Nature of Community Hospital Systems Gives Them a Research Edge

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Although the vast majority of research funding is located at elite academic medical centers, the future of research lies squarely in the domain of community hospital systems. In an era where many community hospitals are looking to cut costs and increase revenue, research operations often end up in the crosshairs of chief financial officers and outside consultants. However, the research programs that maximize resources, facilitate the adoption of cutting-edge technologies and develop projects individually tailored to their community's needs are well-positioned to be innovative, forward-thinking industry leaders.

Academic medical centers commonly are viewed as the primary locus of research, however community hospitals have many unrealized advantages and opportunities in research compared to their academic colleagues. A community hospital system's competitive advantage arises from its deeply rooted relationships within the community, range of care settings, diverse patient populations and ability to move more nimbly.

Centura Health, Colorado's largest health care network, is a multistate integrated health system in Colorado and Kansas that fostered a culture of innovation and produced structural changes to position the organization to embrace the research imperative. These steps towards building a strong research environment strengthens Centura's relationship with pharmaceutical companies, which usually prefer to work with research institutions on clinical trials and other collaborations.

LOCAL NEEDS DRIVING THE RESEARCH IMPERATIVE
Community hospital systems are geographically and ideologically positioned to have an impact on the unique challenges of their local communities, with a special emphasis on the underserved and culturally diverse. This impact is magnified when the system maximizes research opportunities. Research provides the opportunity to measure the effect of one intervention when multiple are at play. It also provides the opportunity to develop generalizable knowledge, which improves outcomes for people within and outside the system's reach.

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Health care systems must use research to address the fiercest operational challenges, the ones that keep hospital CEOs up at night. There is a heightened responsibility for hospitals to address the social determinants of health, behavioral health, high cost of care and value-based models in populations that are often non-adherent and have high skepticism towards providers.[1]

Since community hospital systems operate facilities spanning wide geographic and socio-economic settings, the research they produce has great potential to make a difference in how care is delivered. At Centura, researchers enroll patients living in Denver, an urban community; Frisco, Colorado, a mountain rural community; and Westminster, Colorado, a suburban community. The patients could be enrolled at a Centura hospital, primary care clinic or safety-net clinic. When the results are published, providers can see that the intervention works or does not work in

INSTITUTIONAL REVIEW BOARD

An Institutional Review Board, also referred to as an Ethical Review Board, is the committee sanctioned to ensure that research participants' rights and welfare are protected. Governed by the U.S. Department of Health and Human Services' *Code of Federal Regulations*, their charge is to ensure participants in research studies volunteer freely, the risks and benefits of the research are carefully weighed and participants are treated equally.[1] These are embodied in the federal *Belmont Report's* ethical principles and guidelines for research using human subjects. Autonomy/respect for persons, beneficence and justice are the hallmarks of the ethical conduct of research.[2] IRBs may function at the local institutional level, or institutions may choose to outsource to an external, independent IRB. The use of independent IRBs is common in industry-sponsored research.

For those unfamiliar with the rigor behind producing ethical and scientifically sound clinical research, the IRB review process often is overlooked or misunderstood. Moving away from solely using a local IRB to using independent IRBs is essential for any institution serious about research. This transition makes the institution more attractive to industry sponsors like pharmaceutical companies, because their trials are multi-site, provide a broader lens of ethical oversight of studies and decrease the inefficiencies associated with using local IRBs.[3]

Pharmaceutical companies would rather have one IRB oversee every single research site rather than have splintered IRBs across the country providing sometimes contradictory guidance and oversight. A single IRB also would allow large community health systems to open a study in multiple hospitals without having to gain approval from multiple boards.

Centura recently made the transition away from five separate IRBs functioning with various levels of expertise and proficiency. Each IRB was a distinct body with different policies and procedures, creating variance, inconsistency and confusion. Under the new model, Centura has partnered with one of its sponsors, Catholic Health Initiatives, to provide local IRB review, while ceding oversight to an independent IRB for multi-site studies.

