

A G E N D A

APRIL 11-13, 2011 ■ LINCOLNSHIRE, ILLINOIS



MONDAY, APRIL 11

Pre-Conference Workshops

2:00 PM – 4:30 PM

Can We Improve the Care of Patients Undergoing Long-Term Indwelling Bladder Catheterization?

David Stickler, BSc, MA, D Phil, Chair

The indwelling bladder catheters used in such large numbers today have changed little in design from the devices introduced into urological practice by Dr. Frederick Foley in the 1930s. While they are a convenient way to manage urinary incontinence and retention, complications in the care of catheterized patients are common. The placement of the Foley catheter in the bladder undermines the important defenses of the urinary tract against infection. Catheter-associated urinary tract infection is thus a major problem in both healthcare facilities and the community. The morbidity induced in many elderly and disabled people undergoing long-term catheterization and the costs to health services of dealing with the problems are not acceptable in the twenty first century.

In this workshop the speakers will talk about their experience of dealing with the problems induced by Foley catheters. The attempts made over the years to improve both catheter design and management will be reviewed. The contribution of development of antimicrobial catheters to the improvement of bladder management will be discussed.

Finally, suggestions will be put forward outlining how clinicians and academics could work with medical device companies to produce strategies for draining urine from debilitated bladders that will not cause infection and its associated complications.

2:00 PM

Welcome and Introduction; outlining the program and the aims for this workshop

2:10 PM

Complications in the Care of Patients Undergoing Long-Term Indwelling Bladder Catheterization

Roger Feneley, MA, MChir, FRCS, DSc (Hon)

2:40 PM

What Can Be Done to Improve Catheter Design and Management?

Calvin Kunin, MD, MACP

3:10 PM

Break

3:30 PM

Do Antimicrobial Catheters Prevent Infection?

David Stickler, BSc, MA, D Phil

4:00 PM

Panel Discussion

4:30 PM – 6:00 PM

From Concept to the Market

Al Maslov, BSEE, MSEE, MBA, Chair

This workshop is designed to provide the participant an opportunity to work on the practical aspects of commercializing an idea. The session will be led by four individuals representing the points of view of academia, industry, and the financial world, having between them over 100 years of experience in the field of continence care. The workshop will allow you to work in small groups and address such questions as: Where do new product ideas come from? What steps does one take in developing an idea into a product? How does one get funding to bring the idea to market? What to do to market a continence care idea or product.

Expert Mentors: Jeff Bark, MS, R&D Hollister Incorporated; Jay Goldberg, PhD, PE, Associate Professor Biomedical Engineering, Marquette University; David Hughes, MBA, Vice President, Technology Sourcing

6:30 PM – 9:00 PM

What's New and What's Coming Soon

Alan Cottenden, PhD and Mandy Fader, PhD, RN

In this workshop Professors Alan Cottenden and Mandy Fader will present a digest of all the academic and clinical literature and conference proceedings relating to technology for managing incontinence which have been published since the Innovating conference in April 2009. Although their primary focus will be on products such as catheters and pads, they will also report on a wider spectrum of work which may be of interest to – and have an impact on – incontinence technologists. They will also give brief mention to ongoing work known to them which has yet to be published.

TUESDAY, APRIL 12

7:30 AM

Registration Desk Opens

8:00 AM – 9:00 AM

Breakfast

9:00 AM – 9:15 AM

Welcome and Introductions

Professor Alan Cottenden,

Chair 2011 Innovating for Continence: The Engineering Challenge

9:15 AM – 9:45 AM

Long-Term Bladder Drainage – A Demanding Challenge in the 21st Century

Roger Feneley, MA, MChir, FRCS, DSc (Hon)

Thousands of catheters are used for urinary drainage every day, yet the subject presents many unmet problems. The indwelling catheter, described by Dr. Foley in 1937 as “the finally perfected catheter” remains in universal use worldwide in men and women despite its high morbidity. Professor Feneley will report his studies on the complications

caused by catheter encrustation and blockage in patients undergoing long-term catheterization. Evidence of the association of stone formation in the bladder with recurrent catheter encrustation will be presented. He will propose that new approaches based on detailed attention to the pathogenesis of catheter-associated infections are needed in order to develop a new generation of urine collection systems for the 21st century.

