



DEVELOPING SCIENCE INTRODUCING TECHNOLOGIES

EXPLORE
A Quarterly Publication
from
You First Services Inc.



Satish Sharma M.D., FACS
Executive Chairman

You First Services Overview

Established in 2013 in western New York, You First Services, Inc., has made numerous successful strides. Precise operations, diverse collaborations, excellence in execution, and acquiring new scientific technologies have laid a strong foundation for our continued success. In a short period of time, the company has been awarded with prestigious grants like CAT grant and National Grid grant in recognition of its ongoing innovative endeavors. The company envisions to be a leader in scientific development and continue to expand its horizon with its expanding operations,

steadily increasing international collaborations and contribute towards the economic growth. The company has successfully launched subsidiaries following development of the technologies and has generated employment locally. With our team of world class scientists, we will take benefits of science to the doorsteps where it is needed the most.

Exploring Clinical and Applied Research

Systematic investigation, testing, evaluation and development designed to contribute to generalizable knowledge is research. Applied research is the one used to answer a specific question that has direct application to the world and is intended to solve the problems. Health research should necessarily be more meaningful to individuals. Innovative solutions to the increasing societal needs are much needed to develop sustainable patterns of living as natural resources may not be sufficient for all needs. Societal interests are significantly affected if the research enterprise is impeded or is less robust. New opportunities at an early stage have to be identified and technologies emerging from the knowledge base have to be developed. This however is a daunting task. Science today is changing rapidly and becoming more complex. No single researcher or single site can bring all the expertise to develop and validate medical

innovations. Interdisciplinary collaborations in clinical and the applied research areas have helped meet these challenges significantly. Collectively, these forms of research have led to novel innovations and development of unique applications that significantly impact the healthcare of the individuals while bringing the individual benefits of improved health. Medical research can have an enormous impact on human health and longevity which in turn contributes hugely to the national economy by increasing the productivity of a healthy population. Introducing these technologies to general population is another major challenge that has to be met with innovative strategies and human resources.

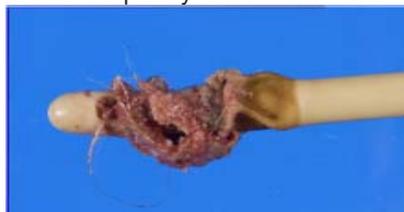
In This Issue

- **Message from the Executive Chairman.**
- **Biofilm Induced Infections.**
- **Superbug Infections and endoscopes. What is the Answer?**
- **Ethical Research at You First Services Inc.**
- **Our Success**
- **Clinical Trials**
- **Welcome New Employees**
- **Our Collaborators**
- **YFS Foundation News**

Bio-film induced infections

Bindukumar Nair PhD.

Catheters and medical tubes are used in clinical applications generally for administering intravenous fluids, blood products, drugs, and parenteral nutrition, and draining fluid or urine from the urethra or gastrointestinal tract. Nosocomial infections frequently arise from bacterial



colonization of medical devices and implants [1]. Catheters are also responsible for a high incidence and risk of complications such as catheter-related bloodstream infections [2], ventilator associated pneumonia, and urinary tract infections [3]. Catheter associated urinary tract infections (CAUTI) are one of the most frequent infections today and the risk



of developing it in the acute care setting is 3 -7% [4]. CAUTI comprise 40% of all institutionally acquired infections [5]. The Centers for Medicare and Medicaid Services (CMS) identified hospital acquired CAUTI as one of eight conditions for which hospitals will not receive additional reimbursement [6]. In spite of the best efforts, an effective agent to prevent catheter related urinary tract infections has so far not been identified.

