FERTILE GROUND
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Gourmets helping infants and families

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New vaccine research aims to prevent diseases in moms and babies

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HOW A NEW ANTIMICROBIAL FILM MAY DELIVER THE ANSWER IN AN EASY-TO-USE PACKAGE
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The first surprise in recent interviews with Drs. Sharon Hillier and Lisa Rohan is this: HIV is on the rise in certain populations of women around the world. “We’re still seeing increases with regard to new infection rates,” says Dr. Rohan, associate professor, Pharmaceutical Sciences at the University of Pittsburgh and associate investigator at the Magee-Womens Research Institute. “So the need for a female-controlled mechanism of protection is extremely important to impact the HIV epidemic globally.”

The next surprise is delivered by Dr. Hillier, director of Reproductive Infectious Disease Research, at Magee. “Women appear to be biologically more vulnerable to HIV than men. By that, I mean that the efficiency with which it’s transmitted from men to women is greater than the efficiency of transmission from women to men. So if you look at a population of 20-year-old women in South Africa, you’ll see that there are many more young women infected than young men. It’s not a level playing field from a biological perspective.”

What isn’t surprising is that these researchers have teamed up to find an innovative solution. To bring it to life, the doctors were recently awarded a grant by the National Institutes of Health (NIH). “This grant is a fantastic collaboration,” says Dr. Hillier. “The idea is to identify a molecule that’s active against HIV, then deliver the molecule into the vagina in the form of a dissolvable film. Our goal is to provide protection for women for a week at a time. It’s something that’s never been developed before. It’s quite innovative research, and we’re really proud of the interdisciplinary team we have here at the Magee-Womens Research Institute. Without it, we wouldn’t be able to do this kind of work.”
Dr. Rohan adds, “We’re planning to develop a product that can be used to protect women against the acquisition of HIV. Currently women are very limited in what they have available in their toolbox of prevention products for many sexually transmitted diseases (STDs), including HIV. Part of our research, and our part of the grant, is designing drug products that women would be willing to use to protect themselves from the acquisition of STDs.”

An earlier foray into topical microbides involved the use of vaginal gel products. “Gels can be leaky and require applicators for administration, making it extremely difficult if not impossible for women to use in a discreet fashion,” remarks Dr. Rohan. “To overcome these issues, one of our goals became trying to develop a platform that would deliver these antiretrovirals in a way that was more convenient and acceptable for women to use.”

Quick-dissolving film strips, like those found in breath strips, present a possible answer. “In previously funded grants from the National Institute for Allergy and Infectious Disease (NIAID) at the NIH and the Bill & Melinda Gates Foundation, we explored the feasibility of using the film platform,” says Dr. Rohan. “We found that the film was quite feasible. So in the newly funded grant from NIAID, we are using some of the knowledge previously gained to develop a better delivery system for extended release utilizing novel strategies including nanotechnologies. We’re trying to go from a product that women would use just prior to sex to a product that women can use once a week. That way, women could have some duration of time where they would be protected from HIV.”

The film strips offer other benefits, too. “They’re very convenient,” Dr. Rohan says. “They can be packaged in small formats and do not require an applicator, so that makes the product profile very slim and discreet. This is especially important in third-world countries where waste generation could be a problem.” Unlike most vaccines, the film platform does not require cold chain storage, which is a huge issue with mass delivery to the people who need it most. Equally attractive is that it’s inexpensive. “We can make these film products for fractions of a penny per dose. So it makes a more economically feasible
product for purchase by the donors who provide health products for women living in high HIV incidence areas.”

To better understand women’s perceptions about using a vaginal film, Dr. Rohan was recently awarded a grant from the Bill & Melinda Gates Foundation to collaborate with behavioral and social scientists at Carnegie-Mellon University. According to Dr. Hillier, “We’re going to be utilizing early prototypes of the film in different sizes and textures to see how women feel about it and how acceptable it is to use.”

One of the most exciting aspects of this research is the collaboration it’s engendered. “Our research spans everything from engineering, pharmaceutics, and clinical trials to obstetrics/gynecology, epidemiology, mucus biology, and virology. That’s pretty astonishing,” says Dr. Hillier. In fact, it’s a multi-institution grant, involving four different projects and three cores.

The first project, led by Dr. Rohan, is to develop the film dosage forms and look at unique delivery systems such as nano-carriers and nano-pattern films to achieve longer durations of effect. Project two, directed by Dr. Charlene Dezzutti, involves using ex-vivo tissue samples from women and bringing them back to the lab to understand how to protect them from HIV infection. Dr. Hillier leads project three, which involves three to four human clinical trials to look at the film’s acceptability and its impact on the vaginal ecosystem in collaboration with Drs. Katherine Bunge and Butch Moncla. In project four, the researchers will partner with a drug company to complete testing and documentation required by the FDA to bring the newly developed film into the clinic.

Also in the scope of the project are core programs involving the Centers for Disease Control and the University of Washington, where researchers will work to test safety and efficacy of the products in monkey models. At the University of Colorado and the University of Buffalo, researchers will conduct experiments looking at blood levels and modeling to predict correlations between what happens in the laboratory and what happens when the drug is tested in women.

And the effects promise to be just as far-reaching.

“The work that we do is important because it has applications across women’s health areas,” says Dr. Rohan. “The film platform can be applied to female health conditions such as bacterial vaginosis and other conditions that affect the day-to-day lives of women. The versatility of the platform and the multitude of potential applications really positions us to be able to make an impact to several critical areas of women’s health research.”

“Women appear to be biologically more vulnerable to HIV than men.”

-Dr. Sharon Hillier
"There’s other work we’re doing in the Microbicide Trials Network (MTN) where we’re beginning to evaluate products that would both provide contraception and HIV prevention,” adds Dr. Hillier who heads the MTN with Dr. Ian McGowan. “These combination products are game-changers: a woman could use a single product to address her family planning needs while protecting herself from infection.”

Dr. Hillier is quick to add that all these efforts are very connected to the people who will ultimately be using them. “Our research is based on the principle of community engagement at every level,” she says. “That means we have people from the communities in which we work, whether they’re in Pittsburgh or Zimbabwe or Peru. Representatives in those committees work with us every single step of the way to develop research that makes sense for those communities. It’s research that’s putting prevention into the hands of people who need it. The MTN is on four continents in terms of the clinical trials we’re doing.”