Professor Feneley is an emeritus consultant urologist in Bristol, England and a Visiting Professor to the University of the West of England. The assessment of bladder function and the management of urinary incontinence have been subjects of major interest throughout his professional life.

9:45 AM — 10:15 AM

Are Smart Textiles Smart Enough to Tackle Incontinence?

Sundaresan Jayaraman, PhD

Smart textiles sense heat, moisture, chemicals, light, pressure and body functions, and log the information or, cleverer still, respond by changing their properties to deliver desired effects. In theory, they might keep you warm, dry, moisturized and free of bacteria, odor and stains while measuring your heart rate. Technology innovations are the key to enhancing the quality of life for everyone. They have the potential to successfully address both the psychological and physical consequences of incontinence. In this lecture we will first examine the issue of incontinence and lay the foundation of a framework for the engineering design of potential solutions to the problem. We will then discuss the role of interactive textiles as a key enabler in realizing a feasible solution. Finally, we will discuss the importance of technology innovation in bringing about transformation change in the area of incontinence, to ultimately enhance the quality of life for those suffering from it.

Dr. Jayaraman is a Professor at Georgia Institute of Technology, School of Polymer Textile and Fiber Engineering, and College of Management.

10:15 AM — 10:30 AM

Discussion

10:30 AM — 10:40 AM

The Lived Experience*

Louise Mott, RN

10:40 AM — 11:00 AM

Break

11:00 AM — 11:30 AM

Misbehaving Bladders: Urinary Incontinence Explained for Engineers

Mandy Fader, PhD, RN

How is the bladder supposed to work? How can it go wrong? If it does, what are the consequences in terms of the frequency, volumes, flow rates and contexts of any

incontinence? Mandy Fader will review the physiology and pathophysiology of the male and female lower urinary tracts, focusing particularly on the facts of interest to those working to develop effective technology for incontinence management.

Dr. Fader is a Professor at the University of Southampton's Continence Technology and Skin Health Group.

11:30 AM — 11:40 AM

Discussion

11:40 AM — 12:40 PM

Incontinence on a Daily Basis: Patient Panel

A key step in successful engineering design is to establish a clear understanding of what consumers want and what matters to them; what are their perspectives and priorities. In this session we will hear from a panel of people, each having many years experience of managing their incontinence. We will ask them to describe: how their bladders and bowels misbehave; how they currently manage (including describing the strengths and limitations of their products); what their incontinence stops them from doing (easily) that they would like to do; and finally to describe what their perfect product would need to do.

12:40 PM — 1:45 PM

Lunch

1:50 PM — 2:20 PM

Mommy, Where Do Ideas Come From?

Paul Plsek, BS, MS

While many believe that creative thinking is a special gift, bestowed on only a few, cognitive science research indicates that the ability to generate innovative ideas is a common capacity that we all possess. Innovation most often occurs at the intersection of fields. It is what happens, for example, when a surgeon works with an adhesives chemist to create glue that closes wounds and eliminates stitches. As this conference is a wonderful collection of individuals from diverse fields, the potential for creative idea generation is high. But this potential energy will only become kinetic if we learn the process to convert it. In this session we will explore the mental mechanics and tools of 'directed creativity' and equip you to produce more and better ideas, both here and when you return home, in order to improve the lives of people with incontinence.

Paul Plsek has an MS in Electrical Engineering from Polytechnic Institute in New York, and is the developer of the concept of Directed Creativity.

2:20 PM — 2:50 PM

The Audacity of Hand Washing: When Hubris and Hunch Confound a Brilliant Innovation

Rick Rader, MD

The adoption of any innovation is impacted by many variables, including cultural climate, timing, vulnerabilities, old guard stamina and sensibilities. Understanding the launch,

the generation of the wave and the hidden land mines can prove as valuable as the “innovation” itself. Using the 19th century concept of hand washing and its innovator Dr. Ignaz Semmelweis as a case study, we can appreciate how these variables and dynamics interact and can destabilize the most inventive of innovations. We will explore how even “evidence based practices” are ignored, jettisoned and destabilized in the face of the gold standards of “proof”. Hand washing is a template for innovating for continence. The incontinence innovator encounters the same obstacles, mythology, barriers and concrete thinking. This session will help identify the milestones on the innovation cycle that will help to insure your successful contribution in continence technology and therapy.

Dr. Rader is a medical futurist. He is Director of the Morton J. Kent Habitation Center at Orange Grove Center in Chattanooga, TN.

