionnaire administration:** The questionnaire was administered to respondents via mail or any other social resources. Google forms are used to collect the required data.
- **Sample design:** The study was a quantitative research approach, and the respondents were people from the medical industry and people with little or more exposure to nursing education and practice.
- **Analysis:** Analysis was done by using Microsoft Excel
- **Sample size:** 63
- **Exclusion and inclusion criteria:** All the people, especially those with Nursing backgrounds, either practice or education were included, and all others were excluded.

4. RESULTS

The study included 63 respondents belonging to the nursing background. The data was collected using Google forms and evaluated appropriately under the designated sub-heads. A questionnaire, with the help of industry experts, was made to understand the awareness of NFCs among nurses and their usage. It was also helpful to understand the usage of NFCs over three-way stopcocks for controlling needle stick injuries and hospital-acquired infections.

It included different parameters like awareness of the product, their preference, and usage, risk factors, and limitations.

Awareness of the product

When surveyed, most of the nurses knew about the product but had limitations for its usage.

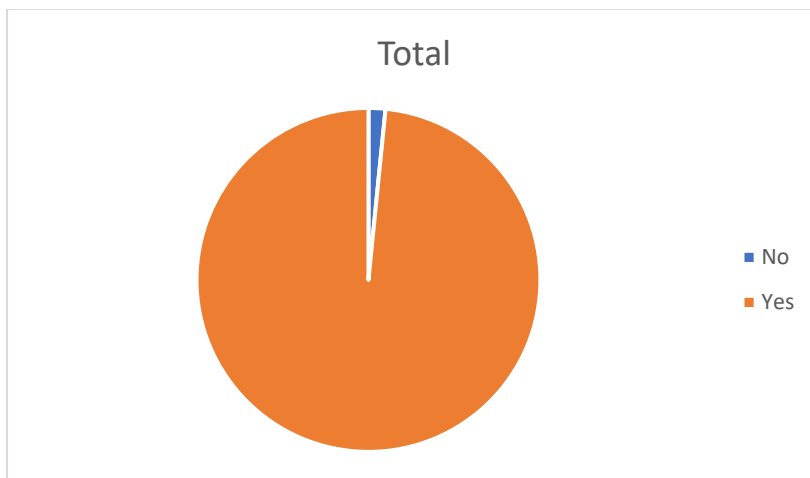


Figure 4.1: Graph representing the awareness of the product.

Most preferred product

Among both the products, three-way stopcocks were mostly used. Some of the limitations included here will be discussed.

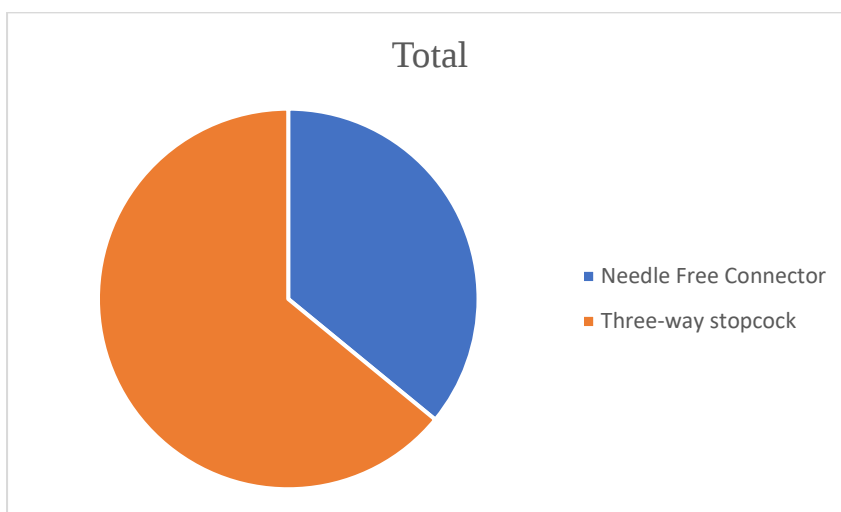


Figure 4.2: Graph representing the most preferred product.

