08 January, 2020

Approaching Zero:

A Convergent Roadmap to Eliminate Infection Associated with Biomedical Devices

Purpose and Overview:

The Approaching Zero Roadmap Initiative is a process that will develop a convergent perspective of medical-device-associated infection and identify an impactful set of steps which can be pursued to create a trajectory that increasingly pushes its rate of occurrence towards zero over the coming decade and beyond.

Each year, millions of medical devices with various complexities are temporarily or permanently implanted in humans in order to administer treatments or replace failing body components. These tissue-contacting devices create conditions that can lead to recurrent complications associated with infection. Device infection rates vary from about 0.1% - 5%, depending on the specific device, but they can be much higher. The infection rate after fixation of an open fracture, for example, approaches 30%.

The CDC estimates that the annual cost of healthcare-acquired infection in the United States is approximately $30-$40B. Significantly, this amount does not account for the often profound and deep impact that infection has on thousands and thousands of patients, their families, and their employers across the country and in all walks of life. The great majority of healthcare-acquired infections involve some form of medical device. Included among them are catheters, sutures, ventilator tubes, shunts, joint prostheses, heart valves, surgical mesh, and many others. All present foreign surfaces that provide a niche environment for microbial colonies to form, and these colonies provide a nidus for infection. In the majority of cases, the infection can be resolved only by removing the device. Surgeries and/or extended hospital stays are often required, and the complications can spiral into compromised life styles and, in some cases, death.

Despite growing recognition since the early 1990's of the device-infection problem and its impact, there have been only small improvements in clinical outcomes over the intervening decades. The underlying reasons are many, including, for example, insufficient basic understanding of microbial biofilms, endemic issues involving regulatory guidelines, hospital/insurer practices, incomplete reporting, inadequate definitions of the problem and its causes, as well as a lack of standards to qualify new technologies, among others. The overall challenge is complex and involves a diverse array of stakeholders with different perspectives, challenges, technical language, and operational constraints.

Roadmap Development:

The Approaching Zero Roadmap Initiative is partially supported by the award of an Engineering Research Center (ERC) planning grant to a team led by Syracuse University (Dacheng Ren), Binghamton University (Karin Sauer), and Stevens Institute of Technology (Matt Libera). The Engineering Research Center program is a mechanism for major and multi-year funding from the National Science Foundation (NSF). ERCs are meant to support convergent science, innovation, and workforce development to address grand challenges that will have major societal impact.

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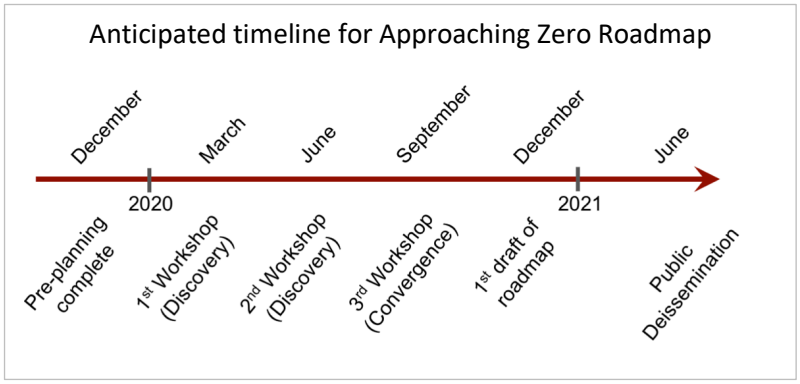
Planning for the Approaching Zero Roadmap Initiative was convened in October 2019 with a roundtable meeting at Stevens Institute of Technology. In addition to Ren, Sauer, and Libera, the roundtable included: Celeste Abjornson (Hospital for Special Surgery); Jordan Katz (Orthobond); Kevor TenHuisen (Stryker Joint Replacement); Scott Weiss (Johnson and Johnson); and Joe Zitelli (Zimmer-Biomet).

The most visible roadmap-development events going forward will be a series of workshops throughout 2020. These will be designed to assemble groups of diverse stakeholders in a process initially of discovery and then of convergence. Each will involve ~25-30 participants and occur at locations to be determined across the country. There will, in addition, be continuous effort behind these workshops to flesh out details, refine the understanding, and plan next steps. The objective is to have an initial roadmap draft by December 2020. The first Discovery Workshop will be held on February 26, 2020 in Alexandria, VA.



Technical Challenges:

The Approaching Zero Roadmap Initiative can be loosely defined by three central and synergistic objectives:

1. *Prevent* device infection from occurring

   This focus includes near-term challenges associated with the development and deployment of next-generation infection-resisting materials and devices.

2. *Treat* an infected device

   This focus includes the detection of device-associated infection and new methods to resolve device colonization by antibiotic-resistant biofilms.

3. *Cure* the device-infection problem altogether

   This far-reaching focus includes advanced concepts associated with microbiome symbiosis and personalized medicine.

The discovery workshops in early 2020 will be designed to inclusively identify sets of core stakeholders - e.g. device manufacturers, clinicians, regulatory agencies, standards organizations, insurers, and academic scientists/engineers, among others. The discovery workshops will further aim to identify the many constraints and challenges each stakeholder group faces in preventing, treating, and/or curing device-associated infection. Finally, the initiative's convergence phase will strive to the find those key stumbling blocks which must be overcome in the short, intermediate, and long-term timeframes in order to drive the rate of device-associated infection towards zero over the coming decade and beyond.