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**Jeffrey Driver**  
([Jeffrey.driver@asu.edu](mailto:Jeffrey.driver@asu.edu)) is Director of Health Care Compliance and Regulations, BS, and Clinical Assistant Professor at Arizona State University – Edson College of Nursing and Health Innovation, Phoenix, AZ.



**Ramona Ramadas**  
([rlramada@asu.edu](mailto:rlramada@asu.edu), [linkedin.com/in/ramona-r-157418/](https://www.linkedin.com/in/ramona-r-157418/)) is Instructor at Arizona State University, Phoenix, AZ.



**Betsy Wade** ([bwade@shccs.com](mailto:bwade@shccs.com), [linkedin.com/in/betsy-wade-mp-h-c-h-c-c-n-a-689555ba/](https://www.linkedin.com/in/betsy-wade-mp-h-c-h-c-c-n-a-689555ba/)) is Chief Compliance & Ethics Officer at Signature HealthCARE, Louisville, KY, and Faculty Associate at Arizona State University – Edson College of Nursing and Health Innovation, Phoenix, AZ.

## Leveraging innovation science to design effective compliance programs and solutions

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by Jeffrey Driver, Ramona Ramadas, and Betsy Wade

The global COVID-19 pandemic has brought and continues to bring a surge of unprecedented demands to the businesses in which compliance professionals operate. Supply chain, health policy, human capital, health information, telehealth, and education are a few large-scale examples that have been subject to a whirlwind of innovation since shortly after our calendars ticked into 2020.

For a compliance professional entrenched in a carefully crafted compliance program immersed in regulatory and legal principles, these unparalleled demands spurred on by necessity may have put compliance professionals in an uncomfortable spot, especially given that the regulatory frameworks they operate in were built in a pre-pandemic world. But as American businessman Bill Maris stated, “the reality is regulation often lags behind innovation.”<sup>[1]</sup> As such, risk and compliance professionals, while mindful of regulatory compliance, have an opportunity to embrace innovation—now more than ever.

This opportunity should be a call to action and may also be considered an essential path forward for compliance programs to adjust to a new reality. This article focuses on how innovation science can be incorporated into the discipline of compliance, compliance program architecture, and compliance practice and risk mitigation.

### Innovation science and compliance program design

The United States Sentencing Guidelines laid the foundation for compliance professionals practicing today and are the central source of authority for building an effective compliance program. Tucked away neatly within Chapter 8 of the guidelines is a lone and very specific word—*design*—within the so-called Eighth Element of components that constitute an effective compliance program, which reads as follows:

“In implementing [the seven elements of an effective compliance program] subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.” <sup>[2]</sup>

The “eighth element” therefore is crucial in that it requires not only a periodic risk assessment, but most importantly as part of the risk response, requires that each element of a compliance program is examined, designed, redesigned (modified), and implemented. Enter innovation science.

The words design and designer have specific meaning in innovation science, which can be conceptually borrowed to fill out the meaning of design in the context of the Eighth Element. In a 2011 seminal work on design, “Change by Design,” Tim Brown and Barry Katz lay out how designers possess a set of design skills that can be applied to solve problems through innovative practices in a wide range of organizational, management, and strategic problems.<sup>[3]</sup> Furthermore, nondesigners such as risk and compliance professionals and other organizational leaders in a spectrum of industries can be taught these design skills; they can apply them to specific problems of practice, thereby intentionally designing a more robust program that blends innovation and risk reduction.

Springboarding from the foundational tenants of design thinking as a proven innovation methodology, an eight-step design thinking innovation practice was formulated as a handbook specifically for a diverse set of healthcare risk managers, including compliance professionals. Leveraging a combination of design thinking, risk management, quality and performance improvement, as well as business strategies, *Discovery Design* may ease an interprofessional team into their entry into the utilization of design thinking principles and practices to cocreate breakthrough compliance and risk management programs and risk mitigation.<sup>[4]</sup>

Following are some examples of how compliance professionals might start their professional journey to acquire and apply design skills from the innovation sciences, tips on building a compliance innovation infrastructure, and making suggestions for infusing innovation practice into compliance practice to enhance compliance effectiveness. We begin with the central question of all designers—“how might we?”

