NOVEL DEVICE FOR AUTOLOGOUS BLOOD TRANSFUSION IN A COMMUNITY HOSPITAL SETTING

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Kitra Marie Henker, titled Increasing the use of Hematuse Through Simulation-Based Training at Mama Lucy Hospital in Nairobi, Kenya and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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ABSTRACT

Purpose: The purpose of this project was to increase anesthesia care provider awareness and knowledge of the 'hemafuse device' through an educational presentation at a community hospital in Casa Grande, Arizona.

Background: The SARS-CoV-2 virus has led to a steep decline in blood available for allogeneic transfusion throughout the United States (US). Autologous transfusion technology can decrease the reliance on allogenic blood for surgical procedures. The hemafuse device was developed as a low-cost technology for autologous intraoperative transfusion. The hemafuse has been used in Ghana and Kenya for intraoperative autologous transfusion due to the chronic blood shortage experienced in those countries. The US is currently in an acute blood shortage in which use of the hemafuse device could be beneficial at a community hospital.

Methods: The anesthesia care providers at Banner Casa Grande Medical Center were the participants in the project. An educational presentation was emailed to all current providers with a post-then-pre survey to complete after watching the video. The video included an explanation of the hemafuse device, the setup, demonstration of the use, and indication and contraindications for use in clinical practice.

Results: Two anesthesia care providers participated in the educational presentation. Both providers reported an increase in awareness of the device and increased knowledge of the indications and contraindications for use. Other measures, such as awareness of the current blood shortage, current autologous technology, desire for hands-on hemafuse training, and utility of the device at BCGMC remained unchanged by the educational presentation.

Conclusions: The hemafuse device could decrease the reliance on allogeneic blood for surgical patients. An educational video can be used to increase awareness and knowledge of the device if it were to become available for clinical use at Banner Casa Grande Medical Center. The hemafuse device could be used to alleviate the reliance on the stored allogeneic blood available for certain surgical procedures. The educational video could be used to increase awareness and knowledge of providers if the device were to become available for use at Banner Casa Grande Medical Center.

INTRODUCTION

The novel SARS-CoV-2 (COVID-19) virus was first discovered in Wuhan, China, in December of 2019 (Chang et al., 2020). The first case in the United States (US) was in January 2020. The virus has caused a pandemic that has stressed the resources of the US healthcare system. One such stressor has been the availability of allogeneic blood for transfusion. The pandemic caused an acute blood shortage (Riley et al., 2021). As a result, the blood supply available for transfusions in a community hospital setting does not meet demand (Roberts et al., 2019). Community hospitals do not have additional resources for autologous transfusions, such as a cell saver device present at large urban institutions.

The hemafuse is an autologous blood transfusion device to improve blood availability and increase patient survival ("Hemafuse," n.d.). The device was first designed and tested in resource-limited settings in Africa, such as Ghana and Kenya. The hemafuse device is an innovative device designed to allow autologous transfusion in resource-limited settings. The hemafuse offers this benefit by suctioning blood from the surgical field, filtering it, and routing it to a collection bag. The blood collected is then transfused as whole blood back to the patient. The overall cost of the device is far less than a cell saver device. Many of the main components are reusable after sterilization in an autoclave.

Providing information about the hemafuse device to providers in a community hospital setting can provide awareness for the technology and improve knowledge regarding using the device for an autologous blood transfusion. Banner Casa Grande Medical Center (BCGMC) is a community hospital located in Casa Grande, Arizona. BCGMC, like many other hospitals in the US, has been experiencing a shortage of allogeneic blood available for transfusion to patients.

BCGMC currently does not have any technology available for autologous blood transfusion. BCGMC serves the residents of Casa Grande and the surrounding area in Arizona. Although Casa Grande, Arizona, is located between two large metropolitan areas, Tucson and Phoenix, many of the residents in Casa Grande do not have the financial means to travel for healthcare. Therefore, Casa Grande experiences a high volume of patients with complex medical and surgical problems who present for care. The combination of a shortage of allogeneic blood and no other available technology for autologous transfusion creates a situation in which BCGMC could be considered a resource-limited setting, with the resource being blood available for transfusion.

Background Knowledge and Significance

Obtaining blood products for transfusion is done through blood donations. There are two suggested reasons for the blood shortage associated with the COVID-19 pandemic (Riley et al., 2021). The American Red Cross canceled blood drives and there was a decrease in people coming to available blood donating locations. Both actions were due to fear of spreading and contracting the virus (Riley et al., 2021). The decrease in blood availability can place certain community hospitals such as BCGMC at an increased risk of not having blood available for emergent needs such as emergency surgery or mass causality events. Roberts et al. (2019) suggest that new technologies, especially technologies that allow for autologous transfusion, can alleviate the shortage in blood product supply.

Autologous Blood Transfusion

Autologous blood transfusion is when a patient's blood is collected and transfused back to the same patient. Allogeneic blood transfusion is when blood from a donor is transfused to a

different patient. The main benefit of using autologous blood for transfusion is avoiding the need for allogeneic blood (Sikorski et al., 2017). Allogeneic blood has a risk of transmission of infections such as hepatitis, HIV, and malaria ("Blood Safety and Availability," 2020). Packed red blood cells can only be stored for 42 days and platelets for only seven days (Riley et al., 2021). The storage limits make it impossible to keep large quantities of blood in case of an emergency. As the storage time for allogeneic blood increases, there are increased levels of 2,3-diphosphoglycerate (2,3-DPG), which causes the decreased release of oxygen at the tissue level after transfusion (Sikorski et al., 2017). Additionally, allogeneic blood stored for more than 21 days can cause deformity of the red blood cell membrane (Sikorski et al., 2017). The increased levels of 2,3-DPG and the deformed red blood cell membrane from storage are not present in autologous blood transfused by intraoperative autologous transfusion devices due to the blood never requiring storage.

In the US, there are many methods of autologous blood transfusion available during surgery. Operating rooms often use a cell salvage machine that spins and washes the collected blood before returning it to the patient (American Society of Anesthesiologists Task Force on Perioperative Blood Transfusion and Adjuvant Therapies, 2015). The cell salvage machine can be expensive and is not always available in all facilities. BCGMC does not currently own a cell salvage machine. The surgical procedures performed at BCGMC do not routinely require the use of intraoperative autologous blood transfusion; however, there are often unforeseen emergencies that present to BCGMC where intraoperative cell salvage would be beneficial and could save a patient's life when the hospital does not have an adequate blood supply. One example is a ruptured ectopic pregnancy. A ruptured ectopic pregnancy can cause massive blood loss into the

abdomen of a patient. The patient often requires blood transfusion due to blood loss (Augustin, 2018). The hemafuse device was designed after witnessing surgery and autologous transfusion on a patient with a ruptured ectopic pregnancy in Ghana. The hospital did not have enough allogeneic blood available for transfusion, so they used autologous transfusion. For the autologous transfusion, the blood was scooped out of the abdomen with a ladle, then dumped over cheesecloth into a dish to remove large clots and other material, then transfused back to the patient (Nsubuga, 2018). The ladle and cheesecloth method is a common solution for the limited blood supply experienced by many countries in Africa. Due to the recent shortage of allogeneic blood, BCGMC could be in a similar situation as Ghana if a patient were to present with a massive hemorrhage due to a ruptured ectopic pregnancy.

Hemafuse Device

The hemafuse device is designed for direct replacement of the ladle and cheesecloth technique. The device is operated manually by pulling on the plunger of the device to suction blood into the device and then pushing the plunger to transfer blood into a blood transfusion bag (Skopec et al., 2019). The device is a low-cost means of cell salvage for uncontaminated blood ("Hemafuse," n.d.). The blood must be free from contamination, such as amniotic fluid, cerebrospinal fluid (CSF), urine, feces, or cancer cells, due to the absence of cell washing in the use of the device ("Hemafuse," n.d.). The clinical benefits of the device are the same as the benefits associated with autologous transfusion. These benefits include decreased transfusion-related complications, elimination of risk of viral disease transmission, and improved tissue perfusion (American Society of Anesthesiologists Task Force on Perioperative Blood Transfusion and Adjuvant Therapies, 2015). The hemafuse device was first designed and tested

in Ghana and Kenya. The device has been in use in those countries since 2018 and has been used successfully over 150 times (T. Goodwin, personal communication). The device was approved for use in the US by the Food and Drug Administration (FDA) in 2021. Approval of the hemafuse device by the FDA was based on data gathered from use of the device in Kenya and Ghana.

Cost related to the implementation of new technologies or practices, such as the hemafuse, is often a significant barrier (Ho et al., 2019; Lizarondo et al., 2019; Mbuthia et al., 2019; Puchalski Ritchie et al., 2016; Sjöholm et al., 2020). The hemafuse design team considered cost with this barrier to implementation in mind. The device can be sterilized for multiple patients ("Hemafuse," n.d.). The average price currently in Kenya is about $200 USD for each use of the device (T. Goodwin, personal communication). This cost includes the device as well as the nonreusable components such as the tubing and filter. In comparison, the costs published in 2007 for a cell salvage device was about $100,000 USD to initially purchase and about $250,000 USD in annual operating costs (Waters et al., 2007). Increased use of the cell salvage device decreases the total cost per device use. The hemafuse device does not require maintenance throughout the year and maintains the same cost per use of the device for each patient regardless of frequency of use. This makes the hemafuse an ideal autologous transfusion device in settings where autologous transfusion is not commonly used.