2:50 PM – 3:00 PM

Discussion

3:00 PM – 3:30 PM

On-Body Electrochemical Sensing

Joseph Wang, PhD

The primary focus of Dr. Wang’s career to date has been on non-invasive or minimally invasive glucose bio-sensing for diabetes management, for which he has developed a fascinating range of electrochemical sensors that can be built into clothing. In this lecture he will describe his work, focusing on how the principles he uses for diverse biomedical applications might be harnessed for ends relevant to people with urinary and fecal incontinence, such as detecting odors or leakage from pads and collection devices.

Dr. Wang is a professor of Nanoengineering at the University of California San Diego.

3:30 PM – 3:40 PM

Discussion

3:40 PM – 4:00 PM

Break

4:00 PM – 4:40 PM

Tango: Lessons for Life – A Visual and Metaphorical Presentation to Enhance Communication, Creativity, Team-Building and Leadership

Jeannette M. Potts, MD

This presentation and live dance will serve as an introduction to synergy and team building for a uniquely diverse group of professionals and scientists, charged with improving the lives of individuals with incontinence. Beyond this conference, “tango lessons” will also provide concepts applicable to work, research, and family life. Argentine

tango is the only dance which is 100% lead and follow, never choreographed nor coerced. Because tango is spontaneous and unpredictable, dancers must learn to be present in the moment. Being prepared and in the moment allows us to better listen to one another and to work more synergistically. Anticipation, conversely, distracts from the present and inhibits growth and creativity. Achievement and conservation are among the many expectations of leadership. Effective leaders in tango inspire, maximize and display the talents of their dance partners, while protecting them on uncharted dance floors. Ironically, it is the strongest leader who never employs force, but rather his sensibilities to direct and support the evolving dance steps as he sets them (naturally) into motion.

Dr. Potts is a practicing urologist also known as Dr. Tango.

4:40 PM – 5:10 PM

Crystal Ball Predictions: The Future of Incontinence Technology

Diane Newman, ANP-C, MSN, FAAN

Millions of individuals with incontinence use some type of device or product to manage or collect urine or feces. In some areas, such as care for persons with chronic intractable incontinence, device and product selection is often based on personal opinion, manufacturers’ claims, convenience of the caregiver, or cost of the product. However, research on their clinical uses, adverse complications, and patient satisfaction is lacking. Collaboration among public and private sectors would result in greater likelihood of high quality clinical research that has sufficient power and integrity, more efficient use of resources specific to each care setting, and expedited application of technologies for patient use. This presentation will discuss technology for incontinence, identify areas where technology needs to change or improve, and “look into a crystal ball” to chart a path for the future.

Ms. Newman is co-director of the Penn Center for Continence & Pelvic Health, Urology, University of Pennsylvania, Philadelphia, PA.

5:10 PM – 5:20 PM

Discussion

5:20 PM – 5:30 PM

Summation

Professor Alan Cottenden

6:00 PM – 7:30 PM

Poster Session and Cocktail Reception

7:30 PM – 10:00 PM

Conference Dinner

Host: Al Maslov – Mr. Maslov is a member of the 2007, 2009, and 2011 Innovating for Continence Planning Committees. Keynote Speaker: Christopher Payne, MD, FACS, Honorary President of Innovating 2011

WEDNESDAY, APRIL 13

8:00 AM — 9:00 AM

Breakfast

9:00 AM — 9:30 AM

Making Pads Smarter:

Methods to Add Functionality to Polymer Films

Toby Jenkins, PhD

Dr. Jenkins is a chemist with a fascination for devising innovative ways of modifying polymer surfaces so as to enhance their properties for various end uses, some of which may have application in incontinence technology. He will discuss his work to date, describing what has so far been achieved, and speculating on the benefits that future work might yield. Incontinence pads have low unit value, are relatively low technology devices which, although they perform their primary function of absorbing urine with increasing effectiveness (thanks to advances in super absorbent polymer technology), could be used as platforms for much more. This talk will discuss two projects currently running at the University of Bath, which could have application in future pad technology: active promotion of skin health by microbial control; and simple colorimetric diagnostic technology for patient health, particularly for diabetics.

Dr. Jenkins is a chemist from the University of Bath in England.

