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Source: Ethicon
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CARDIOVASCULAR

Adult stem cells: a revolution in heart medicine?

Roughly 850,000 Americans suffer an acute myocardial infarction (AMI)—a heart attack—every year. Recent medical advances have sharply reduced the number of heart attacks that result in death, but the resulting heart tissue damage can set off a process leading to congestive heart failure (CHF), a chronic condition with dire effects on quality of life and mortality.

While current treatment approaches have had limited success in improving outcomes for heart attack patients, research has steadily progressed on the use of adult stem cells for the treatment of AMI—a therapy with the promise not only to mitigate the damage caused by a heart attack, but to potentially reverse it.

Despite this ongoing research into the potential of adult stem cells, a number of barriers and questions persist, as researchers recognize a significant gap in existing clinical data. But as trials progress, there is hope in the research community that these cells will fulfill their promise of changing the treatment paradigm for CHF patients.

Positive outcomes, but "early days" for cardiac adult stem cells

Recent and ongoing trials exploring the efficacy of adult stem cells to repair heart tissue are

looking mostly at their use in patients with recent heart attacks.

Says Dr. Thomas Povsic, Assistant Professor of Medicine, Interventional Cardiologist, and Chief of the Endothelial Progenitor Cell Laboratory at Duke University Medical Center, post-AMI is "where by far the most work has been done" in this research.

In these experimental procedures, cells are taken from the patient's own body (autologous) or from a donor (allogeneic)—from one of several parts, such as bone marrow, muscles, or skin—then processed and inserted into the affected artery.

Although most trials are utilizing cells derived from a patient's own bone marrow, researchers point out that it is too early to determine the preferable cell type.

In addition, lingering questions about the most appropriate method and timing of delivery make it unclear how stem cells may best facilitate heart tissue repair in post-AMI patients.

Despite positive short-term outcomes, measured mostly in improvements in left ventricular ejection fraction (LVEF), many trials have seen the beneficial effect of adult stem cells drop off shortly after six months—suggesting that there is

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FACILITY INNOVATION

To build or not: Hospital-architect collaboration in the downturn

The recession has taken a significant toll on hospital facility construction: According to the American Hospital Association's January report on the capital crisis's impact on hospitals, roughly 40 percent of institutions had placed facilities projects on hold—largely as a result of the capital market freeze, investment losses, and continued margin compression.

But a slowdown in facility construction does not necessarily equate to a slowdown in facility planning and facility optimization efforts. While many hospital leaders may be taking a wait-and-see approach, other leading institutions are using this time to plan and regroup.

And, interestingly, many health care architects and facility planners are right there with them, expanding their service offerings and strengthening their relationships with long-term hospital and health system clients.



Ambulatory facility at Bryn Mawr Hospital, designed by Francis Cauffman.

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Source: © 2007 Don Pearse Photographers Inc.

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much work to be done to determine the ideal treatment parameters.

According to Dr. Doug Losordo, Director of the Feinberg Cardiovascular Research Institute at Northwestern University, adult stem cell research is in “such early days. To use another cardio analogy, we’re working on a bare metal stent right now. And once we have a bare metal stent we know is better than what’s out there, then we can work on a drug-eluting stent.”

Cell delivery just one issue on growing list of unknowns

Evidence to date suggests that the benefits of adult stem cells could vary widely depending on not just cell type, but when, how, and in what quantities they are implanted.

Timing of injection in particular could have a major impact on stem cells’ effectiveness. The majority of published trials have involved implantation three to six

days post-AMI or after percutaneous coronary intervention (PCI), and some have suggested benefits to a slight delay in implantation; a 2006 German trial, REPAIR-AMI, found that patients given bone marrow cells at five days or later after PCI experienced greater LVEF improvement than those infused earlier.

Some studies have also found a greater beneficial effect in patients with hearts that are functioning more poorly.

As Dr. Joshua Hare, director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine says, “The evidence suggests that people with larger heart attacks do better [with stem cell therapy].”

Other studies are varying the quantity of cells implanted, attempting to determine the number necessary to create a positive effect.

The ideal delivery method is another question mark. Stem cells are most commonly delivered via intracoronary transplantation utilizing an inflated balloon

catheter, transcatheter (across the innermost layer of the heart’s chambers) injection, or direct injection into the myocardium during open heart surgery.

For those not already undergoing surgical interventions, the less-invasive percutaneous option will remain the go-to choice, but all delivery mechanisms are still in the exploratory stage.

Losordo also points out that the factors of timing and delivery method could be interrelated: “It may be that if you deliver the cells in a different way, that time window changes a little bit.”

Still, he is careful to acknowledge that there are “no answers yet.”

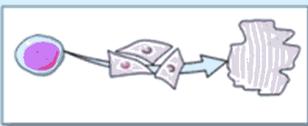
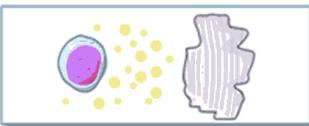
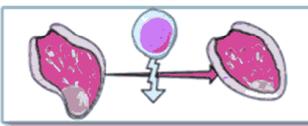
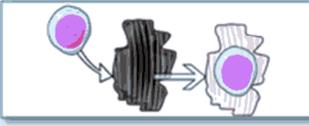
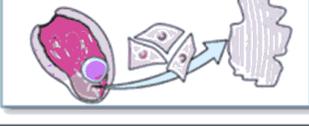
Understanding mechanism of action could guide development of therapies

Stem cells have shown improved outcomes in trials, but the mechanism of action responsible for their effects is not entirely understood—and some research-

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The ways they might work

Adult stem cells' proposed mechanisms of action

	Remuscularisation Through transdifferentiation into viable cardiomyocytes		Paracrine Effects Through secretion of beneficial mediators
	Attenuation of Remodelling Through beneficial effects on scar tissue formation		Cell Fusion By potentially ameliorating lifespan and function of cardiomyocytes
	Arteriogenesis/angiogenesis Through the growth of new blood vessels from existing ones		Influence on Cardiac Stem Cells By promoting endogenous tissue repair

Source: Mollmann, H. et al, “Stem Cells in Myocardial Infarction: From Bench to Bedside,” *Heart*, 2009; 95: 508-514.