Although the low cost can increase the adoption of the hemafuse technology, there are additional barriers to consider. Personnel-related barriers include lack of adequate training, lack of support from hospital management, and lack of ability to maintain skill through training (Lizarondo et al., 2019; Puchalski Ritchie et al., 2016). Although the device is not currently

available at BCGMC, knowing about the device would be helpful in a future situation when it is available and needed.

The hemafuse must be assembled before use. The assembly includes the major parts that can be sterilized and reused as well as smaller parts that are single use. Sjöholm et al. (2020) found that missed opportunities for use were due to two main factors, including lack of provider knowledge and confidence in assembling and using the intraoperative autotransfusion device.

Local Problem

BCGMC is experiencing a blood shortage similar to the national shortage. As a rural community hospital, they would benefit from awareness and knowledge of this device. Additionally, in a community hospital setting, this device could be helpful in increasing the survival of patients needing an immediate transfusion. By informing the anesthesia care providers of this device at this site, they will be aware of the potential option for blood salvage in the operative room (OR) if the device becomes available.

The primary stakeholders for the implementation of this project will be the anesthesia care providers at BCGMC. Management of hemodynamic status is the sole responsibility of the anesthesia care provider. The decision to transfuse blood products is often a discussion between the surgeon and the anesthesia provider; however, it is the task of the anesthesiologist to give the blood products to the patient. Additional stakeholders include OR personnel who might be involved in the setup or operation of the device such as surgeons, surgical scrub technicians, nurses, and other OR ancillary support staff. The hospital management is also a stakeholder because their support can significantly influence the technology's successful adoption (Mbuthia

et al., 2019). The focus for this project will be on improving awareness and knowledge in the anesthesia care providers at BCGMC.

Intended Improvement

Project Purpose

The hemafuse device was designed to provide intraoperative autologous blood transfusion in a resource-limited setting. BCGMC can be considered a resource-limited setting when referring to availability of blood for allogeneic transfusion. The hemafuse device has been utilized successfully in resource-stressed countries such as Kenya and Ghana. There are multiple hospitals that utilize the device, including Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu City, Kenya, and Mama Lucy Hospital in Nairobi, Kenya.

Kenya and Ghana are experiencing a chronic shortage of allogeneic blood. The United States is currently experiencing an acute shortage of blood due to the COVID-19 pandemic. Due to the recent approval by the FDA for use in the US, the hemafuse device could be available for use in US hospitals in the future, including BCGMC. Information regarding the implementation and use of the device can be taken from sites where the device is currently being used in practice. The use of the device provides whole blood transfusion to a patient. Due to the current pandemic, providers and hospitals cannot guarantee the availability of allogeneic blood from a blood bank (Roberts et al., 2019). Therefore, using the hemafuse provides an alternative to needing banked blood.

Project Question

Will providing an informational session on the hemafuse device increase the providers' awareness of the technology and knowledge regarding the use of the device?

Project Objectives

The objective of this quality improvement (QI) project is to inform anesthesia providers of the novel hemafuse device and the benefits it could provide to a hospital in a rural setting.

- Aim 1: Increase provider knowledge of the hemafuse device, including benefits, setup, and indications for use.
- Aim 2: Increase provider knowledge related to the hemafuse device usage after participation in a presentation including setup and use of the device.
- Aim 3: Conduct a pre-then-post survey to assess the providers' awareness and knowledge of the hemafuse device after the educational session with a retrospective pretest design.

Theoretical Framework

Rogers Diffusion of Innovation

Rogers theory of diffusion of innovation (DoI) seeks to explain the adoption of innovation within a system. Implementation of technology often uses the DoI theory (Kaminski, 2011). Everett Rogers developed the theory in 1962 (Kaminski, 2011). The theory was built on prior publications of an S-shaped curve by Gabriel Tarfe in 1903 and the creation of adopter categories by Ryan and Gross in 1943. The DoI theory can guide the knowledge of the new technology, in this case, the hemafuse device, at Banner Casa Grande Medical Center in Casa Grande, Arizona. The theory helps determine components that will require attention if diffusion is to occur (Sanson-Fisher, 2004).

The diffusion of innovation (DoI) theory describes four key elements of the theory. The first element is the characteristics of the innovation. The second is the role of communication in

the adoption process. The third is timing related to the implementation and rate of adoption between individuals. The last element is the social system (Lundblad, 2003).

Characteristics of the Innovation

The first is five factors that contribute to adopting an innovation: relative advantage, compatibility, complexity, trialability, and observability (Roger, 2003).

Relative Advantage. The relative advantage is the ways in which the innovation is superior to the current practice (Rogers, 2003). The benefit of the innovation must be shown to improve quality of care, safety for the patient, and efficiency (Leggott et al., 2016). The relative advantage of the innovation is provided to the stakeholders, with the ultimate decision to adopt resting with those individuals. The DoI theory can break down if there is a mandate to adopt (Leggot et al., 2016).

Additionally, the relative advantage relied on the stakeholders' relationships as it is unlikely to be adopted if there is a negative effect on personal or professional relationships (Sanson-Fisher, 2004). Adopters assess the relative advantage often before evaluating any of the other four factors related to the innovation. The comparative advantage must often be shown to adopters before considering the other four (Côté-Boileau et al., 2019). The hemafuse device can have an advantage over other techniques as it can decrease cost and increase safety and potentially increase the amount of blood salvaged.

Compatibility. Compatibility demonstrates how the innovation will address the adopters' values, experiences, and needs (Rogers, 2003). The literature has described current conditions regarding intraoperative cell salvage techniques (Nsubuga, 2018; Sjöholm et al., 2020). There is a shortage of allogeneic blood. The hemafuse device is specifically designed to address the

values, experiences, and needs of the patients and providers requiring blood salvage in settings with limited blood resource supply.

Complexity. The complexity of the innovation refers to the difficulty of using and understanding the innovation (Rogers, 2003). Innovations that require a high level of skill and knowledge can hinder the innovation's adoption. The hemafuse device requires assembly before the use of the device. Providers have reported mastery of the assembly after three to four iterations. However, a provider reports using the device for the first time when needed during surgery and not including the filter in the device assembly. The consequence of the mistake was a loss of the salvaged blood (A. Asma, personal communication, January 28, 2021).

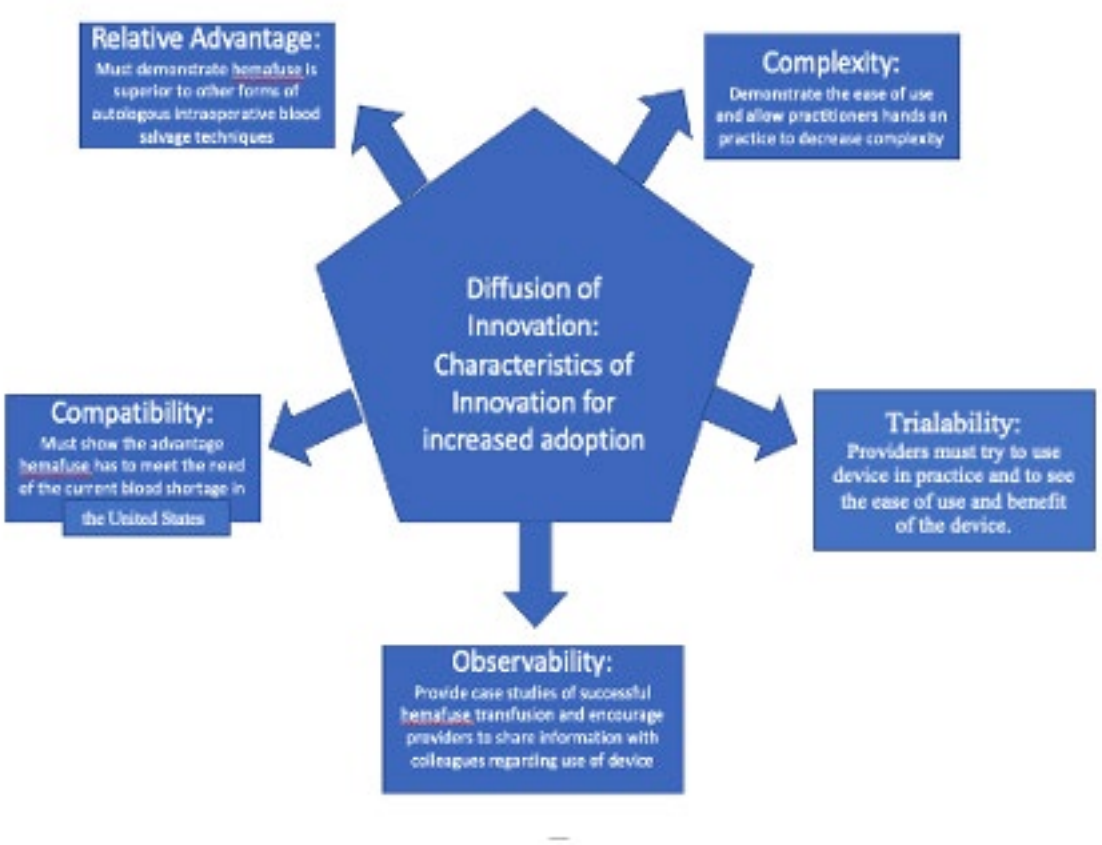
Trialability. The trialability of the innovation is the ability to test the design and assess the outcomes (Rogers, 2003). The hemafuse device can be used in clinical cases by the providers to evaluate the ease of device use and the patient's outcome. The use of the device in the operative setting will assist adoption as the practitioner can observe the benefits stated related to the relative advantage (Sanson-Fisher, 2004). The anesthesia providers will be unable to use the device in clinical practice because it is not yet available for clinical use at BCGMC. Therefore, setup and use of device will be demonstrated in the educational video to provider participants the opportunity to assess the design and outcome.