Virtually all indwelling catheters are colonized by microorganisms embedded in a biofilm matrix. The most commonly isolated bacteria from catheter biofilms are *Staphylococcus epidermidis*, *S. aureus*, *C. albicans*, *P. aeruginosa*, *K. pneumoniae*, and *E. faecalis*. These organisms originate from patient's skin microflora, exogenous microflora from health-care personnel, or contaminated infusates. They gain access to the catheter by migration externally from the skin along the exterior catheter surface or internally from the catheter hub or port. Colonization of these devices can occur rapidly (within 24 hours) and may be a function of host-produced conditioning films, platelets, plasma, and tissue proteins. Most often microorganisms colonize the external catheter surface by adherence and thereby creating a biofilm [7]. Biofilms are complex structures that include bacteria,

host cells and cellular by-products, and are proposed to be a primary mechanism in the development of catheter associated urinary tract infections. Biofilms are responsible for about 60% of all microbial infections in the human body and the induced infections are usually never completely eliminated and are responsible for recurrent infections. Bacteria in the



biofilms could be one thousand times more resistant to antibiotics than the same bacteria grown in liquid medium. This is because the cells produce extracellular polymeric substances (EPS) which form very adhesive gels with water and binds them to the surface [8].

Medical device-associated infections are mainly caused by bacterial attachment to, and colonization of the device surface [9]. There are attempts to prevent bacterial adhesion to the device surface using antibacterial coating [10]. With the empirical observations and historical use of silver and silver formulations as antibacterial materials silver compounds and silver nanoparticles are used for generating antibacterial surfaces. [11]. Silver was almost replaced by other antibacterial compounds after the penicillin revolution of the 1930s.

In order to decrease biofilm formation and encrustation and to reduce the coefficient of friction of the biomaterials of urethral catheters and urethral stents it can be coated with different materials. Hydrogel coatings, which are composed of a hydrophilic polymer, are the most common coating material. Coatings that have been directed against urinary tract infections include various antibiotics, such as ciprofloxacin, silver, nitrofurazone, minocycline and rifampin. Coatings that have been directed against encrustation include phosphorylcholine and pentosan polysulfate sodium.

The widespread use of biomaterials in the urinary tract, such as urethral catheters and ureteral stents, will undoubtedly continue in the future. Ongoing research is essential to optimize biocompatibility and decrease biomaterial related complications, such as patient discomfort or pain, bladder irritability, infection and encrustation within the urinary tract. With continued research into catheter biomaterial development and improvements in biofilm removal

technology we can expect further improvements which will result in a significant decrease in or perhaps even elimination of biofilm related infection and morbidity.

References.

- [1] D.C. Vinh, J.M. Embil, Device-related infections: a review, *J Long Term Eff Med Implants*, 15 (2005) 467-488.
- [2] S.M. Gordon, S.K. Schmitt, M. Jacobs, N.M. Smedira, M. Goormastic, M.K. Banbury, M. Yeager, J. Serkey, K. Hoercher, P.M. McCarthy, Nosocomial bloodstream infections in patients with implantable left ventricular assist devices, *Ann Thorac Surg*, 72 (2001) 725-730.
- [3] C.D. Givens, R.P. Wenzel, Catheter-associated urinary tract infections in surgical patients: a controlled study on the excess morbidity and costs, *J Urol*, 124 (1980) 646-648.
- [4] E. Lo, L. Nicolle, D. Classen, K.M. Arias, K. Podgorny, D.J. Anderson, H. Burstin, D.P. Calfee, S.E. Coffin, E.R. Dubberke, Strategies to prevent catheter-associated urinary tract infections in acute care hospitals, *Infection Control*, 29 (2008) S41-S50.
- [5] U.D.o. Health, H. Services, Urinary tract infections in adults (USDHHS Publication Series 13, No. 157), Hyattsville, MD: US Government Printing Office, (2004).
- [6] S. Saint, J.A. Meddings, D. Calfee, C.P. Kowalski, S.L. Krein, Catheter-associated urinary tract infection and the Medicare rule changes, *Annals of Internal Medicine*, 150 (2009) 877-884.
- [7] S. Saint, J.G. Elmore, S.D. Sullivan, S.S. Emerson, T.D. Koepsell, The efficacy of silver alloy-coated urinary catheters in preventing urinary tract infection: a meta-analysis, *The American journal of medicine*, 105 (1998) 236-241.
- [8] S.M. Soto, Importance of biofilms in urinary tract infections: new therapeutic approaches, *Advances in Biology*, 2014 (2014).
- [9] S. Taheri, A. Cavallaro, S.N. Christo, L.E. Smith, P. Majewski, M. Barton, J.D. Hayball, K. Vasilev, Substrate independent silver nanoparticle based antibacterial coatings, *Biomaterials*, 35 (2014) 4601-4609.
- [10] G.J. Williams, *Antimicrobial surfaces, Russell, Hugo & Ayliffe's: Principles and Practice of Disinfection, Preservation and Sterilization*, 5th Edition, (2013) 485-499.
- [11] M. Rai, A. Yadav, A. Gade, Silver nanoparticles as a new generation of antimicrobials, *Biotechnology advances*, 27 (2009) 76-83.

