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November 7th, 2016

2017 places higher pressure on hospitals to avoid HAIs

LONDON, UK----7th **November 2016----ExpertREACT**. The global threat of antimicrobial resistance dominates news headlines. In the US, ID stakeholders formulate stringent participation standards for hospitals, starting 2017. The case to develop hospital vaccines gets ever stronger.

VacZine Analytics recently attended the **IDweek2016** conference in New Orleans, Louisiana USA (October 26-30). One topic which stood out among others at the meeting was the continued threat of antimicrobial resistance (AMR) and possible counter strategies. This **ExpertREACT** article will give an overview of the key issues and discuss the possible role of vaccination as a preventative tool.

Antimicrobial resistance is an 'urgent' health crisis. In a 2013 report (1), the US Centers for Disease Control and Prevention (CDC) estimated that around 23,000 deaths and at least 2 million illnesses occur each year in the US as a direct result of AMR–many more die due to its complications. These numbers are compounded further if *Clostridium difficile* infection (CDI) is considered. CDI hospitalizes at least 250,000 people each year with an estimated 14,000 deaths. Overall, from a cost perspective, AMR costs the US economy \$20 bn in excess direct medical costs and \$35 bn in lost productivity (1).

The scale of the AMR issue becomes more apparent on a global level as different countries are affected in distinct ways. Poorer nations, burdened with TB, malaria and HIV are impacted by resistant strains to common drugs rarely used in the West. For example, the growing prevalence of drug-resistant strains of TB is well-documented: there were an estimated 480,000 new cases in 2013 – of which the majority went untreated. In fact, a 2014 report predicts that deaths due to all AMR (currently 700,000) in 2050 would number 10 million per year–a level higher than cancer (8.2 million) and diabetes (1.5 million) (2). Deaths due to cardiovascular disease were not presented. The threat of AMR has become so significant that the United Nations held a high-level meeting on the subject in 2016 (3). The body has only met four times in its 70-year history on health-related issues notably HIV and Ebola.

The most surprising thing about AMR is that many deaths can be prevented. A key fact (repeated in many presentations at **IDweek 2016**) is that up to 50% of antibiotic use (the main contributor to AMR) is inappropriate. This means that powerful antimicrobial agents are selected for empiric use but pathogens are later found to be nonsusceptible. Inappropriate antimicrobial use not only increases the risk of selecting MDR organisms themselves, but increases the risk for *Clostridium difficile* infection (CDI). Despite widespread awareness of the issues, reducing antimicrobial use is not an easy task. Many hospitalized patients such as those undergoing cancer chemotherapy, complex surgery, rheumatoid arthritis and dialysis for end stage renal disease rely on antibiotics to fight infections. Antibiotics are among the most commonly prescribed medications in nursing homes. Up to 70% of long-term care facilities' residents receive an antibiotic every year (4).

To help combat inappropriate antimicrobial use the US Joint Commission (JC) has announced a new Medication Management (MM) standard for hospitals, critical access hospitals, and nursing care centers wishing to participate in Medicare/Medicaid (5). The standard MM.09.01.01, which follows suit to CMS, addresses antimicrobial stewardship and becomes effective January 1, 2017. To date effective programs (per IDSA/SHEA guidelines) have improved patient outcomes, decreased antibiotic usage by up to 35% and lowered CDI with an annual savings to institutions of up to \$900 000 (6). Now healthcare providers must establish detailed protocols using a multidisciplinary antimicrobial stewardship team including an ID physician, infection preventionist, pharmacist and practitioner. A wide range of core elements should be included as part of the program namely: accountability, drug expertise, action, tracking, reporting and education.

Many attendees at **IDweek2016** conference workshops admitted their institution was not fully ready for the 2017 JC program. Evidently the requirement for substantial data collection places huge administrative pressure on many hospitals. The new standard recommends the coordinated analysis of electronic health records, surveillance (EPIC, TheraDoc), tracking (monitoring antibiotic prescribing and resistance patterns) and clinical pharmacy programs. Software programs to facilitate these processes were referred to with humor as "complex" and un user-friendly.

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September 7th, 2016

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Furthermore, there are also substantial cost implications for implementing best practices as outlined in the new JC stewardship program. As well as the need for highly trained personnel, newer rapid diagnostic tests such as PCR, nucleic acid, fluorescence in situ hybridization and MALDI-TOF are becoming more widespread often referred to as "game changers". These techniques (advocated by the JC and The National Action Plan) promise earlier organism identification, earlier antibiotic escalation/deescalation which are validated strategies to gaining reductions in length of stay (LOS) and hospitalization costs. However, while successful, such techniques involve the purchase of equipment amounting to hundreds of thousands of dollars which still must past the scrutiny of budget conscious hospital committees. Adoption of newer innovations must be cost-effective.

Since 2008, US hospitals have been penalized under a value based purchasing program implemented by Medicare if patients acquire any of eight infection related conditions, including catheter and vascular catheter-associated infections. This initial measure has evolved into the Hospital-Acquired Condition (HAC) Reduction program which is reported to have saved Medicare approximately \$350m every year (7). In 2017 the rules will become even tighter as MRSA infections become included in Medicare's Hospital Value-Based Purchasing (VBP) scorecard and their weighting increased from 65% in 2015 to 85% in 2017 (8). With hospital profit margins in the low single digits it is highly critical that all available measures are adopted to reduce healthcare associated infections. It is now a business necessity.

Is the implementation of antimicrobial stewardship programs enough to reduce the incidence of infections caused by multidrug resistant or problematic pathogens? Maybe not. The advancement of new antibiotics only appears incremental with a marked increase in cost.

For several years, the industry has grappled with the concept of a "nosocomial" vaccine. Such a vaccine would be given prior to patient risk exposure and protect vulnerable patients also lessening the reliance on antibiotics. There have been some notable high profile failures e.g. NABIS StaphVAX, Merck & Co/Intercell's IsdB and more recently, Valneva's vaccine for *P.aeruginosa* (VLA43). However, Sanofi Pasteur's *Clostridium difficile* vaccine is still in late stage Phase III testing (9) followed by Pfizer's multi-antigen *S. aureus* vaccine (SA4Ag) in Phase IIb (10). Finger crossed these candidates will be licensed, it seems the way things are moving hospitals will need all the help they can get. Research should continue.

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