Observability. Observability is the ability to see that the innovation results meet the needs, and the adopters experience the benefit (Rogers, 2003). Personal experience with the innovation, in addition to the experience of colleagues, influences observability (Sanson-Fisher, 2004).

Figure 1 illustrates the integration of the innovation, the hemafuse device, in the context of the theory of diffusion of innovation components.

Figure 1

Integration of Rogers Diffusion of Innovation Theory on the Implementation of the Hemafuse Technology



Communication

The element of communication in the theory of diffusion of innovation requires knowledge sharing between those who have adopted the innovation and those who have not yet adopted it (Lundblad, 2003). Communication between the two groups is an important element that can facilitate widespread adoption.

Time

Time refers to the timing of the individual's decision to adopt, the adopter category, and the rate of adoption.

The timing of the adoption for an individual follows a five-step progression (Lundblad, 2003). The first is obtaining the knowledge of the innovation. The second is the persuasion stage in which the individual is exploring the benefits of adoption. The third stage is the decision stage. This stage is when the individual is deciding to adopt the innovation. The fourth stage is implementation, and the final stage is confirmation of the adoption. The stage an individual is currently in can vary depending on which adopter category they align with.

The adopter categories are innovators, early adopters, early majority, late majority, and laggards (Rogers, 2003). The adopter type creates a bell-shaped curve with most individuals being in the early or late majority. Each category, described below, has different needs related to the adoption of the innovation. The innovators are the first group to adopt and can be used as change agents or educators for the technology. The next group is the early adopters; this group often serves as the main testers of the innovation and heavily influences the opinions of others. The next group is the early majority who often want to see the proven success of the technology before adoption. The late majority, the next group, is similar in the individual’s desire to see proven results before making a change to their own process. The last group is the laggards, the last group to adopt an innovation, usually after the alternatives have been shown to be worse (Kaminski, 2011). The process of adoption of the innovation must change to meet the needs of each adopter category through time.

Social System

The social system refers to the group of individuals in which the change will be occurring (Roger, 2003). The leaders of the social system are important to identify as they can influence the adoption of the change. The leaders inside of the system are called opinion leaders. Opinion leaders are respected members of the social system, often with experience and competence (Lundblan, 2003). There are also leaders present outside of the system called change agents. A change agent would be the instructor of the simulation for the hemafuse device. A change agent is an individual with specific knowledge and skills related to innovation. The change agent must work closely with the opinion leaders for successful adoption of the innovation (Lundblan, 2003).

Limitations

The main limitation of the theory is the lack of accountability related to the availability of resources in the local setting for the innovation. Community hospitals with limited blood resources have their own barriers that are not accounted for. This theory does not take that variable into account (Zanello et al., 2016). These barriers are often financial but can also be a lack of experienced personnel with the desired skill set to adopt the innovation. Additionally, the device is not currently available for use in the clinical setting which does not allow for hands-on practice or observation of use of the device. Other limitations of the theory are that the theory was not originally designed especially for a healthcare system (Lundblad, 2003). Therefore, the components of the theory might not be able to completely describe the adoption of technology in the healthcare setting.

Literature Synthesis

Literature Search Description

A literature search was completed to assess the effect of the pandemic on the blood supply, the need and benefit of autologous transfusion especially in a setting experiencing a blood shortage, and blood shortage management strategies. The search included papers from areas of the world experiencing chronic blood shortages that have benefited from the use of the hemafuse device to improve translation to the acute blood shortage Banner Casa Grande Medical Center (BCGMC) is currently experiencing. The papers selected came from searches done in three different databases: CINAHL, PubMed, and Google Scholar. The search included filters to ensure the articles were less than five years old. The papers were scanned first by title for appropriateness. Abstracts of pertinent themes were then read, and relevant articles were selected. While reading these papers, if one proved not to be applicable, it was discarded. The search was exhaustive.

The first search terms were related to the effect of the pandemic on the blood supply in the US. All databases used were searched with the terms “blood bank shortage” and “blood shortage COVID 19.” The CINAHL database yielded eight relevant articles with one chosen for inclusion. The PubMed database yielded 16 papers for consideration with two being chosen for inclusion (Appendix G).

The second search included terms related to the benefit of autologous transfusion in blood resource-limited settings. Articles were included from Africa because their chronic blood shortage strategies can translate to the acute shortage the US is currently facing. Additionally, the hemafuse device was first tested and approved in Kenya and Ghana. The data obtained from the

operation of the device in those countries was presented to the FDA for approval of the device in the US. The search terms used included “blood shortage management,” “autologous blood transfusion AND intraoperative,” “autologous blood transfusion AND Africa,” and “Africa AND anesthesia AND blood.” The CINAHL database had 16 relevant papers with two being included for review. The search in PubMed used the same search terms. The search terms “blood shortage management” had 24 results; seven were included based on title, and one article was included in the final literature synthesis. The search terms “Africa AND anesthesia AND blood” yielded 48 results, with one article being selected for inclusion.

Lastly, search terms included were related to blood shortage management strategies used in the US and in Africa. Google Scholar was searched with similar search terms with the addition of “autologous transfusion Africa,” “soup and ladle technique blood transfusion,” and “blood shortage management.” A filter was placed for articles less than five years old, and article titles were scanned for relevance. Publications with surgery, blood shortage, low-income, middle-come, or implementation in the title were then clicked on to read the abstract. Four papers were included from this method.

Comprehensive Appraisal of Evidence

Effect of SARS-CoV-2 on Allogeneic Blood Supply

The first-ever national blood crisis was declared by the American Red Cross on January 11, 2022. The supply of allogeneic blood available for transfusion in the US is at a critically low level throughout the country. The blood shortage is a result of a decrease in donations due to the SAR-CoV-2 virus spread throughout the US. After a shortage was recognized, attempts were made to increase donations (Nieto-Calvache et al., 2021). However, these interventions to

increase supply were unsuccessful at meeting the growing demand for allogeneic blood products (Nieto-Calvache et al., 2021). In addition to increasing supply, many hospital systems made attempts to decrease demand for an allogeneic blood transfusion by canceling elective surgeries (Gniadek et al., 2020). However, most of the allogenic blood used in the operating room is not used on patients presenting for elective surgery (Gniadek et al., 2020). The majority of the allogeneic blood is used on patients needing emergent lifesaving surgery. There is no way to decrease the number of patients presenting for emergent surgery which makes decreasing demand difficult. Authors Gniadek et al. (2020) and Nieto-Calvache et al. (2021) both emphasize the need for novel strategies to combat the national blood shortage.

Stanworth et al. (2020) note that it is important to start to combat the blood shortage prior to experiencing it. The authors mention many strategies that could be used to decrease the shortage even if a shortage might not be currently present at a hospital. The authors suggest mitigation strategies such as following best practice guidelines for transfusion and potentially extending the shelf life of current blood stores. Additionally, the use of whole blood can be used in the setting of a massive transfusion event (Stanworth et al., 2020). The hemafuse is an autologous device that transfused whole blood in the setting of a massive transfusion event. Therefore, autologous transfusion might be a strategy that could be used to decrease the strain of the blood shortage in a community hospital.

Benefits of Autologous Transfusion during Blood Shortage

Autologous blood transfusion can be used intraoperatively. Henderson et al. (2021) found that autologous whole blood transfusion to patients undergoing cardiac surgery did not change patient outcomes. Additionally, although the study sample size was small, it is possible that the

transfusion of autologous whole blood in this patient population benefited the patients by increasing their clotting ability as demonstrated by thromboelastographic readings.

Additionally, autologous blood transfusion can be used as an alternative for allogeneic blood in the context of a blood shortage (Adama et al., 2017). Autologous transfusion was used for patients experiencing a ruptured ectopic pregnancy with 62% of patients having hemoglobin greater than 10g/dL after surgery and the use of an autologous transfusion device (Adams et al., 2017). Adama et al. (2017) conducted their study in Benin, a country located on the continent of Africa. Benin often experiences instances of chronic blood shortage. Countries experiencing chronic shortages of blood available for transfusion can be used as a reference for the current acute blood shortage affecting the US.

Need for Autologous Transfusion

Allogeneic blood has been chronically low in many low- and middle-income countries in Africa (Nsubuga, 2018). Autologous blood transfusion can decrease or eliminate the need for allogeneic blood transfusions (Nsubuga, 2018). The traditional method of obtaining autologous blood in Africa is with the ladle and cloth method. This method is used as a cost-effective means of autologous blood transfusion in the face of chronic shortage. The spoon and cloth method is done by scooping the blood from the body cavity, straining it with a cheesecloth to remove blood clots, and transferring the blood into the patient (Nsubuga, 2018). Nsuguga (2018) conducted a study on the frequency of bacterial contamination when using this method. The study was conducted over seven months; in that time this method was used on 204 women who presented with ruptured ectopic pregnancies. The ladle and cheesecloth method of blood salvage has an infection rate of 76% (Nsubuga, 2018). Although it is unlikely that hospitals in the US would

turn to this technique, as the blood crisis continues to get worse, it is possible that novel techniques for the US, such as the spoon and ladle technique, might be used to save a hemorrhaging patient when there are no other treatment options available.

