

## Case Study: B2B, CRO Health Tech (digital/online)



### Writer responsibilities---

#### → Research

#### → 3 client interviews:

- Executive VP, global operational excellence and innovation, US
- Senior manager, data management, South Africa
- Head of marketing, US

#### → Reviews: SMEs, product manager, legal team

#### → Pre- and post-production quality and brand reviews

### Safety and efficacy. Accuracy and expense.

#### Executive Brief

#### Transformation

From their first week of training with IBM Clinical Development (ICD), MMS staff gained confidence in the team's support and in the easy-to-use technology. Today, MMS has the trust of more of their clients—and is winning more work.

#### Business challenge

To strengthen their position in a highly competitive market, MMS Holdings (MMS) searched extensively for options to complicated, expensive databases. They needed a trusted partner and economical pricing.

## CASE STUDY

### The business challenge story

For any client, efficiently gathering, exchanging and categorizing patient data are all critical to the goal: reaching patients with safe treatments that can improve or even save lives. These data and technology challenges are the focus of MMS Holdings. Their work with small- to mid-sized clients is important to bringing treatments to market.

Five years ago, one of the major challenges their leaders embraced was the complexities involved in automating patient data, which daily impacted the work of their global team of 800. "Very cumbersome and time consuming" is how the leadership describes past electronic data capture (EDC) software. It can also be very costly...

### Transformation story

#### Trust and confidence in the data

The team of specialists at MMS understood their clients' challenges, too. For over 20 years, they've lived it. With their knowledge of the industry and with their clients' goals in mind, MMS engaged IBM Clinical Development, or ICD.

The MMS team dove into IBM's weeklong training to quickly maximize the out-of-the-box features of ICD. And as they began adopting its functionalities, IBM and MMS teams aligned closely to ensure ICD accounted for the nuances of each project....

"The ICD team was very responsive, very willing to hear our feedback," says Doreen Van Huyssteen, senior manager, data management, MMS, in South Africa. "Partnering with them, we were able to continuously improve both the technology and the services [we offered our clients]. We worked together to meet our clients' needs." . . .

### The results story

#### Gains for patients and more

As part of their culture of learning and innovation, the MMS team began to explore new ways to use ICD to support their work. . . .

This performance and value, in turn, led quickly to repeat business, to two more studies using the new modules.

"Even with our new clients, we do one project with them very successfully, and the next year, we might get five more, because they like what they see," Gayari says.

Looking ahead, MMS leaders say they're positioned well for growing trends. "With ICD, we're a solution for clients as they move to doing more," Gayari says. "We have the track record now, and we have the tools to help them."

#### Client quote

*"Some sponsors needed a very basic database; others need a lot of functionality. With ICD, we're able to stay competitive and offer what they need, and sometimes more."*

*— Senior manager, data management, MMS Holdings (South Africa)*

### Your story: Take the next step

To learn more about the IBM solutions featured in this story, please contact your IBM representative or IBM Business Partner, or visit the following websites:

- [Links to resources]

[Full case study available](#)

# Copy by Amy@AveryWrites.com Seller emails, B2B (Payer Summit)

with background research and personas  
provided by product managers

Becker's Payer Event – Thank you email

*Draft for post-event follow-up*

*with options for sender's customization that fit within the  
pre-defined, preformatted email template*



## Subject Line:

Option 1: Top talent, competitive benefits, quality data. The key?

Option 2: With your consultation, employers improve benefits using data

Option 3: With you as consultant, employers improve benefits using data

## Pre-header Text:

Help your employer clients attract talent using data-driven health benefits.

## Heading Line:

Become a consultative partner

## Copy:

Your employer-clients focus on finding top talent. For that, health benefits are a big draw. Speakers at Becker's Virtual Payer event revealed tools you can use to become their consultative partner, providing valuable insights to help them craft the most attractive benefits programs.

Discover:

- How data informs details of benefits plans that are attractive to your clients' employees and prospects.
- How the right benefits programs create meaningful, measurable impact for employers.
- How your data-driven consultation can lead to better client retention and competitive positioning.

## CTA link:

Schedule a consult

**Background:** Written based on SME interview and research, and using detailed buyer personas plus target market and purchase-decision research. *SEO: Clearscope B+ for “the great resignation”*

## **How employee experience will influence the future of work**

### **3 ways technology can help employers manage COVID-19 and address the great resignation**

The COVID-19 pandemic has changed everything, including employee engagement. Employers are scrambling to address record-high levels of people quitting for a different work environment, improved work-life balance and remote work opportunities, fueling what is known to Americans as “the great resignation.” Resignation rates have been highest for those in tech, science and healthcare industries, and employers are seeking retention strategies to fight burnout and help improve the employee experience.

Existing employees are expecting more from employers in the recovery phase of the pandemic. Here are three areas in which benefits leaders, human resources leaders and COVID-19 task forces can use technology to address the changing needs of the workforce and tackle employee turnover:

#### **1. Provide COVID-19 protocols for safe return-to-work sites.**

Since the beginning of the coronavirus pandemic, employers have been wrestling with the best ways to bring American employees back to physical locations. Complicating matters is the U.S. Supreme Court’s January 2022 decision to block a federal mandate that required private-sector businesses with 100 or more employees to require workers either get the vaccine or undergo weekly tests.

Some government policies around vaccinations will affect employer actions:

- The U.S. Centers for Medicare & Medicaid Services (CMS) requirement that healthcare workers at facilities participating in Medicaid and Medicare be fully vaccinated
- A second mandate, which is facing legal challenges, requiring Federal employees and contractors to be vaccinated

This leaves vaccination decisions in the hands of employers and may complicate return to workplace plans and pose a challenge to company success.

While workers might have varying reactions to vaccine requirements, employee sentiment seemingly leans toward support for vaccines. Here’s what they’re saying:

- 60% of employees either “approve” or “strongly approve” of workplace policies that ask them to disclose their vaccination status.
- 61% of employees responded affirmatively to the statement, “I’d rather work for a company that requires employees to be vaccinated against COVID-19 than one that does not.”
- 62% of employees believe companies should require workers to get a COVID vaccine before they are permitted to work in the office.
- 71% of vaccinated respondents feel comfortable joining a vaccine credentialing system.

Regardless of the recent Supreme Court ruling, some employers will still require vaccinations. They must also maintain individuals’ privacy and comply with related regulations, such as the Health Insurance Portability and Accountability Act (HIPAA), General Data Protection Regulation (GDPR), unemployment benefits and California Consumer Privacy Act (CCPA).

Employees will need a compliant, simple, trusted way to share their personal health information with their employers.

