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Innovative Approaches to Combat Healthcare-Associated Infections Using Efficacy Standards Developed Through Industry and Federal Collaboration

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ABSTRACT

Nation-wide, healthcare-associated infections (HAIs) infect one in every 25 hospital patients, account for more than 100,000 deaths and increase medical costs by around \$96-147B, each year. Ultraviolet-C (UV-C) antimicrobial devices are shown to reduce the incidence of many of these HAIs by 35% or more, through the deactivation of the pathogen's DNA chain following irradiation with a wavelength of ~254 nm. This irradiation does not kill the cells, per se but effectively prevents the cells from multiplying. Clinical case reductions of 30-70% in *Clostridium difficile* (*C. diff.*) have been reported with similar results for methicillin-resistant *Staphylococcus aureus* (MRSA), and others. The methodology works, but, the adoption of UV-C technology by the healthcare industry has been sporadic. This is largely due to the lack of definitive knowledge and uniform performance standards or measures for efficacy to help healthcare managers make informed, credible investment decisions. The leveling of the playing field with scientifically certifiable data of the efficacy of antimicrobial devices will enhance acceptance by the healthcare industry and public, at large, as well as facilitate science-based decision making.

The National Institute of Standards and Technology (NIST) has engaged with the International Ultra Violet Association (IUVA) and its member companies and affiliates to explore ways to develop needed standards, determine appropriate testing protocols, and transfer the technology to help to reduce these inharmonious market conditions. Collaborative efforts are underway to develop science-based answers to the healthcare industry's questions surrounding standards and measures of device disinfection efficacy, as well as reliability, operations and durability. These issues were recently discussed at the IUVA 2018 America's Conference in Redondo Beach, CA in several panel sessions. A major output of the sessions was the formation of a formal **IUVA Working Group** for the development of antimicrobial standards and initiatives for the healthcare industry. The goal of this working group is to provide global guidance, with specific programs and deliverables, on the use of UV technologies and standards to combat HAIs and to further the stated aims of the IUVA on its outreach to the healthcare industry. This paper reviews the strong collaboration between NIST and its industry partners pursuing the development of standards, guidelines and guidance documents related to healthcare applications that include standard methods for validating performance of UV devices and test guidelines for efficacy measurements. In addition, an overview of the issues, problems, and a summary of the needs confronting future growth and success of the UV industry in the Nation's healthcare application space is provided.

Keywords: healthcare-associated infections; HAIs; infection control; disinfection; ultraviolet; UV-C; *C.diff.*; standards

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1.0 INTRODUCTION

Healthcare-associated infections (HAIs) are one of the leading causes of death in the United States (U.S.). However, HAI statistics are neither as easily obtained nor as newsworthy as other causes of death, *until a facility is closed for sanitation*. Imagine a world where HAIs are just a concern of the past. It is technically possible, and it could happen. Unfortunately, today that is not the case. Nation-wide, HAIs infect about one in every 25 hospital patients¹. Each year this translates to approximately 1.7 million HAIs occurring in U.S. hospitals, resulting in approximately 100,000 or more

unnecessary deaths and an estimated \$20 billion in U.S. dollars in healthcare costs². The overall direct cost of HAIs to hospitals can be as high as \$45 billion³ and costs due to operational or occupational losses of productivity are estimated at more than \$100+ billion, yielding more than \$145 billion per year of economic impacts on the U.S. economy alone with the caveat that full societal costs have *never* been fully measured or reported⁴.

Comparing these economic data to information obtained from the U.S. Centers for Disease Control and Prevention (CDC, Figure 1) clearly shows that the deaths from HAIs place HAI deaths nearly at the level of those attributed to Alzheimer's disease and *above* the seventh leading cause of death in the U.S., that is, above diabetes.⁵ In 2015, diabetes claimed 79,535 deaths, which is only about three-quarters of the deaths attributed to HAIs. In addition, with the current emphasis in the U.S. on the "Opioid Crisis" where, in 2016, about 63,000 drug overdose deaths in the US were reported,^{6,7} which is, a sad loss but, also much lower than those attributed to HAIs. One should wonder why so little attention is being paid to this potentially controllable, but deadlier, HAI problem.