ABOUT US

HORIZON SCAN

The *Horizon Scan Monthly* is a publication for Technology Insights and Innovations Center members that seeks to illuminate developing trends and analyze news in the world of medical technology with an eye to the impact on the hospital industry.

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PRODUCT BRIEFS

Bariatric Surgery

REALIZE Band-C opens banding to larger patients

Ethicon Endo-Surgery, Inc. recently announced the launch of the REALIZE Adjustable Gastric Band-C, with a modified design that purportedly eases placement and has a 14 percent greater stoma adjustment range to accommodate larger patients. The Band-C is the widest gastric band available, which the company asserts reduces the risk of band slippage. Additional features include an unlockable/relockable closing mechanism that allows intra-operative repositioning, and a removable one-way valve to maintain balloon evacuation during band preparation.

REALIZE and its competitor, LAP-BAND, are seen as largely similar by surgeons. Surgeons may welcome some of Band-C's new features, but it is unlikely to have a major impact on surgical volumes. Although its larger size may allow it to be used on larger patients, the Band-C is not likely to capture a large percentage of the super-morbidly obese population, as surgeons generally view gastric banding or vertical sleeve gastrectomy as better procedures for this population.

BUSINESS BRIEFS

Orthopedics

NuVasive looks to corner cervical disc market

NuVasive announced in late April their acquisition of Cervitech, maker of the PCM cervical disc, a move NuVasive hopes will allow it to accelerate its anticipated entry into the US artificial cervical disc replacement market. The acquisition is indicative of the recent trend of increased competition in this market.

An ongoing U.S. trial of the PCM disc is slated to complete two-year follow-up in the fourth quarter, and NuVasive anticipates submitting a Premarket Approval (PMA) application in the first quarter of 2010, meaning the PCM could make it to market well before the company's own Cerpess cervical disc.

PCM has CE-mark approval overseas, but NuVasive expects only "modest" international sales "in the near term." At home, though, NuVasive projects about \$100 million in annual PCM revenue within three years of commercialization—an aggressive projection, especially given competition from Synthes and Medtronic.

Sources of adult stem cells

- Bone marrow
- Peripheral blood
- Skeletal muscle
- Brain
- Skin
- Cornea
- Heart
- Liver
- Lung



Source: *Technology Insights* research and analysis.

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ers feel unlocking the secrets of the way these cells work could drive the future of stem cell therapy.

One idea is that the stem cells themselves actually replace the myocardial cells. The prevailing theory, however, suggests that paracrine effects—in which the stem cell secretes growth factors and other substances that invoke tissue repair and protection—constitute the underlying therapeutic mechanism.

Says Povsic, "An overwhelming majority of investigators" feel that most of the stem cells studied to date "mediate some type of paracrine signaling which allows heart recovery. They don't seem to work predominantly by generating new heart muscle directly."

But, he says, "How that actually occurs, nobody has been able to totally figure out yet."

Although paracrine effects are widely believed to be responsible for stem cells' beneficial effects, researchers differ on whether they account for all of the changes. Losordo cautions against the notion that these cells operate in just one way: "Nature tends not to be so monolithic in how it behaves, and I would be surprised if these cells were one-dimensional in terms of how they affect tissue repair."

Says Hare, "I think there's a paracrine effect, but I don't think it accounts for everything. Some people do."

But is it important to know *how* these cells are working, or just that they *do* work?

Losordo argues that from a patient's perspective, results are what count: "In the end, the patients won't care how these cells work, if they work. And if they don't work, nobody's going to care how they don't work."

At the same time, he points out that understanding the specific mechanisms involved—especially how different types of cells may operate under different conditions—could open the door to pharmaceutical innovations and the "discoveries of medical-type treatments that one could employ in these patients."

Indeed, if a specific mechanism—paracrine or otherwise—is discovered to be responsible for stem cells' beneficial effects, pharmaceutical companies will likely develop drugs to mimic the effect of that mechanism, potentially making the stem cells themselves irrelevant.

Approval process a question mark, but safety an early clinical hallmark

For now, with the specific mechanism of action undetermined, companies interested in creating intellectual property around adult stem cell therapy are focused on developing proprietary methods of cell isolation, processing, and delivery.

A main example is Baxter, whose Isolex machine is used to isolate a type of stem cell called CD34+ cells. Other companies involved in similar ventures include Angioblast, which has developed a system for processing another type of cells, mesenchymal precursor cells.

But given the wide variety of adult stem cell types, the different processing and delivery methods under commercial development, and the fact that adult stem cells are often derived from a person's own body, there is confusion over how the FDA approval process will work for these therapies.

According to Dr. Timothy Henry, Director of Research at the Minneapolis Heart Institute, "The exact pathway to get approval is still under discussion, and I don't think people know yet."