Superbug Infections and Endoscopes. What is the Answer?

Michael J. DuVal, Project Manager

You First Services is a research and development company focused on solving healthcare problems that plague scientists and engineers of the 21st Century. One of these areas is our global initiative for preventing the spread of infections.

Last year in April 2015 it made US National News. A particular "superbug" is nearly impossible to eradicate if deposited inside re-usable biomedical equipment such as endoscopes. Even after multiple and heightened cleaning and sterilization procedures, complex endoscopes contaminated with drug resistant superbugs are impossible to clean and sterilize with FDA Approved liquid chemical sterilants. The fact is in recent years both in the USA and worldwide the rate of hospital-acquired infections has increased substantially. Infections transmitted from endoscopes is a real problem. As a matter of fact recently some endoscope manufacturers have changed their designs to make them easier to re-process.

Magnitude of the Problem:

What are the existing solutions? There are many FDA Approved products and procedures for re-processing endoscopes between patients. The use of High Level Disinfectants are the most common. Typically endoscopes that make contact only with mucus membranes are re-processed using concoctions of enzymatic cleaners, detergents, and special formulations of 2% glutaraldehyde solution with surfactants. The efficacy of these

methods depends on prior, meticulous manual cleaning with brushes. Manual cleaning is time and labor consuming, and there may be difficulties to ensure coverage.

Since the advent of synthetic materials and the discovery of bacteria and other infectious micro-organisms, it has been well known that infections are spread through making blood or mucus membrane contact with hard surfaces contaminated with infectious micro-organisms. Endoscopes used in procedures that penetrate the blood-tissue barrier are the critical and must be rendered sterile prior to use.

Currently accepted sterilization methods include the use of Vaporized Hydrogen Peroxide, Low Temperature Hydrogen Peroxide Gas Plasma, and Ethylene Oxide, among others. Each one of these technologies has limitations and restrictions for use with endoscopes and devices with long and narrow lumens and intricate mechanical mechanisms.

All of these existing solutions share the same problem: The inability of the sterilants to penetrate or diffuse into long and narrow cavities. Developments that promote enhanced penetration or increasingly rapid diffusion of antimicrobial agents into these hard to reach locations are likely solutions to solve this problem.

Material science and material processing techniques of the 21st century make it possible to produce synthetic materials with extremely complex and intricate shapes. Re-useable medical devices are often fabricated from

synthetic materials drawn into "complex shapes", specifically designed to enter into sterile cavities of the body to produce the least invasive surgeries. Endoscopes and other expensive, intricate, and tubular-shaped medical devices with cavities are becoming more and more popular in diagnostic and surgical procedures.