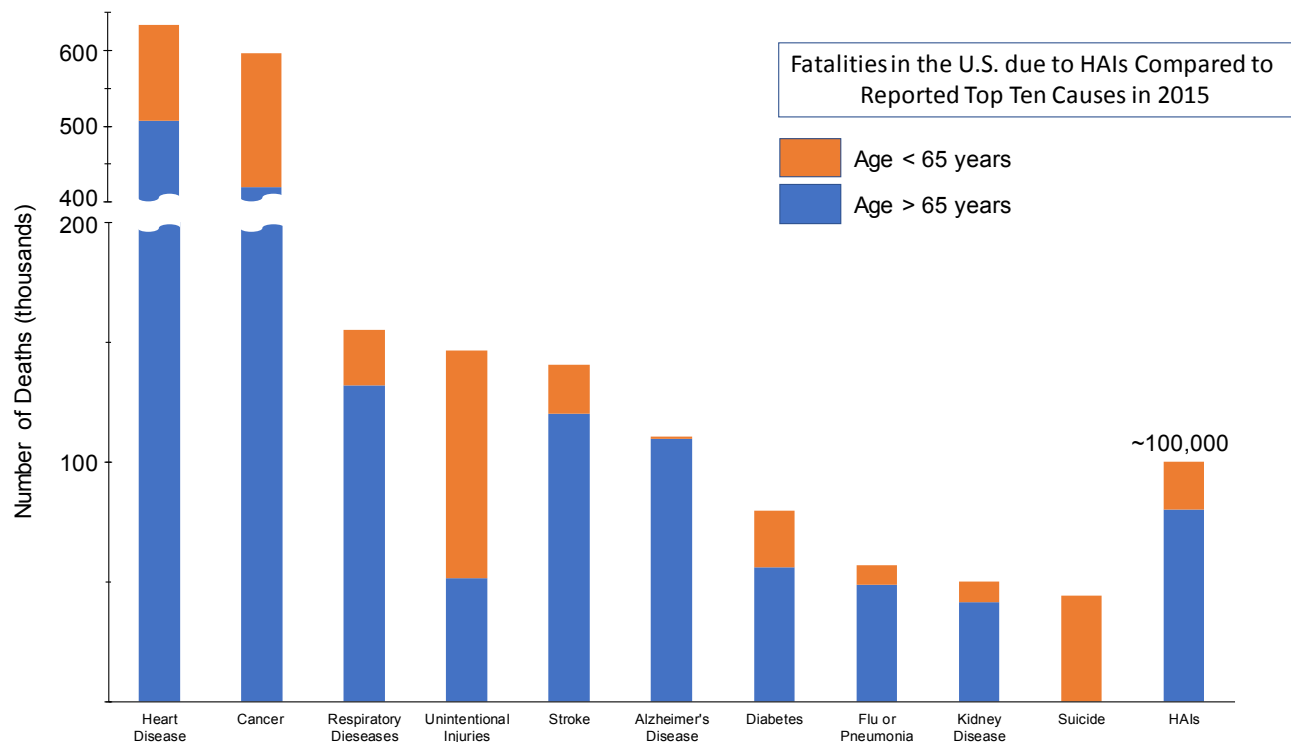


Figure 1. CDC reported top ten causes of death in 2015¹ compared to the reported number of HAI fatalities².

The deadly problem of HAIs, the technologies to combat infectious HAIs, and the identification of barriers and research opportunities to improve the effective and efficient treatment of HAIs, have recently been explored.^{8,9} It is clear an improved understanding of the efficient and effective use of ultraviolet-C (UV-C) in healthcare settings is essential to the widespread adoption of UV-C in healthcare. Moreover, the implementation of standard device industry metrics holds a significant promise to create a safe environment for patient care and mitigate the risk for HAIs. Here we examine the issues with HAI control and present a summary of needs confronting success.

