

## **Vanderbilt SHEPheRD Center for Healthcare Epidemiology and Antimicrobial Stewardship Research:**

With the growing awareness and interest over the past decade in the epidemiology and prevention of healthcare-associated infections (HAIs) and multidrug-resistant organisms (MDROs) as well as the more widespread implementation of antimicrobial stewardship (AS) programs, the need for rigorous, well-designed, and pragmatic research investigations to advance the scientific evidence base in the field of healthcare epidemiology has become essential. The Centers for Disease Control and Prevention's (CDC) Safe Healthcare, Epidemiology, and Prevention Research Development (SHEPheRD) Program has been an important avenue to rapidly develop and support important investigations in the field. Investigators at Vanderbilt University Medical Center (VUMC) are well-positioned to successfully serve within the proposed SHEPheRD network, as the following technical proposal will outline.

The investigators in Vanderbilt's Department of Infection Prevention and Divisions of Adult and Pediatric Infectious Disease have a robust history of successful and innovative infection prevention and healthcare epidemiology programs that have led to marked reductions in HAIs and have advanced the understanding of important infection prevention issues. Importantly, Vanderbilt investigators have been recognized as leading experts in the fields of human healthcare epidemiology, antimicrobial resistance and stewardship, and healthcare safety. Vanderbilt SHEPheRD investigators have extensive research experience focused on diverse aspects of healthcare epidemiology and HAI prevention, including MDROs,<sup>1-6</sup> the burden and prevention of vaccine-preventable diseases,<sup>7-10</sup> HAI outbreak detection and management,<sup>11,12</sup> antibiotic and diagnostic test stewardship,<sup>13-17</sup> and interventions to reduce HAIs.<sup>14,18-23</sup> In addition, they have coupled this experience with wide-ranging work successfully implementing and overseeing operational infection prevention and AS programs in several settings.

As a function of their roles as hospital epidemiologists and AS medical directors and pharmacists, the Vanderbilt SHEPheRD investigators have extensive operational experience in HAI surveillance and prevention, outbreak investigation, and implementation and evaluation of AS initiatives in a diversity of healthcare settings (academic medical center, community-based acute care facility, Veteran's Affairs hospital, and ambulatory care centers). In addition, the SHEPheRD investigators have successfully partnered in collaborations outside of their specific healthcare facilities to study and develop multicenter, regional and state-wide assessments of the epidemiology of HAIs, the assessment of prevention interventions, and the evaluation of antimicrobial stewardship efforts. As highlighted over the rest of this section, Vanderbilt has an extensive track record of successful research investigations, operational expertise in infection prevention and AS, and a very strong infrastructure and capacity that will make it a very successful collaborator within the SHEPheRD network.

**Expertise and Experience - Vanderbilt SHEPheRD Investigators and Collaborators:** The Vanderbilt SHEPheRD investigators, collaborators, and consultants comprise a diverse group of individuals with expertise in many key areas germane to human healthcare epidemiology, antimicrobial resistance and stewardship, and healthcare safety. They have been successful in all facets of scientific study including study design, protocol development, database development, statistical support, background literature review, study implementation and coordination, data

management and analysis, presentation of data, and publication of research findings in peer reviewed literature. They have served as successful collaborators, both in research and in clinical care capacities, providing a rich infrastructure for multidisciplinary investigation. Through this group of skilled investigators listed below, the Vanderbilt SHEPheRD Center will be well positioned to conduct important and innovative clinical investigations focused on key questions in the fields of healthcare epidemiology and AS.

**Thomas R. Talbot, M.D., M.P.H.:** Dr. Talbot is a Professor of Medicine and Health Policy at Vanderbilt University School of Medicine and also serves as the Chief Hospital Epidemiologist for VUMC. His clinical epidemiologic research has focused on occupational infection control,<sup>7,9,10,23,24</sup> including the use healthcare personnel (HCP) vaccination as a means to reduce patient and HCP morbidity, secondary transmission from vaccinations,<sup>25-28</sup> and management of vaccinated HCP exposed to contagious infections. Clinical investigations in which he has served as the principal investigator include two NIH-funded studies examining the transmissibility of smallpox vaccination sites and the impact of site dressing on viral shedding and a CDC-funded study examining the effectiveness of post-exposure prophylaxis in Tdap-vaccinated HCP exposed to pertussis.<sup>27-29</sup> He served as the chair of the Society for Healthcare Epidemiology of America's (SHEA) Task Force on Influenza Vaccination of Healthcare Personnel in 2005 and 2010 and was lead author on the SHEA Position Paper advocating for influenza vaccination as a condition of HCP employment.<sup>30</sup> More recently, his work has included the development of a hand hygiene improvement program as a tool for changing HCP behavior and driving a safe, accountable quality culture.<sup>22</sup> Dr. Talbot has also served as a member of the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC), and on the Board of Directors for SHEA. He also currently co-chairs the Tennessee Department of Health's multidisciplinary advisory group that oversees efforts focused on HAI prevention and reporting in the state. As a part of his role as the Chief Hospital Epidemiologist, he oversees the surveillance and prevention of HAIs at VUMC.