[LINK: Learn more about how employers can create safer workplace health strategies with technology]

#### **2. Support mental health in the workplace beyond traditional employee wellness programs.**

The pandemic’s upheaval has taken its toll on mental health. A September 2021 PULSE Health Poll found that only 20% of people rate their overall mental well-being as “excellent.” Employers are falling short of expectations on providing employee wellness programs. An IBV report found that fewer than 1 in 5 employees give their employers excellent marks for supporting worker well-being during the pandemic.

Employers can offer an array of programs and services to support well-being and mental health in the workplace. Using data and analytics can help them design workplace wellness programs appropriately and monitor their performance.

[LINK: Case study video. Learn how Novartis Business Services helped improve efficiencies and delivered better healthcare programs for its employees]

#### **3. Personalize and simplify employees’ experiences with health benefits.**

One employer saw an increase in usage of our “personalized benefits selection” tool, with 38% of workers using it in 2020—up from 25% in 2018 and 30% in 2019. In an environment that has become increasingly complex and dynamic, employers can greatly improve experiences by making things simpler and more tailored to their employees. This is difficult, especially when employers lack demographic tools and sufficient data to understand who their employees are and what they want.

*[continued, end of sample]*

**Copy by Amy@AveryWrites.com**  
**Cleveland Clinic “eHealthLines”**  
**a quarterly e-newsletter;**  
**target: “highly educated” audience**

## **Surgical Advances in Brain Tumor Treatment**

Treating brain tumors effectively takes a team of physicians who have a high level of expertise in different areas of medicine. Cleveland Clinic Florida has such a team. Highly skilled neurosurgeons offering new surgical techniques are able to remove brain tumors that physicians elsewhere have deemed inoperable.

“With our surgical techniques and the expertise of our physicians, there really are few ‘inoperable’ brain tumors anymore,” says Badih Adada, MD, a neurosurgeon with Cleveland Clinic Florida. “And technology has evolved so much that our patients can expect great outcomes following brain surgery.”

## **Delicate Precision**

Because of their location and their relation to delicate structures, brain tumors can be extremely challenging to treat. “Removing a brain tumor in its entirety and preserving the patient’s functions and quality of life are the ultimate treatment goals,” Dr. Adada says. Physicians at Cleveland Clinic Florida use a combination of surgery, radiation therapy and chemotherapy to reach this goal.

“Until 10 to 15 years ago, brain surgery could result in neurological deficits like poor motor function, cognitive function and speech,” says Richard Roski, MD, Cleveland Clinic Florida neurosurgeon. “But with the development of microsurgery, imaging tools and other techniques, those types of results are extremely rare.”

## **New Techniques to Target Tumors**

In removing a tumor, Cleveland Clinic Florida neurosurgeons rely on their vascular expertise to preserve the intricate blood vessels and nerves of the brain. And their experience in “skull base surgery”—which involves surgery using highly advanced tools, cameras and training to operate through the nasal passages to reach the brain—gives them options to effectively remove tumors without causing dramatic scarring and requiring a long recovery.

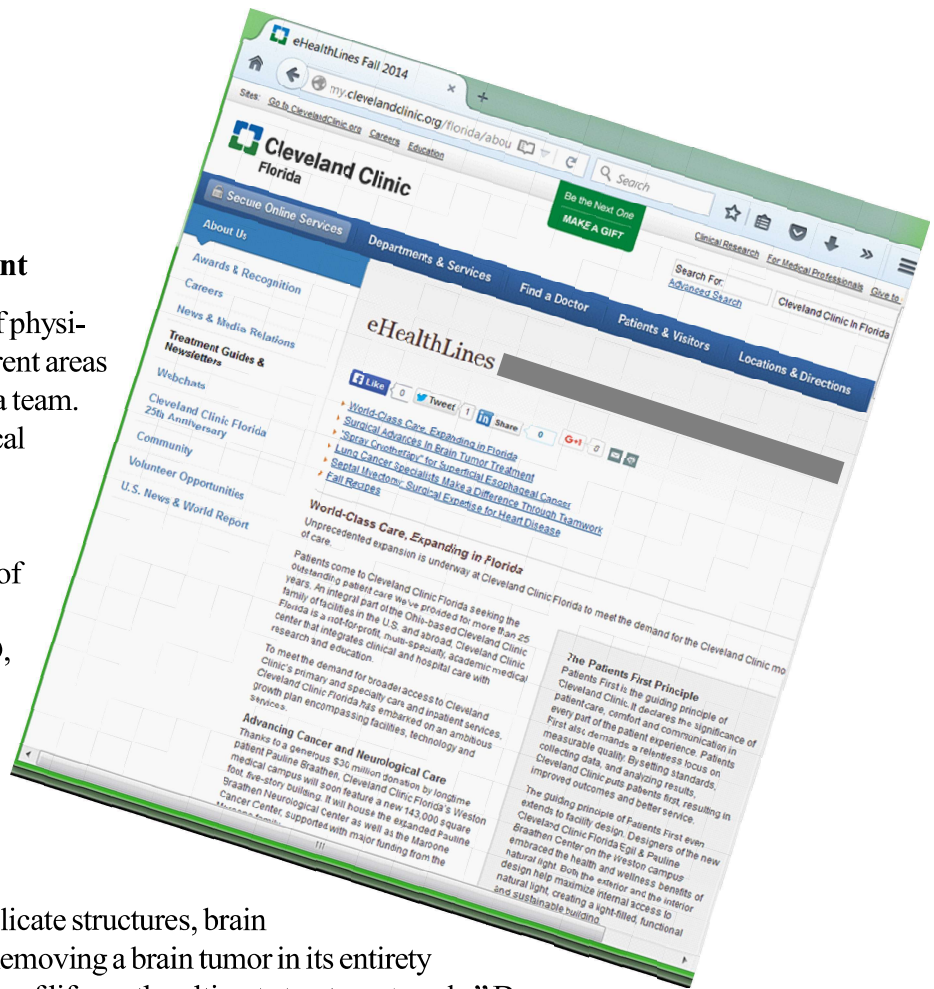
“Our ability to navigate inside the skull and brain has been another of the big breakthroughs to make tumor removal safer,” Dr. Roski says. For example, before surgery, neurosurgeons at Cleveland Clinic Florida use advanced, navigation software and imaging to clearly locate the tumor and plan a safe path to reach it. During surgery, they use ultrasound images to ensure they remain on the right path.

“Our physicians bring a combination of experience and expertise in brain surgery that is unique to our region of the country,” Dr. Adada says. “What that means for our patients is that, though having a brain tumor is a stressful diagnosis, we can offer them hope that our treatment will be successful and that we expect results to be superb.”