**It’s the kind of innovation that could only happen at a place like Magee.**

“The work that we do here in Pittsburgh, with our Pittsburgh collaborators and with our global partners, has the possibility of really impacting global health,” states Dr. Hillier. “People ask me why Pittsburgh is such a hotbed of HIV prevention research. And I say, there is no better place to do it than the place where the polio vaccine was developed. We have that entrepreneurial spirit. Our investment in the work we do and the people who do it is going to bring rewards — not only to the people of Pittsburgh, but globally.”

Dr. Rohan adds, “I have found it wonderful to work at Magee. The collaborations that can be generated, the quality of the researchers that make up the institution, as well as having the volunteers and study participants we work with in our clinical studies, their willingness to participate, is just phenomenal. It’s an ideal place to do reproductive health research.”

It’s a big reason why people and institutions are compelled to fund Magee projects. “Our NIH program officer said that our team has demonstrated that we are able to deliver on our very aggressive timelines and do things that people consider to be high risk,” says Dr. Hillier. “Essentially, even when we propose something that’s a little out of the box and very innovative, people have to have the confidence that we are going to be able to overcome the obstacles that we haven’t even identified yet. I think we were funded because we are seen as a very innovative team that knows how to solve problems and not lose our momentum.”

Dr. Hillier adds, “Magee has a wonderful reputation because we’ve had wonderful care for women for more than 100 years. But we also have great outreach at many different levels, with people who’ve trained here and gone on to other places, as well as collaborative research that we’ve done with partners all over the world. That outward-looking vision in terms of collaboration and training is what makes us really special.”

"Our goal is that the drug would provide protection for women for a week at a time. It’s something that’s never been developed before. It’s quite innovative research, and we’re really proud of the interdisciplinary team we have here at the Magee-Womens Research Institute that allows us to do this kind of work.”

-Dr. Sharon Hillier

To make an impact today that could help save the lives of more women tomorrow, visit [www.mageewomens.org/donate](http://www.mageewomens.org/donate).
When it comes time to test vaccines, there’s one patient population that researchers and drug companies have notoriously shied away from – pregnant and lactating women. Dr. Richard Beigi, chief medical officer for Magee-Womens Hospital of UPMC, is looking to change that.

“The way the drug development pathway has gone for nearly all medications that are used in the population is that pregnant and lactating women are nearly completely excluded from these trials,” says Dr. Beigi. “After the drug receives Food & Drug Administration (FDA) licensure, then obstetric providers assess whether it’s safe or not to use based on a suboptimal database. Then it ends up being used clinically anyway in practice, because pregnant and lactating women have medical conditions that require pharmaceutical attention. This approach is notably paradoxical because in an attempt to protect babies from the unknown effects of pharmaceutical exposures in pregnancy, we as a medical enterprise effectively end up exposing many more pregnant women and fetuses, with less than optimal safety data available to guide appropriate clinical practice.”

Dr. Beigi and his team are working to shift that paradigm by safely and cautiously including pregnant and lactating women in trials for certain compounds and vaccines.

“As sometimes stated, we are aiming to protect pregnant women and their infants through research, not from research,” says Dr. Beigi. He points out that...
immunizing during pregnancy not only prevents diseases in the mother, but also prevents sometimes devastating diseases in newborns. This is because the antibodies that the mom makes after immunization transfer through the placenta into the baby’s circulation, and then persist in the baby for months. "It has a high potential for preventive benefits for both women’s health and the health of their babies," he remarks. “If you don’t test these therapeutics in a responsible manner during pregnancy, the women end up either being exposed to them in early pregnancy, when they don’t know they’re pregnant and with inadequate safety data, or the drugs are used later in pregnancy in an uninformed manner. We’re trying to fill that large knowledge gap in the current research climate in a safe and responsible fashion.”

Dr. Beigi became interested in reproductive infectious diseases in 2001 during a fellowship at Magee. Since then he has also studied the issue of biological preparedness in pregnant women, from natural disasters, man-made disasters, bio-terrorism, and pandemic flu. "Because of my training and interests, I've gotten involved in many aspects of the vaccine enterprise in the United States, from investigative to clinical use to vaccine policy, most specifically in the area of maternal immunization.” One of his goals is to see a maternal immunization platform that focuses on numerous vaccines that are given during pregnancy or in the perinatal period to decrease infectious diseases in mothers and infants. “We may get there because some of our policy efforts have been recognized by the Advisory Committee on Immunization Practices,” he says. As co-chair of the Maternal Immunization Work Group for the National Vaccine Advisory Committee (NVAC), Dr. Beigi and his group make recommendations on national vaccine policy for pregnant women. He’s also working with the American College of Obstetricians and Gynecologists (ACOG), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) on these efforts. In addition, he’s the current president of The Infectious Diseases Society for Obstetrics and Gynecology (IDSO). “It’s a society that has been around for 42 years. Even though it’s a relatively small specialty, members of this group have always been the thought-leaders nationally in these disciplines. As a marker of our local expertise, many previous and current researchers at Magee have been in leadership positions within this society throughout the years.”

**Looking at new vaccines**

Right now, there are national recommendations for use of two licensed vaccines in all pregnant women — the flu vaccine and Tdap, which primarily targets pertussis prevention in newborns. Dr. Beigi and his team at Magee are hoping to help expand those recommendations by participating in studies investigating new vaccines against Group B Strep, RSV (a serious infection of the respiratory tract) meningococcal disease, and potentially CMV, an infection that can cause adverse perinatal outcomes including postnatal developmental delays. "We have numerous trials looking at various vaccine products either already developed or being developed for use specifically during pregnancy,” states Dr. Beigi. “We have also partnered with some of our local pediatric colleagues to perform these studies. These collaborations make sense because these studies involve enrolling pregnant women, immunizing them during pregnancy, following them through delivery, and subsequently following the babies and mothers for about six to12 months postnatal.”
Dr. Beigi adds, “We’re getting ready to launch a new study of a meningococcal vaccine in pregnancy that may help to prevent meningitis in young babies.”

Importantly, Beigi is also getting some research support from pharmaceutical companies. “We’ve done research with two drug companies for the Group B Strep and RSV vaccines. I feel it is very important to support and participate in this research because there are not many companies that are able and willing to delve into clinical trials during pregnancy. I want to support those efforts, because I think pregnant women deserve to be included in clinical studies, and have great potential for benefit from having appropriate products developed specifically for them and their newborns when it’s scientifically and clinically justified.”

