Microfluidic device precisely measures ‘blood vital signs’ in clinical setting

More than 4 million patients are transfused with nearly 21 million blood components in the United States each year. Blood viscosity, coagulation, and red blood cell deformability have been linked with some of the major risk factors for heart diseases, inflammation, and the health of blood products used for transfusion. However, rapid and easy assessment of viscosity, coagulation, and red blood cell deformability is not common because of difficulties in current techniques.

The Solution

A team from the Michigan Center for Integrative Research in Critical Care, including Mark Burns, Ph.D., Kevin Ward, M.D., Chandu Vemuri, M.D., and Sara Mena, Ph.D., is developing the microfluidic viscometer, a single device that precisely measures viscosity of whole blood and plasma, as well as red blood cell deformability and multiple indices of coagulation, in the clinical setting. The easy-to-use device only needs a small amount of blood and can provide rapid results for clinicians, which allows for improvement in diagnosis and management of blood properties related to cardiovascular disease, inflammation, and transfusion medicine.

Early information on blood and plasma viscosity and coagulation, along with red blood cell deformability, could provide insight before symptoms arise and allow intervention before fatal, debilitating events like a heart attack, stroke, or shock.

The University of Michigan Translational Research and Commercialization (MTRAC) for Life Sciences Innovation Hub is supported by the U-M Medical School, U-M Tech Transfer Office, and the Michigan Economic Development Corporation and works to “fast forward” projects that have a high potential for commercial success, with the ultimate goal of positively impacting human health. The microfluidic viscometer is one of 45 projects funded since the program was launched in 2014.
**Significant Need**

More than 11 million people seek emergency care for cardio and cerebrovascular emergencies each year. Another 1 million are diagnosed with sepsis and 4 million require blood transfusions.

**Compelling Science**

The diagnostic continuously pumps two immiscible liquids—the sample of the unknown viscosity (either whole blood or plasma) and an oil phase. The flows interact in a cross-junction where the liquid channel gets pinched, creating droplets. The length of the droplets is correlated to the viscosity and coagulation of the sample at fixed operating pressures over time. Additional channels separate red cells and measure their deformability.

**Competitive Advantage**

Compared to clinical technologies, the microfluidic approach is advantageous because it will be automated, can be manufactured inexpensively, and provides unique integrated information on important blood properties. The technology could also help manage the health of blood being used for transfusion and in the management of patients with sepsis.

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**MTRAC Project Key Milestones**

- Finalize the design of the prototype chip and reader to be mass-produced and scaled
- Participate in Fast Forward Medical Innovation’s fastPACE course to help refine the market and industry potential for technology
- Contact potential licensees that might be interested in technology

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**Overall Commercialization**

- **Intellectual Property**
  - U.S. and International patents have been filed for the technology.
- **Regulatory Pathway**
  - Leverage a 501K pathway based on previously FDA-approved platforms.
- **Commercialization Strategy**
  - Exploring the development of new start-up company given recent acquisition of non-dilutive technology development funding.

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**Device aims to provide early, actionable insight for cardiovascular, inflammatory, and blood diseases**

**Mark Burns, Ph.D.**

**Kevin Ward, M.D.**

There is a critical need to treat blood as an organ, and thus develop new blood vital signs that are reflective of blood health. MTRAC funding has allowed us to develop a diagnostic that could potentially benefit millions of patients who have heart and blood diseases.