**George Nelson, M.D.:** Dr. Nelson graduated from Princeton University in 2002 and Case Western Reserve School of Medicine in 2006. He completed residency training in internal medicine at Vanderbilt University and then served as an Epidemic Intelligence Service (EIS) officer at the CDC in the National Center for Immunization and Respiratory Diseases (NCIRD) where he investigated transmission dynamics and control efforts during various outbreaks.<sup>31-34</sup> He was recognized for his contributions in outbreak control with the NCIRD Honor Award: Excellence in Public Health Protection. He has also served as principal investigator on a large scale evaluation of over 9,500 invasive group A *Streptococcal* infections in the U.S. during a 7 year period. He then completed infectious diseases fellowship at Johns Hopkins Hospital. Dr. Nelson joined the faculty at Vanderbilt in 2014. He currently serves as the Associate Director of Antimicrobial Stewardship at Vanderbilt and the Associate Hospital Epidemiologist for VUMC. His primary research interests focus on the prevention of MDRO infections and the evaluation of AS interventions. He is currently overseeing an investigation in MDRO bacteremia and a substudy on MDRO colonization in India including more than 1,000 patients.

**Steven S. Spires, M.D.:** Dr. Spires graduated from Mercer University School of Medicine in 2009. He completed residency training in internal medicine and fellowship training in infectious diseases at Vanderbilt University. He joined the faculty at Vanderbilt in 2014. He

currently serves as the Hospital Epidemiologist and Medical Director for Antimicrobial Stewardship at both Williamson Medical Center (WMC) and the Tennessee Valley Veteran's Affairs (VA) Healthcare System. He recently led an investigation into a healthcare-associated respiratory viral illness outbreak in a geriatric long term care unit.<sup>35</sup> His primary research interests are focused on the prevention of outpatient central line-associated bloodstream infections (CLABSI), the increased healthcare utilization associated with outpatient central lines,<sup>36</sup> and HAI prevention in a community hospital setting.

**Greg Wilson, M.D.:** Dr. Wilson graduated from Johns Hopkins School of Medicine in 1987. He completed residency training in Pediatrics and fellowship training in pediatric infectious diseases at the Monroe Carell Jr. Children's Hospital at Vanderbilt (MCJCHV). He joined the faculty at Vanderbilt in 1996. As the Chief Hospital Epidemiologist for the MCJCHV, he directs efforts focused on the prevention HAIs in pediatric patients. Dr. Wilson will serve as the SHEPheRD liaison for any projects targeted in pediatric healthcare settings.

**Patty W. Wright, M.D.:** Dr. Wright serves as the Associate Vice Chair for Clinical Affairs in the Department of Medicine and is the Associate Director for Clinical Affairs in the Division of Infectious Diseases. She graduated from the University of Alabama School of Medicine in Birmingham. She completed her residency in Internal Medicine and her fellowship in Infectious Diseases, both at the University of Alabama at Birmingham. Dr. Wright has chaired the Antibiotic Subcommittee of the VUMC Pharmacy and Therapeutics Committee since 2003 and has led the development of the Vanderbilt Antibiotic Stewardship Program since its inception.

**Ritu Banerjee, MD, Ph.D.:** Dr. Banerjee is currently an Associate Professor of Pediatric Infectious Diseases at the Mayo Clinic. She will be joining the faculty in the Division of Infectious Disease in the Department of Pediatrics at Vanderbilt in September 2016, where she will serve as the Medical Director of the Antimicrobial Stewardship Program at the MCJCHV. Her clinical research has focused on the clinical and molecular epidemiology of MDROs<sup>3,4,37</sup> and implementation and evaluation of AS interventions, including use of rapid diagnostics. She led the first randomized controlled trial to assess the clinical impact of a rapid blood culture diagnostic.<sup>13</sup> She is the principal investigator on an NIH-funded multicenter trial to evaluate the impact of rapid bacterial susceptibility testing combined with antimicrobial stewardship on antimicrobial use and outcomes in patients with Gram-negative bacteremia. She is a member of the Pediatric Infectious Disease Society's Committee on Antimicrobial Stewardship.