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Orthopedics

Decision highlights grey area of “custom” claims

On March 30, the U.S. Court of Appeals for the Eleventh Circuit ruled that device maker Endotec's Buechel-Pappas (B-P) ankles are not custom devices and are therefore not exempt from pre-market requirements. The decision ended a seven-year legal battle between Endotec and the FDA, which had argued that Endotec was illegally manufacturing devices that should be subject to pre-market approval (PMA). The decision affirmed an April 2008 district court ruling that Endotec's jaw implant was a legitimate custom device while its B-P knees were not, and it reversed that court's ruling that B-P ankles qualified for the custom device exemption.

Some legal experts have claimed that the decision could create confusion over Congress' definition of a “custom” implant among manufacturers, who traditionally benefit by labeling a product as “custom,” as it allows them to avoid the PMA process and bring a product to market more quickly. The decision also underscores the need for diligence on the part of hospital administrators in interpreting manufacturers' “custom” claims.

CLINICAL BRIEFS

Robotic Surgery

Positive outcomes for transoral robotic surgery

Results of a recent Mayo Clinic study showed promise for the use of transoral robotic surgery for the treatment of tonsil and base of tongue cancers compared to traditional surgery. Despite positive outcomes, however, this is unlikely to become a new blockbuster application for da Vinci, and will probably be restricted to progressive institutions for the near future given the small number of patients—roughly 24,000—diagnosed with throat cancer annually in the US.

Tumor removal was performed in 45 patients, and data was recorded on surgical time, blood loss, surgical complications, tracheostomy tubes, feeding tubes and resumption of oral diet, speech, swallowing, and tumor recurrence. There were no major complications and no procedure was stopped due to inability to remove the tumor. Average hospital stay and time to removal of feeding tubes were significantly shorter with robotic surgery than traditional surgery.

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Losordo sums up the dilemma: “It's exciting to think that autologous cells could be used therapeutically, but you don't want everybody who's got access to a bone marrow needle to declare themselves a stem cell researcher. And so, I think that there's no solution that's going to make everybody happy, but I think there has to be some standard.”

Despite the lack of such a standard, these therapies—at least at this early stage—appear to be largely safe.

Says Povsic, “The overwhelming body of data suggests that it's—at least bone marrow cells are—certainly not harming anybody.”

One area of concern is an apparent heightened risk of arrhythmias—abnormal electrical activity in the heart—seen with the use of myoblast cells in some early trials. Losordo asserts that patients “with heart failure get arrhythmias anyway, so it's not clear cause and effect.”

But he acknowledges the importance of comprehensively testing for safety before moving on in the trial process.

“There are risks to everything, and that's where we are in the phase of testing this,” says Losordo. “Once we know that things are safe, we can start doing the efficacy studies.”

Treatments initially the domain of interventional cardiologists, specialized centers

So how long will it be until efficacy studies begin to answer the many remaining questions about the what, when, and how of cardiac adult stem cell therapies? Researchers concur that it's simply “too early” to know where we stand with these treatments.

Losordo confirms that it is difficult to draw any conclusions right now: “There just isn't enough data yet in humans.”

Experts seem to agree, though, that it will be roughly five years before market approval and widespread availability of these treatments.

Says Povsic, “We still have a lot of work to do.”

But even when adult stem cell therapies become widely available, Povsic thinks this is “something that's going to be delivered at specialized centers for the foreseen

able future,” in large part because of the complexity of some of the delivery methods.

“I don't see it as something that's just going to be delivered at your local county hospital for some time,” he says.

Hare agrees, saying it could “be like organ transplantation, where there are more specialty hospitals first,” before the therapy makes its way to community centers.

Cardiac stem cell therapy also looks set to remain in the domain of interventional cardiologists, who constitute the majority of experts

involved in current research.

An issue with surgical trials is the difficulty in isolating the stem cells' effect from that of the surgery. Some trials are attempting to overcome this barrier, but the majority of clinical data has so far been collected in a non-surgical setting.

Another factor that could limit commercial interest in surgical therapies is, as Povsic says, that there are “a lot more people who need stem cells but don't have an indication for bypass surgery. And the number of people who are undergoing bypass surgery but also have an indication for a particular type of stem cells is even more limited.”

Costs potentially low—but still an X-factor

Although it is still too early to determine what technologies will be necessary for cell processing and delivery, cost isn't likely to be a significant barrier once therapies are widely available.

Dr. James Willerson, president and medical director, director of Cardiology Research, and co-director of the Cullen Cardiovascular Research Laboratories at Texas Heart Institute, agrees that it is too early to determine the costs involved, but says stem cell therapy “should not be terribly expensive... It ought to be much like [the costs of] a cardiac catheterization procedure.”

Several factors could change this, though. Timing of cell implantation could affect the potential profitability of these procedures in the hospital setting. If length of stay is increased after PCI or CABG while patients await cell injection, profitability could suffer.

But if further trial data suggests a benefit to cell introduction after five days, stem

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“You don't want everybody who's got access to a bone marrow needle to declare themselves a stem cell researcher.”

Dr. Doug Losordo, Northwestern University

FDA APPROVALS

Cardiovascular

Watchman not a direct threat to warfarin

An advisory committee decided 7 to 5 on April 23 to recommend that the FDA approve Atritech's Watchman device, declaring the device comparable to warfarin (Coumadin), the current standard of care for treating atrial fibrillation (AF) patients.

The device, which is placed in the left atrial appendage (LAA), is designed to keep harmful sized blood clots that form in the LAA from entering the blood stream. It is not aimed as a treatment for AF itself, but rather to prevent stroke, cardiovascular death, and systemic embolic events associated with AF. Patients with AF are more likely to have clots form in the LAA because their hearts are quivering.

Although Atritech's trial data showed a 99 percent chance the device works just as well as warfarin and an 84 percent chance it is superior, the committee rejected the company's proposal to market the device as an "alternative" to warfarin.