This arrangement provides a distinct advantage for Centura in working with pharmaceutical and device sponsors due to reduced review times and decreased staff time required to prepare the regulatory submission, all without compromising thorough reviews and ongoing oversight. The speed with which community health systems can establish clinical trials with appropriate patient protection, which in Centura's case is under 12 weeks, cannot be matched by large, bureaucratic academic centers and is a strategic differentiator for research at community hospitals as well as a defining contribution to the future of medicine.

NOTES
1. U.S. Department of Health and Human Services, *Code of Federal Regulations*, Title 45, Part 46, "Protection of Human Subjects," effective July 14, 2009. www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.
2. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*, April 18, 1979. www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.
3. Stephanie Pyle, "Benefits of Working with a Central IRB: Improved Efficiencies and Enhanced Human Subject Protections," *ACRP Monitor* website, June 2013. www.sairb.com/IRBForms/Benefits_of_Working_with_a_Central_IRB.pdf.

a number of geographic and socioeconomic circumstances, increasing confidence and implementation of the research's findings. A community health system with Centura's reach also is able to focus on enrolling women and minorities that often are underrepresented in clinical trials.[2] There is a serious concern that this underrepresentation is exacerbating health disparities.[3]

The Internal Revenue Service considers a strong research program to be a community benefit, which gives health systems the opportunity to serve their communities in a more customized fashion. Community members have approached Centura leadership with concerns that certain health issues lacked research, and they offered to make a charitable donation to Centura in order to have the issues studied.

One example is taking shape as an opportunity to investigate the health effects of permanently dwelling at high altitude in the United States. Community members near Centura's Saint Anthony Summit Hospital in Summit County, Colorado, asked if the hospital would study whether there are health risks, such as pulmonary hypertension, associated with living at high altitudes. The project provides a unique opportunity to undertake research using the community as a living laboratory.

CULTURE OF INNOVATION

The community hospital systems that will fully leverage the future of research will be the ones that can cultivate a culture of innovation. This will require making a shift towards a more entrepreneurial mindset. The innovators and entrepreneurs who often prevail are the ones who can facilitate the concept that failure teaches more than success.[4] In order to do this, the organization must facilitate safe brainstorming, risk-taking and the ability to nimbly pivot as needed — not common attributes for most health systems.

Conversely, startup companies seem to be radically disrupting the status quo in almost every industry except health care. To be sure, there have been successful digital health startups, but to date, there have been few "unicorn" companies (private startup company valued at more than $1 billion) in the digital health space. The hospital systems that manage to bend the cost curve will

need to strategically leverage startup companies along the way.

For example, pharmaceutical companies, in order to develop new products and improve their existing ones, are investing in and purchasing small biotech firms with promising offerings. To start to replicate this strategy, health systems must take an active role in bridging the gap between themselves and startups.

The health system challenge to cultivate a culture of innovation and the startup inexperience dealing with health system bureaucracy create the opportunity for a symbiotic relationship between the two.

Part of the reason for startups' lack of success within health care is their inexperience in successfully navigating the health care bureaucracy. Startups often find themselves unable to:

■ Identify the organizational barriers to innovation within health systems

■ Understand health care economics and drivers

■ Quickly gain approval from the correct stakeholders within the health care system matrix

■ Navigate the highly regulated landscape

■ Utilize metrics to measure value

■ Overcome the credo that no one knows what is better for a patient than a physician

Startups are fixated on getting to market with their product. Cash flow is limited, and every day that ticks away without revenue or investment is one day closer to the company's demise. This urgency to get to market oftentimes stands in the way of truly proving efficacy of the product. Health systems aren't going to rush to buy a product without proof of safety and efficacy — the stakes are too high with a patient's well-being at stake.

The health system challenge to cultivate a culture of innovation and the startup inexperience dealing with health system bureaucracy create the opportunity for a symbiotic relationship between the two. Research is a place where the two can

meet in the middle and find success. Health systems can help startups design scientifically rigorous pilot programs to prove that the product does what it says it does, in a safe and ethical manner. If incentives are aligned correctly from the very start of the engagement, this can be a way for the startup to gain a customer and for the health system to ensure that the product fits its needs by refining along the way and putting the technology into a position where it can be scaled across the system when ready.