In addition to the vaccine research, Magee is working hard to advance the health of pregnant women through antiviral research for the prevention of HIV. “The common thread here is that we are doing research during pregnancy and lactation that has never really been done before,” Dr. Beigi remarks. “Under the leadership of Drs. Sharon Hillier and Ian McGowan within the Microbicide Trials Network (MTN) we are responsibly studying drugs on which we have baseline evidence of safety. One of the most exciting facets of this work is that we are doing clinical trials in pregnant and lactating women that are novel in design and impact.

“We have already done some unique trials with microbicide candidates in pregnant and lactating women. The next study we’re planning to do investigates a microbicide ring, which is currently being evaluated on a large scale for efficacy in sub-Saharan Africa among reproductive age women at risk for HIV acquisition. We’re getting ready to start a phase 1 trial of that ring in lactating women at two sites in the United States: Magee-Womens and the University of Alabama, Birmingham. So again, it fits into the overall scheme of trying to do research in populations that have traditionally either been excluded or forgotten about.”

**Gaining acceptance for maternal immunizations**

In regard to the use of the two currently recommended vaccines, Dr. Beigi says we’re starting to see increased uptake among pregnant women. But some women are still justifiably hesitant, particularly with the flu vaccine. “Nationally, there are increasing rates of vaccine acceptance, but it’s not without its challenges,” he says. “Recognizing those challenges and working on methods to overcome them occupies a bit of my time.”

In fact, Beigi speaks across the country about the benefits of the current vaccines and the potential for even greater benefits from new vaccines. “For clinical care, I tell
mothers that it’s recommended, it’s safe, it protects them from disease and, very importantly, protects their newborns from disease as well. And newborns are very susceptible to numerous infectious diseases, since they have such an immature immune system. For pertussis and flu, babies don’t start getting their own vaccines until they’re older, so they have a window of vulnerability with no real ability to prevent and/or adequately fight off these infections. The most effective way to protect them is through use of the efficacious maternal vaccination approach.”

Dr. Beigi finds that a lot of women will accept vaccines based on the fact that they can potentially help their newborn. This is especially true in regard to influenza [the flu], which has been known to cause serious infections in pregnant women. “There’s increasingly compelling information to immunize pregnant women against flu, for their own protection and also for their baby’s protection. There are now numerous studies showing that immunizing moms prevents diseases in the babies, as well as a large and growing body of evidence demonstrating safety.” Parallel safety and efficacy data are also increasingly seen in regard to the use of Tdap in pregnancy for the prevention of neonatal pertussis.

Only at Magee
By doing these research studies, Dr. Beigi believes we can have a tremendous global impact on maternal and neonatal health in terms of infectious disease prevention. “We’re contributing to a new research paradigm for how to responsibly include pregnant and lactating women, and by definition, their fetuses and neonates, in clinical trials. There are very few places in the world doing these kinds of clinical investigations.”

Dr. Beigi says that’s part of what makes Magee so unique. “All together, we have the resources and focus to do this kind of research. The clinical and research niche in reproductive infectious diseases that has been assembled here really doesn’t exist on the same scale anywhere else. We have a large group of full-time clinical faculty members who are trained in infectious diseases and who also are practicing obstetricians and gynecologists, as well as a robust core of full-time reproductive infectious disease researchers. It’s a very unique clinical and investigative service to have in an obstetrics and gynecology department and I feel very fortunate to be a part of this special group.”

To make a difference in immunization research to help mothers and their babies, visit www.mageewomens.org/donate.
Magee-Womens Research Internships Provide the Experience Needed to Take on Real-World Projects

Magee-Womens Research Institute’s college summer internships provide practical learning experience to a select group of college students, allowing them to participate in eight weeks of hands-on research in Magee’s laboratories, mentored by credentialed research experts from the Department of Obstetrics, Gynecology & Reproductive Sciences and other biomedical areas.

The college program at Magee-Womens Research Institute has significantly impacted the career decision process for a large number of young individuals interested in pursuing a career in science. Our college program provides the necessary skill sets and experiences for these students to gain insight into the various aspects of medical health research, says Lisa Rohan, PhD, senior researcher at Magee-Womens Research Institute.

This year, there were 143 possible candidates. Out of those 143, only eight were chosen.

Erin Gorse, a senior and pharmacy major at Duquesne University, was one of those eight. She applied for several summer internships — including one with NASA, which she turned down — before she chose to work in Dr. Rohan’s lab on a project which develops HIV-fighting drug products.

“I chose the Magee program because it fit better with the pharmacy program I am taking at Duquesne. The NASA program was basically a traditional chemistry one. The Magee internship was so much more. I learned how much detail goes into the technology required to engineer and design HIV drugs that are cost-effective enough to be marketed to third world countries.

“I love research and this internship provided some amazing experiences. I gained more insight into the biologic side of research and how drugs are developed, something in which I previously had little experience.”

Erin is continuing her work with Dr. Rohan’s lab as she enters the Doctor of Pharmacy Program at Duquesne University. “It’s an amazing project with great goals. I’m grateful for the appointment.”

According to Dr. Rohan, “Erin represents one of the bright promising students who have trained in our program. Erin’s summer project contributed to the development of a nanopatterned film dosage form which is being evaluated to deliver anti-HIV drugs to the vagina. HIV continues to be a global epidemic with women now representing more than half of those infected in some parts of the world. It is imperative to develop female controlled methods for protection against HIV infection.

Given their discreet nature and low cost, films are being evaluated as a potential dosage form platform to provide protection against sexual transmission of the virus. Erin’s work will help with the development and optimization of this product platform.”

In addition to experience in the lab, interns attend lunch and learn sessions where investigators discuss biomedical science as a possible career and relate their personal perspectives about the vocation.

At the end of the program, students present their research findings to fellow interns, Research Institute faculty, and staff during the annual College Program Presentation Day.

“My commitment to educating the next generation of scientists is the basis for my passion for our summer internship program at Magee-Womens Research Institute. It is extremely rewarding to have the opportunity to work with the exceptional students within our program who truly represent highly motivated students with a bright future ahead of them. I am confident that these students will contribute in some way to the improvement of human health in the future,” says Dr. Rohan.