All patients in the company's trial were on warfarin for at least 45 days, making a head-to-head comparison of the Watchman versus warfarin impossible. The clinical studies indicated, however, that the device led to a 32 percent reduction in the combined rate of stroke, cardiovascular death, and embolic events compared with prolonged warfarin therapy. Overall, there was a 39 percent less chance of dying among patients who received the Watchman compared with those who did not.

Although warfarin is the current standard preventive therapy for stroke patients with AF, managing patients with warfarin is very difficult due to interactions with other medications and foods, as well as the need for frequent blood testing.

The five panelists who voted against recommending approval expressed worries about the higher upfront safety risks associated with the device, especially a higher rate of ischemic strokes in the Watchman group. However, the rates of more severe hemorrhagic strokes were lower with the Watchman than with warfarin only.

The panel recommended physicians undergo a training program before implanting the device, noting poorer outcomes in the company's trials among less-experienced operators. The panel also recommended that only facilities with cardiac surgery capabilities implant the device and that the sponsor perform a large registry study and follow the trial's original participants for five years.

GENETICS

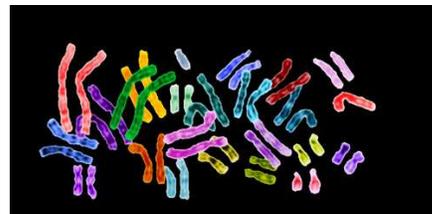
Leading institutes advancing the implementation of genomic medicine

Since the human genome was sequenced in 2003, research in the field of genetics has exploded as scientists attempt to unravel the function of genes, including their impact on human health. Physicians and scientists have long acknowledged the role of genetics in the development of disease and for decades have used genetic tests to diagnose and manage certain rare illnesses, such as birth defect syndromes and Huntington's disease.

Discovering these genetic associations to illness used to be a painstaking process—and virtually impossible to demystify for common diseases influenced by multiple different genes—but the sequencing of the human genome was an incredible technological advance that allowed scientists to begin to more systematically and efficiently unravel the role of genes in disease development.

Academic medical centers have been leading contributors to research in this field, and many centers have developed "genomic institutes," which typically focus on basic laboratory research into the association between genes and disease.

While much remains to be discovered in this area, a handful of genomic institutes are moving beyond basic research towards the next great challenge: imple-



Source: National Human Genome Research Institute

menting genetic advances into routine clinical care.

These centers are leading the field of genomic-driven medicine, and will play a key role in shaping the personalized medicine care delivery models practiced across the health care system in the future.

Rapid growth in known gene-disease connections—but clinical value largely unknown

Basic genomic research—the mechanism driving a better understanding of associations between genes and diseases—has been rapidly outpacing research into how this information can actually be used to improve clinical care. About 40,000 genetic variations have been linked to complex diseases, but scientists and clinicians have not yet been

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cell treatment could be a separate case with a second hospital admission, increasing overall revenue.

Another factor that could add costs is the use of imaging during stem cell implantation.

Basic imaging such as MRI—already available in most hospitals—is necessary to track cells once they are inserted into the heart, but some studies have explored the use of other modalities such as intra-operative MRI (iMRI) or a device called the Noga XP, a catheter-based, electro-mechanical imaging probe that allows for highly-targeted delivery of stem cells.

Though some trials have shown benefits from using iMRI, there is not yet enough data to suggest it would be beneficial. If iMRI is eventually shown to be necessary, however, its \$1 million-plus price tag would add significant capital

costs to a new stem cell program; the Noga would add only a modest \$150,000.

Although many questions persist, adult stem cell therapy holds significant promise for the treatment of heart failure. Trials are showing transitory but real benefits, and researchers are bullish that their promise will be borne out—and that these cells could eventually change the way heart failure is treated.

Willerson believes that stem cells could eventually be used to regenerate whole hearts—and many other organs.

"I don't have a doubt in my mind that this is going to be critical in medicine," he says.

Says Hare, "In essence, we're starting to do the equivalent of bone marrow transplantation for all kinds of solid organ diseases, not just leukemias and lymphomas. It's going to change the whole field of transplantation in general."

GENETICS

(Continued from page 5)

able to use this information to develop more effective clinical interventions.

For example, certain genes such as *APOE* have been associated with the development of cardiovascular disease. However, performing genetic tests to identify the presence of mutations in these genes within a patient does not correspond to value in the clinical setting because preventive interventions targeted to these mutations have not been developed.

A physician might recommend that a patient with higher genetic risk of cardiovascular disease exercise more—the same advice he would give all of his patients.

For other genetic tests, the clinical value appears clearer, but strategies for integration into care are underdeveloped.

As an example, two genes play an instrumental role in a patient's response to warfarin, a commonly prescribed anticoagulant used as a prophylactic measure for patients with increased risk for thrombosis. The appropriate dose of warfarin for an individual patient is determined on the basis of several clinical factors, as well as trial and error.

A physician must balance the risk of undertreatment—which would not prevent clots, defeating the purpose of the medication—with that of overtreatment, which would result in dangerous side effects.

Including genetic testing in this process could help clinicians better determine the proper dose and thus avoid dangerous and costly adverse events, but the algorithm to calculate the correct dose based on a patient's genetic and clinical information is still being standardized.

And progress could be slowed by a recent CMS decision to only provide Medicare reimbursement for the warfarin dosing genetic tests in the context of randomized, controlled clinical trials, due to a lack of evidence that the tests improve patient outcomes.