1.1 HAI Infections. A patient who enters a hospital infection-free expects to leave the hospital infection-free. As pointed out above, that is often not the case (Figure 2). The sources of the major HAI infections are well documented.^{10,11,12,13,14} Most HAI fatalities are caused by bacterial and viral microbes including: *Clostridium difficile* (*C.diff.*), Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant *enterococci* (VRE), and multidrug resistant Gram-negative bacteria such as Carbapenemase-resistant *Enterobacteriaceae* (CRE). Additionally, "new" drug resistant

yeast, *Candida auris*, is now starting to spread in the US.¹⁵ Several of these “super bugs” have adapted and evolved to the point where they are resistant to known prescriptive drugs and hence place the patient in antibiotic resistance peril. New approaches to this problem must be explored and successful methods rapidly applied to this problem, as these super bugs will continue to adapt and add to their grim statistics.

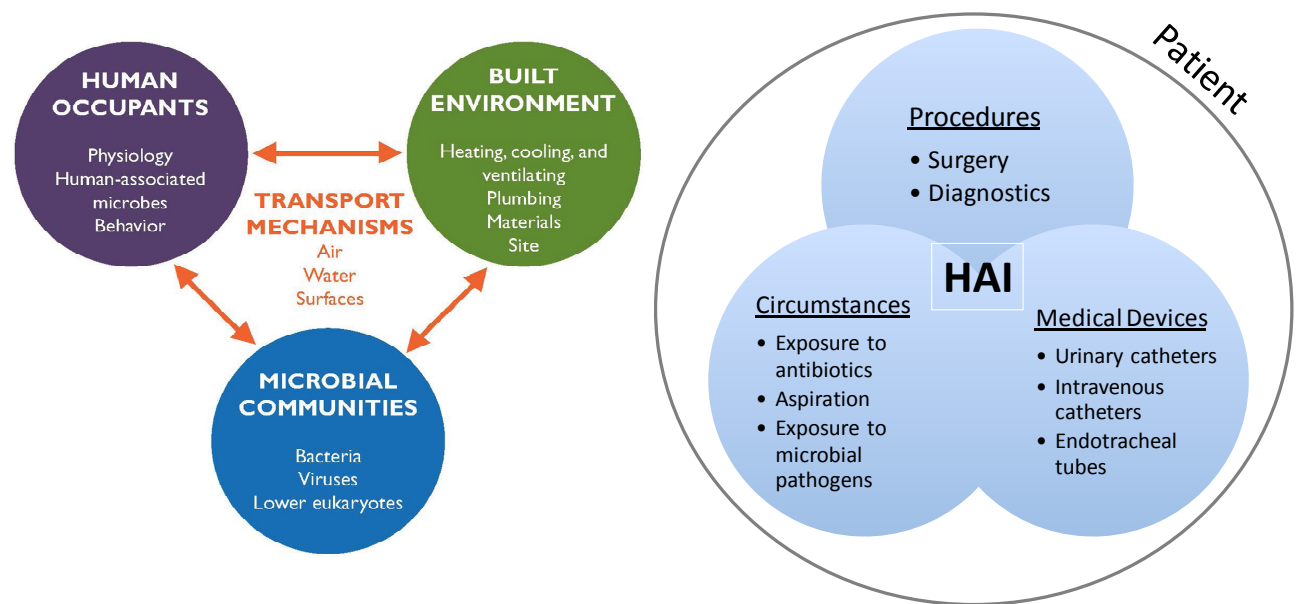


Figure 2. Healthcare facilities are complex, with continuous operations in an environment often crowded and loaded with equipment. There are also numerous types of surfaces and materials coupled with a confluence of sick patients and persons with compromised immune systems and other vulnerabilities, leading to risk for healthcare associated infections.¹⁶