Sterilizing medical devices composed of long and narrow lumens is You First Services primary area of focus for our new products. The tradenames EQM Technologies Inc. GloTran™ Plasma and H2-Flo Hydrogen Peroxide diffuser. These two products are specifically targeted to solve the endoscope lumen problem in the area of terminal sterilization of reusable hard surface lumens in the medical field. Hospitals, endoscopy clinics, dental clinics, many more medical institutions will hugely benefit after these technologies are approved for use. This package will offer medical professionals a new convenient, rapidly-acting plasma sterilizer. It incorporates a low-temperature hydrogen-peroxide gas plasma designed to permit enhanced diffusion to previously inaccessible medical device lumens in the following categories of re-usable medical devices:

- Endoscopes
- Duodenoscopes
- Biopsychannels
- Pleuravideoscopes
- Laryngoscopes
- Rhinolaryngoscopes
- Cystoscopes
- Bronchoscopes
- Gastrosopes
- Ureteroscopes
- Duodenoscopes

And many more

Ethical Research

Jeffrey S. Eberhard, Ph.D., Quality Systems and Regulatory Affairs Manager

When most people think of ethics (or morals), they think of rules for distinguishing between right and wrong, such as the Golden Rule ("Do unto others as you would have them do unto you"), a code of professional conduct like the Hippocratic Oath ("First of all, do no harm"), a religious creed like the Ten Commandments ("Thou Shalt not kill..."), or a wise aphorisms like the sayings of Confucius. This is the most common way of defining "ethics": norms for conduct that distinguish between acceptable and unacceptable behavior. There are several reasons why ethical conduct of research is important.

- The norms for conduct promote knowledge, truth and avoidance of error,
- These norms promote the values that are essential for collaborative work,
- Public accountability is important, and
- Adherence to these norms promotes public support for research,
- Research norms promote other social values such as social responsibility, human rights, animal welfare, compliance with the law, and public health and safety.

It follows then that the principles comprising ethical research include:

- Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, research sponsors, or the public.
- Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required. Avoid or minimize bias or self-deception. Disclose personal or financial interests that may affect research.
- Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.
- Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.
- Share data, results, ideas, tools, resources. Be open to criticism and new ideas.
- Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.
- Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.
- Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.
- Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.
- Respect your colleagues and treat them fairly.
- Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.
- Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors not related to scientific competence and integrity.
- Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.
- Know and obey relevant laws and institutional and governmental policies.
- Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.
- When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

Adapted from D.B. Resnick, "Research Ethics," December 2015

Our Success

New Products

You First Services has successfully developed research based technologies introduced by Independent Companies under the banner of Swish Energy (www.swish4energy.com), Lubricity Innovations (www.lubricityinnovations.com) and EQM Technologies (www.eqmtechnologies.com). The company continues to develop multiple research projects in the field of infection, environmental research, health care



Strategic Partnership with TPRC, University at Buffalo

You First Services, Inc., and the Translational Pharmacology Research Core (TPRC) at the University at Buffalo's Center of Excellence, will enter into a strategic academic business partnership for global implementation of technologies. The TPRC is an internationally recognized leader in antiviral pharmacology, and has an expanding global health program. You First Services, Inc., a recipient of Start-Up New York, is a research and development company, who commercializes technologies that have been invented by scientists of repute. The company strives to explore innovative and unique health solutions to enhance and improve lives through research and development. You First has an interest in global health initiatives, specifically in reducing the transmission of secondary infections. We target scientific collaborations, high profile partnerships, and scientific ventures with progressive, innovative and ethically like-minded groups such as Dr. Morse and the Translational Pharmacology Research Core (TPRC) at the University at Buffalo's Center of Excellence.

Western New York's Innovation Hot Spot Grant

You First Services, Inc. has been awarded **Innovation Hot Spot Grant**. The grant promotes cooperation among incubators and expands entrepreneurial services to dramatically help incubated startups and grow wealth in the Western New York region. You First Services has received this grant due to the company's good standing with the University at Buffalo Technology Incubator.

You First Services, INC. Awarded CAT Grants

You First Services, Inc. has been awarded two "University at Buffalo Center for Advanced Biomedical and Bioengineering Technology (UB CAT) Grants. The first project, "Phase II: Xerostomia Dry Mouth Relief IRB Clinical Trial," was developed with the Center for Dental Studies at the State University of New York (SUNY) at Buffalo. The Center for Dental Studies has a productive and successful history of working within the industry. Perhaps the most important strength of the center, is its ability to provide comprehensive services such as developing research protocols, performing basic scientific and clinical studies for new product introduction and/or product enhancement, coordinating multi-center research, and facilitating technology transfer to industry. The second project, "Removal of Biofilms from Catheters," has also been awarded with the above mentioned grant. You First Services, in coordination with multiple University at Buffalo departments, is pursuing this exciting clinical research to introduce innovative technology to combat catheter acquired infections.