9:30 AM — 9:40 AM

Discussion

9:40 AM — 9:50 AM

The Lived Experience*

Mr. Paul LaPorte

9:50 AM — 10:20 AM

Getting to the Guts of What the Bugs Can Do

Glenn Gibson, PhD

Professor Gibson is from a food science department in a university. However, unlike his colleagues, he is far more interested in food after it is eaten than beforehand! His fascination is with the human gut, specifically the trillions and trillions of bacteria in there and what they can do for health. All of us have 20 times more bacterial cells inside us than human ones; so, we are 95% microbe and only 5% human! We need to look after them so they can look after us. Dr. Gibson has built his own laboratory version of the human gut which digests the food it is given and produces feces. He uses this to plan studies in the ultimate model – humans. In this lecture he will describe this kit and share his thoughts on how it might be used to help with work on managing fecal incontinence, possibly by searching for links between diet and odorous flatulence, or providing realistic gut contents for testing of prototype collection devices. In particular, he will discuss the main bacterial causes of fecal

odor; their precursors and alternative gas production routes that are less “odoriferous”.

Professor Gibson is from the Department of Food and Nutritional Sciences, University of Reading, England.

10:20 AM — 10:30 AM

Discussion

10:30 AM — 10:45 AM

Break

10:45 AM — 11:40 AM

The Challenge of Fecal Incontinence

Panel Chair: Christine Norton, PhD, MA, RN

There are few products designed specifically for fecal incontinence. Yet the issues faced with incontinence of urine and feces are understandably quite different, both in terms of local anatomy and their consistency, effect on skin health and odor of the incontinence. In this session Professor Norton – a nurse with over 30 years’ experience in helping people with incontinence – will invite a panel of experienced caregivers to describe the practical difficulties, as well as the emotional effects, that impaired bowel control has on the lives of those they have cared for, and to indulge in some wishful thinking as to what sort of products would make a real difference to their patients’ quality of life. The intention is to give the audience a chance to interact with the panel to refine the “product specification” for some developments that would help real people with real problems.

Panelists: Donna Bliss, PhD, RN, FAAN; Nancy Norton, MA; Jeannette Tries, PhD; Toby Jenkins, PhD

11:40 AM — 12:10 PM

Why are Foley Catheters So Vulnerable to Encrustation and Blockage and What Can Be Done About It?

David J. Stickler, BSc, MA, D Phil

The encrustation and blockage of Foley catheters causes major complications in the care of many people undergoing long-term indwelling bladder catheterization. The problem stems from infection by urease producing bacteria, particularly *Proteus mirabilis*. These organisms colonize the catheter surfaces forming bacterial biofilms composed of enormous populations of cells embedded in a protective polysaccharide matrix. The bacterial urease enzyme generates ammonia from urea and this elevates the pH of the urine and the biofilm. As the pH rises, crystals of calcium and magnesium phosphates form in the urine and biofilm. The continued development of the crystalline biofilm blocks the flow of urine through the catheter and induces a crisis in patient care. The reasons why all currently available catheters are vulnerable to encrustation and blockage will be discussed. Dr. Stickler will also explain how his research on the mechanisms of catheter encrustation has led to a strategy for its prevention and control.

Dr. Stickler is a bacteriologist from the Cardiff School of Biosciences, Cardiff University, Wales.

WEDNESDAY, APRIL 13 *Continued*

12:10 PM – 12:20 PM

Discussion

12:20 PM – 1:30 PM

Lunch

1:30 PM – 2:00 PM

Incontinence and Obesity:

A Double Challenge for Product Designers

Sharon Sarvey, PhD, RN

An increasing number of Americans are becoming morbidly obese, which obviously means a similar trend is evident in the subset of the population with incontinence. Obesity not only adds major difficulties to the management of incontinence for the sufferer and their caregivers, but also raises serious challenges for those seeking to develop effective continence technology. Reduced mobility and difficulty accessing the perineal area, for example, can be highly problematic. In this session Dr. Sarvey will share her experience in nursing bariatric patients with incontinence and will describe the various challenges of this patient population, and also offer her thoughts and insights on potential solutions.

Dr. Sarvey is Dean of the Barton School of Nursing in Wilson, NC and current President of the National Association of Bariatric Nurses.

