LifeFlow®

# A Novel, Handheld Infuser for Rapid Delivery of Blood or Fluids in OB-Related Hemorrhage

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## Executive Summary

Obstetric (OB) related hemorrhage is the most common and dangerous complication of pregnancy. It is the leading cause (94%) of maternal deaths worldwide. Approximately 20 in 100,000 women die from maternal hemorrhage yearly in North America, and the mortality rate is even higher in developing countries. [1]

Two recent studies of pregnancy-related deaths in the United States demonstrated that between 73% and 93% of deaths secondary to postpartum hemorrhage (PPH) were preventable.[2] Delays in recognition and treatment can result in significant maternal morbidity and mortality.

Inpatient OB units with an evidence-based massive transfusion protocol and access to a transfusion pack that includes O-negative blood and an easy-to-use rapid infuser have improved OB-related hemorrhage outcomes.[3] Early and adequate resuscitation can save lives and minimize morbidity, mortality, and the need for additional interventions. [4]

## Problem

Currently, the tools and equipment available to most first responders and freestanding emergency departments (EDs) are often insufficient to provide adequate resuscitation during an OB-related hemorrhage. In particular, equipment and personnel-related challenges complicate rapid blood administration.

Intravenous (IV) infusion pumps with a maximum rate of 999 ml/hr are commonly used in the ED, but they are too slow to rapidly correct acute hypovolemic shock during the resuscitation phase. A pressure bag is also commonly used for rapid transfusion, but in practice, pressure bags are slower than perceived, especially when a provider is not continuously re-inflating the bag or when large-bore IV access is not available.

Some hospitals have mechanical rapid infusers for transfusion, but they are typically stored in the trauma bay or operating room and not readily available in many ED's nor in an OB unit for an emergent OB patient. Also, mechanical rapid infusers often do not work efficiently through smaller gauge IV catheters and they appear to function poorly with IO access.[5] Lastly, these traditional rapid blood infusers are complex to set up and expensive.[6] The time, expertise, and staffing required to

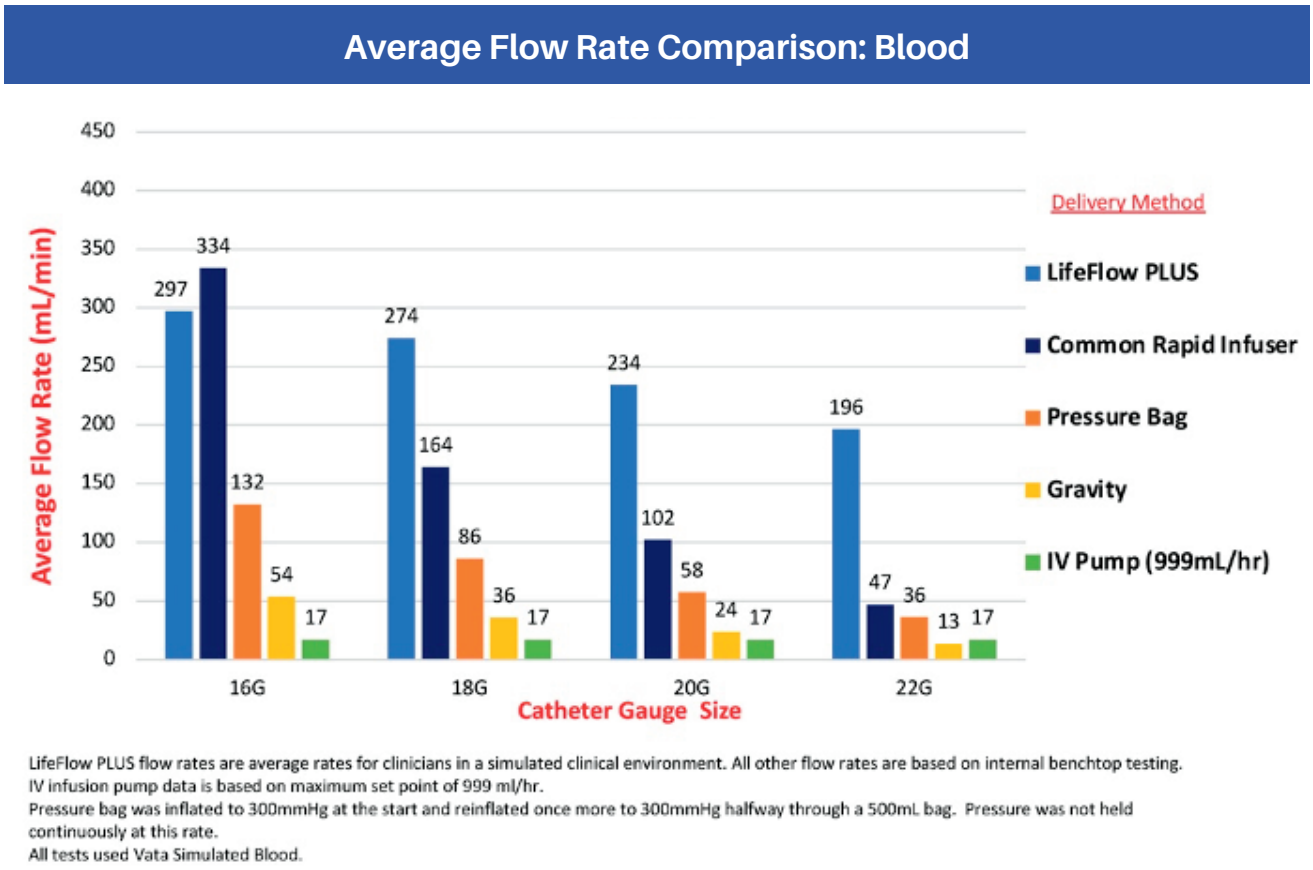
set up and operate these devices make them inefficient in a time-sensitive emergency. Maintaining the essential competency and familiarity with this equipment is a continuous challenge for providers.