## **Other stories in this issue:**

**“Spray Cryotherapy” for superficial esophageal cancer**

**Lung cancer specialists make a difference through teamwork**





## Copy by Amy@AveryWrites.com B2Clinician, B2Staff, B2Donors

I offer decades of experience in communications for the diverse stakeholders in the healthcare industry for organizations like Cleveland Clinic, UNC-Chapel Hill School of Medicine, Blue Cross Blue Shield N.C., Talacris Pharmaceuticals, and more

### Media:

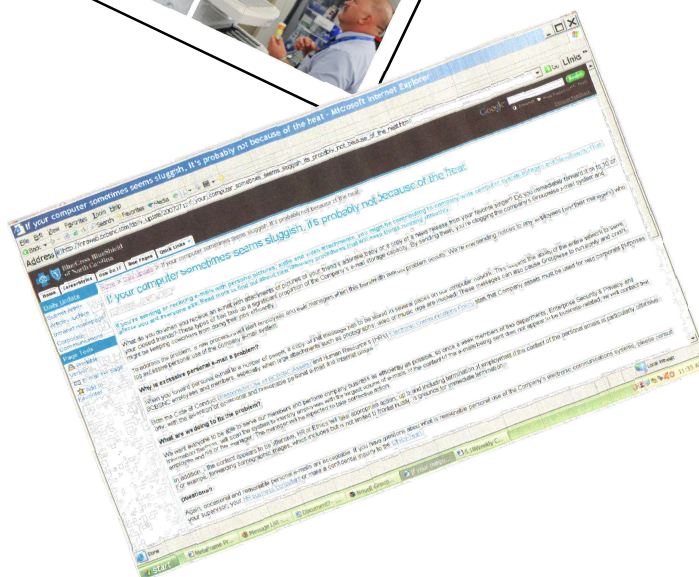
- ◆ Daily e-news
- ◆ Weekly print and e-newsletters
- ◆ Monthly and quarterly print newsletters
- ◆ Posters
- ◆ Classes and scripts
- ◆ Powerpoints

### Internal Stakeholders:

- ◆ Employees
- ◆ Physicians
- ◆ Researchers and Partners
- ◆ Volunteers
- ◆ Financial Donors
- ◆ Boards of Directors

### Messaging:

- ◆ Administration-to-stakeholders
- ◆ Physician-to-physician
- ◆ Employee-to-employee
- ◆ Crisis communications
- ◆ Human Resources support



# Long-term incentives for key executives

## *A benefit for all stakeholders*

When designing executive pay plans for key leadership positions, non-profit hospitals today must consider much more than base salary and annual incentives. Top-performing hospitals create total compensation packages that build in long-term incentive measures, measures which, compared to other forms of compensation alone, offer far greater value both to key executives and to the organization.

For any healthcare organization, such plans should at least withstand regulatory scrutiny while they incent and retain leaders. In optimal circumstances, they can engender even greater benefits to the organization and to the patients it serves by focusing executives' energies on key projects that advance the hospital's mission. Such a focus is increasingly important as industry challenges grow more and more complex.

### **Executives and their compensation**

According to Hay Group's 2011 Healthcare Compensation Study, incentive plans in 2011 reflect the healthcare industry's increased focus on long-term improvement. For instance, while integrated health system (IHS) CEOs' median rate of increase to base salary has grown by 1.5 percentage points in 2011, the rate of change for median total cash has dropped 2.3 percentage points. This appears to be due to a decline in the emphasis of annual incentive plans. In fact, the prevalence of annual incentive plans for not-for-profit IHS has dropped 10 percent since 2007, when a high of 89 percent of systems offered these plans. Today, only 79 percent of not-for-profit IHS offer one-year plans – the lowest in at least six years. At the same time, the popularity of long-term incentive plans (LTIs) has increased dramatically from 2006 when only 14 percent of IHS offered LTIs to senior executives; 25 percent of IHS offered these plans in 2011.

During this same period, government regulations, budgeting, physician relations, etc. have all become more complex. These complexities circle back to the organization, putting greater demands on them to attract and retain skilled, experienced leadership.

Long-term incentives (LTIs) have become an important way to address these challenges. First, these incentives allow a board to reward certain executives—those who have the position and ability to become change agents—for performance without increasing base salaries or annual incentives. For the executives, meeting LTI goals allows them to demonstrate their competencies in a more definitive way than a raise to base salary or annual incentive could reflect. More important, perhaps, long-term incentives focus executives' efforts on addressing complex challenges that can be addressed only with substantial time. This gives them the flexibility, over a period

of three or more years, for example, to make sustained progress on issues that are important to the hospital's mission.

### **Annual incentives are not enough**

The presence of LTI plans can enable not-for-profit organizations greater equity gains overall, compared to those that merely rely on base salary annual incentives as executive compensation pillars. However, only a quarter of integrated health systems have long-term incentive programs, according to Hay Group's 2011 Integrated Health Systems Compensation Survey, so there are many providers that have yet to realize the true benefits of these structures and the positive shifts that can occur in leadership focus. For example, executives charged with budget cuts might opt to keep a nursing unit closed during high-volume flu season, though the community would be better served by more inpatient beds. A CEO charged to focus primarily on annual operational budget goals might do so at the expense of making long-term investments to meet future market demands.

In contrast, the highest performing healthcare organizations reach for big-picture goals – goals that direct quality and efficiency improvements throughout the entire organization. Execution on the goals can often take longer than a 12-month window. Building an effective LTI structure to meet these goals is a form of risk management; it ensures that each party remains focused on progress while financial reward obligations are budgeted over many years and not awarded prematurely.

Well-designed long-term incentives for key executives can become the drivers for performance excellence for the entire organization. So, in an industry where both stakeholder expectations and government regulations continue to shift towards a value-based model of care, the financial viability of a healthcare organization might actually rest, in part, on well-structured long-term incentives. It's balance and thoughtful linkages that will lead to the best possible progress in areas that matter to leaders, the organization and the community to which they serve. Organizations should:

- Set both measurable short- and long-term goals.
- Link the system's quality goals with its operation and financial goals.
- Embed system-wide goals into individual hospital leaders' goals.
- Link bonuses to performance targets in the system's key strategic areas.

*[article continues, with topics including:]*

### **What do long-term incentives look like?**

#### **Linking finance and quality**

#### **and greater details about the subject matter**

**Copy by Amy@AveryWrites.com**  
**Health System and Health Tech**  
**PowerPoint slide deck and notes**  
**for National Professional Conference:**  
**ACHE**

**Physicians and the Electronic Health Record**  
**What if we build it,**  
**and**  
**they don't come?**

HIMSS Annual Conference:  
 Transforming Healthcare through I.T.

**Learning Objectives**

**or**

**Why are you here today?**

- Identify common barriers to implementing an electronic medical record (EMR)
- Identify specific barriers to physician adoption
- Learn how to avoid catastrophic failure

**Sentara**

**Healthcare:**

**An Overview**

**The EMR Today**

- Environmental Variables
- Organizational Variables

**8 Steps to Change Management**

1. Create a sense of urgency.
2. Form a powerful guiding coalition.
3. Create a vision.
4. Communicate the vision.
5. Empower others to act.
6. Create short-term wins.
7. Consolidate improvements.
8. Institutionalize what works.