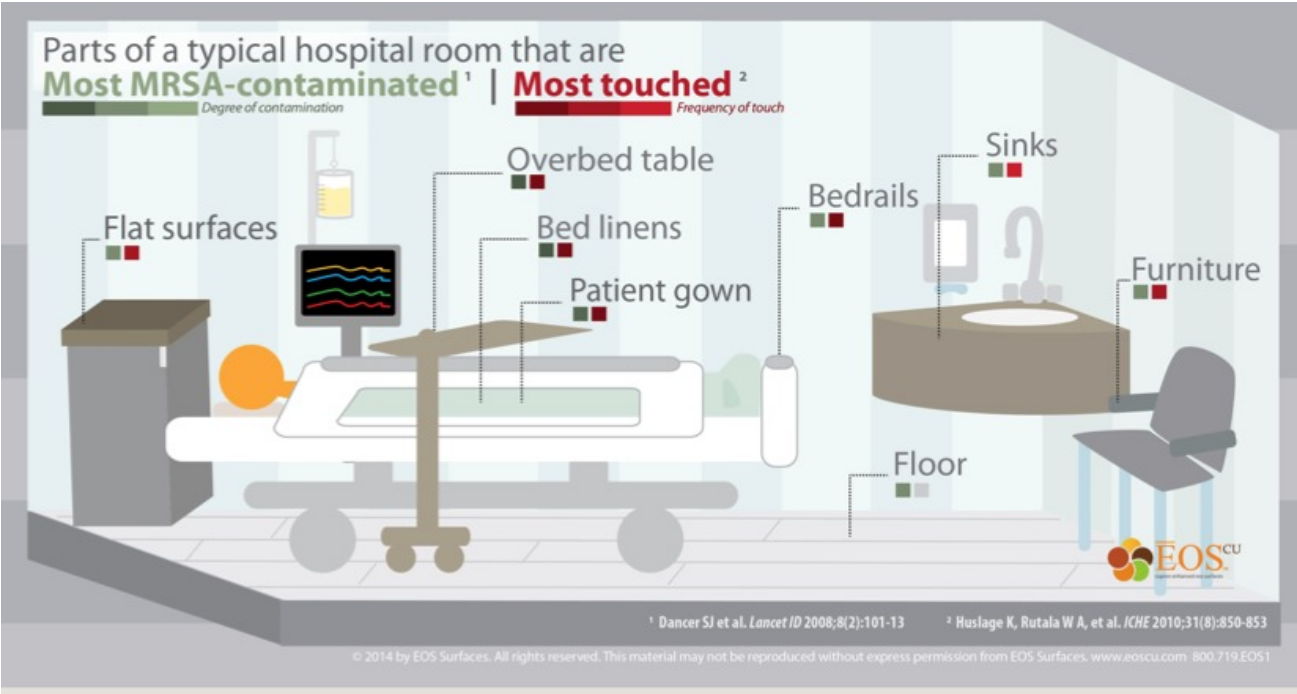


Figure 3. Hospital rooms are complex with many surfaces. UV-C devices may attack whole room surfaces.

Reducing HAI strategies have focused on improving hand hygiene, however, new studies indicate the whole room must be considered (Figure 3). Both high- & low-touch contaminated surfaces can pass pathogens to patient or healthcare workers. Floor cleanliness is increasingly suspect as a major contributor.

2.0 POTENTIAL SOLUTION

In 2016 the U.S. CDC concluded that the incidence of HAI-causing organisms can be reduced by up to 35% after adding antimicrobial UV-C emitting devices to standard cleaning strategies based on a study of the benefits of enhanced terminal room disinfection.¹⁷ It was demonstrated in the aforementioned study that automated UV-C emitting devices decrease the bioburden of important pathogens in hospital rooms. Clinical case reductions of 30% to 70% in *C. diff.* have been reported, with similar results for MRSA and others.¹⁸ The methodology works, but, the adoption of UV-C technology by the healthcare industry has been sporadic. This is largely due to confusion and low confidence resulting from the lack of definitive knowledge and uniform performance standards or measures for efficacy to help healthcare managers make informed, credible investment decisions. Therefore, maintaining the status quo seems to be the most effective and safest investment approach. However, the leveling of the playing field with scientifically certifiable data of the efficacy of antimicrobial devices will help facilitate science-based decision making.

Regulated by the U.S. Environmental Protection Agency (EPA), UV devices have long been used in the drinking and waste water treatment industry for disinfection of water-borne microorganisms. UV devices are regulated by the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)¹⁹ as pesticidal devices. Pesticidal devices are not registered like pesticides but are subject to many of the FIFRA provisions including those regarding misbranding and false claims. The lack of a standard laboratory efficacy test method has resulted in manufacturers using different approaches to make efficacy claims. This lack of standardization has led to the confusion in the healthcare industry. For example, when looking at HAI-related uses of UV in healthcare facilities for applications to air and surface decontamination, EPA regulations only require registering manufacturers of UV antimicrobial devices, not the devices, nor are there any efficacy standards for demonstrating performance. Moreover, any germ-killing efficacy claims by the manufacturer may or may not be supported; when they are, the claims are based on the manufacturing company's laboratory tests (either in-house or by an independent laboratory) and whatever standard the testing laboratory may choose. While many manufacturers have excellent data to support disinfection claims, there are no efficacy standards, metrics or uniform testing methodologies for comparing one device's data against others, making it a "Wild West" in the healthcare market.