Cell saver is another technique that can be used for intraoperative autologous transfusion. However, cell savers can be expensive, which can prohibit their use in resource-limited settings. Duramaz et al. (2018) found that cell salvage use during orthopedic procedures increased cost as compared to those where cell salvage was not used. The cost is often a major barrier to implementation, especially in resource-limited settings (Lizarondo et al., 2019). Rural community hospitals in the US also face the issue of the cost related to obtaining and use of a cell salvage device. Therefore, a cost-effective autologous blood transfusion device would be the most beneficial in the context of a blood shortage in a rural community hospital setting.

Strengths of Evidence

Many authors have described the current acute shortage of blood products available in the US with many mentioning the need for alternative strategies to combat the shortage (Gniadek et al., 2020; Nieto-Calvache et al., 2020; Stanworth et al., 2020). Autologous transfusion has been identified to be an acceptable strategy that can decrease the amount of allogeneic blood needed during and after surgery (Adama et al., 2017; Duramaz et al., 2018; Nsubuga, 2018). The hemafuse is an autologous transfusion device designed for this purpose. Similar findings are a strength of the evidence.

Weakness, Gaps, and Limitations of Evidence

The weaknesses of the literature are that this crisis is novel in the US. There is limited information regarding the specific use of autologous transfusion to combat a blood crisis. The

best evidence comes from countries experiencing a chronic blood shortage. Additionally, there is a lack of evidence regarding the use of the hemafuse device. The device was approved in the US in 2021 and is not currently being widely used.

METHODS

Project Design

There is a recognized blood shortage in the US. The hemafuse device has the potential to alleviate some of the burdens of the blood shortage. This quality improvement (QI) project aimed to increase providers' awareness and knowledge regarding the novel hemafuse technology, including setup, operation, indication, and contraindications for use. Increasing provider awareness and knowledge was done by viewing a short educational presentation. The participants then completed a post- then pre-survey about the hemafuse device.

The project design was a retrospective pretest design. The participants submitted the survey upon completion of the educational activity, answering questions related to their awareness and knowledge after the presentation as well as reflecting to their thoughts before the intervention. The retrospective pretest design can eliminate response shift bias (Howard et al., 1979). Response shift bias is due to participants answering pretest questions in a different comparison standard than posttest questions (Little et al., 2020). An individual might over- or underestimate their knowledge, beliefs, and attitudes on a pretest. After participation and with increased awareness of the intervention, the respondent is better able to accurately evaluate themselves. This variation between the comparison standard of the pretest and posttest impacts the ability of the assessment to accurately evaluate the intervention (Little et al., 2020). However, if participants fill out the pretest and posttest evaluations at the same time, there is a consistent

comparison standard for the participant responses. Therefore, the survey is better able to detect changes due to the intervention (Little et al., 2020).

Consequently, for this project, the data was collected at the end of the educational presentation. The participants responded as to their current awareness and knowledge, then reflected on their previous levels before the intervention. The educational presentation and participant survey were developed by the principal investigator (PI). See Appendix E for a link to the presentation. See Appendix D for the participant survey.

Model for Implementation

The quality improvement (QI) project's goal is to improve patient care delivery by increasing safety and efficacy (Institute for Healthcare Improvement [IHI], 2021). The QI project evaluates changes in the system to assess for improvements in patient care and processes. The QI project followed the Model for Improvement (MFI) published by the Institute for Healthcare Improvement (IHI). This model has two different parts: first, three fundamental questions are answered, and second, the Plan-Do-Study-Act (PDSA) cycle guides the change to assess for improvement (IHI, 2021).

The three fundamental questions in the model are: what are we trying to accomplish? How will we know that a change is an improvement? And what change can we make that will result in improvement? The project investigator intended to increase awareness and knowledge of the use of the hemafuse device through an educational presentation. This presentation introduced providers to the hemafuse device as well as information about device setup, operation, and indicated clinical scenarios. The PI anticipated increased awareness of the availability of the technology and increased knowledge of the device's usage from all those who

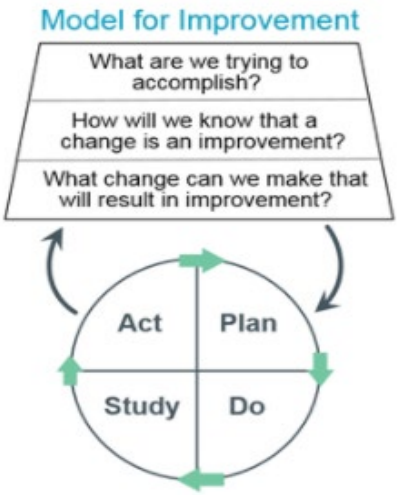
could interact with the device in the OR setting. The awareness and knowledge of the providers who participated in the simulation session was measured with a post- then pre- survey completed by participants.

Plan-Do-Study-Act (PDSA) Cycle

These questions then feed into the PDSA cycle (Figure 2). The PSDA cycle is a means of testing the effectiveness and longevity of the implementation (IHI, 2021). This cycle is an action-oriented application of the scientific method (IHI, 2021). The cycle continues to repeat after each implementation of a change. The first implementation is on a smaller scale and changes are made each time the cycle repeats to increase the successful adoption of the change (IHI, 2021). The cycle will be applied throughout the development of the educational presentation to evaluate, adapt, or change components of the presentation if needed. The PDSA cycle will be applied to each draft of development to assure changes are being made so the goals of the project are being met.

Figure 2

Model of Improvement



Retrieved from http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementHowtoImprove.aspx

Plan

The 'plan' is the first component in the PDSA cycle (IHI, 2021). The plan includes the questions of *who*, *what*, *where*, and *when*. The first component of these questions is *who*. This will be the selection of the team for the training. Team selection should include three different kinds of expertise (IHI, 2021). The PI consulted with public health officials in resource-limited settings to assess the need for the project and implementation site. The implementation site was chosen based on the potential benefit from the availability of the hemafuse device. Once the practitioners at the implementation site expressed a desire for the project, the PI obtained information about the use of the device at the site, such as the setup of the device and published indications and contraindications for clinical use. This information was then integrated into the educational presentation. The educational presentation will be sent to the project committee for approval. Feedback will be assessed and changes made to assure the presentation will fit the objective for the project. The PI will work with the implementation site to assess the best form of recruitment. An email will be sent to the intended providers in the OR, inviting them to view the educational presentation in an online recorded format. The surveys will be provided as a link in the recruitment email for completion after viewing the presentation. A test trial of the presentation will be completed with the PI and others involved in the project.

Do

The second step in the PDSA cycle is 'do' (IHI, 2021). This is when the implementation is assessed on a small scale. Feedback will be gathered from committee members in order to make any necessary changes and assure the effectiveness of the presentation. The

implementation of the educational presentation is planned for February/March 2022. The goal is to complete implementation by the end of March 2022.

Study

The third step in the cycle is 'study' (IHI, 2021). The study step in the cycle is to examine the data being collected. The data should assess the provider's awareness of the technology and knowledge regarding the use, including setup, indications, and contraindications. The PI predicts that the participants will experience increased awareness of the potential availability of the H=hemafuse technology and increased knowledge regarding the use of the device. The data will be assessed to assure the objectives of the project were met. The final project results will be shared with the site.

Act

The final stage in the cycle is the 'act' stage in which an assessment to *adapt*, *adopt*, or *abandon* then *change* is determined (IHI, 2021). The survey results will be assessed to determine if the goals were met for the project. If the project goals are not met, the PI will discuss changes that could be incorporated into the educational presentation to be more effective in meeting the project objectives. These changes will then be applied and the PDSA cycle will be completed again to assure increased provider awareness and knowledge in using the hemafuse device and intent to change and use the device in clinically indicated situations.

Setting and Stakeholders

The hemafuse device received 510k approval by the U.S. Food and Drug Administration (FDA) in August 2021. The intended setting for the device is in areas with limited blood resources available. The setting for the project will be Banner Casa Grande Medical Center

(BCGMC) in Casa Grande, Arizona. BCGMC is a community hospital serving Casa Grande, Arizona, as well as the surrounding areas. BCGMC is experiencing a blood shortage that is similar to the shortage in other hospitals around Arizona and in the US. A notice was published in October 2021 telling providers about the critical shortage at BCGMC.

The setting has many operating room staff at various levels, from those in training to those with many years of experience. The majority of the providers are not aware that technology for autologous transfusion, such as the hemafuse, is available. Therefore, it is important to first provide education on the presence of the device as well as setup and use of the device.

Due to the current COVID-19 pandemic, the investigator and participants will virtually complete the project. The educational training will be available online for participants to view at their convenience.