**What is eCare? Sentara eCare Health Network**

- Technology
  - EPIC Systems Electronic Medical Record (EMR)
  - Document Scanning & Management
  - Medication Barcodes & Scanner
  - Device Integration
- Processes
  - Planned redesign of 18 major processes
  - Finding new ones that need improvement!

**What is the business case?**

**Total Cost of Ownership & Benefits**

**Common Barriers To Adoption**

(And how to get over them)

**Develop a focused approach to:**

- 1<sup>st</sup>: Implement
- 2<sup>nd</sup>: Stabilize
- 3<sup>rd</sup>: Optimize

**Change Management is key**

- It's NOT about the Technology
- Attitude Not Aptitude
- Transparency
- Control / Influence
- Strong Communication
- Circles of Influence
- Be Patient
- Embrace the Skeptics / Manage the Disruptive
- There is no Perfection

**WII FM**

(What's In It For Me?)



(design by client)



## Knees, don't fail me now

*Want to play tennis in 10 years? Go skiing in 30? Jog around the track when you are an octogenarian?*

Orthopaedic specialists at The Cleveland Clinic say you have considerable control over keeping your knees in shape now—and into your 80s and 90s. Additionally, advanced technologies offer new options to repair injured or damaged joints for athletes young and old.

That is promising news, since a recent study shows that almost half of all adults will have painful arthritis of the knee by age 85.

“As a large medical center, we’re afforded the opportunity to provide our patients with cutting-edge techniques and equipment,” says Brian Leo, MD, orthopaedic surgeon, researcher, and sports medicine specialist at The Cleveland Clinic. “Our goal with any treatment is to help people get to the highest levels of activity possible—to get them back on the field or back on the job.”

### The whole person

With each patient, The Cleveland Clinic’s orthopaedic surgeons discuss:

- Overall health
- Risk factors
- Surgical and non-surgical treatments
- Realistic goals
- Importance of rehabilitation

“We focus on the whole person, not just on the knee joint,” Dr. Leo says.

### Overweight at 45?

When people understand the causes of knee problems, they can better prevent problems now and in the future. For example, high contact sports such as soccer and football, as well as running and tennis, can lead to osteoarthritis of the knee later in life, in addition to injuries at any age.

“Also, the heavier you are, the more likely you are to develop knee problems,” Dr. Leo says.

In fact, people who are obese at age 45 are 60 percent more likely than people at a healthy weight to have osteoarthritis of the knee in their 80s, according to a recently published study funded by the Centers for Disease Control.

### Innovative, targeted treatment

Not every patient is an appropriate candidate for every procedure, Dr. Leo notes, but physicians at the The Cleveland Clinic offer a variety of innovative treatments, including:

*“Partial” joint replacements:* “Bone is like ‘precious metal’,” Dr. Leo says. “We use techniques that will keep as much bone in place as possible, and for as long as possible.” This includes replacing only part of the knee joint.

*Two ACL options:* Reconstruction of the anterior cruciate ligament (ACL) requires replacement of the torn ligament in the knee with a new one. When the ligament comes from the person’s own leg muscle, it is an “autograft” procedure.

Surgeons at Cleveland Clinic also offer a second option, called an “allograft,” in which the new ligament has been donated by an organ donor.

“Both procedures are very successful,” Dr. Leo says.

*Arthroscopy:* This is one of the most common treatment procedures nationally because it requires only a very small incision.

“Arthroscopic technology and equipment—including new implants, sutures and techniques—continue to improve,” Dr. Leo says. “We’re able to do more advanced knee surgeries this way today, because we’re taking advantage of innovations in the field.”

*Non-surgical options:* Some patients simply do not want or cannot have surgery, so The Cleveland Clinic’s orthopaedic surgeons offer a range of nonsurgical treatments:

- Anti-inflammatory medication
- Physical therapy
- Injections of cortisone artificial joint fluid

Many patients get significant benefit with these treatments. Some can return to playing football, for example, or to daily walks without pain.

“Our goal is to treat athletic types of injuries in people of all ages,” Dr. Leo says. “As much as I enjoy seeing the collegiate football player return to the field, I also get a kick out of the 80-year-old athlete who gets back on the court to play doubles [tennis] with friends.”

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### Sidebar

#### Game. Set. Match.

Growing up, Marshall Goldstein always enjoyed playing sports, including football and running up to 30 miles a week. Now at age 53, tennis is his game.

But sharp knee pain ended his doubles match one day last summer. The pain did not subside even after weeks of rest.

“That’s when I found Dr. Brian Leo, an orthopaedic surgeon, using The Cleveland Clinic website,” Mr. Goldstein says. Tests confirmed a torn meniscus, the knee’s shock absorber. Ten days later, Dr. Leo performed surgery.

“I chose him in part because he specializes in sports medicine,” he says. “He even treated arthritis in my hip, as well.”

Today, Mr. Goldstein is on the tennis courts, playing doubles twice weekly, as usual.

“My knee is so much better than it was even before the injury,” says Mr. Goldstein. “That first game back was great! I loved it.”



Copy by Amy@AveryWrites.com

Ochsner Health System, New Orleans (over 50 hospitals and health centers)

*Physician Notes* magazine

**Audience:** medical staff and referring physicians

**Goal:** re-introduce a specialty service

## **Pediatric and Adult Congenital Cardiovascular Surgery**

### **Medical center resumes specialty CV surgery**

For both the pediatric patient who needs cardiac surgery and the adult with a congenital heart defect, the Medical Center has recently recruited two experienced, board-certified, fellowship-trained cardiothoracic specialists. With their initial surgeries at our flagship hospital this past fall, they have jump-started the system's Pediatric Heart Care Services after a two-year absence.

"Since (Hurricane) Katrina, the region has been underserved," said Douglas S. Name, M.D., Chairman of the Hospital for Children. "We had kept our infrastructure of facilities and equipment in place, and we're proud now to re-start our program with two skilled surgeons."

**Referring physicians** include adult and pediatric cardiologists, pediatricians, neonatologists, and OB/GYNs. We offer same- and next-day appointments and consultations.

Moms and neonates are sometimes referred after imaging studies. In addition to patients with overt symptoms, children and adults might be referred if they have a strong family history of heart conditions.

Our services focus not only on pediatric patients, but also on patients of any age with suspected or diagnosed congenital defects.

#### ***Meet our team***

**Dennis M. Specialist, M.D.**, an experienced pediatric cardiovascular surgeon, is the Medical Center's new Director of Pediatric and Adult Congenital Cardiovascular Surgery. He comes to Louisiana after serving 10 years as Chief of Pediatric and Congenital Cardiothoracic Surgery at Connecticut Children's Medical Center, Hartford.