A number of genetic tests, however, have already become routine in the clinical practice setting, such as *BRCA* testing for breast cancer predisposition and cystic fibrosis carrier testing for couples planning a pregnancy.

The tests for these conditions are associated not only with meaningful clinical management options but also with a defined practice model: genetic counseling.

A patient at high familial risk of breast cancer will be educated by a genetic counselor about eligibility for genetic testing, and a patient with a positive result may



Source: National Human Genome Research Institute

consider a number of interventions including prophylactic mastectomy.

For the most part, however, only rare diseases have achieved this integration into clinical practice.

Despite the explosion of basic genetic research into common, chronic conditions such as cardiovascular disease, clinical management and practice models for the integration of genetic information into the care of patients with these diseases is almost non-existent.

Dr. Geoff Ginsburg, the director of the Center for Genomic Medicine at the Duke Institute for Genome Sciences & Policy, says, "Physicians always want to know what genomic tools are relevant to the patients they're seeing in the next hour. And the answer today is 'not many'—but the few that we have are quite good, and the ones on the horizon will have a significant impact on the delivery of health care."

Institutes crafting new clinical practice models for genomic medicine

While genomic institutes at many academic medical centers continue to lead basic science advances in genomics, several, including the Center for Genomic Medicine at Duke, are attempting to address the next frontier: the dearth of research on clinical implementation of genetic tools, particularly for common diseases.

According to Dr. Ginsburg, his center is helping not only to develop those tools but also to build the infrastructure needed to deliver them by "creating a firm handshake between the scientific genomic enterprise and health care delivery, which in most institutions are separated by a wide chasm."

Through clinical research programs, the Center for Genomic Medicine is creat-

ing and evaluating prototype practice models for the integration of genetic information into care.

One of the Center's projects involves partnerships with primary care physicians to conduct research on the use of genomics in the primary care setting.

One program seeks to disseminate genetic and genomic technologies focused on complex chronic diseases, such as diabetes and heart disease.

Another example is the work being conducted at the Center for Personalized Health Care at Ohio State University Medical Center, where CEO Dr. Clay Marsh is developing a holistic, patient-centered approach to personalized medicine.

As Marsh states, "Personalized medicine is not just genetics—it is an approach to sub-defining patient populations and moving from disease orientation to wellness orientation."

He believes that the patient home will be an important setting for personalized medicine—including but not limited to genetic information—and is currently developing a medical home team model for managing the most resource-intensive, chronically ill patients.

The Genomic Medicine Institute at Cleveland Clinic and the Institute of Genomic Medicine at the University of Medicine and Dentistry of New Jersey (UMDNJ) both facilitate the use of genetic information by leveraging large in-house genetic counseling programs, building on the traditional model for providing genetic services.

At Cleveland Clinic, the Genomic Medicine Institute's 11 genetic counselors advise patients on their genetic risk of disease at clinics held in the Institute's building as well as in satellite clinics throughout the health system.

Ron Rerko, the Director of Translational Development at the Genomic Medicine Institute believes that this is one of the key determinants of success for their model: "We spend a great deal of effort expanding our personnel and embedding our genetic counselors in different specialties for weekly clinics. Genetics can't just sit in one spot and expect people to come; outreach to where the physicians practice is critical."

Similarly, the Institute of Genomic Medicine at UMDNJ has four clinical geneticists and six genetic counselors who provide services to patients and advise all the major clinical departments in the institution of new genetic tests that are available.

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CONFERENCE ROUNDUP

SAGES wrap-up: NOTES adoption lags as SIMIS techniques nab spotlight

Technology Insights' Michael Levin-Gesundheit reports on the latest trends and developments in minimally invasive surgery from the recent annual conference of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).

Natural orifice transluminal endoscopic surgery (NOTES) faces the same safety and technological hurdles that *Horizon Scan Monthly* reported one year ago, but the path toward NOTES adoption appears bleaker today—especially given the steady pace of progress in single-incision minimally invasive surgery (SIMIS).

While researchers at this April's SAGES conference displayed great enthusiasm for NOTES, it appears that surgeon adoption has stalled, leaving the future uncertain for this long-heralded surgical technique.

NOTES offers a paradigm shift in surgical technique, which is the source of both fanfare and controversy surrounding the approach.

Rather than enter the body through an incision in the epidermis, NOTES surgeons maneuver flexible endoscopes through natural orifices—the mouth, anus, or vagina—to reach the site of surgery.

By snaking the endoscope through a perforation in the stomach, esophagus, colon, or retrouterine pouch, surgeons then have access to the abdominal cavity, where they can perform procedures such as cholecystectomies and appendectomies.

NOTES proponents hope that the technique will lower complication rates, reduce length of stay, and speed recovery time for patients who otherwise would have undergone open or laparoscopic surgery, but NOTES' greatest attraction is the promise of scarless surgery.

While the demand for improved cosmesis has no doubt been one of the drivers

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GENETICS

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Physician education a linchpin of success for applied clinical genomics

While these genomic institutes are implementing innovative clinical programs and research projects to integrate genetics into care, an important challenge facing further progress is the limited genetics education that the health care work force has received.

The vast majority of currently practicing physicians have not received significant clinical genetics education in medical school and—perhaps even more importantly—face a growing onslaught of information on the impact of genes on health.

All of the aforementioned institutes recognize this challenge and are working to educate physicians in a systematic and effective manner.

Genomic “grand rounds”—regularly scheduled seminars on various genomic medicine-related topics—provide a means to educate physicians about the field at Ohio State University, UMDNJ, and Duke University.