**Bryan Harris, M.D., M.P.H.:** Dr. Harris completed his internal medicine residency and chief residency at Vanderbilt in 2013. He received his Master of Public Health (M.P.H.) degree and completed his infectious diseases fellowship in 2016. His research focuses on HAI epidemiology and prevention with a particular interest in ventilator-associated events (VAE).<sup>38,39</sup> He has presented his original research findings at IDWeek 2015 (recognized as a top oral abstract presentation) and the SHEA 2016 scientific meeting and recently won a 2015 SHEA Trainee Award. He is currently an Assistant Professor in Infectious Diseases and an Associate Hospital Epidemiologist at Vanderbilt. In July 2016, he will take over medical leadership of the infection prevention and AS programs at the Tennessee Valley VA Healthcare System from Dr. Spires.

**Matthew Greene, M.D.:** Dr. Greene will complete his infectious diseases fellowship in June 2016 with plans to join the faculty at Vanderbilt. With interest in AS, his research during fellowship at Vanderbilt has focused on risk factors for acquiring highly drug resistant enterococcus (vancomycin-resistant enterococcus [VRE] strains also resistant to daptomycin and linezolid).<sup>5</sup> His research will be presented in May 2016 at the SHEA scientific meeting in Atlanta, and he will join the Vanderbilt Antimicrobial Stewardship Program upon graduation in June 2016.

**Whitney Jones, PharmD, B.C.P.S.:** Whitney Jones is the AS Pharmacist for VUMC. She also serves as the Secretary of the Antimicrobial Subcommittee of the Pharmacy Therapeutics and Diagnostics Committee and PGY-1 Pharmacy Practice Residency Director. She has been the lead author of chapters awaiting publication in Kucers' *The Use of Antibiotics* and for the Society of Healthcare Epidemiology of America's upcoming textbook on AS, *Practical Implementation of Antimicrobial Stewardship Programs*. She has served as a member of the Membership Committee for the Society of Infectious Diseases Pharmacists (SIDP) as well as the Programming Committees for SIDP and the Tennessee Society of Health-System Pharmacists. She has been an integral part of the creation of the febrile neutropenia algorithm, antifungal use guidelines, and antimicrobial criteria for use guidelines at VUMC.

**Jessica Gillon, PharmD, B.C.P.S.:** Jessica Gillon is the AS Pharmacist for the MCJCHV, having served in this capacity since the program's inception in 2011. In partnership with the MCJCHV AS Medical Director, she has developed and implemented several successful operational programs that have led to reduction in inappropriate antimicrobial utilization, development of standard protocols, and reductions in MDROs.<sup>15,17,40</sup> Her leadership has been instrumental in improving antimicrobial use for the pediatric patients at VUMC.

**Pratish C. Patel, PharmD, B.C.P.S.:** Pratish is a Clinical Pharmacist at Vanderbilt University Hospital (VUH). Where he manages the Therapeutic Drug Monitoring Service and associated clinical dashboards to provide oversight and coordination of antimicrobial monitoring throughout VUH. He also reviews and provides guidance in the development of clinical pathways, protocols, policies and procedures involving antimicrobials. His recent research has involved a prospective, multi-center, observational study of adult patients with confirmed MRSA bloodstream infections treated with vancomycin to evaluate prospectively the critical day 2 AUC/MIC exposure-outcomes findings from previous studies. He is also involved in an analysis to characterize outcomes of *Clostridium difficile* infections in neutropenic patients.

**Henry J. Domenico, M.S.:** Dr. Domenico is has been a member of the Vanderbilt Department of Biostatistics for five years. In that time, he has had extensive experience in translational research, study design, and predictive modeling. He has served as the primary statistician in Vanderbilt Center for Quality Improvement, and in that role he has evaluated performance improvement initiatives, run education sessions teaching staff and faculty important statistical concepts, and helped the group become more data-driven in their decision making process. As part of his work in healthcare quality, he has developed predictive models for readmissions, length of stay, pressure ulcers, and other adverse outcomes using existing electronic health record data. In addition, he was the primary statistician in a recently published

cluster-randomized trial examining the use of chlorhexidine bathing for the prevention of healthcare-associated infections (on which Dr. Talbot was also an investigator).<sup>19</sup>

**Expertise and Experience - Prior Research Projects Led by Vanderbilt SHEPherD**

**Investigators:** The Vanderbilt SHEPherD investigators have been very successful in conducting an array of scientific research studies focused on many important topics in the fields of healthcare epidemiology, infection prevention, AS, and patient safety. Projects conducted by these investigators (Table) have encompassed a diversity of study designs and methodology and have included randomized control trials,<sup>13,27,29,41</sup> prospective surveillance,<sup>7,25,26</sup> case-control risk factor analysis,<sup>1,2,42,43</sup> quasi-experimental studies using interrupted time-series analysis,<sup>21,22,44</sup> pragmatic cluster randomized trials,<sup>19</sup> and observational and descriptive epidemiologic studies.<sup>6,9,10,23,25,45-54</sup> These have included low-cost pragmatic investigations as well as larger multicenter collaborations.<sup>41,45,48,55</sup>