Joining him is **Shaun Alsost, M.D.**, our second new Pediatric Cardiovascular Surgeon. He has completed a three-year fellowship in Cardiothoracic Surgery and another in Congenital Cardiac Surgery. (See biography sidebar.)

"The Medical Center has a strong group of specialists already in place, and we work with a team that includes intensivists and an excellent support staff who are also

well-versed in the field," Dr. Specialist said.

Our clinical staff offers broad experience in many diagnostic and treatment areas, including pediatric cardiac catheterizations, pediatric electrophysiology, pediatric interventional cardiology, and more.

#### ***Special requirements for congenital CV surgery***

"Congenital cardiac defects are very different than acquired heart conditions," Dr. Specialist says. "The disease pathway is very different, and there are structural variations that are different with almost every patient."

Children, too, need pediatric specialists and sub-specialists, plus equipment that is scaled to their smaller bodies.

"The Medical Center has demonstrated its commitment to meeting the needs of these patients," he said. "We're excited to be here, to be providing a level of specialized care that builds on what's already available."

#### ***Geographic reach, easy access***

Referring physicians can schedule same-day and next-day consultations and appointments with these surgeons. This ease of access makes them a resource for physicians with patients throughout Louisiana plus parts of Alabama, Mississippi, Texas and Florida.

"The entire state of Louisiana, plus many areas bordering it, needs pediatric and congenital CV surgery services," Dr. Specialist says. "The area has been underserved."

"We're in a position to create an excellent regional hub for specialty heart care," he says. "We've gotten off to a great start with these new services."

*When a small medical device company in Texas was ready to begin a large post-approval trial of its high-tech heart valve, it turned to Tiempo's Clinical Research Software.\* Cost savings were only one of the company's goals.*

### **The Opportunity: Better product, fewer medications**

Vascular Technologies (VT),\* based in Austin, knew it had a great product with its new prosthetic valve.

"We'd spent over a decade on this technology, and the valve was already at the top of its class in valve performance," said John Crisp, Executive Vice President for Regulatory Affairs. "Patients were seeing important quality of life benefits that merited additional study, and we were ready for the next phase: post-approval research to explore these benefits."

With FDA approval, the valve would be the only mechanical heart valve available in the U.S. for low-dose anticoagulation therapy.

"We had to find the right partners to work with us," John says. "We needed a web-based product that met all of our needs for data capture and study management."

VT gained FDA approval to begin the trial, and medical researchers in dozens of prestigious medical centers across the U.S. were in place to begin.

### **Small company, high stakes**

The randomized control clinical trial of the VT Prosthetic Heart Valve involves up to 1,200 patients across 40 different medical centers nationwide. Compared to other medical device trials, theirs is a large study. Stakes were high in finding an experienced company with the software to manage, track and report on all facets of the study.

Some software providers proposed charging five figures per month to provide what VT needed. With healthcare IT costs coming down in many other areas—for storage in particular—these high costs did not make sense to the decision-makers at VT. John kept looking.

"At that time, the issue of upfront costs was also especially important," John says. "As a small medical device company, we needed a partner who could work with us."

After researching five vendors, they chose Tiempo's clinical research software platform.

"From a total cost perspective, we were able to offer significant savings," says Tiempo's David Jones. "Even considering the role of their internal team, savings approached 50 to 60 percent."

"Not only was the cost reasonable, they were willing to offer flexibility on payment terms," John said. "Trials are expensive, and they understood our needs."

### **Solutions: Robust software, responsive service**

As the VT team put the software to work, their choice of Tiempo was confirmed.

"John knows the regulatory environment," David says. "He knew exactly what functionality he needed in a software product to track and report progress on the VT heart valve."

Since beginning the trial, site investigators have offered their own evaluations of the software. They say data entry is simple, the web-based platform is convenient, and the paperless system has huge advantages. Investigators also told VT officials that the "serious adverse event" notification is particularly helpful.

"The software deployed quickly, and the investigator sites love it," John said. "Several investigators have actually volunteered to tell us how well Tiempo functions to manage the studies. The fact that they haven't been contacting us with problems attests to that fact, too."

### **Streamlined processes, valuable reports, cost savings**

By choosing the right partner, VT and their investigator teams are now concentrating on patient outcomes and evaluating clinical benefits, not on paperwork and documentation. Tiempo has streamlined those tasks.

And due to VT's dedication to their product, patients who need prosthetic heart valves are many steps closer to eliminating a lifelong need for higher doses of anticoagulation medication.

Officials expect that the cost savings realized by relying on the Tiempo software can be invested into further product development.

VT has also turned to Tiempo products and services to support its patient safety registry.

### **More information**

To see how the team at Tiempo can support you with your next important post-approval or investigator-initiated clinical trial, contact us.

[Contact information]

*\*A pseudonym*

## The Duke Endowment (foundation) Annual Report Feature: Healthcare Quality

Throughout the Thanksgiving holidays last year, Nelson Gunter, 56, was coping with the stresses of a cancer diagnosis and recent surgery to remove a large mass from his colon.

“The surgery was very successful. I was healing as expected and was supposed to go home from the hospital in less than a week,” he said.

But because of an error or oversight that occurred sometime during his stay, a dangerous infection set in; the surgery site had to be re-opened; and he ended up staying in the hospital for over a week.

**As a patient -- and also a physician and healthcare quality expert himself -- Dr. Gunter offers an important perspective of mistakes in care.**

“No one at that hospital had any mal-intent,” he said. “Everyone wants the best for the patients. But I got an infection because of poor quality. It was preventable.”

Dr. Gunter is far from alone in this view. Hospitals nationwide have long focused on improving healthcare quality and patient safety. Mistakes cost billions of dollars in medical care, lost wages, lost productivity, disability and death.

There are quality of life costs, too.



*A note about accompanying graphics (middle left): Based on interviews, I recommended a photo of Dr. Gunter and grandsons fishing on his property, to emphasize the quality of life issues discussed in the article.*

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*(story, continued)*

“The worst part of the experience was the extended length of time I had to leave the wound open [to promote healing], finding someone to change the bandage three times a day, and walking around with saline-soaked clothes for weeks,” said Dr. Gunter, who has recovered and is cancer free. “That’s the human side of the issue of poor quality of care.”

Fortunately, North Carolina’s healthcare leaders now have concrete, collaborative resources to identify and prevent problems like those that Dr. Gunter experienced. A new Center for Hospital Quality and Patient Safety, which was established by a grant from The Duke Endowment, is the focal point on which quality initiatives converge.

“You don’t get training in quality in nursing school, or even in medical school,” said Carol Koeble, MD, Director of the Center, based at the North Carolina Hospital Association. “We and the hospitals throughout the state share research, resources, expertise and success stories.”

