Robotic Phlebotomy Critique by Lloyd Marks, MD, MBA, FACC
4/27/20

[redacted] has developed a highly accurate robotic phlebotomy device. It was first described in 2013. The current version of the device uses ultrasound guidance and 3D near-infra-red (NIR) stereoscopy markedly improve accuracy . (The technology is patent pending). This differentiates it from the market leader, Accuvein, which uses only NIR to help find veins. The STAR device was shown to have greater first stick accuracy than a phlebotomist. The STAR system found 99% of veins compared to 76% by phlebotomists. Successful cannulation was achieved in 87% of all patients, 97% of "non-difficult" patients. Not surprisingly, this generated great commercial interest as the initial idea of replacing phlebotomists with machines seemed interesting, as in this article published in Forbes. A portable hand held version using stereoscopic near-infra-red (NIR) imaging to assess vessel depth was shown to be very successful in-vitro. Machine development and improvement continued. It became more accurate by adding ultrasound localization and was coupled with a point-of-care analyzer to provide a "one-stop solution" where blood could be both drawn and analyzed within minutes. This was described in a detailed article in 2016.

To analyze the commercial potential of this instrument, several issues must be considered. First of all, many people are afraid of needles. In a paper, published in "The Journal of Anxiety Disorders," they point out that "10% of patients are "needle phobics" and 56% of needle phobics had fainted upon exposure to needles" (fainting rate 5.6%). 27% of people have a vasovagal reaction (slowing of the heart rate often accompanied by light-headedness. 1% of experienced patients who have had their blood drawn before and 1.7% of first timers have a serious vasovagal reaction leading to bradycardia and syncope. Therefore, the idea of unattended phlebotomy is, in my opinion, unrealistic. Someone who can reassure scared patients and deal with episodes of vasovagal syncope must be with the patient regardless of how the blood is drawn. Also, if a robot is used, someone who can deal with inevitable machine malfunctions must be present. Phlebotomists, on average, earn $31,415 per year. As you can see here, physician assistants get paid more than phlebotomists (who are not only trained in dealing with scared patients and vaso-vagal events but have considerable experience in dealing with them). Furthermore, in anecdotal interviews with 8 friends, all of them said that they would be uncomfortable with a robot drawing their blood, especially if they were unattended.

In my opinion, this technology could result in 5 products:

1- Unattended phlebotomy robot
2- Attended phlebotomy robot
3- Handheld device to improve phlebotomists' first stick success without robotic needle insertion and blood withdrawal
4- Handheld device to improve phlebotomists' first stick success with robotic needle insertion and blood withdrawal
5- Phlebotomy robot that is coupled with a point-of-care analyzer.

These should be considered separately on their own merits.

1- **Unattended Phlebotomy Robots** – Based on the above discussion, I believe this is unrealistic and should be not considered a viable product

2- **Attended Phlebotomy Robot** – There are protocols at blood drawing centers, such as this one, that generally say that a phlebotomist should only attempt 2 sticks before allowing a second phlebotomist to try. In this clinic a maximum of 9 sticks are allowed. First stick success rate is only about 75%, so there is definitely room for improvement. The phlebotomy robot could be used for a first stick or after a failed first stick. The problem with this, as I see it, is that unless this becomes a separately billable procedure, I'm not sure that hospitals and companies like Labcorp and Quest will want to buy it. After all, they almost always eventually get the specimen, even if the patient has to endure multiple sticks. Also, the patients would have to be attended as vasovagal events are unpredictable. An argument could be made that this would save some time, but, as mentioned earlier, phlebotomist salaries are not high. Furthermore, such devices would be limited for used as fixed locations, such as blood drawing facilities and not available for bedside use.

3- **STAR Handheld Device to Improve Phlebotomists' First Stick Performance *without* Robotic needle Insertion and Blood Withdrawal** – If you ask Accuvein, a company that makes a popular handheld near-infra-red vein finder, they have already solved the problem. They claim that they improve fist stick accuracy by 18% in some of their literature, but also claim improving first stick accuracy by 3.5x. They don't explain exactly what these numbers mean. They cite an article that concludes that the Accuvein improves pediatric cannulation from 47% to 97%. However, there are other published articles which claim that the Accuvein does not improve either venous or arterial cannulation. In yet another study, no improvement was found. So I remain unconvinced that the Accuvein product is that helpful. However, it appears to be financially successful. Accuvein claims that by 2014, their device was used in 2000 hospitals and growth was accelerating at 40% per year. Further information about the company's success and its competitors can be found at https://www.owler.com/company/accuvein. This is classic "good news and bad news." The bad news is that there are already several competitors. The good news is that there is clearly a big market for hand held devices that can improve blood drawing. In my opinion, a superior hand held device which use stereoscopic NIR ***combined with ultrasound*** to markedly improve accuracy would be a successful product. The Accuvein sells for $3899. A superior STAR device which sold at a comparable or even higher price would be a formidable competitor. Without knowing the cost of goods or manufacturing, a robust pro-forma profit/loss projection cannot be produced at this time. Nonetheless, this seems like an *exciting , viable product*. Needle insertion and blood drawing by a robot are not essential, as long as phlebotomist's first-stick performance is markedly improved by the vein localization technology. Eliminating

the robotic drawing would reduce product cost, making it more competitive. Also, because it would be portable, it would be available for use at the bedside.