2.1 Confusion Runs Rampant. The uncertainty in the landscape stems from several reasons. First, there are many manufacturers of UV sterilizer products and antimicrobial devices which are effective and useful for many applications (Table 1 and Figure 4).

Table 1. UV-C light sources for sterilizer products and antimicrobial devices.

<u>Primary UV light sources</u>	<u>New wavelengths of interest</u>
<ul style="list-style-type: none"> Mercury-based <ul style="list-style-type: none"> primarily low pressure ~85% spectral output at 254 nm Xenon-based - broad spectrum LEDs – output wavelength can be specified 	<ul style="list-style-type: none"> Vacuum-UV (100 nm – 200 nm, 205nm, 222nm); often in portable, hand-held devices Violet - blue light (>400 nm), used in a high-intensity narrow-spectrum light environmental disinfection systems

Depending upon the model and design of UV-C light sources, each can differ greatly in their specifications, for example the spectral bandwidth and power output can be vastly different among devices. Hence, instrument comparisons are difficult, if not impossible. In addition, no standardized testing procedures are in place to compare or measure the performance of these devices.

The lack of regulation and standards has led to the development and introduction of unique testing and evaluation programs throughout the industry, often with the use of different pathogens, concentrations, testing methodologies and

efficacy criteria. The over-abiding result is that there are no clear-cut paths for comparing one unit against another easily, thus often allowing cost to be the deciding factor for a hospital administrator. But, should cost be the only available deciding metric? Going forward, it is expected the development and use of performance parameters and metrics that are acceptable by industry and customers will be necessary to tame the “Wild West” market landscape.



Figure 4. Examples of the more than 40 manufacturers of UV sterilizers. Manufacturers produce all types of devices for air, water and surfaces. More than a dozen companies manufacture UV whole-room devices.

2.2 The International Ultra Violet Association Approach. The International Ultra Violet Association (IUVA) and its member companies and affiliates feel it is incumbent upon them to recognize this knowledge, performance and metrology gap – and act. The IUVA is helping to explore ways to develop science-based answers to the healthcare industry’s questions surrounding standards and measures of device disinfection efficacy, as well as reliability and durability. To that end, in September 2017 the National Institute of Standards and Technology (NIST)¹ hosted IUVA and RadTech—The Association for Ultraviolet and Electron Beam Technologies, to meet and discuss how UV

¹ As a non-regulatory agency of the U.S. Department of Commerce, NIST promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. To learn more about NIST, visit www.nist.gov.

antimicrobial devices may reduce HAIs and how efficacy standards could enhance those life-saving results across the healthcare industry^{8, 20}.

In collaboration with NIST, IUVA and RadTech are exploring ways to reduce these discordant market conditions and answer the healthcare industry's questions surrounding standards and measures of device disinfection efficacy, as well as reliability, operations and durability, and are turning to NIST for help to solve the standards dilemma. The Associations sought to draw from NIST's collaborative partnerships experience with manufacturers, their associations, academia, and the public sector in standards development and are looking for ways to establish a Federal-industry-public sector initiative in this technical area. It is envisioned that the adoption of standardized UV technology in the healthcare industry is a solution to combating HAIs and saving lives. The conversation with NIST on standards development and partnerships has been a great place to start for realizing this vision.

2.3 IUVA 2018 America's Conference. Combating HAIs through standards development was most recently discussed at the IUVA 2018 America's Conference in Redondo Beach, California in several panel sessions with subject matter experts from industry, academia and government in attendance as participants and speakers. An output of the HAI panels was the formation of a formal IUVA Working Group for the Development of Antimicrobial Standards and Initiatives for the Healthcare Industry. The goal is to provide global guidance, with specific programs and deliverables, on the use of UV technologies and standards to combat HAIs and to further the stated aims of the IUVA on its outreach to the healthcare industry.