**Table: Summary Table of Prior Experience in Research Studies and Operational Project Implementation Focused on Human Healthcare Epidemiology, Antibiotic Resistance and Stewardship, and Medication Safety by Vanderbilt SHEPherD Investigators**

<b>Topic Area</b>	<b>Specific Focus (reference)</b>
<b>Epidemiology of HAIs</b>	Outpatient CLABSI risk factors, <sup>36</sup> VAE burden and costs, <sup>38</sup> MRSA soft tissue infections in the ED, <sup>51</sup> cardiac surgical site infection risk factors, <sup>42</sup> epidemiology of CLABSI outside of the ICU <sup>48</sup>
<b>Epidemiology of MDROs</b>	Morbidity of MDR- <i>Acinetobacter</i> infections, <sup>1</sup> morbidity of cephalosporin-resistant <i>Enterobacter</i> bloodstream infections, <sup>2,56</sup> epidemiology of invasive and antibiotic-resistant <i>S. pneumoniae</i> , <sup>33,43,57</sup> epidemiology of multidrug-resistant Gram-negative pathogens, <sup>4,37,58</sup> resistance mechanisms in <i>S. aureus</i> , <sup>3,6</sup> risk factors for acquisition of daptomycin-linezolid-resistant VRE <sup>5</sup>
<b>Outbreak Management</b>	Tuberculosis exposure in a neonatal ICU, <sup>46</sup> Group A <i>Streptococcus</i> intraoperative transmission to a HCP, <sup>24</sup> fungal meningitis related to contaminated corticosteroids, <sup>59</sup> evaluation of outbreak detection algorithms, <sup>11</sup> management of a respiratory virus outbreak in a residential care facility <sup>35</sup>
<b>Prevention of HAIs and MDROs</b>	VAP <sup>44</sup> and VAE <sup>39</sup> prevention via the ventilator bundle, evaluation of use of collaboratives to reduce HAIs, <sup>55</sup> use of chlorhexidine bathing to prevent HAIs in the ICU, <sup>19</sup> compliance with contact precautions as incidence increases, <sup>45</sup> immunization against <i>S. aureus</i> to reduce colonization <sup>18</sup>
<b>Surveillance of HAIs</b>	VAP and ventilator days methodology, <sup>52</sup> central line day assessment <sup>50</sup>
<b>Respiratory Infection Prevention</b>	Prospective surveillance of respiratory infections among HCP, <sup>7</sup> developing surveillance metrics for respirator use in healthcare facilities <sup>60</sup>
<b>Immunization of Healthcare Personnel</b>	PEP for HCP immunized with Tdap, <sup>29</sup> attitudes of HCP regarding Tdap, <sup>10</sup> risk of transmission from attenuated and live vaccines, <sup>25-28</sup> interventions to improve HCP influenza vaccination rates <sup>8,9</sup>
<b>Implementation of Antimicrobial and Test Stewardship Interventions</b>	Antimicrobial use and dosing in pediatric patients, <sup>61,62</sup> use of rapid microbiologic diagnostic testing, <sup>13,63</sup> implementation and evaluation of a diarrhea testing advisor, <sup>16</sup> evaluation of vancomycin dosing strategies, <sup>40</sup> use of real-time feedback on antimicrobial utilization <sup>15</sup>

<b>Quality Improvement and Safety Interventions</b>	Hand hygiene improvement, <sup>22</sup> sharps safety program implementation, <sup>23</sup> burden and prevention of blood culture contamination, <sup>20,21,53,64,65</sup> burden of urine culture contamination, <sup>66</sup> evaluation of instrument sterilization practices in orthopedic surgery, <sup>54</sup> improving surgical antibiotic prophylaxis, <sup>49</sup> evaluation of a clinical practice guideline for complicated appendicitis in children <sup>17</sup>
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CLABSI: central line-associated bloodstream infection; VAE: ventilator-associated events; MRSA: methicillin-resistant *Staphylococcus aureus*; ED: emergency department; ICU: intensive care unit; MDR: multidrug-resistant; VRE: vancomycin-resistant enterococcus; HCP: healthcare personnel; VAP: ventilator-associated pneumonia; HAI: healthcare-associated infection; Tdap: tetanus, diphtheria, and acellular pertussis vaccine

