Technical Note

Scenarios: The Phlebot™ In Various Medical Environments

Introduction:

Patient blood collection is required for a variety of purposes and the Phlebot™ can substitute for traditional phlebotomy whenever a series of samples are needed. This Technical Note proposes eight different examples showing potential benefits of automation for specific types of medical care.

1 **Drug Trial**

A drug trial with 40 subjects is carried out in a CRO clinic and 20 blood draws are needed over 24 hours from each subject over two days separated by 7 days to wash out the drug before the next dose. 800 x 2 = 1600 blood draws. Two drugs and a biomarker panel are to be monitored by three different methods for potentially 4,800 unique blood draws, with no additional phlebotomy labor costs.

Challenges: Finding phlebotomy staff, getting the work done according to protocol, organizing the excel spread sheet for each subject and recruiting subjects who don't like "sticks" but do like the check they will get for participating. At each of the 20 timepoints, three assays are required, each with different blood volumes, one for blood serum with no anticoagulant, one with heparin and the other with EDTA as anticoagulants. This would be a challenging protocol for a manual study, especially for short-interval samples at the beginning (e.g. 5 minute, 10 minute and 15 minute draws).

Phlebot: Phlebotomy labor is reduced 50%+, pain is eliminated, the correct volume of blood is collected to 1% precision, little is wasted, the time points are accurate, the spreadsheet is automatic and operators are protected from accidental exposure to patient blood. Three separate samples can be collected sequentially throughout the study with three different volumes (e.g. 25 µL, 1 mL and 4 mL) with appropriate anticoagulants in each vial.

2 **Intensive Care Unit (ICU)**

ICU nursing staff is shorthanded and busy attending to patients. The post-op patient in room 465B is having a problem indicated by heart rate, temperature, respiration rate and uses the call button.

Challenges: No one is immediately available. When a nurse arrives frazzled within a few minutes, attending the patient is the first priority and fiddling with a catheter to get a blood sample for diagnostic chemistry at the point-of-care is a distraction.

Phlebot: When the nurse arrives, the blood sample is ready to go for the critical care chemistry and hematology parameters. In fact several samples are lined up from before the "event" happened. With rapid turnaround time (TAT) the chemistry data can be ready for the attending physician in short order and corrective action taken. The trend information for the data is available and the catheter patency is automatically attended to. (Further on in time: An algorithm is developed based on data from a smart head-of-bed suite which automatically triggers a blood sample based on changes recorded in temp, HR, pulse ox, etc.)

3 **Sepsis**

A patient suddenly develops sepsis. It appears to be antibiotic resistant.

Challenges: Time is critical. What is the chemistry doing? How are the cell counts and

biomarkers varying over time? What is the response to an antibiotic that has been tried? What is the circulating concentration? Have we got that right? Are there interactions among the multiple drugs in circulation?

Phlebot: A sample is automatically drawn every 10 minutes (or whatever interval is wanted, downloaded wirelessly from a tablet computer). The sample labels are linked to the patient wrist band ID so they don't get confused with other patients or times for blood draws. Analysis of three consecutive samples shows a trend, a peak concentration, an increase or decline in the titer of the infectious agent. Collection into sterilized vials enables cultures to be prepared, if needed.

4 VLBW Infant in NICU

A premature, VLBW (very low birth weight) infant is in an incubator.

Challenges: Multiple drugs are administered to manage infection risk, open airways and deal with other issues. Blood concentration must be monitored in these children whose immature livers and kidneys metabolize and clear drugs differently than older children or adults. Blood sampling is challenging. Veins are both tiny and fragile. Moving the baby or creating discomfort, fiddling with tubing, pulling on syringes, causing hemolysis, and wasting precious blood are undesirable.

Phlebot: A Phlebot attached to the mobile incubator collects a sample with no waste, no hemolysis, no labor, no open catheter, and no need to open the incubator (isolette). The mechanism for removal/return of blood is gentle on both veins and the sample. With less blood wasted, more samples can be obtained with minimum risk to the baby.