Both the Center for Personalized Healthcare at Ohio State and the Institute for Genomic Medicine at UMDNJ have held conferences to bring together thought leaders in the field and educate their clinicians and faculty, and Duke's Center for Genomic Medicine has even launched a website to educate patients directly.

In addition to these more formal strategies, the clinical and research programs implemented by these institutes also serve an invaluable educational function.

Genetic counselors at the clinical and research programs implemented by these institutes not only provide patient services but also educate the physicians with whom they work.

Dr. Peter Tolia, Director of the Institute of Genomic Medicine at UMDNJ explains, “Through our genetic counseling program, we advise the major clinical departments of new tests that are available; we proactively contact and educate them through seminars and symposia rather than simply receive inquiries.”

Additionally, at the Center for Genomic Medicine at Duke, the primary care physicians involved in clinical genetics research are informally helping to demonstrate the value of genetics to other practicing physicians.

As a result, Dr. Ginsburg has observed “a sea change in provider interest and understanding of the role of genetics in their practice over the last two to three year period.”

And these primary care physicians have started to build more formal educational programs.

Movements such as these help to lay both the cultural and infrastructural tracks that are elemental to effective applied clinical genomics, but will these models percolate into the community setting?

Community setting the next step

True integration of genetic information into routine clinical care is still in its inception, and much of this work has not yet moved beyond rare diseases and the realm of the academic medical center.

Plus, implementation of genomic-driven medicine in the community setting faces even greater challenges—mainly financial—than in academic medical centers.

Nevertheless, in preparation for this movement towards genomic-driven medicine, community-based hospitals can take steps to prepare themselves.

While fraught with barriers, the groundwork being laid by genomic institutes in the academic setting is sure to reach the community. All the institutes espouse explicit goals of engaging with community-based practices and hospitals as they work to define optimal strategies for implementation of genetic information in clinical care.

Most importantly, these centers are serving as incubators of new practice models around genetic information, shaping the future of personalized health care delivery.

The Innovation Center and Technology Insights will be co-hosting a teleconference entitled “The Genomics Institute of the Future” on June 4th, in which we will address the challenges and opportunities of genomic medicine, as well as near-term action steps for both academic and community hospital administrators; we invite you to join.

CONFERENCE ROUNDUP

(Continued from page 7)

in surgery's evolution from open to laparoscopic techniques, however, many surgeons are wary of flouting the doctrine of avoiding internal organ perforation.

Potential NOTES drawbacks may not be as significant as thought

With a symposium dedicated to the topic, advancements in NOTES were certainly a highlight of the SAGES conference. While presenters did not share news of further adoption in the United States, NOTES surgeons showed that some progress has been made in establishing further evidence of NOTES' safety.

Dr. Lee Swanstrom of the Oregon Clinic, a major innovator in NOTES surgery who has performed eight transgastric cases, explained that more than 500 to 1,000 NOTES cholecystectomies have been performed to date without a single bile duct injury.

Even so, he affirmed that further evidence is required to eliminate concern over the potential for novel complications from surgery, including internal wounds and gastroesophageal reflux disease (GERD).

Turning to a less controversial NOTES pathway, Dr. Emily Lukacz of the University of California at San Diego presented evidence showing that the odds of infection in transvaginal hysterectomy are lower than in conventional and laparoscopic hysterectomy. She found a 1.6 percent rate of infection in nearly 80,000 hysterectomies performed over 23 years, while the infection rate for transvaginal hysterectomy registers at only 0.42 percent.

Addressing a common criticism of procedures such as transvaginal cholecystectomies and appendectomies, Lukacz said she did "not see how a small 1.5-centimeter incision in the cul-de-sac would affect fertility."

At least three of Dr. Lukacz's patients have had successful pregnancies after transvaginal procedures.

While SAGES presenters reported some positive case outcomes, most speakers spent their time defending NOTES in the face of safety and technological obstacles.

Dr. Scott Melvin, director of the Center for Minimally Invasive Surgery at Ohio

State University, devoted his lecture to countering criticism that NOTES invites contamination.

Arguing that the harm of bacterial contamination from the body's natural orifices has not been established, he said, "The surgical dogma of sterility should be challenged for NOTES."

Dr. Antonio Lacy of the University of Barcelona also asserted that NOTES surgeons must "break dogmas."

He argued that transrectal access for NOTES procedures must be explored because, despite the risks of fecal contamination, the ease of closure in the colon may make it a favored avenue for access to the abdomen.

Meanwhile, surgeons called for investigation of new technologies that could address the technological challenges of NOTES and help propel it into the mainstream.

Swanstrom called for a new generation of flexible endoscopes designed not for examinations but surgery.

Describing NOTES procedures as an "ergonomic nightmare," he suggested that with technological improvements, operative times could fall from what are often far longer than standard laparoscopic procedure times.

Other surgeons echoed his concern about technological advancement.

"NOTES technology has a future, and we need cooperation from industry," noted Dr. Karl Fuchs, a professor of surgery in Frankfurt, Germany.

Industry, however, does not appear focused on NOTES technology, and it was clear at SAGES that research and development budgets have been diverted from NOTES to SIMIS technologies.

SIMIS progress steals the day

While few products have been released specifically for NOTES, the vendor floor featured an array of devices targeted at surgeons interested in performing SIMIS.

Often described as a competitor to NOTES, SIMIS also faces technological hurdles. Surgeons must complete procedures in the abdomen with only one incision, and while standard laparoscopic tools may suffice, industry aims to use new access devices to make SIMIS accessible to non-academic surgeons completing everyday cases.

The need for new technology is arguably not as great in SIMIS as in NOTES, however.