4- **STAR Handheld Device to Improve Phlebotomists' First Stick Performance *with* Robotic needle Insertion and Blood Withdrawal** - If robotic needle insertion and blood drawing further improves first stick performance, that could provide a different, more expensive product. However, this device would presumably be larger, heavier and more expensive than #3. This device, although heavier than #3 would also be available at the bedside. However, I'm concerned that it might be more unwieldy.

Testing and Market Potential of Handheld Devices#3 and #4

Testing to determine best form factor - Working prototypes of #3 and #4 should be compared head-to-head with the latest Accuvein device (as Accuvein is the current market leader). The study should be conducted ASAP by opinion leaders in the field and would have to demonstrate clear superiority of the STAR device(s) to the Accuvein.

Market potential - There are 124,000 phlebotomists in the U.S. alone. There are 924,000 hospital beds in the U.S. If there were 1 unit per 10 beds, that would add 92,000 potential sales. There are 9280 surgicenters. If there were 2 units per surgicenter, that would add 18,560. Thus there are potential sales of at least 234,000 units. If, hypothetically, they sold for $5000 and $1000 profit were earned per unit, that would translate into $1.2 billion in potential domestic sales and $23.4 million in potential profit. I like these versions of the product (leaning toward the version without needle insertion and blood drawing as it would be smaller, lighter and less expensive) and think they should be studied in a clinical trial that is designed to meet the requirements for FDA approval. This requires contacting, discussing, and designing the clinical trial with the FDA's assistance before it is done.

5- Robotic Device Coupled with Point-of Care (POC) Testing – Point-of-care testing is a rapidly growing market; one market report indicated that it there was a $28B market in 2019 and there is an estimated annual growth rate of 10.8% - The i-Stat by Abbot is a popular product which sells for about $6500. Hospitals and laboratories appear to be embracing point-of-care testing, despite it's limited number of tests and inferior coagulation panel results when compared to standard testing. There is a pro-con debate regarding point-of-care testing, but regardless of the negatives, the technology in commercially successful and growing rapidly. Thus, the combination of robotic blood drawing with point-of-care testing is intriguing as a product idea. The patient would have to be accompanied by someone who can reassure them and handle vaso-vagal events. There is a question, yet to be answered, if the results would be superior to finger-stick point-of-care testing. I suspect that the hematology and potassium results would be superior because of hemolysis which occurs during finger sticking. It is unknow if the robot-POC combined would improve test result accuracy. There is a device called the Cpette by Labcon which cost only $0.89 apiece and which allows blood from a

vacutainer to be transferred to a POC device; this could eliminate errors due to hemolysis that occur during a fingerstick. The people at Labcon (personal communication) do not know if INR (a coagulation test) errors in POC machines are due to hemolysis and they don't know if any other errors due to finger sticks are eliminated or reduced in POC machines by using the Cpette.

Conclusions:

1-I am not enthusiastic about the non-handheld versions of this device as patients must be attended if their blood is drawn by a robotic device which may be intimidating and result in a vaso-vagal event. Also, it is not suitable for bedside use.

2-I am enthusiastic about the use of some or all of the aspects of the STAR technology, particularly, the ultrasound guidance, to produce a commercially successful hand-held device that will compete favorably against the Accuvein, perhaps even make it obsolete. Adding robotic needle insertion and blood withdrawal to the vein finder technology may or may not significantly further improve first stick success of a phlebotomist. It would surely make the product more expensive, heavier and possibly more difficult to use, but it might be worth it if it had a significantly higher first stick success than the hand held device without needle insertion and blood drawing. + I would suggest a 3 pronged rigorous clinical trial, up to FDA standards which compares a handheld STAR technology based device without the robotic withdrawal feature, a handheld STAR technology based device with the robotic withdrawal feature, and the Accuvein device. This trial should be designed, endorsed, and probably coauthored by an opinion leader in the field such as Dr. Dennis Ernst at Mayo.

I am less enthusiastic about the combined robotic phlebotomy – POC device. If it would produce results equivalent in accuracy to current finger-stick POC devices, I'm not sure there would much of an advantage. I can't see it improving throughput that significantly. If the results were more accurate than current POC devices, that could improve medical care, but you would still have to convince hospitals and labs to buy something that would not necessarily save them money. Also, remember, some patients will always prefer finger sticks to needles for POC lab testing. I could find no literature indicating that syncope was associated with fingersticks.

The fastest way to earn money from this invention would be by licensing the technology to a company that has established access to the target market. Thus, a partnership with Accuvein might be worth exploring.