Best practice for OB-related hemorrhage care demands a device available to emergent patients in all settings, including OB units, ED's, rapid response teams, and prehospital emergency medical groups. There is a clear need in high stress environments for a device that can be set up quickly and easily, giving providers time to reassess and intervene in a timely manner.

## An Innovative New Solution

LifeFlow PLUS is a novel handheld rapid infuser designed to allow an emergency provider to quickly and easily infuse multiple units of blood in a hemorrhagic shock patient. LifeFlow was designed to be easy to set up and use, even for a new or infrequent user. A new user can set up LifeFlow in less than three minutes and administer a unit of blood in less than two minutes (Figure 1), enhancing the speed and efficiency of blood resuscitation and improving care for patients with life-threatening OB-related hemorrhage. It is also especially effective at infusing blood where large bore vascular access is not an option.

Figure 1




LifeFlow PLUS flow rates are average rates for clinicians in a simulated clinical environment. All other flow rates are based on internal benchtop testing.
IV infusion pump data is based on maximum set point of 999 ml/hr.
Pressure bag was inflated to 300mmHg at the start and reinflated once more to 300mmHg halfway through a 500mL bag. Pressure was not held continuously at this rate.
All tests used Vata Simulated Blood.

A retrospective review of the use of LifeFlow at WakeMed Health & Hospitals for rapid fluid delivery and resuscitation of patients with OB-related hemorrhage identified immediate improvement in blood pressure and shock index (Table 1).

Table 1

Within patient comparison of vital signs before and after delivery of fluids and/or blood products via LifeFlow (n=28)

| Vital Signs | Before RFI (IQR) | After RFI (IQR) | Median difference (IQR) | P-value |
|---|---|---|---|---|
| SBP, mmHg | 90 (69,106) | 110 (90, 119) | -21 (-37, -5) | 0.001 |
| Heart Rate | 109 (82,120) | 88 (74, 112) | 10 (0, 32) | 0.001 |
| Shock Index | 0.98 (0.79, 1.37) | 0.78 (0.71, 1.03) | 0.22 (0.02, 0.53) | 0.001 |
| MAP, mmHg | 60 (47,75) | 76 (67, 86) | -14 (-23, -6) | 0.001 |

Source: *Wanda, Lisa et al. A Novel Rapid Infusion Device for Patients Experiencing Severe Obstetric Hemorrhage. Poster Presentation, SOGH. September 2022.*

The study findings are limited to descriptive analysis and within-patient comparison. Controlled studies are needed to compare LifeFlow to standard methods to determine the impact on patient outcomes.

## Case Studies

A 36-year-old pregnant female arrived by personal vehicle at the Baptist Emergency Department in Jacksonville, FL. She had two syncopal episodes at home witnessed by her husband before becoming pale, diaphoretic, and displaying a decreased level of consciousness. The second syncopal episode involved a fall in which the patient sustained a concussion.

The patient's husband revealed to the ED staff that she was ten weeks pregnant with twins. They had just had a visit with their obstetrician about 12 hours earlier, and it was determined by sonography that her embryos were implanted in the uterus just above her cervix and that one of the embryos was no longer viable. For the next 12 hours, they monitored her pads for blood loss per physician's orders. However, the husband stated that they had difficulty tracking the amount of blood loss because it was primarily clotted.