2:00 PM – 2:10 PM

Discussion

2:10 PM – 3:10 PM

Lessons from Industry:

New Technical Approaches to Continence Care:

Hydrocolloid External Continence Devices

Dennis Kay, MD, CEO Bioderm

Hydrocolloids are well-established materials with proven efficacy in the wound healing and ostomy sectors. In his lecture, Dr. Kay will describe his work over many years to exploit the properties of hydrocolloids to achieve an effective seal with the skin in external continence devices for men. He will describe the design challenges and his approaches to addressing them, from preliminary work through to clinical evaluation. The talk will culminate in a brief discussion of the applicability of hydrocolloid technology for the management of female urinary incontinence.

Dr. Kay is a board certified emergency medicine physician, inventor, scientist, and businessman with extensive medical device industry experience, including more than 20 years with hydrocolloid materials.

The Challenges of Developing an Occlusive Device

Elan Ziv, MD, CEO ConTIPI Ltd,

Amir Perle, VP of R&D ConTIPI Ltd

Women with stress urinary incontinence have few manage-

ment options and most use pads to contain their leakage. A number of attempts have been made to design devices to support the urethral closure mechanism, but none has proved widely efficacious or commercially successful. In this lecture Dr. Ziv and Amir Perle will describe the development of a new product, an IntroVaginal Incontinence Device (IVID), inserted into the vagina with a small applicator and removed by a pull of a string. The lecturers will explain the philosophy behind the design and present technical and preliminary clinical test data. Along the way, they will point out some of the challenges encountered by designers from establishing a clear specification, through generating, sifting, testing and refining different design concepts, to commercialization.

Dr. Ziv is a urogynecologist with a long standing interest in the non-invasive management of urinary incontinence in women, pelvic organ prolapsed, and vaginal drug delivery.

Mr. Perle is a mechanical engineer and VP of R&D at ConTIPI Ltd, a start-up company in Israel.

PTNS: Transforming Bladders One Ankle At a Time

Susan Hartjes Holman, COO Uroplasty, Inc.

Overactive bladder syndrome affects the lives of over 30 million people in the US. Neuromodulation therapy uses electrical stimulation to target specific nerves in the sacral plexus that control bladder function. Percutaneous Tibial Nerve Stimulation (PTNS) is an innovative therapy which provides peripheral, non-surgical neuromodulation to treat overactive bladder, targeting the sacral plexus from an accessible, minimally invasive entry point into the nervous system – the posterior tibial nerve. During treatment, a thin needle electrode is temporarily placed above the ankle to stimulate the tibial nerve and provide symptom relief of OAB. Patients receive weekly 30-minute treatments over 12 weeks, with occasional treatment thereafter to maintain symptom control. This presentation will review the history of this technology and the unique clinical research study design and execution of the Level I SUMiT Trial.

Ms. Holman's biomedical career has spanned preclinical research, manufacturing, quality, regulatory affairs, and clinical affairs. She is the COO of Uroplasty, Inc. with an international focus over two decades on solutions for urinary and bowel dysfunctions.

3:10 PM – 3:25 PM

Discussion

3:25 PM – 3:45 PM

Break

3:45 PM – 3:55 PM

Lived Experience*

Alicia Schuyler Oberman

3:55 PM – 4:45 PM

The Challenges of Caring: The Caregivers Perspective

Many people with incontinence rely on the help of others

WEDNESDAY, APRIL 13 *Continued*

to manage their incontinence. In this session we will invite caregivers – be they professional or family members – to share their perspectives on the challenges of managing incontinence, including the product limitations they have encountered and the impact of those limitations on the quality of life of both the end user and the caregiver.

4:45 PM – 5:00 PM

Evaluations & Closing Remarks

Professor Alan Cottenden

5:00 PM – 6:30 PM

Wine and Cheese Party

**In order for attendees to have a better understanding of intractable incontinence, Mr. LaPorte, Ms. Mott, and Ms. Oberman will speak to the challenges they live with daily in order to manage their incontinence and live full productive lives.*

Planning Committee

The following people have generously donated their time to the development, coordination and planning of the 2011 conference meeting

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England

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Panelists

The Simon Foundation for Continence wishes to thank our panelist for their valuable contributions:

Jean Cavanaugh, Christine Cornell, Mandy Fader, George Flores, Mary Radtke Klein, Janice LaPorte, Louise Mott, Kaoru Nishimura, Rick Rader, Anita Saltmarche, Carolee Stanmar, and Clarinda Valentine.



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