Dr. Paul Curcillo of Drexel University, co-developer of Single Port Access (SPA) surgery, a form of SIMIS, performs his procedures without any special equipment.

Although Curcillo has expressed concern that rapid adoption of SPA could lead to poor outcomes, he argued that his stepwise elimination of ports allows surgeons to safely transition to the technique.

Attendees at Curcillo's talk, which was sponsored by Ethicon and Karl Storz, appeared intrigued by SPA.

Enthusiasm also followed reports that surgeons had used SIMIS techniques for bariatric surgery procedures.

Dr. Ninh Nguyen of the University of California at Irvine reported success in SIMIS vertical sleeve gastrectomy, and argued that others should pursue SIMIS bariatric procedures because he believes his patients recover faster and suffer less pain than with standard laparoscopy.

In arguing for SIMIS, surgeons referenced its minimally invasive cousin, NOTES, and asserted that SIMIS adoption should come first.

Nguyen said that SIMIS is more attractive than NOTES because SIMIS is more easily reimbursable.

And when asked about his procedure's relationship to NOTES, Curcillo explained that SPA should be considered a stepping stone: "If I've proven that [SPA is safe], don't we just have to move the hole?"

NOTES optimism persists despite odds

SIMIS certainly represents a relatively low cost option for surgeons seeking to maintain or secure a reputation as an innovator. But the relative success of SIMIS does not signify that NOTES is irrelevant to the future of surgery over the next decade.

Increasing adoption of devices like EsoPHYX, a transoral surgical treatment for GERD, may pave the way for future NOTES surgeries, and surgical leaders across the board support further NOTES research.

Dr. Mark Talamini of the University of California at San Diego presented an impassioned call for further NOTES investigation at a debate on the future of the technique, and waxed optimistic as he predicted that in five years NOTES procedures will be commonplace.

"I'm quite convinced that the proper tools can be created to make [NOTES] as easy as a lap. choly," said Talamini.

Industry does not appear focused on NOTES technology, and it was clear that research and development budgets have been diverted from NOTES to SIMIS technologies.

FACILITY INNOVATION

(Continued from page 1)

With fewer new projects in the pipeline and an influx of architects with limited health care experience now bidding on every new hospital project, health care architecture firms have to bring their “A-game” to thrive in this hyper-competitive environment. That, in turn, is creating opportunities for savvy hospital leaders—who can take advantage of these architects’ experience and unique “spatial problem-solving” backgrounds—to ensure that they’re maximizing the return on investment (ROI) of both existing facilities and planned facility projects (even those that may be on hold).

In this article, we’ll explore some of the ways that hospitals, architects, and facility planners are working together to maximize the value of current *and* future infrastructure investments during this challenging economic period.

Asking tough questions...

The economic climate has severely limited capital availability, causing hospital leadership teams to re-evaluate planned expansions, renovations, and replacement facilities.

One of the most important ways that architects are helping hospitals through the downturn is by supporting these re-evaluations—and in many cases, they’re helping hospitals reevaluate the very projects they were going to design.

For example, after supporting a long-term capital and facility planning initiative in preparation for managing the ensuing projects, Parsons Commercial Technology Group, a multi-national engineering and construction firm, is working with a 30-hospital system in the Southeast to “take another look at their slated projects, as well as those they passed over before, to reconsider their value.”

As hospitals and their design partners “take another look,” they are asking (or should be asking) four pressing questions: What do we really need? What can we realistically afford? What should we do now versus later—and what are the consequences of delay? And, when the time is right, how can we design and build those top-priority projects most efficiently?

To help their clients, health care architects and facility planners are drawing on their experiences with other hospitals and health systems, their position as a neutral third party, and their knowledge of building economics.

As Harry Hummel, principal in charge of health care with the national design firm Francis Cauffman, notes, “we have to



Architect’s rendering of new building at Miami Valley Hospital, partnering with architecture firm NBBJ on several prefab initiatives.

Source: NBBJ

help our clients ask the tough questions... and then we need to be creative in solving their problems.”

Architects interviewed for this article shared recent stories of questioning everything from the need for a planned open-heart program in a region already suffering from overcapacity to the need for specialty-specific ORs and healing gardens.

And sometimes, they question the need for a new facility altogether.

As Heather Chung, a principal at national architecture and planning firm SmithGroup explained, “at the end of these types of discussions, we have advised [the client] not to build. As architects, we love to design and build new hospitals, but that’s not always the right answer.”

...establishing priorities...

Prioritizing the “nice to have” versus the “need to have” is only one part of the equation. Hospitals must also be both realistic and open-minded when considering what they can afford to build—or how they can secure additional financing.

Some hospitals locked out of the bond market are turning to third party developers to finance those highest-priority initiatives. And here, too, architects, are providing assistance, making introductions to developers they’ve worked with in the past—or even, as is the case with New England architecture firm Morris Switzer, taking on some MOB development projects of their own.

Yet, in today’s tough economic climate, many hospitals are still finding that

they have less available capital than they need for even their top priority projects. But some institutions, working with their architects as partners, have identified creative ways to break up and then phase in such initiatives. When a northeastern hospital that had recently hired a new orthopedics group found that they didn’t have sufficient funds for the “orthopedic-friendly” OR suites they wanted to build, their long-standing architects, Francis Cauffman, helped them identify ways to do a portion of the specialty OR conversion, while maintaining flexibility for the development of future phases.

On a larger scale, Kathy Silard, the COO of Stamford Hospital in Connecticut, praised Stamford’s long-time “strategic partners,” WHR Architects, for helping them prioritize a variety of planned projects and map a strategy for phasing in a major campus renovation (starting with a brand-new ED). As the COO explained, “we worked together to figure out how to leverage the resources available to maximize the effort we were going to put in place.”