Authorization for the hospital site was approved by the clinical coordinator for nurse anesthesia residents at BCGMC (Appendix A). The anesthesia care providers are the primary stakeholders. Additional stakeholders would be surgeons, surgical technicians, and the operating room nurse. The anesthesia care providers will be the main focus for the initial project. The hemafuse device requires at least two operators, one to collect blood and one provider to transfuse the blood back to the patient. However, in emergency situations all providers should have the skills and knowledge to set up all components of the device if needed. The patients were also stakeholders as they are receiving blood from this autologous transfusion device. Other patients of the hospital, not just those undergoing surgery, would also benefit from potential increased availability of blood that is not being used for a patient in the OR. The hospital

administration personnel are also stakeholders in the project. They are the key authorities allowing for the creation of the availability of the technology at the hospital site.

Planning the Intervention

The intervention was an online educational presentation with PowerPoint voice-over and video familiarization and setup of the device. A link to the presentation is available in Appendix E. The educational presentation had two main goals. The first was to increase awareness of the presence of the device now on the US market. Second, the device setup and operation were discussed, followed by clinical indications and contraindications for device use. After viewing the educational video presentation, the participants were be asked to fill out the post-then-pre survey.

Participants and Recruitment

The providers of anesthesia at BCGMC are contracted through Arizona Anesthesia Solutions (AZAS). Therefore, participants were anesthesia providers employed by AZAS who either work or have worked at BCGMC within the last three years, March 2019 to March 2022. The recruitment was done by the clinical site coordinator sending an email to the providers, explaining the project, and inviting participation. The email will also include information about the PI and academic affiliation in case of questions regarding the project or participation. See Appendix C for details of recruitment emails sent. A follow-up email reminding potential participants of the project was sent a week after the initial email (Appendix C). Data was collected for three weeks following the initial recruitment email. Inclusion criteria was anesthesia care providers who have worked or currently provide anesthesia at BCGMC. Other operating room providers were excluded from recruitment.

Consent and Ethical Considerations

The project was be submitted to the Institutional Review Board (IRB) at the University of Arizona as well as the IRB at the implementation site. The project was not designed as research and was not designed as human subject research. Participation in the project is voluntary. Consent information was included in the recruitment email to potential participants (Appendix B). Consent was assumed when the participants choose to complete the survey at the end of the presentation. Privacy of the participants was ensured by not collecting names or identifying information. The data will be stored in a password-protected computer that can only be viewed by the PI. A Determination of Human Research form will be completed prior to recruitment of participants. There are not risks foreseen for the individuals who participate in this project.

Timeline

A timeline (Appendix F) was created to ensure adequate completion of the QI project. The dates were adapted based on University of Arizona IRB approval, educational presentation development, site approval, and requests and implementation.

Data Collection

A survey was given after the completion of the educational presentation to all participants. Qualtrics was used to collect the data from the survey. Qualtrics is a program designed to allow creation of surveys and collection of data from participants (Qualtrics, 2020). The survey is included in ticles D. The only person with access to the information collected by the survey was the PI. The data was kept securely in the University of Arizona Qualtrics account of the PI. Data collected included age, length of anesthesia practice, international/rural anesthesia experience, and gender. Hemafuse device awareness and knowledge will also be assessed. Both

awareness and knowledge will be assessed with a Likert scale. The data will be stored with the University of Arizona for the time required by the Office of Human Research Protections.

Data Analysis

Qualtrics (2020) is an online program designed to allow for creation of a survey and analysis of the results. The questions regarding awareness and knowledge of the hemafuse device are Likert-scale style questions with a 1-5 scale, using "5" as *strongly agree* and "1" as *strongly disagree*. Questions of other demographic and anesthesia background questions are multiple choice questions. The PI will assess the post- then pre-responses. The data was analyzed using a Wilcoxson signed rank test to determine the differences between pre- and post- survey responses. Survey qualitative feedback was assessed to determine intervention strengths, weaknesses, and gaps in relation to the educational presentation.

RESULTS

The initial email containing a link to the educational video and the survey was active from February 18, 2022, to March 11, 2022. The first email inviting participation was sent on February 18, 2022, and the follow-up email was sent February 25, 2022.

Sample Size and Demographics

The survey was sent to a total of 12 anesthesia care providers. There was a low response rate (17%) with only two participants in the project at the conclusion of the project. Both participants completed the entire survey. One participant was in the 36 to 45 age group, and one was in the 56-65 age group. One respondent was a male and one was a female. Both participants have been practicing anesthesia for more than nine years with one participant having practiced

for more than 20 years. Both participants have worked at a community hospital and one of the respondents has delivered anesthesia in a developing country.

Outcomes

Due to the small sample size, a statistical analysis was unable to be completed. Therefore, the results will be described below.

Awareness

The first two questions on the survey were about the participant's awareness of the current shortage of blood within the US as well as the available technology for autologous transfusion. Both participants reported current awareness of the shortage of blood both before and after participation in the educational video with the response of "strongly agree." The participants also reported an awareness of available technology as the same before and after viewing the video with one respondent reporting "strongly agree" and one reporting "somewhat agree." Both participants responded the same for after in the intervention and reflecting to before the intervention. Therefore, the intervention did not change the participants' awareness of the current blood shortage or available autologous transfusion.

The next two questions in the survey were about the awareness of the hemafuse device. Both participants reported a low awareness of the hemafuse device before participation. In response to awareness of the hemafuse device one participant responded with "strongly disagree" and one responded, "somewhat disagree." After watching the educational video, the participants reported "strongly agree" and "somewhat agree" regarding awareness of the hemafuse device. Therefore, the educational video seems to increase the awareness of the hemafuse device.

Table 1

Pre- and Post-Survey Results for Question 1 - Awareness of Blood Shortage in US

	Pre	**Post**
Strongly agree	2	2
Somewhat Agree	0	0
Neither agree/disagree	0	0
Somewhat disagree	0	0
Strongly disagree	0	0

Table 2

Pre- and Post-Survey Results for Question 2 - Awareness of Autologous Transfusion Technology

	Pre	**Post**
Strongly agree	1	1
Somewhat Agree	1	1
Neither agree/disagree	0	0
Somewhat disagree	0	0
Strongly disagree	0	0

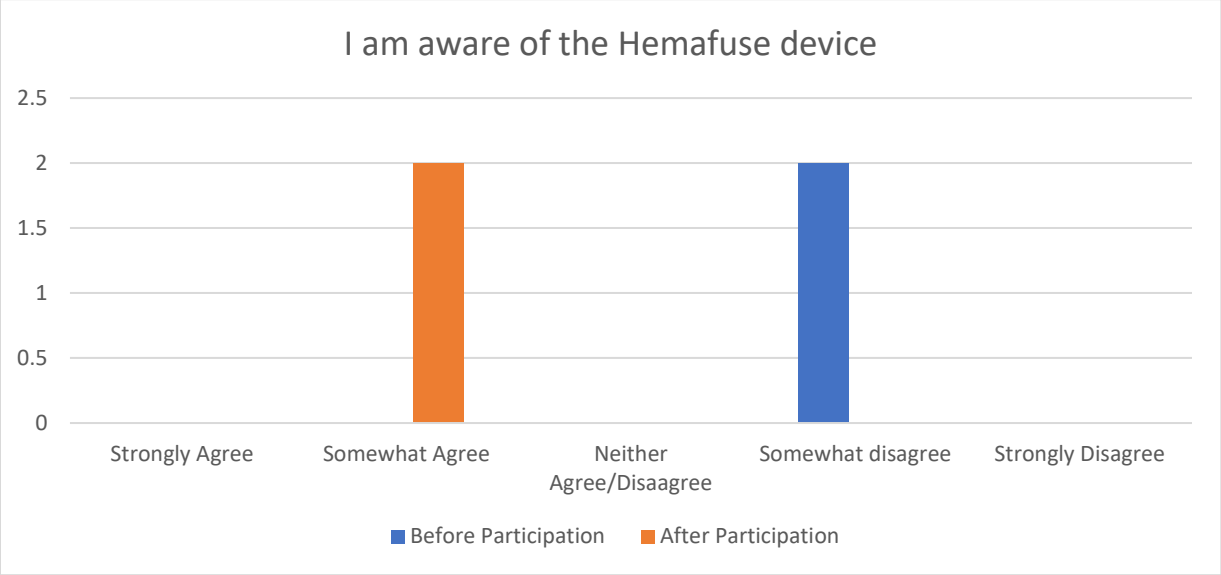
Table 3

Pre- and Post-Survey Results for Question 3 - Awareness of Hemafuse Technology

	Pre	**Post**
Strongly agree	0	1
Somewhat Agree	0	1
Neither agree/disagree	0	0
Somewhat disagree	1	0
Strongly disagree	1	0

Figure 3

Participant Responses Regarding Awareness of the Hemafuse Device Before and After Viewing the Educational Presentation



Knowledge

The next question in the survey relates to knowledge of the hemafuse device. Prior to participation in the educational presentation, both participants reported "somewhat disagree" in response to feeling comfortable knowing the indications and contraindications to use of the hemafuse device. After viewing the presentation both respondents reported "somewhat agree" in response to their comfort with this knowledge.

The last two questions in the survey relate to the desire for more knowledge regarding use of the hemafuse device in the clinical setting. The fifth question related to the interest in a hands-on, in-person training with the device. The answers were the same for both before and after viewing the educational video. One respondent answered, "somewhat agree" and one responded with "neither agree nor disagree." The sixth and final question was if the participants

thought the hemafuse technology would be useful in their current clinical setting. The responses of the participants reflecting on their awareness and knowledge before the intervention were one "somewhat disagree" and one "neither agree nor disagree." The results for this question after the intervention were both participants responded, "neither agree nor disagree."