### **Other Potential Collaborators:**

**C. Buddy Creech, M.D., M.P.H.:** Dr. Creech is an Assistant Professor of Pediatrics and is board-certified in Pediatric Infectious Diseases. He also serves as the Associate Director of the Vanderbilt Vaccine Research Program (VVRP) and as Co-PI of the NIH-sponsored Vanderbilt Vaccine and Treatment Evaluation Unit (VTEU). Dr. Creech has conducted clinical and translational research for the past fifteen years, focusing on the epidemiology of bacterial infections and vaccine-preventable diseases.<sup>18,67-73</sup> His primary focus has been on defining the clinical and molecular epidemiology of *S. aureus* disease, in particular, MRSA in children and adolescents. In his role as Co-PI of the VTEU, he has conducted numerous Phase I-IV clinical trials of vaccines in infants, children, and adults. As a result of his knowledge of clinical research and collaborations in place with other investigators at Vanderbilt, he is uniquely positioned to combine expertise in clinical epidemiology, molecular epidemiology, and human immunology to answer fundamental questions regarding bacterial and viral diseases in children and pediatric healthcare settings. In July 2015, he will transition to the role of Director of the VVRP and Principal Investigator of the VTEU. Dr. Creech also leads the VVRP Laboratory, a translational science laboratory with expertise in molecular epidemiology of gram-positive organisms (e.g., streptococci and staphylococci) and human immunology, including functional assessment of human antibodies. The work of the laboratory includes experiments designed to answer questions regarding staphylococcal colonization in infants, children, and adults.

**Marion Kainer, M.D., M.P.H.:** Dr. Kainer is an infectious diseases physician and serves as the Director of the Hospital Infections and Antimicrobial Resistance Program for the Tennessee Department of Health (TDH). She has over 20 years of experience in infection control, hospital epidemiology and antimicrobial stewardship.<sup>59,74-79</sup> She was an EIS officer in the Division of Healthcare Quality Promotion (DHQP), CDC from 2000-2002. She is the chair of the HAI subcommittee, and co-chairs the HAI data standards committee for the Council of State and Territorial Epidemiologists (CSTE). She also co-chairs the CDC's National Healthcare Safety Network (NHSN) steering working group and is a liaison to the NHSN change control board. She is a member of the CDC/CSTE antimicrobial resistance surveillance taskforce which was formed in response to CSTE position statement 13-SI-01 on strengthening antimicrobial resistance surveillance; Dr. Kainer was the submitting author of that position statement. She was honored by the White House as a Champion of Change for Prevention and Public Health in 2013. Dr. Kainer was a member of the antibiotic resistance work group for the President's Council of Advisors in Science and Technology (PCAST) that issued its report in September 2014 and was accompanied by the President's Executive Order on Combating Antimicrobial Resistant Bacteria. Dr. Kainer has been nominated by CSTE to be a member of the Presidential

Advisory Council for Combating Antimicrobial Resistant Bacteria. Dr. Kainer also is a member of the TDH mission coordination group for Ebola response and many of her staff hold key leadership roles under incident command structure (ICS) at the TDH State Health Operations Center.

**William Schaffner, M.D.:** Dr. Schaffner is a Professor of Preventive Medicine in the Department of Health Policy, Professor of Medicine in the Division of Infectious Diseases, and Associate Hospital Epidemiologist at VUMC. He has been a leading expert in the field of healthcare epidemiology for over 40 years. He served in the U.S. Public Health Service as an EIS Officer with the CDC from 1966 to 1968. He then returned to Vanderbilt and established a close collaboration with the TDH that continues to the present. He has authored or coauthored many peer-reviewed articles on important infection control and public health topics, including antibiotic resistance, outbreaks of nosocomial infections, immunization practices and infection control for patients infected with HIV.<sup>80-89</sup> He has served as President of SHEA (1983) and the National Foundation for Infectious Diseases (2010-12); he has served on the Board of Directors of the International Federation of Infection Control (1985-90) and twice on the elected Board of the Infectious Diseases Society of America (2000-3; Secretary 2007-10). He is a Senior Associate Editor of *Infection Control and Hospital Epidemiology* and Associate Editor of the *Journal of Infectious Diseases*. He has written over 480 scientific articles and textbook chapters and is a consultant in public health policy and communicable disease control for numerous local, national, and international institutions, including the CDC and the WHO among others. He also serves as co-Principal Investigator for the Tennessee Emerging Infections Program which conducts studies of community and hospital-onset MRSA, *C. difficile* and influenza infections and other pathogens. He served as the Hospital Epidemiologist at Vanderbilt for over 35 years until 2006, where under his direction, the Department became a major influence in the prevention of HAIs throughout the region.

**Patty W. Wright, M.D.:** Dr. Wright serves as the Associate Vice Chair for Clinical Affairs in the Department of Medicine and is the Associate Director for Clinical Affairs in the Division of Infectious Diseases. She graduated from the University of Alabama School of Medicine in Birmingham. She completed her residency in Internal Medicine and her fellowship in Infectious Diseases, both at the University of Alabama at Birmingham. Dr. Wright has chaired the Antibiotic Subcommittee of the VUMC Pharmacy and Therapeutics Committee since 2003 and has led the development of the Vanderbilt Antibiotic Stewardship Program since its inception. She has also been an active member of the VUMC EVD preparedness team, particularly in the areas of physician staffing and training.

