WHITE PAPER

SKYDANCE VASCULAR INC.

Advancing Toward the Expansion of Catheter Related Blood Stream Infection Reporting to Include PIVs

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Background

The National Healthcare Safety Network of the Centers for Disease Control and Prevention (CDC), is the nation's most widely used health care-associated infection (HAI) tracking system. Since 2009, infection data has been reported to the NHSN to track the national progress of the reduction of HAIs.

Every 5 years, the Department of Health and Human Services (HHS) announces new targets for the national acute care hospital metrics for the National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (HAI Action Plan). The latest targets have been in effect for 5-years (2015 to 2020). They include:

- Reduce central line-associated bloodstream infections (CLABSI) in intensive care units and ward-located patients
- Reduce catheter-associated urinary tracts infections (CAUTI) in intensive care units and ward-located patients
- Reduce the incidence of invasive health care-associated methicillin-resistant Staphylococcus aureus (MRSA) infections
- Reduce hospital-onset MRSA bloodstream infections
- Reduce hospital-onset Clostridium difficile infections (CDI)
- Reduce the rate of Clostridium difficile hospitalizations
- Reduce surgical site infections (SSI)

During this period, the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Disease Society of America (ISDA) published an update to their CLABSI compendium document, introducing the concept of possible peripheral intravenous catheter (PIV) surveillance expansion. PIVs also earned national recognition by making the top 10 patient safety concerns of 2019 by the ECRI institute. Finally, the CDC in 2019 issued a public call for comments, regarding extending CLBSI surveillance to encompass all hospital onset bacteremia including PIVs. These activities provide strong indicators toward the inclusion of PIV quality data to the HHS targets in the next published update due in 2020.

References: www.cdc.gov/ https://www.shea-online.org / ECRI, Health Technology Hazards Executive Brief (2019)

About the Author

Michael Anstett is an accomplished clinician, corporate executive, armed services veteran, and entrepreneur. Michael's clinical career started in 1987 as a US Army Combat Medic. He went on to receive his nursing degree and became a board-certified Registered Nurse in 1994, followed by two additional registrations in 1997 and 2011 respectfully: Certified Registered Nurse Infusion (CRNI) and Vascular Access Board Certification (VA-BC). Michael excelled in clinical practice and eventually accepted the responsibility of establishing and managing a vascular access team of ten staff nurses in a 1000 bed level-one trauma center in Tampa, FL. Michael then founded his private practice known as Professional Infusion Consultants, Inc., which contracted with vascular access nurses from around the state of Florida to provide outsourced vascular access throughout the state, an endeavor that Michael successfully exited from in 2012. Michael accepted the newly created position of Director of Clinical Operations at Medical Components, Inc. in 2013. Michael supported all aspects of the company's business including R&D of new products, business development, clinical education, regulatory and is named on multiple medical device patents. Michael is a member and strong supporter of the Association for Vascular Access (AVA). He has been invited to lecture at national AVA conventions as well as local AVA meetings. Michael is published in JAVA 2003 and won clinical

manuscript for that year. He is the Founder and Chief Clinical Officer of SkyDance Vascular, Inc. – inventor of the Osprey vascular access device.

About SkyDance Vascular

SkyDance Vascular, founded in 2017, is working to redesign the Peripheral Intravenous Catheter (PIV). The new product called Osprey, to be launched in 2021, is expected to provide a positive impact on PIV bloodstream infections utilizing a uniquely designed process called Skin Avoidance Technology. Its goal will be to deliver greater first attempt success and lower complication rates, improve dwell times, greater completion of therapy rates, and improve patient satisfaction. The company has assembled an executive leadership group comprised of individuals with decades of executive, clinical, regulatory, and engineering experience, and who together have built and successfully exited other companies in the vascular access space.

FDA Disclaimer

No statement in this document has been evaluated by the FDA. At the current time, and until 501(k) clearance is obtained from the FDA, all expressed claims made and/or indicated are exclusively the belief of SkyDance Vascular, Inc. (Company).

The Company intends to proceed with obtaining FDA 510(k) clearance to support what it believes to be appropriate claims, but until such time as FDA 510(k) clearance is achieved all information in this, and other Company documents is for informational purposes only.