...and weighing difficult tradeoffs

For hospitals and health systems considering ways to scale back larger ambitions or break up major initiatives into smaller discrete projects, Hummel offers these words of advice: “Don’t do anything that will stop the idea from being a complete thought. The design should still incorporate flexibility, operational efficiency, and ROI.”

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FACILITY INNOVATION

(Continued from page 9)

In conversations with HSM, both architects and hospital executives underlined the importance of carefully weighing tradeoffs before committing to any new path.

Working together with their facility planners to consider various scenarios, hospitals can identify the right balance between cost savings today and flexibility tomorrow.

As Silard noted, Stamford's slower, phased-in approach may cost them more in the end—but it at least allowed them to move forward in a rational and strategic fashion.

Partnerships persist beyond planning phase

When it comes time to move forward with a project—even those that have been significantly scaled down—many hospitals are leaning on their architects and external project managers (sometimes called “owner’s representatives”) to ensure that those projects are delivered as efficiently as possible.

Some hospitals and health systems are opting to contract with design-build firms, like HBE Corporation or Erdman, to manage the entire process under a single contract.

Others, such as Sutter Health, are

pursuing integrated project delivery (IPD) models, which prioritize interdisciplinary collaboration and extensive up-front planning in an effort to reduce change orders and compress timelines downstream.

In a design-build collaboration, Francis Cauffman and Bryn Mawr Hospital identified some traditional ways of “fast-tracking” timelines for a recent ambulatory facility; by overlapping phases wherever possible (e.g., they began ordering steel and framing the core while still finalizing interior design details), architect and hospital partners went from project approval to occupancy in under 23 months.

Hospital leaders can also leverage their architects’ and project managers’ depth and breadth of experience with both health care and non-healthcare facilities in order to help them think through pros and cons of different project delivery models and identify the process that best suits their institution’s needs.

As Parsons’ director of healthcare, Lee Roy Ash, says, “We’re currently helping one large system by offering insight into alternative delivery methods that will allow them to retain some of their final project goals, while reducing the overall project cost. We’re helping them rethink not only what to do, but also how to do it.”

Maximizing facility ROI: How to do more with less

For hospitals and health systems moving forward with planned projects in the downturn, it has never been more important to maximize the facility’s ROI.

During the boom times, hospitals and architects were equally guilty of super-sized ambitions—larger spaces, more high-end amenities and materials, more buildings designed to make a “statement.”

But now, hospitals and health systems must figure out how to do more with less.

With many projects delayed or put on hold, some are focusing instead on maximizing the return on existing facilities.

And here, too, some hospitals are partnering with architects in new and interesting ways—tapping into their spatial and technical knowledge in an effort to improve operational efficiency.

Together, they’re looking for cost-effective ways to turn beds faster, consolidate administrative spaces, and streamline registration processes.

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As Jim Hannon, SmithGroup’s senior vice president and national healthcare practice director, explains, “the first thing I ask now is ‘Are they really getting optimal use of their existing infrastructure? How can we help?’”

Sometimes, solutions come from facility planners positioned to ask the politically risky questions hospital leaders may not be ready to ask.

Curtis Skolnick, a principal of health care facility solutions provider KLMK Group, cited multiple examples of hospital clients that planned for added capacity based on aggressive projections of market growth rather than actual market need.

“In today’s climate,” he notes, “we all need to scrutinize every aspect of a project’s scope to ensure it will achieve the institution’s strategic and market needs.”

In other instances, architects are identifying creative ways to use pre-fabricated materials in order to minimize fabrication

and installation time, ultimately reducing costs without compromising quality or aesthetics.

Bryn Mawr Hospital and Francis Cauffman opted for prefab panels on some exterior walls of their new ambulatory facility. As an additional benefit, they chose a local vendor in Allentown in order to reduce transportation time and costs.

Likewise, Miami Valley Hospital and NBBJ have partnered on five prefab initiatives for their new facility, including mechanical/electrical/plumbing racks, a temporary bridge, and even the patient rooms.

The bridge alone saved more than \$1 million in material and labor costs, and will be reused permanently on campus.

Plus, according to Tim Fishking, a principal with NBBJ, none of the initiatives has sacrificed the “integrity of the larger design” in any way.

Perhaps most critically in these uncertain times, hospitals are tapping architects’ unique spatial and systems training to maximize the operational efficiency of their new facilities.

As Stan Chiu, vice president and director of design at HGA’s Los Angeles office explained, “All challenges involve people, process, space, and technology. Architects are uniquely trained in the space element, but to do that well, we must understand the interrelationship between space and those three other things... We live at the intersection.”

Need for innovation greater than ever

Dennis Brandon, a principal in NBBJ’s Columbus, Ohio, office, suggests that the entire design process should be viewed as an opportunity for “change—even transformation.”

While a return to the construction “boom times” of the past several years is highly unlikely, the need for innovative, cost-effective, and patient-centric designs may be more important than ever. As technological evolution and payment reform continue pushing care away from our traditionally high-cost, resource-intensive inpatient hospitals, the facility needs of our care delivery system must shift as well.

Hospitals and health systems open to partnering with architects in support of this larger endeavor—those that are open to using the facility design process as a means of dramatically rethinking traditional ways of doing things—stand to reap the benefits of facilities that are truly better equipped to meet payers’ demands for high-quality, cost-effective care.

“In today’s climate, we all need to scrutinize every aspect of a project’s scope to ensure it will achieve the institution’s strategic and market needs.”

Curtis Skolnick, KLMK Group