Table 4

Pre- and Post-Survey Results for Question 4 - Knowledge of Hemafuse Technology

	Pre	**Post**
Strongly agree	0	0
Somewhat Agree	0	2
Neither agree/disagree	0	0
Somewhat disagree	2	0
Strongly disagree	0	0

Table 5

Pre- and Post-Survey Results for Question 5 - Desire for Hands on Training

	Pre	**Post**
Strongly agree	0	0
Somewhat Agree	1	1
Neither agree/disagree	1	1
Somewhat disagree	0	0
Strongly disagree	0	0

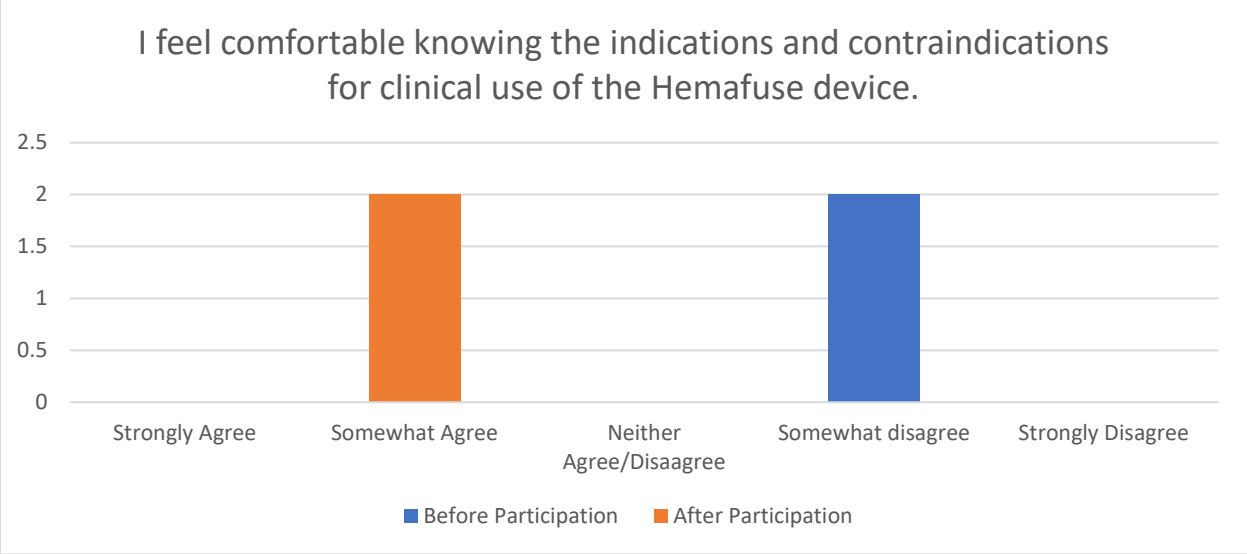
Table 6

Pre- and Post-Survey Results for Question 6 - Utility of Device at BCGMC

	Pre	Post
Strongly agree	0	0
Somewhat Agree	0	0
Neither agree/disagree	1	2
Somewhat disagree	1	0
Strongly disagree	0	0

Figure 4

Participant Responses Regarding Knowledge of the Hemafuse Device Before and After Viewing the Educational Presentation



Summary of Findings

The two participants only reported a change in their results from the pre-survey to the post-survey in two categories. The first was question three, knowledge of the hemafuse device where both participants reported an increase in awareness of the device. The second was the

knowledge of indications and contraindications for use of the device. Both participants reported an increase in that knowledge after viewing the educational video.

DISCUSSION

Summary

The US is currently experiencing a shortage of allogeneic blood available for transfusion (Stanworth et al., 2021). The shortage is due to canceled blood drives as well as donors not wanting to go to blood drives (Nieto-Calvache et al., 2020). Elective operative procedures were canceled during this time; however, canceling these procedures does not decrease the demand for blood needed for transfusions (Gniadek et al., 2020). Kenya has experienced a similar lack of blood as a resource. The chronic shortage in Kenya and many other African countries has led to innovations for use of intraoperative autologous blood transfusions. The hemafuse device was developed to meet the needs for autologous blood transfusions and is currently being used in both Kenya and Ghana (Skopec et al., 2019). The hemafuse device takes about 10 minutes for setup and use. The cost of the hemafuse is also significantly less than the cost associated with a unit of blood or the use of other cell saver technology (Duramaz et al., 2018; Skopec et al., 2019). The hemafuse device was approved by the FDA in 2021 for use in the US.

The project objective was to increase awareness and knowledge of the hemafuse device. Although the device is not available for use currently at the implementation site, in the future it could be an option to decrease the reliance on allogeneic blood for certain surgical procedures. An educational video was made to explain the hemafuse device, including setup of the device, how to use it, indications, and contraindications for use. The results of the project show that this educational video did increase providers' awareness and knowledge of the hemafuse device.

Interpretation

Awareness

The first three questions in the survey focused on the awareness of the current blood shortage, available autologous technology, and the hemafuse device. Both participants were aware of the current blood shortage. This is more likely due to the publicity of the current problem as well as bulletins sent by BCGMC informing providers of the current shortage at that particular healthcare facility. Autologous blood salvage is often used routinely in certain high blood loss surgeries that the participants would have been exposed to either in training or while working at other facilities. Although providers were already aware of the current state of blood availability and technology for autologous transfusion, the educational video did increase the awareness of the hemafuse device. Awareness of the device could be beneficial in the future if the device becomes available for use at BCGMC.

Knowledge

The main question that related to knowledge of the device was regarding the indications and contraindications for use. Both participants reported an increased knowledge regarding this information after the educational presentation. The knowledge of indications and contraindications for use can inform a provider of the utility of the device. If there are few situations within the clinical setting in which the device would be indicated, this could decrease the desire to seek more information. Responses were the same or similar for the desire for a hands-on training and the usefulness of the device at BCGMC. The lack of a desire for further training could be due to the device being currently unavailable for use at BCGMC. However, the

increased awareness and knowledge could be useful in a situation where the device is available and there is an indication for its use at BCGMC.

Implications (Practice, Education, Research and Policy)

The hemafuse device could potentially assist with the burden on the supply of allogeneic blood at BCGMC. If the device were to become available for use, education would need to be done with all providers within the operating room (OR). The educational video used in this project could be used as an introduction video. The video would need to be followed up with an in-person training where participants would be able to handle and set up the device in a practice situation.

Further research would need to be done regarding the use of the hemafuse device within practice in the US. The current data on the device is from Ghana and Kenya where the device is currently being used. As research on the device in the US increases, the presence of the device in community healthcare settings could be more likely. If the device were to become available at BCGMC, certain policies would need to be created to ensure competence and confidence of device usage. The hemafuse device can be used in the community hospital setting in an emergence situation such as a ruptured ectopic pregnancy. Therefore, there would be limited time to review operation of the device. Educational presentations and hands-on training would need to be incorporated into policies to maintain provider confidence while using the device.

Strengths

The strengths of the project were that it was available in an online format which allowed the participants to view at a time and location that was most available to them. Additionally, the project related to a relevant topic of blood shortage within the US.

Limitations

One limitation of this project was the lack of participation. Only two providers participated in the project, which limited the ability to infer from the results obtained. No statistical analysis was able to be done due to this as well. The intended audience was limited due to the small number of anesthesia care providers who provide anesthesia at BCGMC. This could have been a contributing factor to the small response.

Another limitation in the project was the lack of the hemafuse being available at BCGMC. The hemafuse device received 501k FDA clearance in 2021. It is relatively new to the US even though it has been used in Kenya and Ghana for many years. The lack of clinical use of the device at BCGMC could deter participation and affect the responses of those who did participate.

DNP Essentials Addressed

The Doctor of Nursing Practice (DNP) degree has specific essentials to ensure competencies necessary to the advanced practice nurse role (AACN, 2016). These competencies are universal and do not depend on the specific area of practice an individual has been trained in. There are eight essentials published by the American Association of Colleges of Nursing (AACN), five of which were addressed in the development and implementation of this project.

DNP Essential I is the *scientific underpinnings for practice* (AACN, 2016). The focus of DNP Essential I is taking scientific knowledge and using it in practice. The project addresses DNP Essential I by providing an advanced strategy to enhance healthcare delivery in a community hospital setting. DNP Essential II, *organizational and systems leadership for quality improvement and system thinking,* focuses on the ability to improve patient care and outcomes.

DNP Essential II also focuses on the ability to provide cost effective, safe patient care (AACN, 2016). The project addresses DNP Essential II by providing education on a cost-effective alternative technology to improve patient safety and outcomes. DNP Essential III is *clinical scholarship and analytical methods for evidence-based practice*. The project addresses DNP Essential III through the extensive literature review and evaluation of evidence-based practice as the foundation of the project. DNP Essential IV is *information systems/technology and patient care technology for the improvement and transformation of health care* which focuses on the ability to use internet-based learning and assessment tools to integrate into patient care. The project addresses DNP Essential IV by being based completely online. The educational video, survey, and recruitment were all done with various forms of technology through the internet. Lastly, the project addresses DNP Essential VIII, *advanced nursing practice*, which focuses on mastering the specific specialty area and developing advanced clinical knowledge and assessment skills in delivery of care. The project addresses DNP Essential VIII by giving provider indication and contraindications for use of the device that rely on the clinical judgment of the practitioners within each situation.