When they presented to the ED, the patient was barely conscious with an initial BP of 48/27. Believing that she was within minutes of cardiac arrest and knowing that time was critical, the clinicians immediately ordered blood to be delivered via LifeFlow PLUS. LifeFlow was set up immediately and multiple units of blood were infused quickly and safely. Ultimately, surgery was successful and the patient was stabilized and discharged home.

> "I had no idea what LifeFlow was, but I watched as they quickly set it up and administered multiple units of blood and plasma, stabilizing her so they could transfer her to the OR. She may not have survived if they had used another other traditional methods."
>
> **- The patient's husband**

Baptist has been using LifeFlow for over a year. An ER nurse stated that they have used it numerous times and prefer it over any other rapid blood-infusing device.

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A 28-year-old female presented to a large urban ED after developing vomiting, diarrhea, and syncope while at dinner with friends. The patient revealed that she was 7.5 weeks pregnant and had not yet been seen by her obstetrician. On exam she had very mild abdominal tenderness, normal vital signs (BP 101/62, HR 80), and a negative bedside Focused Assessment with Sonography for Trauma (FAST) exam.

Labs and a formal ultrasound were ordered, which were delayed for over an hour due to high patient volume. Further delays occurred while waiting for a radiologist to interpret the results, so the images were reviewed by the ED team. The ultrasound revealed dramatic changes from her FAST exam highlighting extensive free fluid in her peritoneal cavity. This confirmed the suspicion of ruptured ectopic pregnancy. The patient's vitals remained stable, but the diagnosis triggered a call to on-call obstetrics (OB) for surgical intervention.

The on-call OB was notified of the patient's critical status but the OR was busy with another procedure. The ED team decided that if the patient's pressure dropped further, they would immediately intervene to resuscitate.

The OB physician came down to the ER and within the next few minutes the patient suddenly became lethargic with reduced responsiveness. Her BP had dropped to 84/46. An order for blood transfusion via LifeFlow PLUS was immediately initiated as her BP continued to fall, hitting a low of 68/36. Once blood was obtained, the staff were able to quickly set up the LifeFlow and deliver 2 units of cross-matched blood in under 5 minutes while transporting the patient to the OR.

The patient's pre-op BP was recorded at a recovered level of 130/100. The procedure resolved a ruptured ectopic pregnancy with 1800mL of free blood in the abdomen. The patient received one additional of unit PRBCs, did well in post-op, and was discharged the next day without further incident.

## Conclusion

OB-related hemorrhage is the most common and dangerous complication of pregnancy. Signs and symptoms of hypovolemic shock such as tachycardia or hypotension may be masked in the pregnant woman.[7] Compensated or uncompensated hypovolemic shock can lead to complications such as acute renal failure (ARF), coagulopathies, and maternal or fetal death. Maintaining the patient's hemodynamic stability in a time-sensitive emergency ensures continued perfusion to vital organs. Early initiation of transfusion is a life-saving intervention.

The LifeFlow PLUS Blood & Fluid Infuser is compact,


inexpensive, and easy to use. It is a novel, handheld device that can deliver a unit of blood with speed and control in two minutes. This efficiency allows providers to reassess the patient's hemodynamics and quickly make the next set of treatment decisions. It takes approximately one minute for an experienced provider to set it up and only three minutes for a new user. Providers can use the infuser with appropriate venous access, including small gauge peripheral IVs.Use of a rapid transfusion device such as LifeFlow answers the challenges of providing adequate tools for resuscitation in pregnancy-related hemorrhagic shock.

## REFERENCES:

1. James, A.H., et al. Disparities in obstetric hemorrhage outcomes. 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8818495/
2. Haeri, S., et al. Maternal Mortality from hemorrhage. 2012. Seminars in Perinatology. https://www.sciencedirect.com/science/article/abs/pii/S014600051100156X?via%3Dihub
3. Bukaloo, B. et al. Obstetric hemorrhage: use of the "4 R's" to improve patient outcomes. 2019. Innovative Programs Obstetric. https://www.jognn.org/article/S0884-2175(19)30133-9/fulltext
4. Berg, Cynthia J. et al. Preventability of Pregnancy-Related Deaths: Results of a State-Wide Review. Obstetrics & Gynecology: December 2005 - Volume 106 - Issue 6 - p 1228-1234. https://pubmed.ncbi.nlm.nih.gov/16319245/
5. Auten, J. et al. A pilot study of four intraosseous blood transfusion strategies. 2018. J Spec Oper Med. https://pubmed.ncbi.nlm.nih.gov/30222837/
6. Kapoor, D, et al. Novel rapid infusion device for patients in emergency situations. 2011. Scand J Trauma Resusc Emerg Med. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3127777/
7. Wormer, K.C., et al. Acute postpartum hemorrhage. 2022. https://www.ncbi.nlm.nih.gov/books/NBK499988/