5 Heart Attack

A 60 year old man has a heart attack.

Challenges: A published 2011 study[1] from St. Luke's Hospital Mid-America Heart & Vascular Institute in Kansas City discussed the amount of blood drawn for diagnostics purposes from such patients. The authors concluded that the volume of blood drawn was so excessive as to put the patient at risk for anemia. Vacutainers routinely pull far more blood than is actually required for analysis. Pulling blood from a catheter lock involves routinely wasting blood as the initial sample of blood diluted with the saline locking solution is discarded.

Phlebot: Sample volumes can be specified to as low as 10 µL and are collected automatically with no excess or waste. The biochemical status of the patient can be assessed as frequently as every 5 minutes with no labor required for the mundane task of drawing blood. The amount of blood required is dependent on the analytical method, but the Phlebot will collect exactly that amount. Wasted blood is reduced by a huge percentage.

6 Cancer Treatment

A cancer drug is to be intravenously infused into an elderly patient with late stage disease who is currently dosed with 12 different drugs that have never been tested in this combination. The drug indications include treatment of pain, inflammation, nausea, hypertension, depression, and oncology.

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[1] Salisbury AC, Reid KJ, Alexander KP, Masoudi FA, Lai SM, Chan PS, Bach RG, Wang TY, Spertus, JA and Kosiborod, M., Diagnostic Blood Loss from Phlebotomy and Hospital-Acquired Anemia During Acute Myocardial Infarction, Archives of Internal Medicine, 2011 Oct. 10, 171 (18): 1646-53. Epub: August 8, 2011.

Challenges: We have no idea how the disease or the cocktail of other drugs will influence the circulating concentration of this new medicine. In effect, all such scenarios are clinical trials with N= 1. The oncologist is estimating an approach based on previous experience with different patients and is frustrated by the lack of data. Did the hospital pharmacist prepare the drug solution correctly for the infusion pump and for this particular patient? How will this patient's liver handle the metabolism? Should we wait until the next treatment to find out?

Phlebot: Samples are programmed with the start of the infusion pump. They are fed to a near-patient mass spectrometer. The drug concentration is available to the physician within a short turnaround time (TAT). The drug concentration is seen as OK, or can be increased or decreased to reduce the potential risk of cardiovascular or other adverse side effects. Multiple drugs and biomarkers can be monitored at will.

7 **Combat Medical Flights or Voyages**

On a combat casualty care flight from Ramstein Air Base in Germany to Texas, there are multiple patients on intensive care airlift palettes. On a medical transport ship, there are hundreds of casualties evacuated from a war or natural disaster.

Challenge: Monitoring chemistry in addition to physical vital signs and maximize the productivity of the medical care staff attending these wounded soldiers. Avoid the need to insert catheters in patients aboard an aircraft subject to turbulence or a ship buffeted by a storm.

Phlebot: Samples are drawn automatically on a schedule throughout the flight, or as "stat" samples. Medical personnel are relieved from the task of maintaining indwelling catheters with locking solutions or repeatedly puncturing a vein. They can focus instead on patient care and processing/analysis of the samples.

8 **Glycemic Control in Post-Op**

In recent years there has been a movement to tighten glycemic control in post-op patients (not only diabetics) by using an insulin infusion.

Challenge: Monitoring glucose on a regular time schedule so that the insulin can be appropriately and safely adjusted.

Phlebot: A perfect solution to precisely acquiring the needed samples at the exact time and in the appropriate volume to determine glucose (and other parameters) and then respond by adjusting the insulin infusion. A dual lumen, indwelling catheter permits both the automated blood collections and insulin infusion.

Conclusion

These projected scenarios all have potential for improved care, getting the patient out of the hospital faster (saving cash) and reducing nosocomial infection risk which is not reimbursed. The first example allows for more detailed pharmacokinetics and pharmacodynamic data for fewer subjects, speeding up drug trials and reducing cost. Our goal is to speed up turn around time (TAT) for both clinical trial and ICU data.