Conclusions

The educations video on the hemafuse device increased providers' awareness of the device and knowledge of indications and contraindications for use of the device. The project showed that an online video can be used to increase provider awareness and knowledge of novel technology related to autologous blood transfusion. However, the small sample size does limit the ability to truly assess the impact of the educational video on anesthesia care providers. The device not being available for use at BCGMC could also affect the utility of the educational

presentation. The current blood shortage in the US could increase the likelihood of use of the device in the future where the awareness of knowledge of the device would be beneficial to the provider.

Plan for Sustainability

Currently, the hemafuse device is not clinically available for use at BCGMC. Therefore, although this technology could be useful in this setting, it is unlikely that providers would be interested continued education about the device. However, in the future if the device does become available, the video could be used to give providers a quick overview before a more in-depth and hands-on training with the device.

Plan for Dissemination

Following completion of the project, the results were shared with the anesthesia care providers who are currently providing anesthesia services at BCGMC. Additionally, a poster with results was presented at the Arizona Association of Nurse Anesthesiologist (AzANA) annual spring meeting, which was attended by some providers included in the project. The educational video was given to the anesthesia team to review in case the technology became available for use at the site.

APPENDIX A:

ARIZONA ANESTHESIA SOLUTIONS SITE APPROVAL/THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD DETERMINATION LETTER

Arizona Anesthesia Solutions
Office (480) 420-4027
Fax (602) 535- 0940

2/2/2022

University of Arizona Institutional Review Board
c/o Office of Human Subjects
1618 E Helen St
Tucson, AZ 85721

Please note that Ms. Kitra Henker, UA Doctor of Nursing Practice student, has permission of Arizona Anesthesia Solutions to conduct a quality improvement project at our facility for her project, "Novel Device for Autologous Blood Transfusion in a Community Hospital Setting."

Ms. Henker will conduct a survey of health care providers employed by Arizona Anesthesia Solutions contracted by Banner Casa Grande Medical Center. She will recruit providers through an email sent by either the chief CRNA or Clinical site coordinator. The email will provide a description of the project, what they will be asked to do, the time involved, and a link to the online survey. Ms. Henker's activities will be completed by April 30, 2022.

Ms. Henker has agreed to provide to my office a copy of the University of Arizona Determination before she recruits participants. She will also will present aggregate results to the providers at their monthly staff meeting.

If there are any questions, please contact my office.

Signed,

Katherine Porter CRNA

Katherine Porter, CRNA
Clinical Site Coordinator, AZAS- Banner Casa Grande Medical Center

THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

845 N Park Ave., Suite 537A
Tucson, AZ 85719
Fax: 520-621-9810
VPR-IRB@arizona.edu

NOT HUMAN RESEARCH

February 9, 2022

Kitra Henker

Dear Kitra Henker:

On 2/9/2022, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title:	Novel Device for Autologous Blood Transfusion in a Community Hospital Setting
Investigator:	Kitra Henker
IRB ID:	STUDY00000799
Sponsor:	None
Prime Sponsor:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Advisor attestation, Category: Regulatory Documentation; • Consent Document , Category: Consent Form; • IRB Protocol For Determination of Human Research , Category: IRB Protocol; • Recruitment Material, Category: Recruitment Materials; • Site Authorization Letter, Category: Institutional Approval; • Survery Questions, Category: Data Collection Tool; • Video Presentation , Category: Participant Material;

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving humans in which the organization is engaged, please submit a new request to the IRB for a determination. You can create a modification by clicking **Create Modification / CR** within the study.

APPENDIX B:

CONSENT DOCUMENT (DISCLOSURE STATEMENT FOR CONSENT TO PARTICIPATE CONTAINED WITHIN RECRUITMENT EMAIL)

Consent disclosure statement:

Participation in this project is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose to withdraw at any time, and you may also skip any survey questions you choose not to answer. No identifying information will be collected, and the survey responses will remain anonymous. The project does not contain foreseeable risks to participants. By participating in this project, you do not give up any personal legal right you may have as a participant in this project.

APPENDIX C:

RECRUITMENT MATERIAL (RECRUITMENT EMAIL AND REMINDER EMAIL)

Subject line: Invitation to participation in a DNP Project for Kitra Henker

Dear Anesthesia Team,

My name is Kitra Henker and I am currently a student in the Doctor of Nursing Practice Nurse Anesthesia program at the University of Arizona. I am conducting a quality improvement (QI) project surrounding the use of a novel device for autologous blood transfusion. The title of the project is "Novel Device for Autologous Blood Transfusion in a Community Hospital Setting."

As a part of this project, I would like to invite you to view an educational video on the hemafuse autologous transfusion device. The video will include information about the device, the setup and device use, and indications/contraindications. The educational video is about 10 minutes long. When opening the video, it might be helpful to enlarge to side video especially during the explanation of the setup of the device to view the setup of a hemafuse device. After completion of the video, there is a survey that will take about 10 minutes to complete. Consent for participation in the project will be assumed for participants who choose to complete the survey following the presentation.

Participation in this project is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose to withdraw at any time and you may also skip any survey questions you choose not to answer. No identifying information will be collected and the survey responses will remain anonymous. The project does not contain foreseeable risks to participants. By participating in this project, you do not give up any personal legal right you may have as a participant in this project.

Questions or concerns regarding this project can be directed to the Principal Investigator via phone or email.

Sincerely,

Kitra Henker

khenker@email.arizona.edu

cell: 412-352-2478

Link to educational video: https://arizona.voicethread.com/share/18949892/

Link to survey:
https://uarizona.co1.qualtrics.com/jfe/form/SV_cNMQN3Gy7EaIN9A

Follow-up email to be sent one week following initial email:

Subject line: Follow-up email for Henker DNP project participation

Hello again Anesthesia Team,

You recently received an email inviting you to participate in a DNP project. The quality improvement (QI) project is surrounding the use of a novel device for autologous blood transfusion. The title of the project is "Novel Device for Autologous Blood Transfusion in a Resource-Limited Setting." This is a follow-up email to invite you to participate if you have not done so already. The video and survey will be available for two weeks following this email send date.

As a part of this project, I would like to invite you to view an educational video on the hemafuse autologous transfusion device. The video will include information about the device, the setup and device use, and indications/contraindications. The educational video is about 10 minutes long. When opening the video, it might be helpful to enlarge to side video especially during the explanation of the setup of the device to view the setup of a hemafuse device. After completion of the video, there is a survey that will take about 10 minutes to complete. Consent for participation in the project will be assumed for participants who choose to complete the survey following the presentation.

Participation in this project is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose to withdraw at any time and you may also skip any survey questions you choose not to answer. No identifying information will be collected and the survey responses will remain anonymous. The project does

not contain foreseeable risks to participants. By participating in this project, you do not give up any personal legal right you may have as a participant in this project.

Questions or concerns regarding this project can be directed to the Principal Investigator via phone or email.

Thank you for your support of my DNP project,

Kitra Henker

khenker@email.arizona.edu

cell: 412-352-2478

Link to educational video: https://arizona.voicethread.com/share/18949892/

Link to survey:
https://uarizona.co1.qualtrics.com/jfe/form/SV_cNMQN3Gy7EaIN9A

APPENDIX D:

EVALUATION INSTRUMENTS (SURVEY QUESTIONS)

Survey Questions

1. What is your age group?
   23-35 36-45 46-55 56-65 >66

2. Which gender do you most identify with?
   Male Female Nonbinary/third gender Prefer not to say

3. How long have you been practicing as a CRNA?
   New grad-2 years 3-8 years 9-14 years 15-20 years >20 years

3. Have you traveled internationally to deliver anesthesia? Yes No

5. Do you practice anesthesia at a rural community hospital? Yes No

Education Survey

1 = strongly agree, 2= somewhat agree, 3= neither agree nor disagree, 4= somewhat disagree, 5= strongly disagree

Statement	Before Presentation	After Presentation
I am aware of the current shortage of blood products available for transfusion.	1 2 3 4 5	1 2 3 4 5
I am aware of available technology for autologous transfusion.	1 2 3 4 5	1 2 3 4 5
I am aware of the hemafuse device.	1 2 3 4 5	1 2 3 4 5
The hemafuse device would be useful in the current clinical setting in which I am working.	1 2 3 4 5	1 2 3 4 5
I would be interested in a hands-on training for hemafuse use.	1 2 3 4 5	1 2 3 4 5
I feel comfortable knowing the indications and contraindication for clinical use of the hemafuse device.	1 2 3 4 5	1 2 3 4 5

https://uarizona.co1.qualtrics.com/jfe/form/SV_cNMQN3Gy7EaIN9A

APPENDIX E:

PARTICIPANT MATERIAL (EDUCATIONAL PRESENTATION SLIDE SHOW, LINK TO VIDEO, AND TYPED TRANSCRIPT)

Novel Technology for Autologous Transfusion: Hemafuse

Kitra Henker, SRNA

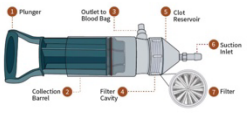
1

Blood Shortage

- Blood transfusion are needed in a variety of emergency surgeries
- Current shortage of autologous blood available for transfusion.
- Cell salvage technology is not always available and can be expensive.