In 2006, the center’s first full year of operations, over 800 professionals from over 100 hospitals across the state gathered eagerly to consult with each other during conferences and learn during training sessions.

“With this Center,” Dr. Koeble said, “we now have a tremendous network of hospitals and their employees who are working together to improve the care they give to every citizen of North Carolina.”

The process of incorporating each quality initiative will take time, but the goal is worthy: to create the safest and best hospitals in the United States.



Copy by Amy@AveryWrites.com (ghostwritten)

B2B. Pharma Trade Journal, London (2,100 words, excerpt)

## Topic: Child-Resistant Drug Packaging in Europe

A staggering 110,000 children are injured by poisonings each year in the 52-country European Region (1). In almost all poisonings involving medications, the packaging itself could offer children protection (2). . . .

Decades of experience in some European countries and the U.S. demonstrate that child-resistant (CR) packaging can make these products safer for children worldwide. For example, since the onset of strict U.S. packaging laws in 1974, an estimated 460 deaths of children under age 5 have been avoided due to CR packaging of oral prescription drugs (4). . . .

European children have been at risk, as well. In 2002, noting that 180 children aged 1 to 4 years old were hospitalised yearly because of iron overdose, the Health Minister of the United Kingdom called for and implemented new safeguards for packaging of iron as well as aspirin and paracetamol. In the Netherlands, CR packaging, including blister packs, led to a reduction in poison-related hospitalisations for children five years old and under (7). . . .

### More drugs in the home, more potential for harm

Historically in Europe and the U.S., most drug poisonings occur in the home. All drugs are a risk, but pediatric medications are an obvious starting point for CR packaging.

First, they can present an “attractive nuisance.” Chewable medicines and others with colourings, flavors, sweeteners and other taste-masking agents are attractive to children.

Second, pediatric medications are entering the marketplace—and homes—at an explosive rate. Manufacturers performed more studies on pediatric medications during one recent five-year period than in the prior 30 years combined (9). . . .

### Adult strength equals child danger

. . . By one estimate, 80 percent of the drugs prescribed for children are “off label,” and have not been tested or approved for children (12). With these medications, the line between “therapeutic” and “overdose” is not defined, and so their presence in the home makes CR packaging even more important. . . .

### Resistance to child-resistance

The sheer number of languages and governments that must agree on broad European CR packaging

guidelines has to date stymied child-safety advocates pushing for international standards.

And some manufacturers themselves have resisted CR packaging,

for several reasons. They say, correctly, that consumers with strength and dexterity problems simply cannot open some CR packaging. . . . One U.S. study showed that over a third of children poisoned by the prescription drugs had ingested the medications of their grandparents (13). And 25 percent (3,766) of the calls to U.S. poison centers about beta-blockers involved children under age 6 (14).

Drug manufacturers in Europe, benefiting from such U.S. experiences, have proposed international packaging standards that include detailed requirements for testing by diverse populations, including children and senior citizens. . . . Effective CR packaging could simply involve “cognitive barriers,” such as requiring an unusual fold or action that a child cannot accomplish but that an adult can. . . .

### Learning from experience

European manufacturers do not have to reinvent the proverbial wheel, or the blister pack, in order to embrace the medical, social, financial and marketing benefits of CR packaging for their diverse European markets. . . .

“Child-safe, senior friendly” has become a mantra of U.S. pharmaceutical packagers. They offer options that they believe would be well received by both the pharmaceutical manufacturers and consumers in Europe. For example, wallet packaging is available as a portable, senior-friendly package with a high child-safety rating. Like other packaging platforms that marry the unit-dose inner card to the outer package, this packaging not only keeps important drug information close at hand, but also provides excellent pharmaceutical marketing and branding opportunities.

### Bottom-line decisions

Child-resistant packaging is about the bottom line, but that bottom line is not necessarily a formula of hard and fast expense and profit figures. . . .

There are clear challenges ahead for the industry in addressing public safety concerns. But for those rising to meet those challenges—working with the right partners and without regulatory pressure—the rewards for all are likely to be better, safer and more profitable medicines.



Excerpts from a 3,600 word magazine article

## How TB employees help improve lives, save lives across the world

Do you know which of our products soldiers deliver using parachutes? How about which one is important to missionary families overseas? How many of our products let people go to school or work when they could not otherwise?

This article answers those questions. It will also give you lots of answers when your friends and family ask, “What do you make at TB?”

### To clot or not to clot? We have the answers...

*Hematology is the study of blood disorders. We make two products to help people with these disorders. One helps blood clot properly. The other prevents clots that are harmful.*

### Drug 1: Some people with hemophilia rely on this product every single day

Hemophilia A is a condition that causes people’s blood not to clot properly. So they bleed for longer than other people. They often bleed inside their bodies because of a bruise, as well as from a scratch on the skin, for example. They must plan carefully before having surgery, going to the dentist or even clipping their fingernails. (*Explanation of Factor VIII*).

**How does it work:** “It puts Factor VIII back into their blood,” he said, “so blood will clot normally.” It is made from human plasma.

**How our medicine is special:** About 20-30 percent of people who have Hemophilia A develop antibodies sometime during their lifetime. Some of them can no longer take other types of hemophilia medication while antibodies are in their blood. But often times, they can still take our product. Because of the special way we produce it, the body does not attack it.

“So it’s really important that this therapy is here for these patients,” he said.

**Who needs this drug?** About 1 in 10,000 children and adults worldwide have Hemophilia A. It is passed down from some parents to their children....

**Growing needs:** Over time, more people are developing antibodies to the other types of hemophilia medicine. So TB expects more patients in the U.S. to need it.

---

### Drug 2: The *only* treatment the FDA approves for certain blood clot conditions.

For a small number of people, surgery or pregnancy can cause life-threatening blood clots to an arm or leg, and in the lungs, for example. These people do not have certain proteins in their



blood to prevent the clots. It’s a condition passed down through families that is called “hereditary antithrombin deficiency.”

**How do we help:** Drug 2 puts the blood-clotting agent, antithrombin, back in the blood. Our product is the only FDA-approved treatment for the condition.

**Who needs our help:** About 2,000 to 5,000 people have this condition. ....

**Our challenges:** “One of our biggest challenges is that not many physicians are aware of hereditary antithrombin deficiency,” he said. “So they’re also not aware of this drug.”

**Our strengths:** TB began an awareness campaign last year to reach physicians ....

**Coming up:** TB is exploring how patients with other conditions might benefit from the drug. ....

---

### Drug 3: “An immune system in a bottle”

When it works properly, the body’s immune system helps keep people well. For those whose immune system isn’t working correctly, they get sick so often that they cannot have normal lives.

Drug helps many of these people to get back to normal activities and improve their quality of life.