Health systems are running up against an inescapable tension: on one hand, health system margins are thinner than ever, and on the other, there is an increased expectation for systems to address issues that were traditionally outside of their scope.

This can be thought of as a mutual mentoring relationship between a creative, T-shirt-wearing millennial and a seasoned, suit-wearing health care executive. The health system learns to act more innovatively, designing interventions and leveraging data with the end-user in mind, and the startup learns how to drive outcomes within a health system.[5]

FUTURE OF MEDICINE CONFERENCE

An important element of its efforts to cultivate a culture of innovation lies in Centura's Future of Medicine conference. This is an annual event convening diverse stakeholders to explore the convergence of technology, bioethics, population health and preventive medicine. Research is at the core, and topics covered in the conference often stretch beyond the current practice of medicine to technologies in their infancy like gene editing, personalized medicine, virtual reality, fully embedded wearables and artificial intelligence. Being at the forefront of such discussions helps to ensure that these technologies will be adopted effectively and ethically when they become more widely available. The pharmaceutical industry has been very supportive, sponsoring the event, attending and being involved in the external stakeholder steering committee.

The conference highlights community hospitals' research opportunities in front of a broad group of stakeholders that are not often brought together. Clinicians, tech entrepreneurs, scientists, bioethicists, academics, transdisciplinary health care innovators, creatives, patients, politicians and community leaders discuss the newest thinking and best practices in the future of medicine. Certain sessions of the event are open to the public so that consumers can participate in discussions aimed at demystifying health care and utilizing the patient voice to design ethical health systems.

The conference fuels Centura's spirit of innovation by assuring its associates and patients of the organization's commitment to being on the cutting edge. Attendees come back from the conference revitalized and ready to tackle their fiercest issues with creative solutions.

After the 2017 conference, one of Centura's nurse practitioners working in Centura's global health initiatives was so inspired during a session about 3-D printing that she convinced leadership to purchase two 3-D printers for their global mission efforts in Haiti. The 3-D printers would be used to replace broken parts in medical devices instead of having them shipped, which can take many months. The printers already have been used numerous times in Haiti for such purposes. Centura's Future of Medicine conference shows that strong partnerships with pharmaceutical companies, medical device companies and others can fund this type of endeavor and ensure sustainability and have unimaginable benefits far beyond the walls of the hospital.

CONCLUSION

Health systems are running up against an inescapable tension: on one hand, health system margins are thinner than ever, and on the other, there is an increased expectation for systems to address issues that were traditionally outside of their scope. Innovation through research is the opportunity for community hospital systems to turn this challenge into an opportunity. Addressing the current challenges while focusing on the future will position community hospitals to sur-

vive and thrive into the foreseeable future. The systems that leverage research to integrate promising new pharmaceuticals and medical devices, virtual reality, artificial intelligence, 3-D printing, genetic and molecular diagnostics, real-time patient data collected from embedded wearables, and other technologies into operations will set the pace. These systems will solve operational challenges and better address the needs of their local communities. This is imperative, as diverse communities and the underserved are the backbone of community hospital systems and deserve world-class research and access to cutting-edge technology right in their local communities.

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NOTES
1. Barry Ronan, "Hospital Impact: Here's What Keeps This CEO Up at Night," *FierceHealthcare* website, Dec. 7, 2017. www.fiercehealthcare.com/hospitals/hospital-impact-here-s-what-keeps-ceo-up-at-night.
2. Society for Women's Health Research and U.S. Food and Drug Administration Office of Women's Health, *Dialogues on Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials*. www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf
3. *Dialogues on Diversifying Clinical Trials*.
4. "Schumpeter" blog, "Fail Often, Fail Well," *The Economist* (April 14, 2011). www.economist.com/node/18557776.
5. Advisory Board, "Millennials Should 'Reverse Mentor' Health Care Leaders. Here's Why," *Advisory Board Daily Briefing* website, Oct. 19, 2017. www.advisory.com/daily-briefing/2017/10/19/millennial-mentor?WT.mc_id=Email|DailyBriefing+Headline|DBA|DB|2017Oct19|FinalDB2017Oct19||||&elq_cid=2262240&x_id=003C00000224PQiIAM.

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