Read more about Magee-Womens Research Institute’s High School Internship Program in the next issue of MAGEE magazine.

To support educational programs, like the College Internship Program, at Magee-Womens Research Institute, call 412-641-8977 or visit www.mageewomens.org.
The Women’s Auxiliary Board at Magee-Womens Hospital is a group of women who give their time to ensure that the medical needs of women and children in the Greater Pittsburgh area are met. Originally known as the Women’s Auxiliary of Magee-Womens Hospital, it was first organized in 1937.

Today, the group helps raise funds for research, education, and patient care at Magee. One of the main ways they raise funds is through the Clothes Line resale shop on Liberty Avenue in Bloomfield. The Clothes Line offers gently used, and sometimes never worn, clothing and other items of interest to women. Donors bring in items for resale and are given a receipt for their donations. The money received for the sale of these articles is used to fund the needs of the hospital. Since 2009 the funding has focused on Magee-Womens Research Institute projects. Money raised from the sale of items helps fund projects that attract the best young scientists and investigators.

Susanna Fussenegger has been the Women’s Auxiliary Board president for the last nine months. She has been involved with the Clothes Line resale shop since 2006.

When Susan Fuhrer, who had been the Women’s Auxiliary Board president for 12 years, asked if anyone was interested in taking over the position, Susanna raised her hand. “I was very interested in the research aspect of Magee and wanted to be more involved,” Susanna explains. Then she laughs and says, “And I was the only one who raised my hand!”

“We have two main projects to help raise funds,” Susanna explains. “The Clothes Line and the Baby Picture program, the latter of which employs professional photographers to take pictures of the infants delivered at Magee. A percentage of the proceeds from photo sales goes toward Women’s Auxiliary projects.”

Two of their current programs are aimed at attracting the best research talent to the Magee-Womens Research Institute. “One,” says Susanna, “is MARS, which stands for the Magee Auxiliary Research Scholar program, a program which supports the research work of young investigators. The other is the Bright Star Award, which funds a one-year research project in the amount of $25,000.”

To support the group’s focus on recruiting the top talent in women’s health research to Magee, the Women’s Auxiliary established the...
MARS Scholar Endowment with a gift of $2 million. The first scholar selected for the MARS gift was Judy Yanowitz, MD, who was funded for two-and-a-half years. Dr. Yanowitz’s lab studies the mechanisms that underlie human reproductive aging.

This year, the MARS scholarship was awarded to Mellissa Mann, PhD, who joined Magee-Womens Research Institute in August. Formerly an associate professor of Obstetrics and Gynecology and Biochemistry at the University of Western Ontario, Dr. Mann will investigate epigenetic mechanisms that control genomic imprinting during early embryo development and the impact of assisted reproductive technologies on this regulation.

This 2015 Bright Star Award was awarded to Shannon Grabosch, MD, a postdoctoral associate at Magee-Womens Research Institute. Dr. Grabosch will use the funds to continue research established in during a fellowship at Magee in the area of immunotherapy for aggressive ovarian cancer. The Bright Star funding will provide Dr. Grabosch additional bench work experience that will allow her to cultivate her technical skills and develop a broader understanding of experimental design and laboratory studies as she begins her career as a researcher.

“The support of the Women’s Auxiliary has been instrumental in the Research Institute’s ability to foster the best minds in medicine. These are the researchers who will one day identify break-through discoveries that will yield new cures, more powerful treatments, and innovative therapies,” said Arthur Scully, III, vice president, Development and Communications, Magee-Womens Research Institute.

If you are interested in becoming a member of the Women’s Auxiliary Board, call the Volunteer Office at Magee at 412-641-4185. If you are interested in volunteering for the Clothes Line resale shop, which is located at 4804 Liberty Avenue, call 412-621-2498. The shop is open Monday through Saturday from 11 a.m. to 4 p.m. and volunteers can work a morning shift from 11 a.m. until 1:30 p.m. or an afternoon shift from 1:30 until 4 p.m.
FERTILE GROUND

Promising studies are exploring how genital tract infections affect reproductive health
Plain and simple, sexually transmitted diseases (STDs) can affect individuals of all backgrounds. And because many STDs have no symptoms, people who are infected often don’t know it, and can continue to transmit their infections to others.

“All sexually active individuals who are at risk for STDs should be concerned,” says Dr. Harold Wiesenfeld, director, Division of Reproductive Infectious Diseases and Immunology at Magee. “Research in STDs and other reproductive tract infections is critical because of potentially devastating long-term consequences of common STDs. While you might say chlamydia and gonorrhea are not overly serious to the majority of women, we know that those infections can cause infertility, and they are co-factors in the spread of HIV. Women who are infected with STDs are at an increased risk for HIV acquisition. So if we can drive down the number of women who are infected with STDs, we’re going to dramatically impact, in a positive way, the HIV transmission rates.”

Dr. Wiesenfeld was always fascinated with how microbes interact with the body and how they can overwhelm the host’s defenses against infection and cause significant disease. “In medical school, I realized that infectious diseases have a major impact on the reproductive health of women. It was an area that most obstetricians and gynecologists didn’t focus on. I recognized the need to improve the field of reproductive infections and try to understand their effects on reproductive health.” In fact in 1992, Dr. Wiesenfeld was the first fellow in Reproductive Infectious Diseases at Magee under the guidance of Dr. Richard Sweet, a former Chair of the Department of Obstetrics, Gynecology and Reproductive Sciences.

“My biggest focus is understanding how reproductive tract infections, particularly sexually transmitted diseases like gonorrhea and chlamydia, cause pelvic inflammatory disease and how those infections go on to cause infertility in women. Our group explored and furthered the understanding of how these sexually transmitted diseases can cause infertility in the absence of major symptoms of infection.”

Dr. Wiesenfeld and his team discovered that some women who have gonorrhea or chlamydia also have subclinical pelvic inflammatory disease (PID), which is inflammation of the fallopian tubes and uterus. The difference is, they don’t have the classic painful symptoms that most physicians associate with PID. “In the absence of symptoms, nobody thought a woman could have pelvic inflammatory disease. So to take a step back, we know that infertility in women due to blocked Fallopian tubes is quite common. In those women who have blocked tubes, a large portion have had chlamydia or gonorrhea in the past. And yet some of them don’t even know that they’ve been infected with those bacteria or had any consequences as a result of those infections. We did some of the landmark studies to demonstrate that women who present with chlamydia or gonorrhea commonly have inflammation and infection in their uterus, and are not aware that these bacteria had ascended into their upper genital tracts.”