Usage of Needle-free connector over three-way stop cock

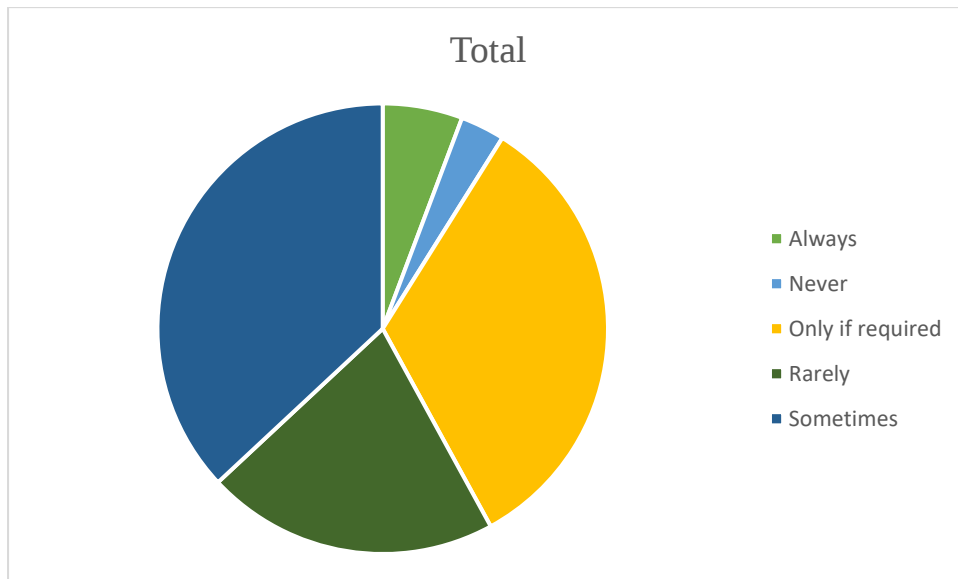


Figure 4.3: Graph representing usage of NFC over 3WSC.

The risk of Needlestick injury and hospital-acquired infections is high for

Chances of needle stick injury and infections are high for three-way stopcocks as the lid is to be opened separately to administer the drug. The chances for the same in the needle-free connector are negligible.

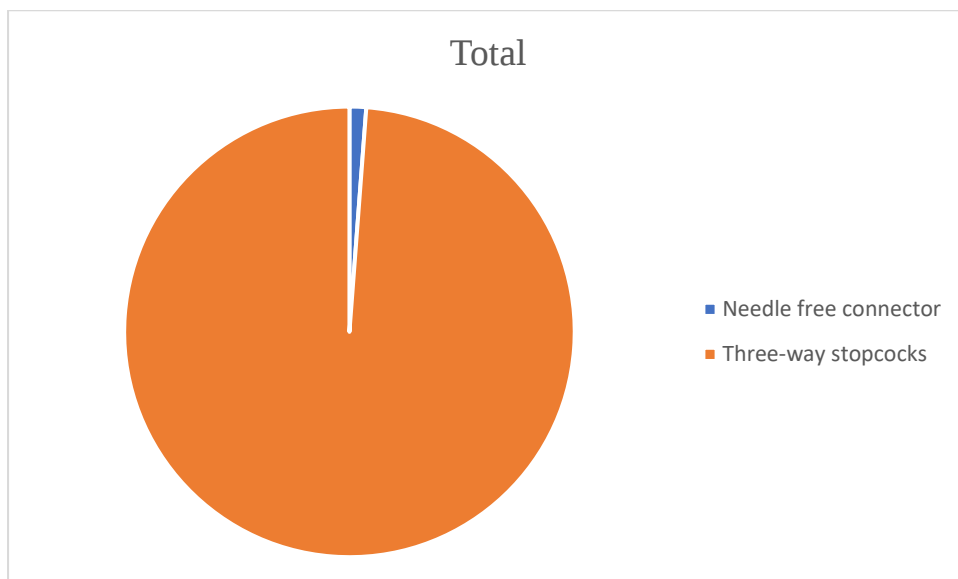


Figure 4.4: Graph representing the risk of NFC and 3WSC.

5. DISCUSSION

The incidence of needlestick and sharp injuries is mostly encountered in emergency wards. Every year, 6 lakhs to 8 lakhs occupational needlestick injuries are estimated to occur and it can lead to serious or fatal infections with bloodborne pathogens such as HBV, HCV, or HIV.

Awareness about the product:

Many nurses and the nursing staff were aware of the needle-free connectors. Going in-depth, few of them knew how to use it and few of them need training and demo sessions to understand the product. A negligible number of nurses did not know about needle-free connectors and were using three-way stopcocks. Proper training would help the nurses in understanding the benefits of the product.

Most preferred product:

Three-way stopcocks were most preferred than needle-free connectors. Even though most of the hospitals were aware of needle-free connectors, pricing was a limitation. Even though the infection control and prevention of NSI was a great feature, it had another limitation, which was infusion for the high quantity of liquid. The passage of fluid was difficult when the quantity of fluid was huge and needed frequent support from the health staff. And so, for smaller quantity infusion NFC was used often.