The working group will develop a set of standards, guidelines and guidance documents related to healthcare applications that include standard methods for validating performance of UV devices and test guidelines for efficacy measurements, as well as discussing the development of a UV roadmap for overall healthcare to include outlines of issues, problems, potential solutions and needs for the future growth and success of the UV industry in healthcare application space. Standards development activities have proven to have a pronounced effect on product development and the success of businesses in the marketplace. Implementing standards and science-based metrology to ensure that product compliance and other requirements for trade have been successfully met, has been shown to streamline manufacturing processes and trim costs leading to increased market share and an improved bottom line.

2.4 Need for Standards. It was clear from the IUVA 2018 America's Conference HAI panel discussions that the development of UV light measurements and standards is critically needed to grow and expand UV technology in all phases of disinfection. Industry wide collaboration and cooperation is needed. The first step is to identify the main needs and then determine positive solutions. It is clear that consensus-based measurements and standards are needed in the UV technology sector; they are infrastructural and typically, if designed properly, *pose no competitive advantage to one single company*. Companies can openly and readily cooperate together at that level. Once the required solutions are identified addressing the infrastructural measurement and standards needed, the solutions can be taken back "behind the curtain" and developed and applied to proprietary processes throughout the industry at the discretion of individual companies. This approach has been extremely successful for the semiconductor and other industries and can be readily applied to the UV industry.

The Working Group, comprised of members from industry, academia, and government, are developing standards and an approach for the implementation of these by:

- 1) developing methods to measure the angular dependent radiant intensity of UV devices
- 2) developing methods for the:
 - a. electrical and UV measurement of low and medium pressure mercury lamps and LEDs;
 - b. electrical and spectral radiant intensity and irradiance of UV luminaire disinfection systems;
- 3) modeling the exposure of surfaces within an environment to be disinfected based on the radiant intensity distribution;
- 4) comparing the exposure to the amount of flux needed to inactivate the target organisms; and
- 5) verifying, after installation, the model and implementation are effective.

3.0 CONCLUSION

Ultraviolet-C devices have been shown to reduce the incidence of many healthcare-associated infections by 35% or more, yet there are many science-based needs that must be addressed for the wide-spread adoption and use of the technology. Healthcare administrators need credible and comparable results for making decisions on investments in lamps for HAIs in new or retrofit hospitals. The lack of Federal or industry standards have led to the development of one-off metrics. Metrics tend to vary by manufacturer and efficacy measurements vary with use of percentage of pathogen reduction vs. percentage reduction in hospital infection rates, coupled with or without other cleaning regimens. There is also a variation of the basis of tests with respect to *C. diff.*, MRSA, or others, and there is no common basis for evaluating one UV device with another.

NIST has engaged with the IUVA and its member companies and affiliates to explore how standards and measures of device disinfection efficacy, reliability, operations and durability may help address these needs. Leveraging this partnership is essential to implement standards through federal participation in the development and use of voluntary consensus standards and in conformity assessment activities.

Clearly, the potential for this technology is huge. Industrial cooperation and coordination is foremost to develop the needed roadmap. There are many facets to this industry, but this is no different than other similar entities. Perhaps a consortium of the companies to coordinate these activities and provide the infrastructural guidance and roadmapping exercises is in order. Such a consortium can speak for the entire industry and provide leverage no single company can wield. Fundamental change can be affected through a path of advancing UV efficacy standards and testing protocols to demonstrate the advantages of UV for combatting HAIs while advocating its increased implementation through education and outreach programs targeting the Nation's healthcare sector.

Acknowledgements: Thank you to the members of the working group for their enthusiasm, hard work, and thoughtful discussions on standards development for combating HAIs. Visit www.iuva.org for more information on the working group. A special thanks to Gary Cohen of the IUVA for his leadership, guidance and input. Thanks as well to Mickey Fortune for his support and help with logistics and coordination.

Disclaimer: Certain commercial equipment is identified to adequately describe the experimental procedure. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that the equipment identified is necessarily the best available for the purpose.

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