Most recently, Dr. Wiesenfeld is working to try to understand how best to treat women with PID in order to preserve their reproductive function and fertility. “We just completed a large randomized controlled trial exploring the best antibiotics to treat women with acute PID,” he remarks. “This was the only study in the U.S. of women with acute PID. The results, when they become available, will help guide national
treatment recommendations that are disseminated by the Centers for Disease Control and will influence how women in the United States and worldwide will be treated for this important and common infection.”

In other studies, Dr. Wiesenfeld is focusing on the spread of herpes from mothers to babies during the birth process. “We’re looking at how common it is for women in labor to shed the herpes simplex virus in their vagina. That virus can be transmitted to babies during the birth process,” he says. “When shedding of the virus occurs in the vagina, babies can be at risk for infection. Herpes in babies can be serious. It can cause a decrease in IQ, mental retardation, birth defects, pneumonia, encephalitis. We’re partnering with the National Institutes of Health [NIH] on a study looking at determining what proportion of women in labor are actually shedding the virus, using a rapid lab test that can tell us in a matter of hours whether a woman is shedding the virus at the time of labor. Ultimately, we hope that the results of this study will help guide a future study to determine whether babies who are born to women who have herpes in their vagina during labor should be given antiviral medications right after birth to prevent neonatal infection. This has major implications for future studies on how to prevent the transmission of herpes from the mother to her baby, and hopefully will prevent the often devastating effects of this virus on babies.”

While preventing infertility as a result of STDs is Dr. Wiesenfeld’s main goal, he also hopes for a broader impact. “As part of my research, I’d love to increase awareness of healthy sexuality and awareness of risk reduction strategies to reduce the chance of acquiring an STD. Ultimately, I’d like my work to lead to a reduction in sexually transmitted diseases, particularly in women.”

And he believes Magee is the best place to pursue his goals. “We have a national reputation as being leaders in maternity health,” remarks Dr. Wiesenfeld. “We are looked at by providers in the Pittsburgh region as a resource and referral source, and we have a large number of patients who are seeking our care. We have the expertise to provide top-level care in infectious diseases in women. Magee’s Division of Reproductive Infectious Diseases and Immunology has the largest number of women’s health clinicians and researchers dedicated to the study and the care of women with infectious diseases. And we also are fortunate that we have an internationally recognized infectious diseases research laboratory under the direction of Dr. Sharon Hillier that provides us not only with state-of-the-art diagnostics for these reproductive tract infections, but also cutting-edge research in microbiology of the female reproductive tract. The recognition of the importance of infectious diseases to the health of women has always been a priority of the women’s health leadership at the hospital, from the president to the chairman. Our current chairman, Dr. Robert Edwards, is a nationally known expert in human papilloma virus, which can lead to gynecologic tract cancers. The recognition and support of our leadership is critical to our mission to be the leaders in the field of reproductive infectious diseases. And we are. We have the longest running fellowship in reproductive infectious diseases and immunology, training the upcoming leaders in the field. We are proud that our trainees have gone on to be successful academicians in obstetrics and gynecology.”

To support this important research, visit www.mageewomens.org/donate.
RECOGNIZING OUTSTANDING CAREGIVERS: What it Takes to Be a Great Nurse

Anthony Iannamorelli knows how a great nurse can positively impact a hospital stay. He and his wife were lucky enough to have one with them during the difficult delivery of their baby. The nurse was Jill Szoszorek, a nurse in the Magee Womancare Birth Center, Obstetrics/Intensive Care.

“My wife’s pregnancy was high-risk due to an irregular heartbeat,” says Mr. Iannamorelli. “Because of her status, she had to give birth in the ICU wearing a heart monitor, with a crash cart nearby.

“She did not have an easy delivery. Her epidural failed three times and the baby’s heart rate dropped dangerously low at one point. It was Jill’s fast action that brought everyone together to ensure a safe delivery. Throughout the whole delivery, she was with us, staying long after her shift ended and returning the next morning at 7 a.m.”

Jill was inspired to become a nurse when her father became ill with cancer. She helped care for him and stayed with him during his last nine days in hospice. The dedication of the nursing staff made an impression on her.

Jill’s trained at Shadyside School of Nursing and she has been with the Magee Womancare Birth Center for five-and-a-half years.

She credits her preceptor [nursing mentor], Angie DeFelice, RN, for teaching her how to handle all the procedures involved with the prenatal, delivery, and post-natal care needed during a patient’s pregnancy. When a physician was not available at the time of a patient’s delivery, Ms. DeFelice was there with her to guide her through the process.

Jill remembers a particularly poignant delivery. “It was discovered when a patient was about 30 weeks into her pregnancy that the baby had anencephaly, a condition in which a major portion of the brain, skull, and cap are missing. The couple decided to have the baby anyway and donate the organs to CORE, an organization which handles organ donations.

The baby lived less than 30 minutes, but the mother got to hold her baby.

“What keeps me going when things are bad are letters from patients, like the email Anthony Iannamorelli sent. I think about the nurses who went above and beyond taking care of my dad and about how much impact we as nurses can have on patients’ lives.

“The team at Magee Womancare Center is such a cohesive one. No one could do this on their own. It’s so good to be able to bounce things off each other; team members have each other’s backs.”

Because of her dedicated care, Jill has been nominated to receive a DAISY Award for Extraordinary Nurses. The award recognizes the amazing work nurses do every day. DAISY recipients exemplify the kind of nurse who patients and families, as well as the entire health care team, recognize as an outstanding role model.

You can honor a Magee nurse by donating online at www.mageewomens.org/donate.
SAVOR PITTSBURGH:
GOURMETS HELPING INFANTS AND FAMILIES
Stage AE was the setting for the 10th annual occurrence of Savor Pittsburgh: A Celebration of Cuisine. On August 27, 2015, Pittsburgh’s hottest chefs and 1,400 guests came together for food and fun as a way to help families who are facing the possibility of premature birth. Savor Pittsburgh raises awareness of premature birth and provides financial support to researchers at Magee-Womens Research Institute.