**Infrastructure and Capacity:** Coupled with the successful clinical investigators noted above, the Vanderbilt SHEPheRD Center has the facilities, resources, and data management capacity to initiate and lead multiple steps across the spectrum of scientific inquiry, including formulating a research question, developing a detailed research plan and protocol, successfully implementing the protocol, analyzing and interpreting results. This infrastructure and capacity are outlined below.

**Infrastructure and Capacity - Participating Healthcare Facilities:** Multiple facilities, including all of VUMC, are available to the Vanderbilt SHEPheRD investigators for research

projects. These comprise a diverse group of patient populations and clinical care settings, including acute care hospitals, outpatient clinics, an inpatient rehabilitation hospital, outpatient dialysis units, and an outpatient surgical center. In 2014, there were over 1.8 million ambulatory clinic visits, over 118,000 emergency department visits, and over 53,000 surgical procedures performed at VUMC. All facilities, with the exception of WMC, utilize the same integrated electronic medical record with data deposited in the VUMC electronic data warehouse. Access to similar data at WMC is available to SHEPherD investigators through their roles in the medical leadership.

Two key parts of the healthcare system germane to the SHEPherD program are the VUMC Department of Infection Prevention and the Vanderbilt Antimicrobial Stewardship Program (VASP). The Department of Infection Prevention is led by Dr. Talbot as the VUMC Chief Hospital Epidemiologist, and consists of two associate epidemiologists (Nelson, Harris), MCJCHV epidemiologist Greg Wilson, a Director, and a staff of nine preventionists, two health systems database analysts, a program coordinator, and a data abstractor. The Department is primarily responsible for conducting surveillance of HAIs, implementing and evaluating prevention interventions and programs, and investigating and controlling outbreaks or infection clusters among patients and HCP. IP staff also evaluate new and existing products, examine the latest innovations in personal protective equipment and safety devices, and conduct detailed special projects focused on infection prevention issues throughout VUMC. Established in 2012, VASP is a multidisciplinary team with members from adult and pediatric infectious diseases, pharmacy, microbiology, and infection prevention. The VASP is led for the adult enterprise by Dr. Wright with Drs. Nelson and Greene serving as additional physician support and Whitney Jones serving as the as the lead pharmacist. For the MCJCHV, Dr. Banerjee will serve as the physician director of the program upon her arrival in Sept. 2016 with Jessica Gillon serving as the MCJCHV AS pharmacist, a role that she has served in since the program's inception in 2011.

#### **A. Acute Care Facilities:**

**1. Vanderbilt University Hospital (VUH):** VUH serves as the major academic tertiary care adult hospital in middle Tennessee with 834 acute care beds. It has active services in general medicine and surgery as well as most surgical subspecialties, medical subspecialties, neurology, and obstetrics and gynecology. VUH also houses multiple specialty intensive care units (total 142 beds), including medical, cardiovascular, neurosciences, trauma, surgical, and burn ICUs. VUH serves as Middle Tennessee's only Level 1 trauma center and has several active and comprehensive transplantation programs (bone marrow and stem cell, liver, cardiac, lung, and renal).

**2. Monroe Carell Jr. Children's Hospital at Vanderbilt (MCJCHV):** MCJCHV is a tertiary care, 271-bed facility that provides care for children in middle Tennessee, southern Kentucky, and northern Alabama. This free-standing facility combines high level pediatric and sub-specialty treatment, research and academics under one roof. Programs include Centers of Excellence for the treatment of diabetes and congenital heart disorders, pediatric heart transplant and cardiology, bone marrow transplant, a level 4 neonatal ICU, endocrinology and gastroenterology among others.



**3. Psychiatric Hospital at Vanderbilt (PHV):** The PHV is an 88 bed facility that offers inpatient and partial hospitalization services to children, adolescents, and adults with psychiatric and substance abuse problems. Infection prevention at PHV is covered by dedicated nurse who works in close collaboration with the Department of Infection Prevention.

**4. Williamson Medical Center (WMC):** Part of the Vanderbilt Health Affiliate Network (VHAN), WMC is a community-based hospital with 185 adult acute care and 12 pediatric acute care beds that provides comprehensive inpatient and outpatient care including emergency services, with credentialed physicians in 53 specialties and sub-specialties. A large number of WMC patients are admitted for orthopedic procedures, especially joint arthroplasties and spinal surgeries. Many patients admitted from surrounding nursing homes and long-term care facilities in Williamson County. SHEPheRD Investigator Steven S. Spires is the Hospital Epidemiologist and Medical Director of the Antimicrobial Stewardship Program at this facility. The WMC Infection Prevention Program is chaired by Dr. Spires and is supported by 2 infection preventionists. The IP program reported directly to the Medical Executive Board. The WMC ASP is comprised of an ID-trained pharmacist and Dr. Spires.