“This drug is an amazing, life-altering therapy – essentially an immune system in a bottle,” said TB’s Director, U.S. Product Management. “Many patients who use it are really loyal to us. We should be proud of that.”

**Who needs our help:** .....

**How it helps:** ....

---

### [Sidebar:]

#### IGIV: Making sense of the alphabet

**IG:** In medical terms, the disease-fighting parts of the blood are called immune globulins, or “IG.” In people with normal blood, immune globulins are made in the blood plasma. (By the way, immune globulins are also called “antibodies.”)

**IV:** Patients get our drug, which is a liquid, into their veins through a tube and needle. This way of getting medication is called “intravenous,” or through an “IV.”

The drug is therefore called an “IGIV” therapy.

IGIV therapies replace what people’s blood is missing.

*Short-form introduction:*

## Cola: Bad for the bones

**Study surprises researchers, shakes up women's attraction to cola**

Researchers and parents have long understood that nutritionally bereft soft drinks often replace healthier choices in the American diet. One study now also suggests that colas actually rob bones of calcium, making them brittle. The large study, published in the *American Journal of Clinical Nutrition*, yielded several surprises both for researchers and for those who indulge in carbonated cola.

“We have long suspected a link between bone mineral density and cola consumption, but little research has explored the relationship between the two,” said lead author Katherine L. Tucker, Ph.D., with Tufts University in Boston. “We showed a significant relationship, but we were also surprised at how strong and consistent the results were.”

### Bad news for girls, women

According to the study, drinking cola significantly lowers bone mineral density in the hips—in women, but not in men. Bone mineral density, or BMD, is a proven indicator of bone strength. Low BMD leads to osteoporosis and to millions of expensive, debilitating and even life-threatening hip and other bone fractures each year, according to the National Osteoporosis Foundation.

Several studies have found that girls with low BMD have more fractures than others, in part because drinking cola leaves less room for milk and other bone-building dairy products. But calcium displacement does not explain low BMD in women, the study showed, because women cola drinkers consumed as much calcium as non-cola drinkers. . . .

“There’s just something about cola, and that includes diet colas, too,” Tucker said. “That’s one of the more important results, because many women think that diet colas have no negative effect.” . . .

The bottom line for women? Read the label. [Read more...]

**Background/  
implications:**

**Before you  
drink that  
cola....**

**Read the  
label**

The major difference between carbonated cola and non-cola drinks are caffeine, phosphoric acid and cola extract. Caffeine intake is a risk factor for osteoporosis, but it is the phosphoric acid, added to cola for tartness, that is now the targeted suspect, Tucker said.

“Phosphoric acid releases hydrogen in the blood and makes it more acidic,” she said. “We believe that’s related to the body pulling calcium out. Each time you drink cola, there’s a small effect on the bones; but over years, there’s a cumulative effect that results in lower bone mineral density. It starts to show more in middle and old age.”

Bones naturally become less dense and weaker with age, and four times as many women than men today have osteoporosis, though it does affect both.

“That’s why these results are so important,” Tucker said. “We’ve noticed that bone is more sensitive than people realize to all sorts of items in the diet. Research will continue to make clearer the benefits and risks of items in the food we eat.”





Copy by Amy@AveryWrites.com

By-lined feature included in award-winning series

Audience: "Highly educated" consumers

# Exploring the twists and turns of the DNA helix

Both practical and promising research is emerging from virtually every twist and turn of the DNA helix.

Discoveries are quickly advancing our understanding of the relationships between human genetics and disease.

"We're experiencing a paradigm shift in the way medicine is being practiced," says Geoffrey S. Ginsburg, M.D., Ph.D., director of the Center for Genomic Medicine at the Duke University School of Medicine in Durham, N.C. "There's a real opportunity to learn early in our lives about our genetic risks and to proactively plan to avoid illnesses. As a researcher, that's what gets me up in the morning."

The range of genetic research encompasses studies of health before birth and chronic disease later in life; mental health disorders and physical illnesses; inherited traits passed from parent to child and those shared by siblings and cousins.

"Families have a remarkably strong sense already that the kinds of diseases their relatives have can increase their risk for those diseases," says Elizabeth Hauser, Ph.D., Interim Chief of the Division of Medical Genetics at Duke.

"If we can understand the genetic components of that risk, we can offer more targeted treatment, and maybe even prevention," she says. "Genetics puts some specificity in the phrase, 'it runs in the family.'"

## Encouraging breakthroughs

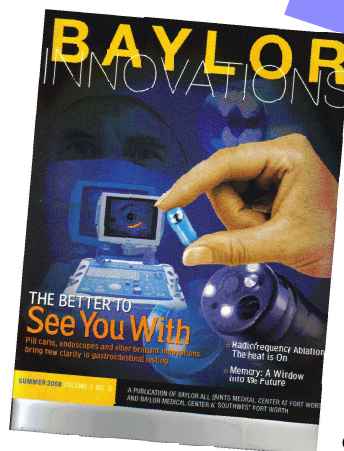
Study of the human genome and increasingly specific components of genes is offering solid medical strategies to diagnose, treat and predict disease. In the past two years alone, scientists have pinpointed around 50 new genes related to chronic conditions that had been previously impervious to research, according to experts.

Hauser and fellow researchers, for example, have been following the genetic trail of over 900 families who have histories of early-onset (before age 50) coronary artery disease (CAD).

"We've been doing this study for 10 years, and I'm starting to see light at the end of the tunnel," she says. "I'm starting to see ways our research can help these families, how it can give family members a more complete risk profile that they each can use individually."

## Hundreds of studies

Scientists are exploring the relationship between diseases and genetics across a broad array of medical disciplines.



Part of award-winning publication:  
**Gold Winner: Aster Awards**  
for excellence in medical marketing for a  
publication series

They have identified different genetic risk factors for neural tube defects, multiple sclerosis, age-related macular degeneration and cardiovascular diseases, for example.

Researchers are also investigating potentially inherited dermatological conditions such as eczema; ophthalmic conditions such as eye movement disorders;

neurological disorders such as Alzheimer's disease, restless leg syndrome and multiple sclerosis; plus others related to severe obesity and septic shock.

Other scientists begin with studies such as these, then explore how external factors like exercise, diet and stress affect genes to cause disease.

"We used to sit around and postulate about the role of genetics and of the environment," Hauser says. "But with the increase in information available today, we're developing the ability to stratify patients, to group them with risk factors and identify ways to reduce health risks."

## Dramatic choices

As research leads to more definitive diagnoses, it also leads to therapies. As reported this year in the *Journal of the American Medical Association (JAMA)*, in one study of overweight patients, scientists found that half of the patients who received nutrition counseling based on results of individual nutrigenomics testing lost significantly more weight on average than those who received conventional nutritional counseling.

Research also enables geneticists, pharmaceutical researchers and physicians to proffer preventive treatments even before a disease produces its first symptoms. Another *JAMA* study on genetic mutations related to osteoporosis offers insights that might lead to drugs that target the disease.