## Applying innovation science to compliance practice

The concept of innovation in a corporate setting may conjure various images ranging from closed-door think tanks to “cool” office spaces where speakeasies, ping pong tables, and Koosh balls can be found in abundance. Regardless of how close to the truth these descriptions may be, important myth-busting needs to be conducted to set up new innovators for success.

The first myth is that only a special few individuals can practice this skill. The practice of innovation and innovation science must be inclusive to be effective—drawing on intersection, interface, and interaction to release innovation and bring the best ideas forward for action.<sup>[5]</sup> The second myth is that innovation should happen behind closed doors. In fact, innovation should be transparent and visible across the organization, with a variety of opportunities for all members of an organization to engage.

With these myths successfully addressed, it should come as no surprise that innovation science strives to explain the act of innovating versus the resulting innovations themselves. Joseph Sinfield defined innovation science in 2020 that brings these concepts together:<sup>[6]</sup>

“Design has classically been expressed as a goal-oriented activity that progresses from identifying a problem to developing and deploying a solution.”

But work on high-impact design has revealed that achieving non-incremental outcomes—to lead through innovation—may require design that more holistically (convergently) explores linkages between problem and solution, and exploits multifaceted perspectives of a functional, social and emotional nature.

“Building these perspectives through Innovation Science can facilitate the convergence that addresses complex, multidiscipline problems. This can establish a problem-solving language that lets different disciplines interact and more effectively engage, and offers a way to characterize different classes of problems and the methods and solutions that achieve impact.”

Numerous models and tools exist to support the act of innovating. One of the best places for new innovators to begin is with Paul Plsek’s eight heuristics for innovative thinking:<sup>[7]</sup>

1. Make it a habit to purposefully pause and notice things.
2. Focus your creative energies on just a few topics that you care about.
3. Avoid being too narrow in how you define your topic.
4. Try to develop original and useful ideas by making novel associations among what you already know.
5. When you need creative ideas, remember attention, escape, and movement.
6. Pause and carefully examine ideas that make you laugh the first time.
7. Recognize that your streams of thought and patterns of judgment are not inherently right or wrong.
8. Make a deliberate effort to harvest, develop, and implement at least a few ideas you generate.

Compliance and risk professionals do not need to gain a seat at the innovation table to engage with these techniques. They can be applied immediately to individual practice as an initial step and then broadened into the work of the team and the team’s projects, followed by larger organization-wide efforts later or as competency and confidence increase.

From this foundational model, a simple but team-based, iterative innovation model from Scott Endsley outlines the following questions innovators should ask as they work through an innovation challenge:<sup>[8]</sup>

- What is the design challenge?
- What do we know about the challenge?
- What ideas might work?
- How do we test the ideas?
- How do we implement them?

Compliance and risk professionals are uniquely positioned to contribute to the conversation, as suggested by this model. Compliance and risk can bring insight into the challenge. For example, they may be able to draw on their knowledge of the regulatory aspects of the topic—experience that other members of a multidisciplinary innovation team may be missing. Compliance and a diverse population of risk managers may also have intimate

skills and expertise in navigating the technical systems used to manage the issue the team is working through inside and outside the organization. Finally, compliance and risk are in a unique position in the organization—almost everything flows into or through them. As a result, the relationships held within an organization by a compliance or risk officer may surpass those of a much higher level in the organizational hierarchy. As you work in teams to solve innovation challenges, how might you use one of the most powerful tools of all—the power of relationships—to identify others to come to the table to solve the organization’s problems?

## **Tips for expanding innovation into compliance**

Given that innovation is here to stay, now is the time for compliance professionals to change from innovation consumers to innovation creators in their healthcare organizations. Instead of being resistant to innovation, compliance professionals should embrace innovation and look for ways to help their organizations implement new technology and new ways of doing things.

A great place to begin this journey is a partnership with human resources or your organization’s training or professional development team. Working with these partners in your organization can help the compliance department build a formalized roadmap to develop and maintain the team’s innovation skill set. Taking the time to formalize innovation as part of ongoing professional development will accomplish several goals: creating a culture of innovation within the compliance organization, increased competence and confidence with innovative techniques, and the immediate ability to apply innovation to the problems faced by the team or the organization.