For most parents, anticipating the impending arrival of a new baby brings happiness and joy. For some, however, that arrival comes too soon. The people who work for Magee-Womens Hospital of UPMC and Magee-Womens Research Institute are dedicated to helping families who find themselves in this devastating situation. Funding from Savor Pittsburgh opens the door to the development of new research and tools to help families cope.

Prematurity occurs in up to 13 percent of all pregnancies and presents serious challenges to a baby’s survival. Infants who are born between 22 and 26 weeks of gestation often do not live, and those who do are at risk for disabilities ranging from mild to severe. This period of extreme prematurity is known as periviability, and it necessitates the making of some very difficult decisions.

“It is very challenging to ask families to think about end-of-life care, especially at the beginning of life,” says Katherine Himes, MD, an obstetrician and gynecologist at Magee and a specialist in maternal fetal medicine. “The decisions they must make are emotionally, cognitively, and ethically demanding.” Adding to the challenge is the fact that most families must make these decisions quickly. Premature birth often comes as a surprise.

Under stress and without adequate information, families can find themselves at a loss. Physicians, too, may find it difficult to initiate conversations without a clear understanding of each family’s feelings and beliefs. Dr. Himes and other professionals at Magee will use funding from this year’s Savor Pittsburgh to address this gap in caregiving. The multidisciplinary team, which includes clinicians, social workers, spiritual advisors, and developers, is creating an electronic decision-support tool that allows parents, doctors, and others to share information and settle on plans that reflect the family’s values. The prototype of this tablet-based tool is in the development phase; programming and testing should follow within the next year. By taking a medical-models approach and including families in the tool’s design, the team intends to set the standard for decision support in the context of periviability.

“We’re hoping to create a robust, easy-to-use, multi-layered tool that helps families work through their emotions and arrive at decisions that are based on factual information about their baby’s prognosis,” says Dr. Himes. Standardized clinical content, accessible in varying degrees of detail, along with interactive features that elicit and distill the family’s values, will ensure that families’ decisions are based on both facts and feelings. Initial testing with families will fine-tune the design, and formal, rigorous testing will ensure that the completed tool addresses the gap between what patients and caregivers feel is important.

By developing this tool to facilitate factual, values-based communication, the Magee team hopes to help families in distress and ease some of the burden of decision-making at a time when they need it most.

To support this project at Magee, visit www.mageewomens.org/donate or call 412-641-8977.
Recognizing the Exemplary Mentorship Shown to Dr. Sabbagha by Drs. T. Terry Hayashi and Donald Hutchinson

Throughout his career, Dr. Rudy Sabbagha has utilized a myriad of written and spoken words to describe, explain, and educate colleagues, residents and women on topics in the intricate field of obstetrics and gynecology. When he arrived at Magee–Womens Hospital in 1965 from the American University of Beirut in Lebanon for a residency position, he met his two mentors, Dr. T. Terry Hayashi and then chairman, Dr. Donald Hutchinson. These two doctors left a lifelong impression with him and played a pivotal role in his career. Then and now, Dr. Sabbagha needs only one word to describe them — "exemplary."

Thinking back about the long days that he as well as the other starting residents at Magee went through, he reminisces, "I used to cover the labor suite from 7 a.m., continue until 11 p.m., sleep from 11 p.m. to 4 a.m., then cover the labor suite again, until 5 p.m. That second day always ended at 6 p.m., following a one-hour conference discussing various topics on patient management." Even with the demanding days and hectic schedule his Magee memories are rich in companionship, camaraderie, and excellent training.

One significant part of that training was his relationship with Drs. Hayashi and Hutchinson. "I was so impressed with the interpersonal relationship these two doctors had with the residents. They were always very involved in the teaching conferences and general reviews," Dr. Sabbagha explains.

Dr. Sabbagha remembers Dr. Hayashi "taking me under his wing." He knew I was interested in research and he showed me how his lab was run. He had a major National Institutes of Health (NIH) grant to study preeclampsia as well as placental transfers to the fetus. In fact, my first scientifically published paper in the American Journal of Obstetrics & Gynecology along with Dr. Hayashi was regarding the placental transfer of L4C-thiouracil in pregnancy.

Likewise, Dr. Hutchinson, whose research was in Rh sensitization as well as fetal growth and anomalies, was always available to give his perspective on the day to day complications in obstetrics and gynecology. His tolerance with residents was well above what is normally expected of a department chairman. He was also instrumental in coaxing the American Board of Obstetrics and Gynecology to approve the development of the sub-speciality of maternal-fetal medicine.

The end result from all this time and research spent together was an open, frank, and lifelong friendship. This connection led Dr. Sabbagha to write to Dr. Hayashi in 1969 to see if he could carry out his postgraduate fellowship with Professor Ian Donald in Glasgow who was conducting research on using ultrasound for diagnostic imaging in pregnant women. Previously, Professor Hutchinson, had quickly accepted Dr. Sabbagha’s application for fellowship since he was not only well aware of but also quite impressed with Magee from his days as a visiting professor. Drs. Hayashi and Hutchinson approved and arranged the funding for this fellowship. "Overall, their exemplary mentorship fostered an environment of curiosity and open mindedness. As such, it allowed me to venture into and develop expertise in the new field of diagnostic ultrasound," says Dr. Sabbagha. This enticing technology made the actual visualization and assessment of the fetus a reality for the first time in the history of mankind."

In recognition of the impact Drs. Hayashi and Hutchinson had on his training, and career, Dr. Sabbagha endowed a lectureship that will create educational opportunities for current and future residents and fellows at Magee. Through his generosity, he is honoring his exemplary mentors and ensuring their legacy continues. As part of the program, the hospital’s auditorium was renamed the Dr. Donald Hutchinson and Dr. T. Terry Hayashi Auditorium in recognition of Dr. Sabbagha’s gift and in honor of the two doctors who “brought magnificent surgical training and research to Magee-Womens Hospital.”

Dr. Sabbagha, his family, and the family of Dr. T. Terry Hayashi celebrate the renaming of the auditorium.
Yoel Sadovsky, MD, director, Magee-Womens Research Institute, reflects on the philanthropic support of Elsie Hillman, who passed away in August, and the impact that she and the Hillman Family Foundations have made on women’s health research.