#### **B. Inpatient Rehabilitation Facilities:**

**1. Vanderbilt Stallworth Rehabilitation Hospital (VSRH):** VSRH is an 80-bed inpatient rehabilitation hospital that offers comprehensive inpatient rehabilitation services designed to return patients to leading active and independent lives. The hospital opened in November of 1993 and is a joint venture between VUMC and HealthSouth, one of the nation's leading rehabilitation services provider. VSRH provides a wide range of physical rehabilitation services, a vast network of highly-skilled, independent private practice physicians and HealthSouth therapists and nurses. In addition to caring for general rehabilitation diagnoses such as orthopedics, pulmonary and cardiac conditions, Stallworth has specialized inpatient programs for stroke, brain injury, spinal cord injury, amputations, hip fractures and neurological conditions.

#### **C. Ambulatory Care Centers:**

**1. The Vanderbilt Clinic (TVC) and Vanderbilt Medical Group (VMG) Clinics:** The TVC serves as the main center for outpatient services at Vanderbilt, providing a full range of diagnostic and treatment services. In addition, there are more than 800 VMG physicians on staff, comprising over 160 outpatient specialty practices. TVC and the VMG clinics utilize all components of the VUMC electronic medical record system.

**2. MCJCHV Doctor's Office Tower:** The Vanderbilt Children's Hospital Doctor's Office Tower is an 11-story facility that houses comprehensive outpatient services, including general pediatric primary care, pediatric medical and surgical subspecialty care, pediatric acute care, and the Pediatric Clinical Research Center.

**D. Outpatient Dialysis Units:** VUMC has two large outpatient dialysis facilities with a total 165 chronic hemodialysis patients and 45 peritoneal dialysis patients. There are dedicated staff members responsible for tracking clinical outcomes in the dialysis patients, including but not limited to hospitalizations, deaths, immunizations, infection episodes, antibiotic use and other dialysis related outcomes.

#### **E. Ambulatory Surgery Centers:**

**1. Vanderbilt Bone and Joint Surgical Center (VBJ)** - The VBJ is Vanderbilt's free-standing outpatient orthopedic surgical center, averages over 2,200 visits per year. Procedures performed at the VBJ by 14 surgeon faculty members include outpatient and early morning admission hand, wrist, and forearm procedures, knee arthroscopy, anterior cruciate ligament repair, shoulder arthroscopy, and total joint replacement. The facility has 3 operating rooms and performs around 3,500 procedures annually.

**F: Vanderbilt Affiliate Health Network (VHAN):** Started in 2015, VHAN is the largest provider-organized network of doctors, regional health systems and other health care providers in Tennessee and surrounding states. Network providers actively collaborate to provide patients with high-quality, efficiently coordinated and cost-effective health care services. Currently, over 2 million patients and more than 3,400 physicians and other health care providers are in the VHAN. As this network matures, it provides an exciting setting for potential SHEPherD projects.

#### **Infrastructure and Capacity - Resources:**

**Center for Clinical Quality and Implementation Research:** Part of the Vanderbilt Center for Health Services Research, this interdisciplinary Center seeks to advance research on the quality, safety, and delivery of care at VUMC and elsewhere. The Center supports the evaluation and dissemination of quality initiatives by providing assistance with study design, outcome assessment, and scientific writing for peer-reviewed publication. A biweekly seminar series covers key theoretical and methodological content in Implementation Science. By providing educational resources in these areas, as well as offering active collaboration, the Center provides an important resource for faculty, trainees, and others at Vanderbilt who are interested in evaluating the quality of health care or interventions to improve care. Faculty and work-in-progress sessions for this Center will be available to provide feedback on task order responses.

**Vanderbilt Institute for Clinical and Translational Research (VICTR):** VICTR is Vanderbilt's virtual home for clinical and translational research. Supported by the Vanderbilt Office of Research and the NIH sponsored Clinical and Translational Science Award, VICTR offers many important services including daily biostatistics clinics for Vanderbilt researchers who have methodologic or analytic questions about their research project and design studios. The VICTR Studio Program strives to improve research quality and rigor by offering and broadly implementing a wide range of supportive research from study design and set-up to analysis and publication, available to new and experienced researchers. These sessions may focus on hypothesis generation, specific aims development, study design and implementation, data analysis and interpretation, and manuscript review prior to submission.

**Clinical Trials Center (CTC):** The CTC provides a menu of services to support investigator-initiated research (such as short-term regulatory support or full-service research protocol administration including budget administration, recruitment operations and study visit support). The CTC occupies 3000 square feet in the Village (an on-campus facility) and has two dedicated research exam and treatment rooms, specimen processing and storage facilities, two

monitor visit rooms, a waiting area with a receptionist, office space for administrative and nursing staff, and convenient parking for participants.