Usage of the needle-free connector over a three-way stopcock:

Of all the respondents, 37% of them said that they would use NFC sometimes over a three-way stopcock and 33% of the respondents chose that they would use it only if required. 21% of them said they would use it rarely. Needle-free connectors were used mostly in corporate and large-scale hospitals and medium to small scale hospitals, nursing homes preferred three-way stopcocks.

Risk of Needlestick injury and hospital-acquired infections:

The main problem with three-way stopcocks is it is an open system. So, the Luer lock must be opened separately for the administration of medications and sometimes the cap is kept aside for the administration, and this is a spot of contamination and the second is the chance of misplacing the cap. If the cap is lost the system remains open and it becomes a hotspot of contamination. Hence, the risk of contamination and infections is high for a three-way stopcock whereas in a needle-free connector, once the opening is disinfected, it is clear. It is a closed system with a silicon layer. Once the site is disinfected, the syringe can be inserted. When the syringe is inserted, the silicon layer goes down making the pathway for the fluid to pass. Similarly, when the syringe is taken out, the silicon layer goes back to its normal position closing the pathway. Thus, it decreases the chance of contamination.

6. CONCLUSION

Needle-free connectors and three-way stopcocks are used to connected to the end of the vascular-catheters to enable catheter access or safe IV access for infusions and aspiration.

When accessing these sites with three-way stopcocks, there is a Luer lock which can be a point of contamination as it is an open system. A needle-free connector is a closed system helping in infection control and preventing the HCW from needle stick injuries. A survey was conducted among the nurses to understand their awareness about NFC, preference, usage, risk, and limitations.

But, in the practical world, even though NFCs are better in infection control and injury control, three-way stopcocks are mostly used. Factors like pricing, market scenario, requirement, the quantity of fluid to be infused play a major role. Also, from the survey, we understand that most of the nurses were aware of the product, and they require product training to understand the benefits and usage of the product. This study can be further researched by including an in-depth study of the limitations.

7. REFERENCES

- Victor D Rosenthal, Sep 2019, Impact of needle-free connectors compared with 3-way stopcocks on catheter-related bloodstream infection rates: A meta-analysis.
- Jun Oto, Hiroshi Morimatsu, et al, November 2007, Comparison of contamination between conventional three-way stopcocks and needleless injection device: A randomized control trial.
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- Humaira Bashir, Syed Shuja Qadri, A study on needle stick injuries among health care workers in a tertiary care hospital in India.
- Omar F Khabour, Khalil H Al Ali, Waleed H Mahallawi, May 2018, Occupational infection, and needle stick injury among clinical laboratory workers in Saudi Arabia.
- Teshiwal Deress yazie, Kasaw Adane Chufa, Mekonnen Girma Tebeje, August 2019, Prevalence of needlestick injury among healthcare workers in Ethiopia.
- Padma Srikanth, Yazhini Ravi, Shyamala Mani, 2018, Needle stick injury, a perspective.
- Mehdi Jahangiri, Akbar Rostamabadi, Naser Haboubi, Neda Tadayon, Ali Soleimani, March 2016, NSIs and their related safety measures among nurses in a university hospital, Iran.
- Dechasa Adare Mengistu, et.al, 2021, Worldwide prevalence of occupational exposure to NSI among healthcare workers.

QUESTIONNAIRE

1. Do you have any idea about needle-free connectors and three-way stopcocks?
(YES/NO)
2. The needle-free connector can help in preventing?
 - a. Needlestick injuries.
 - b. Contamination.
 - c. Hospital-acquired infection.
 - d. Only a and b
 - e. All the above.
3. How do you disinfect the skin surface before cannulation?
 - a. Rubbing the cotton swab with a disinfectant in a circular motion towards the outside.
 - b. Rubbing the cotton swab with a disinfectant in a circular motion towards the inside.
 - c. Just rub off with disinfectant in a straightaway.
4. According to you, what is the most preferred: NFC or a three-way stopcock?
(NFC/3WSC)
5. How frequently you use an NFC over a three-way stopcock?
(Always / Sometimes / Rarely / Only if required / Never)
6. Three-way stopcocks are one of the reasons for HAIs and NSIs?
(YES/NO)
7. NFCs are better in controlling HAIs and NSIs?
(YES/NO)
8. Risk of contamination is high for?
(NFC/3WSC)
9. Risk of Needlestick injury is high for?
(NFC/3WSC)
10. Do you think there are any limitations for NFC?
(YES/NO)
11. If yes, what are they?

12. Any limitations for a three-way stopcock?
(YES/NO)
13. If yes, what are they?