Once the training foundation has been set, a second strategy compliance professionals can use to transition into an innovation creator engine for the organization is networking outside the immediate team to offer their expertise. Many organizations have agile teams,<sup>[9]</sup> blue ocean strategy approaches,<sup>[10]</sup> innovation departments, innovation officers, incubators, or other formalized teams or processes for incorporating innovation into the organization’s work. If compliance doesn’t have a seat at the table, now is the time compliance professionals trained in innovation techniques to step forward and offer themselves as resources. To support these conversations, an internal marketing approach may be valuable—with executive summaries or slide decks prepared to showcase the value compliance professionals can bring to innovative projects and offer examples of ways to use the compliance team.

According to an article in *Modern Healthcare*, a quarterly survey of top healthcare CEOs showed 92.9% of those surveyed “described the pace of innovation over the past year as speeding up.”<sup>[11]</sup> The pandemic was the primary driver of innovation. Examples of innovation resulting from the pandemic are seemingly endless. In a conversation between Leslie Morgan, Clinical Assistant Professor, Health Care Compliance and Regulations, Arizona State University – Edson College of Nursing and Innovation, and Raena Raebel, Auditor Specialist, AHCCCS Office of Inspector General, onboarding new employees and engaging compliance interns that otherwise would have taken place in person were conducted via video conferences, classes moved online, and networking with other professionals transitioned to technology platforms such as LinkedIn. At the 25th Annual Health Care Compliance Institute, George Diaz, MD, Infectious Diseases at Providence Regional Medical Center in Everett, Washington, mentioned that Providence Regional engaged compliance when working with Microsoft to create a chatbot that could help assess the likelihood of a patient having COVID-19.<sup>[12]</sup> Derek Kang, Chief Compliance Officer at UCLA Health, indicated compliance also worked hand in hand with operations at UCLA Health in Los Angeles, California, on privacy, security, consenting, and billing as it expanded telehealth from about 300 patient visits per week to tens of thousands.<sup>[13]</sup> And, Patricia Kunz Howard, MD, Enterprise Director of Emergency Services at University of Kentucky Healthcare, said compliance was at the table working through regulatory considerations at the University of Kentucky Hospital in Lexington, Kentucky, as it implemented telehealth in the emergency room, allowing the physician to talk with patients remotely via Zoom to decrease

exposure to COVID-19.<sup>[14]</sup> UCLA Health implemented similar technology using robots equipped with iPads in the emergency room to protect staff when there were no vaccines and to preserve personal protective equipment, stated Kang.<sup>[15]</sup> Many healthcare providers also shifted their strategic focus to infection prevention to make their organizations as safe as possible for their patients and staff.<sup>[16]</sup>

Strategy, clinical, infection control, and purchasing worked closely with risk management, compliance, and legal to put together infection prevention tools that would help the organization comply with new standards from the Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and Occupational Safety and Health Administration.

## Using innovation science to enhance compliance effectiveness

Compliance officers not only can engage in innovation to help advance their organizations but also assist their departments with their day-to-day work. Without innovation, the compliance officer role would make an already challenging job even more difficult and require more human resources and time to ensure organizations meet regulatory requirements.

Compliance professionals may not give it much thought; however, many use innovation every day to help operationalize the Seven Elements of Compliance and manage their oversight role in their healthcare organizations. Innovation allows compliance professionals to complete their work more quickly, accurately, and with the requisite documentation to provide to regulatory agencies. In fact, examples of innovation are evident in all aspects of compliance programs. Examples of innovation that compliance professionals may use daily include:

- Software to manage excluded provider checks, licensure checks, annual administration of conflict-of-interest statements, and company policy and procedure workflows
- Software to record and manage hotline calls and compliance investigations
- Software to record non-monetary compensation for physicians and their immediate family members to comply with the Stark law
- Learning management systems to provide and track completion of compliance education
- Videoconferencing to give updates on new regulations to employees who may be in remote locations
- Survey tools when completing annual risk assessments and compliance effectiveness reviews
- Data mining to identify potential outliers and risks to assist with auditing and monitoring
- Apps that allow compliance staff to take the contents of their computer with them on a smaller device like a tablet or smartphone
- Web-based portals to track COVID testing results and vaccination data for reporting to state and local health departments, state health information exchanges, and CDC's National Healthcare Safety Network database in compliance with CMS requirements
- Apps to track and report medical director time and activities in compliance with the physician's contract and the Stark law<sup>[17]</sup>

## Conclusion

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With today's technological advances and the continued push to innovate, compliance should be included in everything an organization does, and work closely with strategy and innovation teams. Engaging compliance on the front end can help businesses solve problems through innovation while remaining compliant with existing—or changing—laws and regulations. Compliance should not resist innovation but embrace it.