2

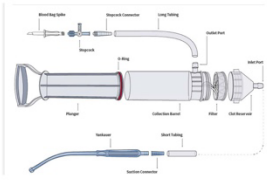
Hemafuse Device



- Designed for cost effective autologous blood salvage
- Mixture of reusable and one time use components

3

Hemafuse Device Setup

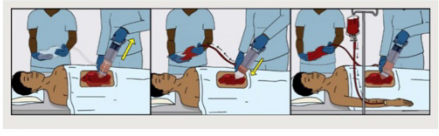


https://www.medgadget.com/2018/03/hemafuse-autotransfusion-blood-internal-hemorrhage.html

4

Indications for Use of Hemafuse

Collection of whole blood from a surgical site during times of hemorrhage



https://www.usaid.gov/actionforhocal/stories/usu-global-health

5

Contraindications Hemafuse Use

- Contamination!
  - Feces, urine, amniotic fluid, bile, CSF, hemostatic agents, bone cement
- Systemic Infections, coagulopathies, impaired renal function, or malignant tumors
- Not indicated in orthopedic procedures

6

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7

Transcript of Video

SLIDE 1

Hello

Welcome to a presentation on novel technology for autologous transfusion. First, thank you so much for participating in this project. Upon completion of this video, please fill out the survey linked in the original email.

SLIDE 2

Blood transfusions are often needed in the operating room. The COVID-19 pandemic has affected the accessibility of blood products available for transfusion. There are a few different reasons for this shortage. The first is that many blood drives and donation centers were closed in March 2020 when the SARS-COVID-2 virus was first discovered in the United States and spread rapidly. As you can see from the graphic, 2,700 blood drives were canceled, resulting in a loss of 86,000 blood donations. Additionally, blood drives had a significant decrease in participation due to people not wanting to leave home and potentially be exposed to the virus. The combination of these two factors has led to a nationwide shortage of allogeneic blood available for transfusion.

One method to combat the need for allogeneic blood transfusion in the operating room is to use cell salvage technology such as a cell saver device. However, this device is expensive, making it cost-prohibitive in specific rural and community hospital settings.

SLIDE 3

The hemafuse device was designed to meet the need of resource-limited settings with shortages of allogeneic blood. The device was first released in countries in Africa, such as Ghana and Kenya, to combat the chronic blood shortage that is faced in those counties. The FDA recently approved the hemafuse device in the United States for use in austere environments. This device could be helpful in a community hospital due to the low cost and ability for some of the components to be sterilized and reused.

As you can see, the design and function of the device are analogous to a syringe. The plunger is used to remove blood from a cavity in the body, through a filter and into the collection barrel; the plunger is then used to expel the blood from the barrel and into a collection bag for transfusion back to the patient. Every component in the displayed graphic is reusable except for the filter, which is a one-time use component.

SLIDE 4

The graphic shown is a visual representation of setting up the device, which I will not explain with a model. (Continues to show device set up with live model)

SLIDE 5

The indication for the use of the hemafuse device is the collection of whole blood from a surgical site during times of hemorrhage. If there is a large pool of blood within a body cavity, the hemafuse device can autotransfusion that blood. Examples of potential uses would be a ruptured ectopic pregnancy, abdominal aortic aneurysm rupture or repair, and bleeding from a traumatic injury with vessel damage. Hemafuse must be used when there is a pool of blood, as the suction of air with the device could cause excessive clotting of blood in the machine.

The graphic is a visual representation of how the device functions in surgery. As you can see in the far-left photo, the blood is initially removed by withdrawing the plunger from the device to fill the chamber. The middle image demonstrates pushing the plunger back into the barrel to push the blood through the filter and into a collection bag. The collection bag contains citrate to prevent coagulation in the bag. The collection bag is then placed on a blood transfusion line and transfused to the patient. Another benefit of this technology is that it is the transfusion of whole blood instead of individual components.

SLIDE 6

The blood collected by the hemafuse device is not washed. Therefore, contamination is the main contraindication for use. Contamination can include feces, urine, amniotic fluid, bile, CSF, hemostatic agents, or bone cement. Additionally, transfusion in patients with systemic infections, coagulopathies, impaired renal function, or malignant tumors is not recommended. The device is also no indication for orthopedic procedures.

SLIDE 7

The hemafuse device is a novel autologous blood transfusion technology that is a low-cost option when there is a blood shortage either locally within the hospital or globally as we are currently experiencing in the United States. The device could save a life in an emergency when there is a shortage of available blood products.

Thank you again for participating in this project. Kindly now return to the original email and click the link to complete the post-survey.

Link to Video:
https://arizona.voicethread.com/share/18949892/

APPENDIX F:

PROJECT TIMELINE

Completion Date	Planning	Pre-Implementation	Implementation	Evaluation
November 1, 2021	Submit proposal to project chair			
November 16, 2021	Record education video and send to chair for approval			
October 1, 2021	Connect with contact at intended site	Receive site authorization letter		
October 1-7, 2021		Revise methodology section		
November 15, 2021		Send to committee chair (full project proposal)		
November 20, 2021		Obtain proposal approval from committee chair		
December 1, 2021		**Proposal Defense Presentation**		
January1-10, 2022		Revise project proposal given by committee		
January 30, 2022	Submit to College of Nursing Research Committee			
January 30, 2022	Investigate need for IRB approval from site			
February 10, 2022		Make revisions from College of Nursing research committee		
February 20, 2022		Obtain UA IRB approval		
February 21, 2022			Send email invitation for participation in project	

February 21-March 14, 2022			Implement / Collect Data	
March 14-18, 222				Analyze Data
March 18-20, 2022				Present project poster at AzANA
April 2022				Final Defense Presentation of Project Results

APPENDIX G:

LITERATURE REVIEW GRID

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
Adama et al. (2017)	Place of autologous intraoperative blood transfusion in the treatment of broken ectopic pregnancy (EP) at the Chiphra Hospital of Ouagadougou, Burkina Faso	Cross-sectional descriptive study	Autologous transfusion was used in patients experiencing a broken ectopic pregnancy. With autologous transfusion, hemoglobin was improved to greater than 10 g/dL in 62% of patients.	Autologous transfusion is an effective treatment method for those with a ruptured ectopic pregnancy in a setting of limited access to other transfusion methods.
Duramaz et al. (2018)	The role of intraoperative cell salvage system on blood management in major orthopedic surgeries: a cost-benefit analysis	Comparative study	Use of intraoperative cell salvage technology significantly increased the cost of the surgical procedure.	Cell salvage technology can be cost prohibitive in a limited resource setting.
Gniadek et al. (2020)	Expansion of hospital-based blood collections in the face of COVID-19 associated national blood shortage	Prospective review	Canceling elective procedures alone cannot statistically decrease the amount of blood needed by an institution. However, creation of an in-house donation program can help meet the demand for blood at a single institution during a national blood shortage.	Elective procedures are often not the ones where blood transfusion is needed. If an institution does not have the ability to create an in-house donation program, there is a need of other ways to mitigate the need for transfusion.
Mbuthia et al. (2019)	Organizational management of hospital blood transfusion services in Nairobi County, Kenya: evidence of implementation	Descriptive cross-sectional study	The hospitals that showed the most success with implementing the blood management system were the ones that had senior management personnel who were involved and worked hard to provide necessary resources	When implementing a new system there also must be a way to ensure the quality of that system. This article outlines many reasons for success when implementing new blood management systems and reasons for hospitals that struggled with it.
Nieto-Calvache et al. (2020)	Dangerous shortage of blood banks as an indirect effect of	Retrospective descriptive study	Blood donations declined through the pandemic despite interventions to increase donation. The need for blood remained the same creating a	Increasing donation of blood product is not always possible especially in a resource-limited setting. There should be new strategies to combat the blood shortage.

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
	SARS-CoV-2: An obstetrics perspective		worsening mismatch between supply and demand.	
Nsubuga(2018)	Prevalence and factors associated with bacterial contamination of intraoperative salvaged blood in women with ruptured ectopic pregnancy at Mulago Hospital, Kampala, Uganda	Cross sectional study	Bacterial contamination of salvaged blood by the spoon and cloth method is 76%. The bacterial contaminants were various organisms.	The traditional spoon and cloth method of blood salvage has a very high risk of bacterial contamination. Although a cost-effective method, other technology with a decreased risk of bacterial contamination is needed.
Roberts et al. (2019)	The global need and availability of blood products: a modeling study	Modeling study	The study found a supply demand ratio of 1:12 globally. Every country in sub-Saharan Africa had an insufficient supply to meet the needs of the population.	Africa can be used as a reference when applying management strategies for management of a blood shortage.
Stanworth et al. (2021)	Effects of the COVID-19 pandemic on supply and use of blood for transfusion	Systematic review	Information was collected regarding planning for blood shortages during the pandemic. The author suggests early planning for an upcoming shortage. Additionally, adherence to the best practice guidelines for patient blood management	Even if blood supply is not short at a given time, strategies should be implemented to limit demand in anticipation for an upcoming shortage. One strategy recommended is the use of whole blood if available during a massive hemorrhage event. Transfusion need in patients with COVID-19 infection is rare.

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