Clinical Trials

VAGINAL DRYNESS

Estrogen levels decline during the menopause transition and after menopause. One of the consequences of this normal decline in estrogen is vaginal atrophy, which in many women causes symptoms of dryness, lack of lubrication and dyspareunia. In this study we propose to test a novel lubricating solution for treatment and tolerability in women with symptomatic vaginal dryness.

XEROSTOMIA TREATMENT

A number of patients suffer from xerostomia. Xerostomia may be caused by medications, or various conditions which affect the salivary glands, including Sjogren's syndrome. These individuals have difficulty in eating, have irritated oral tissues, and a poor quality of life because of this. There is a need for an oral care product to make these patients more comfortable.

DRY MOUTH AND DIABETES

Xerostomia (dry mouth) has been reported to be a common complaint of patients with diabetes, Without adequate saliva production, both hard and soft tissues of the mouth can be severely damaged and become more susceptible to infections. In this study, we propose to test a novel solution for treatment of dry mouth and its tolerability in type 2 diabetes patients with symptomatic oral dryness

SPEECH THERAPY PATIENTS

One common concern of those undergoing invisalign treatment, is the development of speech impairment upon invisalign tray delivery. There is a need for an oral care product to make these patients more comfortable. In this study, we propose to test a novel mouth lubrication solution for the improvement of articulation problem during invisalign treatment.

DRY MOUTH IN SLEEP APNEA

Dry mouth or xerostomia, happens when the mouth doesn't produce enough saliva for proper lubrication or the saliva produced dries up due to some medical conditions. During routine clinical practice, it is observed that patients with suspected obstructive sleep apnea (OSA) often reported waking up with a dry mouth during the night or in the morning and impacts quality of life. There is an urgent need for an oral care product to make these patients more comfortable.

WELCOME NEW EMPLOYEES



Jeffrey Eberhard
 Manager of Quality Systems
 And Regulatory Affairs.



Robert Eisenhauer
 National Sales Manager



Collaborators

Manoj Jacob Mammen

Dr. Mammen is an Assistant Professor of Medicine, Division of Pulmonary, Critical Care and Sleep Medicine at the State University of New York at Buffalo. He also serves as the medical director of the Western New York Lung Cancer screening program at Kaleida Health. His research expertise is in the fields of Pulmonary medicine; Critical Care medicine; Biomedical informatics; airways proteome; airways microbiome.

Michael Hatton

Dr. Hatton is currently a Clinical Associate Professor in Oral diagnostic Sciences. He has served as the school's Director of Oral Medicine and Urgent Care Dental Services. He was in the private practice of Oral and Maxillofacial Surgery for 25 years, and has taught students and residents since 1985. He has been a full time faculty member at the School of Dental Medicine since 2007, after retiring from private practice. Dr. Hatton has over 30 papers, and 35 abstracts in the scientific literature. He was Chairman of the Department of Dentistry at the Millard Fillmore Hospitals from 1988-2001, and Chief of Oral and Maxillofacial Surgery during that time.



YFS FOUNDATION

YFS foundation is a charitable organization formed by You First Services Corporation in order to promote or aid charitable, scientific, educational and humanitarian activities with a special emphasis on those activities that improve the lives of girls in developing and underdeveloped worlds. YFS Foundation is a 501(c)(3) tax exempt charitable organization.



CONTACT: YOU FIRST SERVICES, Inc. 1576 Sweet Home Rd, Suite 219, Amherst, NY 14228
 Ph: (716) 204-7215
 Any questions please contact: Bindukumar Nair Ph.D., bnair@youfirstservices.com