Directing the largest independent research institute in the nation to focus exclusively on women’s health, I’m privileged to work with some of the best minds in medical research. Magee-Womens Research Institute is home to world-renowned reproductive biology and medicine scientists who are experts in translating discoveries made in the lab into caring, compassionate treatment at the bedside. Our organization, through its affiliation with both Magee-Womens Hospital of UPMC and the University of Pittsburgh, participates extensively in clinical trials that accelerate the pace of innovation and help to ensure healthier lives for women and their children.

As the Elsie Hilliard Hillman Chair in Women’s and Infant’s Health Research, I’m honored to be associated with one of the world’s leading lights in philanthropy. Elsie Hillman was a remarkable force, who channeled her resources into causes about which she cared deeply. Never content to imagine that she had done enough, she spent years passionately working to facilitate the growth of organizations that improve the lives of millions.

In 1998, the Henry L. Hillman Foundation awarded a grant to endow the Elsie Hilliard Hillman Chair in Women’s and Infants’ Health Research, the first academic honor of its type at Magee. Its establishment has contributed to the astonishing growth of our research programs and to the enduring reputation of Magee as a champion for research in women’s health worldwide.

Magee has been caring for women and babies for more than a century. Our culture of compassion is the cornerstone of our mission: to continue to help families lead healthy lives both now and in the future. But we are more than patient-focused care. Magee is part of a much larger effort to advance the science of women’s health, the study of which has traditionally been neglected. Thanks to significant grants from the National Institutes of Health and gifts from generous donors, our investigators have access to the most technologically advanced facilities. We are able to attract the best scientific minds—superior both in academics and in clinical care. Because of people like Elsie Hillman, our teaching hospital and research facilities are consistently recognized as being among the world’s best.

The Elsie Hilliard Hillman Chair in Women’s and Infants’ Health Research is a major component of our ability to lead the way. Our innovative cross-disciplinary studies focus on uncovering the causes of disease and developing treatments for challenges both common and uncommon. We are studying why fetuses may be getting inadequate support during pregnancy, leading to a lifelong risk of disease. We are working on determining the cell of origin for both breast and ovarian cancers. We analyze proteins that shape germ cell development in the ovary and testis, and investigate factors that determine the health of the pelvic floor.

We could not engage in this breadth and depth of research without generous philanthropic gifts. Thanks to the Hillman family’s generosity and Elsie’s vision, the future of health care holds the promise of better lives for women, infants, and families in our own region, in our nation, and in every corner of our world.
Mylan® and Magee –
A Successful Partnership for a Better World
“Through our sponsorship of Savor, we are proud to support research that helps advance knowledge about premature births to help improve health care outcomes for mothers and their babies.”

-Mylan CEO Heather Bresch

Ask any executive chef what wine works perfectly with red meat and their answer would be a beautiful Cabernet Sauvignon. Or ask wine experts what is the ideal wine to pair with some delicious appetizers, and they would definitely say to uncork the champagne. Ask Mylan CEO Heather Bresch why their partnership with Magee-Womens Research Institute & Foundation’s Savor Pittsburgh event is so important and she’ll enthusiastically respond that Mylan “is inspired by Magee’s fight against premature births, which affects 500,000 babies each year.”

For the second year, Mylan was a presenting sponsor at Savor Pittsburgh which supports prematurity research and clinical care. “Both Mylan and Magee have a strong ambition to make a lasting, positive impact for generations to come. Like Magee, our hope is that every baby brought into this world has the opportunity to live a long, healthy, and fulfilling life. Through our sponsorship of Savor, we are proud to support research that helps advance knowledge about premature births to help improve health care outcomes for mothers and their babies,” says Ms. Bresch.

It is a great partnership and one that fulfills the mission of each organization of being committed to women’s health and providing the best health care possible. Since Mylan’s inception 50 years ago, the company has made it a priority to give back to the communities where we live and work. When we learned about Savor we felt it was an extremely worthwhile cause that aligned with our mission.”

Both Magee and Mylan have a long-standing history of striving to leave a positive and permanent imprint on future generations both locally and around the world.

According to Ms. Bresch, “at Mylan we put people and patients first. This philosophy, which we call doing good and doing well, reflects our belief that Mylan is not just a company, we’re a cause. Today we express that cause as delivering better health for a better world. Specifically, we aim to set new standards in health care and provide the world’s 7 billion people access to quality health care, one person at a time.”

One of the ways Mylan achieves this goal is by tirelessly advocating for changes in public policy nationally and internationally to help people everywhere access affordable, high quality health care. For instance, they have led initiatives to help alleviate some of the most severe public health crises of our time, such as HIV/AIDS and life-threatening allergies, or anaphylaxis.

“We also believe our people are our most important asset, which is why we have assembled, nurtured, and rewarded a passionate global workforce, whose more than 30,000 members have distinguished themselves through their dedication to integrity, service, and reliability,” says Ms. Bresch.

“It is through the hard work of our people that we will be able to help change the world for the better.”

Through partnering with Mylan, Magee’s fight against premature births through research and clinical care is closer to being won.
Researchers Seek New Targets for Ovarian Cancer Treatment

Researchers from Magee-Womens Research Institute and the University of Pittsburgh Cancer Institute (UPCI) have found that identifying molecular changes that occur in tissue after chemotherapy could be crucial in advancing treatments for ovarian cancer. According to Shannon Grabosch, MD, a gynecologic oncology fellow at Magee-Womens Hospital and the lead investigator for the study, treatment advances for ovarian cancer haven’t moved forward as quickly as they have for other cancers. “We wanted to understand what changes occurred to the local tumor environment after chemotherapy was administered, with the idea that these changes could eventually be targets for new, personalized ovarian cancer treatments.”

Dr. Grabosch and her team were able to identify chemotherapy-induced molecular changes, finding significant changes between the peritoneal cavity and blood samples. “Now we need larger studies to determine whether the changes that occur in the tumor microenvironment after chemotherapy could be potential targets for new, more personalized drugs and to further understand the mechanisms of intraperitoneal chemotherapy,” said Dr. Grabosch.