In addition, discovery of the "BRCA" gene mutations that lead to specific types of breast cancer defines important options for those who inherit the gene. Some choose to keep a tight schedule for regular screenings. Others choose preventive mastectomies even before cancer develops.

## Early diagnosis

In other cases, DNA research offers patients and their physicians the chance to catch diseases early, when treatment and prevention can be most effective. The Duke study on early-onset coronary artery disease is one such example.

...continued (available upon request)

Copy by Amy@AveryWrites.com

## The Duke Endowment/Foundation UNC-Chapel Hill School of Medicine Annual Report Feature (excerpt)

In church sanctuaries throughout the country every week, parents stand alongside their children, singing hymns. It's routine, maybe even mundane for many.

For parents like David and Shell Keim, however, hearing all six children sing with them was not something they even imagined to hope for. Their fourth child, Micah, is hearing impaired.

"Probably one of the toughest things someone can tell you is that there's something wrong with your child," said David Keim, of Cary, N.C. . . .

The Keims dove immediately into research, and what they learned added urgency. Speech and language delays can permanently limit learning, especially in young children.

"Early intervention is a one-way track," said Craig Buchman, M.D., professor of otolaryngology at the University of North Carolina School of Medicine in Chapel Hill and Medical Director of a unique early intervention program. "If a child doesn't get help early on, the brain gets trained in a way so that it can no longer use sound signals." . . .

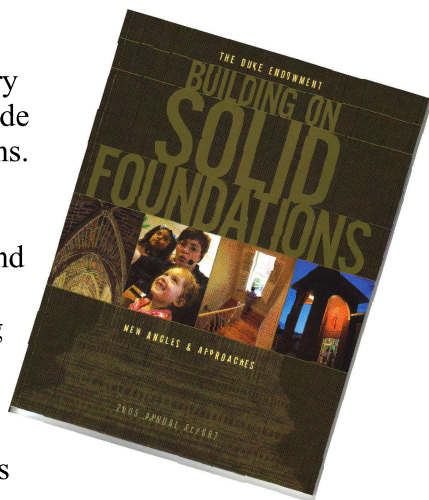
### Learning to hear is hard work

A team of professionals who specialize in hearing and speech for the deaf embraced Micah and his family. Staff provided focused, intense therapy to help him first with hearing aids and later with a cochlear implant, a permanent device that electronically translates sound into digital information that the brain can understand.

"It's hard work to interpret sounds heard through 'electronic hearing,'" said Carolyn Brown, Program Coordinator for the Carolina Children's Communicative Disorders Program (CCCPD), an affiliate of CASTLE.

CASTLE's on-site educator, three speech-language pathologists, a teacher for the deaf, and assistant teacher all help preschoolers understand the meaning of sounds they've never before heard, and to speak in ways past generations could not.

"Deaf kids can talk," Brown said. "When we blend the new technology with advanced teaching interventions, it really does happen." . . .



Teachers  
become  
students

North Carolina is on the cutting edge of speech-language programs, and CASTLE and its affiliate CCCPD, both part of the UNC School of Medicine, support professionals across the state.

"We have a two-fold approach," Brown explained. "We provide services directly to children who are deaf and hard of hearing and also provide professional training to those working in the schools."

Said one 24-year veteran teacher, "What CASTLE has done for me is raise the bar for what my students can accomplish through listening. When I left the Center [after training], I had really gained customized skills that I could take back to my schools and my students." . . .

### New sounds, this time for the family

From Micah's initial evaluation, to finding support and information, to his learning to listen and then to speak, the Keims give credit to CASTLE for bringing great changes to their lives.

Even for an untrained observer, the impact is clear.

Micah, now 7, busies himself with a drawing, but stops to delight in the click, click, click, click of the spring-loaded button on an ink pen. His speech, too, comes more and more easily.

"I'm going to be a pediatrician," he told an observer, nimbly and clearly pronouncing the complex name of the profession.

Watching his son, happy and drawing intently, Keim said, "I don't know what we would have done without the people there."

"It's hard to find . . .," he started slowly, then hesitated to find the right words.

"A CASTLE," Micah finished for him, never looking up from his drawing.

Micah's practice at preschool has given him a confidence that anyone can hear, and about a month after he began using the cochlear implant, it was his family's turn to hear something new. During church services with the entire family, they were caught by one of the most exciting sounds ever to resonate through the sanctuary.

"Micah was singing along," his father said. "I don't think I've ever heard a more beautiful sound."

**Top Award Winner:**  
**Silver Quill for feature writing**  
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Geisinger Health System, Penn.  
The Cleveland Clinic, Fla.  
Scripps Health, Calif.  
Atlantic Health, N.J.

#### *Publications/Media:*

*Journal of Healthcare Information Management*, national  
*Pharmaceutical Manufacturing & Packing Sourcing* magazine, London  
Web patient and donor testimonials  
e-Newsletters

### **Education & Special Interests**

Master's level study in marketing and healthcare management  
Master of arts degree in education, focusing on adult communication and communication theory  
Health literacy and plain language communications  
Ethical use of AI; 50-hour foundations course (2026)  
Industry courses, workshops, webinars

### **Professional Involvement**

American College of Healthcare Executives  
Association of Healthcare Philanthropy  
Society for Healthcare Strategy & Market Development (Advisory Board; national speaker)  
Center for Health Literacy  
International Association of Business Communicators  
American Marketing Association

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## **Unsolicited comments about my work:**

**Someone asked who was doing our marcom [marketing communications], and I hesitated to tell him--I don't want you to get too busy and forget me! But I did, and I told him you are a bargain, worth every dime.**

*-- County Economic Development Director*

**Excellent. Well written and well researched. A very practical article and a valuable piece for our journal.**

*-- Reviewer for a national industry publication, for a ghostwritten journal-length article*

**This is one of the best-written case studies I've ever read. Well done.**

*-- Marketing V.P., B2B healthcare*

**Wow! You did such a great job! Thanks for making me sound so amazing. No wonder they hire professional writers for these things! --interview subject for a branding campaign**

**I just wanted to call to say 'job well done.' You took a complicated topic and made it easy to understand.**

*--Professional interviewed for a feature*

**I am glad we have you to support our efforts. We just can't do it all ourselves, and I appreciate your help.**

*--From a client's boss, for on-going contract work*

**YES!!! This is what I was envisioning. Excellent job!**

*--From a client regarding fundraising collateral*

**The client was very pleased. I can't tell you how happy we are. Thank you for all your hard work!!!!**

*--From a national agency representative*

**Amy, these are WONDERFUL stories. You're a great addition to our magazine team. . . . Hope you'll be interested in an assignment for the next issue.**

*--Corporate Magazine Editor*