## Takeaways

- Historically, regulation has lagged innovation, but the global COVID-19 pandemic has allowed compliance professionals an opportunity to change that.
- Compliance professionals can help organizations solve business problems with innovation while designing compliance programs that keep businesses compliant.
- Compliance professionals should consider innovation and not resist it because it can help organizations comply with existing or evolving laws and maintain compliance.
- Compliance professionals can engage with human resources, training, and strategy to immerse themselves in professional development that will help them get more involved in innovation.
- Engaging in compliance early can help businesses solve problems through innovation while remaining compliant with laws and regulations.

<sup>1</sup> BrainyQuote.com, Bill Maris, accessed February 13, 2023, [https://www.brainyquote.com/quotes/bill\\_maris\\_728857](https://www.brainyquote.com/quotes/bill_maris_728857).

<sup>2</sup> United States Sentencing Commission, *2018 Guidelines Manual Annotated*, Chapter 8 – Sentencing of Organizations, November 1, 2018, <https://www.ussc.gov/guidelines/2018-guidelines-manual-annotated>.

<sup>3</sup> Tim Brown and Barry Katz, “Change by Design,” *Journal of Product Innovation Management* 28, no. 3 (2011): 381–383, <https://doi.org/10.1111/j.1540-5885.2011.00806.x>.

<sup>4</sup> The Risk Authority et al., *Discovery Design: Design Thinking for Healthcare Improvement* (Palo Alto, CA: Risk Authority Stanford, 2017).

<sup>5</sup> Tim Porter-O’Grady and Kathy Malloch, *Innovation Leadership: Creating the Landscape of Health Care* (Sudbury, MA: Jones and Bartlett Publishers, 2010).

<sup>6</sup> Joe Sinfield, “Innovation science: There’s a method to that light bulb going off in your head,” *Purdue College of Engineering Review*, June 19, 2020, <https://medium.com/purdue-engineering/innovation-science-theres-a-method-to-that-lightbulb-going-off-in-your-head-ce65a978422>.

<sup>7</sup> Paul E. Plsek, *Creativity, Innovation and Quality*, (Milwaukee, WI: ASQC Quality Press, 1997).

<sup>8</sup> Scott Endsley, “Innovation in action: A practical system for getting results,” in *Innovation Leadership: Creating the Landscape of Health Care*, ed. Tim Porter-O’Grady and Kathy Malloch, (Sudbury, MA: Jones and Bartlett Publishers, 2010): 59–86.

<sup>9</sup> Stephen Denning, *The Age of Agile: How Smart Companies are Transforming the Way Work Gets Done*, (New York, NY: AMACOM, 2018).

<sup>10</sup> W. Chan Kim and Renee Mauborgne, *Blue Ocean Strategy: How to Create Uncontested Market Space and Make the Competition Irrelevant*, (Boston, MA: Harvard Business Review Press, 2015).

<sup>11</sup> Jessica Kim Cohen, “How CEOs are thinking about innovation challenges, interop and tech giants,” *Modern Healthcare*, May 18, 2021, [https://www.modernhealthcare.com/operations/how-ceos-are-thinking-about-innovation-challenges-interop-and-tech-giants?utm\\_source=modern-healthcare-covid-19-coverage&utm\\_medium=email&utm\\_campaign=20210520&utm\\_content=article1-headline](https://www.modernhealthcare.com/operations/how-ceos-are-thinking-about-innovation-challenges-interop-and-tech-giants?utm_source=modern-healthcare-covid-19-coverage&utm_medium=email&utm_campaign=20210520&utm_content=article1-headline).

<sup>12</sup> Patricia Kunz Howard, George Diaz, and Derek Kang, “Compliance on the Pandemic Front Lines,” 25th Annual Health Care Compliance Institute, April 21, 2021, <https://compliancecosmos.org/general-compliance-session->

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