Magee Surgeon Leads Treatment Guidelines for Identical Twin Preganacies

The North American Fetal Therapy Network published a study of evidence-based and consensus-driven recommendations for the management of monochorionic twin pregnancy (a pregnancy in which identical twins share one placenta), led by Stephen Emery, MD, a maternal-fetal medicine surgeon at Magee-Womens Hospital. “Identical twin pregnancies present some of the most challenging complications a maternal-fetal medicine specialist can face,” said Dr. Emery. “We hope these guidelines help general obstetric practitioners understand some of the complexities that can affect the development of identical twins sharing one placenta.”
Study Finds Gene Mutations Cause Some Cases of Male Infertility

Alexander Yatsenko, MD, PhD, has found that some cases of male infertility are caused by mutations in the maternal X chromosome that prevent development of viable sperm. According to Dr. Yatsenko, nearly half of male infertility cases not due to a physical obstruction are estimated to have genetic roots, and about 20 percent of infertile men have azoospermia, where they are unable to make functional sperm. Dr. Yatsenko noted the only causes for infertility that have been identified are defects of sex chromosomes, such as the deletions of the Y chromosome or duplication of the X chromosome in Klinefelter syndrome.

“Eight times out of 10, conventional genetic testing doesn’t reveal a chromosomal or genetic problem, so the cause of infertility is considered idiopathic,” Dr. Yatsenko said. “This study is among the first to describe specific gene mutations on the X chromosome that contribute to azoospermia and male infertility.” The study was published online in the May 13 issue of the New England Journal of Medicine.
June 12, 2016

NICU Reunion
Where: Pittsburgh Zoo & PPG Aquarium, Pittsburgh, PA

June 12, 2016

Cancer Survivors’ Breakfast
Where: Sheraton Pittsburgh Hotel at Station Square

June 26-27, 2016

Noah Angelici Golf Outing
Where: Nemacolin Resort

For more information, go to www.mageewomens.org or call 412-641-8977.
Magee’s NICU Reunion, celebrating the patients and families who went through Magee-Womens Hospital’s neonatal intensive care unit (NICU), was held at the Pittsburgh Zoo & PPG Aquarium. The 12th annual reunion had 370 families in attendance this year.

The Angelici family presents a check for $20,000 to Magee on behalf of the Noah Angelici Hope Foundation. The Foundation holds the annual Noah Angelici Memorial Golf Outing in memory of Noah, who suffered from Twin-to-Twin syndrome. “Dr. Fred Sherman (pictured below) accepted the generous donation on behalf of Magee. Proceeds from the event benefit Dr. Stephen Emery and the Fetal Development Program at Magee. For more about Dr. Emery’s work, see page 26.
Sharon Hillier, PhD, spoke at a Capitol Hill Panel on Women and HIV/AIDS on the topic “HIV, Reproductive Health, and the Search for Multipurpose Prevention Technology,” in March.

Richard Guido, MD, became the president of the American Society for Colposcopy and Cervical Pathology (ASCCP) in June.

Sharon Hillier, PhD, spoke at a Capitol Hill Panel on Women and HIV/AIDS on the topic “HIV, Reproductive Health, and the Search for Multipurpose Prevention Technology,” in March.

Lisa Rohan, PhD, and Sharon Hillier, PhD, received a five-year U19 grant from the National Institute of Allergy and Infectious Diseases (NIAID), entitled “Film Antiretroviral Microbicide Evaluation.” Dr. Hillier and Dr. Rohan received $17.4 million for the grant.

Judy Gruss, a clinical research manager at Magee-Womens Research Institute, is this year’s recipient of the Robin Haff Research Award, for her contributions in the research efforts of the urogynecology department, and other division faculty, fellows and residents. The award recognizes the important roles that clinical research nurses and research coordinators play in the clinical research process.

Elizabeth Krans, MD, received a two-year grant from NIDA entitled “Facilitating HCV treatment through tailored prenatal care for HCV-infected, substance using pregnant women.” Dr. Krans received $450,000 in grant funding.

Mellissa Mann, PhD, joined Magee-Womens Research Institute in August. Formerly an associate professor of Obstetrics and Gynecology and Biochemistry at the University of Western Ontario, Dr. Mann will investigate epigenetic mechanisms that control genomic imprinting during early embryo development and the impact of assisted reproductive technologies on this regulation.

Yoel Sadovsky, MD, received the rank of University of Pittsburgh Distinguished Professor of Obstetrics and Gynecology.

Alex Yatsenko, MD, received a two-year R21 grant from NICHD entitled “Genomic signatures of X-linked and autosomal candidate-genes in azoospermia.” Dr. Yatsenko received $450,000 in grant funding.
Gestational Diabetes Diagnostic Methods Study

Recruiting women 18 to 45 years old who are currently less than 24 weeks pregnant with one child and plan to deliver at Magee-Womens Hospital to participate in a study to compare testing methods for gestational diabetes. Participants will be asked to complete two or three visits, which will usually occur the same day as regularly scheduled prenatal visits, where they will take a diabetes test and answer a questionnaire. Participants must not have diabetes, are not taking high blood pressure medication and have not already had a 50gm GTT. Participants will be compensated for parking validation or travel, as well as compensation up to $80 (plus miscellaneous small gifts) upon completion of study measures. For more information, contact Bridget Lane at gd2m@pitt.edu or 412-586-9817.

Help Support Clinical Trials

Magee-Womens Research Institute is one of the leading institutes in the country for clinical trials supporting women’s health. Through the support of our philanthropic donors and gifts, we have more opportunities to pursue further research that will help women in the Pittsburgh area and around the globe. To learn how your gift will benefit the future of women’s health research or to donate, please visit www.mageewomens.org/donate.

Contraceptive Hormone Induced Changes (CHIC-II)

Recruiting healthy women 18 to 34 years old who are not currently using hormones for birth control but would like to start to participate in a study of immune cell changes within the reproductive tract as the result of birth control. Participants will be asked to complete three to four visits at Magee-Womens Hospital over the course of six months, where they will undergo observation of their preferred method of birth control. We also are looking for women who do not need or want birth control and are not at risk of pregnancy for a control group. Women who enroll in the program will be compensated up to $470 for their time and travel costs upon completion, and birth control is provided at no cost to the participant or their insurance. For more information, call 412-641-5496.
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There are many gift options to choose from including bequests, gifts of real estate, and gifts of stock.

For more information about making a meaningful gift to Magee, please contact Arthur Scully at ascully@magee.edu or 412.641.8973.