**IRBshare:** Vanderbilt is the current operator of the IRBshare System, a joint IRB review model for multisite studies that provides a mechanism to streamline IRB submission and the IRB review process at all phases of IRB review through the sharing of and reliance on IRB-approved documents between IRBs. This will be available for Vanderbilt SHEPheRD investigators for any multisite SHEPheRD research project.

**Tennessee Department of Health/Tennessee Emerging Infections Program:** Unique among many academic medical centers, VUMC has established a close, collaborative partnership with the Tennessee Department of Health (TNDOH), particularly the Communicable and Environmental Disease Services branch, led by Timothy Jones M.D., the State Epidemiologist for Tennessee. In addition, Dr. Jones and Dr. William Schaffner are the co-Principal Investigators for the Tennessee Emerging Infections Program (EIP), which is part of a population-based network including the CDC and nine other state health departments. The core activity of the EIP is active surveillance of laboratory-confirmed cases of reportable pathogens, including participation in the Active Bacterial Core Surveillance program, FoodNet, and the Healthcare Associated Infections-Community Interface projects. The Tennessee EIP also conducts population-based surveillance for invasive MRSA infections in Davidson County residents (2014 estimated population 668,347), including ascertainment of community vs. healthcare-associated status based on hospital medical record review. This includes collection of all MRSA isolates from VUMC and of appropriate denominator data.

### **Infrastructure and Capacity - Data Management:**

**Vanderbilt Infection Prevention Electronic Resource (VIPER):** Developed by Vanderbilt, VIPER is the Department of Infection Prevention's HAI surveillance platform. Using rules based on the CDC's HAI surveillance definitions, VIPER reviews microbiology records daily. Specimen results that may indicate an HAI are evaluated further to assess for the presence of invasive devices (in the case of device-associated infection surveillance) and other laboratory testing. VIPER has algorithms to identify MDRO and *C. difficile* infections as well as rules to flag specimens that are positive for contagious infections that require use of specific transmission-based precautions (e.g. a specimen positive for *B. pertussis* is flagged as requiring Droplet Precautions). A separate surgical site infection (SSI) module monitors all patients eligible for SSI surveillance post-procedure for any potential SSI-related triggers (antibiotic prescription, new microbiology results such as wound cultures, new radiologic tests, readmission, and return to the operating room). This then directs the infection preventionists to examine these events and assess if a new SSI has occurred.

**REDCap:** Collecting data in a standardized manner is integral to research quality, consistency, and reproducibility. Vanderbilt has developed REDCap (Research Electronic Data Capture) to help research teams plan, create, and conduct data management for clinical and translational research studies. REDCap is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: an intuitive interface for data entry (with data validation); audit trails for tracking data manipulation and export procedures;

automated export procedures for seamless data downloads to common statistical packages such as SPSS, SAS, Stata, and R; procedures for importing data from external sources; and advanced features, such as branching logic and calculated fields. Starting as a Vanderbilt initiative, REDCap was further developed for widespread applicability to the larger research community. The consortium also includes partners from research centers and minority institutions. This critical infrastructure allows for continuous collaborative development and enhancements to data capture software that simultaneously benefits researchers at Vanderbilt and around the world. Further, because of the breadth of REDCap, we have achieved an institutional economy of scale for support staff in technical development and dissemination, enabling efficient deployment of a cohesive group for future technological advancements. The REDCap software is shared at no cost to academic and non-profit institutions. Vanderbilt's REDCap system is hosted and maintained by the staff at the Informatics Center.

**Vanderbilt Informatics Center:** Under the leadership of William Stead M.D., the Informatics Center staff of over 500 individuals has developed many successful tools that have received both national and international recognition, and manages almost 2 million Vanderbilt patients. Relevant examples include StarChart, an up-to-date, comprehensive, electronic medical record with web-accessible Intranet retrieval tools and currently has more than 31 million documents; HEO, a decision support and order entry tool with a relational database of all orders entered on all Vanderbilt inpatients since January 1998; StarPanel, an integrated application providing clinicians access to electronic information from one screen; RxStar, Vanderbilt's outpatient order entry system; and MyHealth@Vanderbilt, a patient portal used by more than 2,000 patients per day (300,000 registered) to access their electronic medical record and message with their care team. The synergy from this group creates a robust laboratory for informatics research, fostering multidisciplinary rapid prototyping and deployment of applied systems, and evaluation of their impact.

## **List of Tables**

Table: Summary Table of Prior Experience in Research Studies and Operational Project Implementation Focused on Human Healthcare Epidemiology, Antibiotic Resistance and Stewardship, and Medication Safety by Vanderbilt SHEPherD Investigators

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