iac

innovation advisory committee

medical technology and devices

vision

Nurses practicing in all facets of care are an integral part in the patient care technology and device ecosystem - acting as leaders in the research, design, development, selection, implementation and improve-ment of such technology and devices.

Committee Members

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contents

In compiling these innovation resources our goal was to ensure unique information across all eight resource guides and to avoid redundancy. You may find additional content around **Medical Technology & Devices** in the general resource guide. We thank the Med Tech & Devices committee for contributing content to advance nurse-led innovation.

iac med tech + devices

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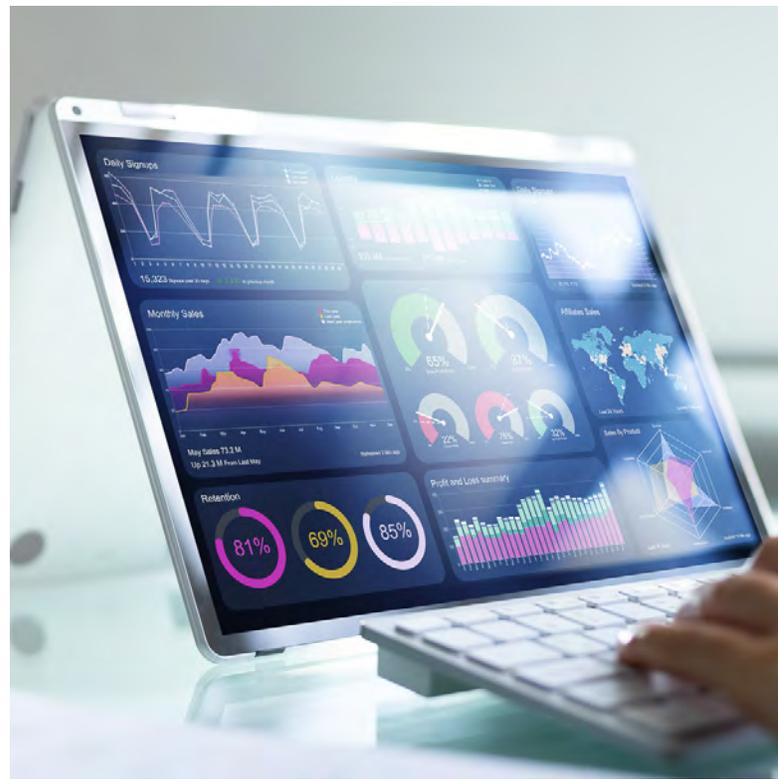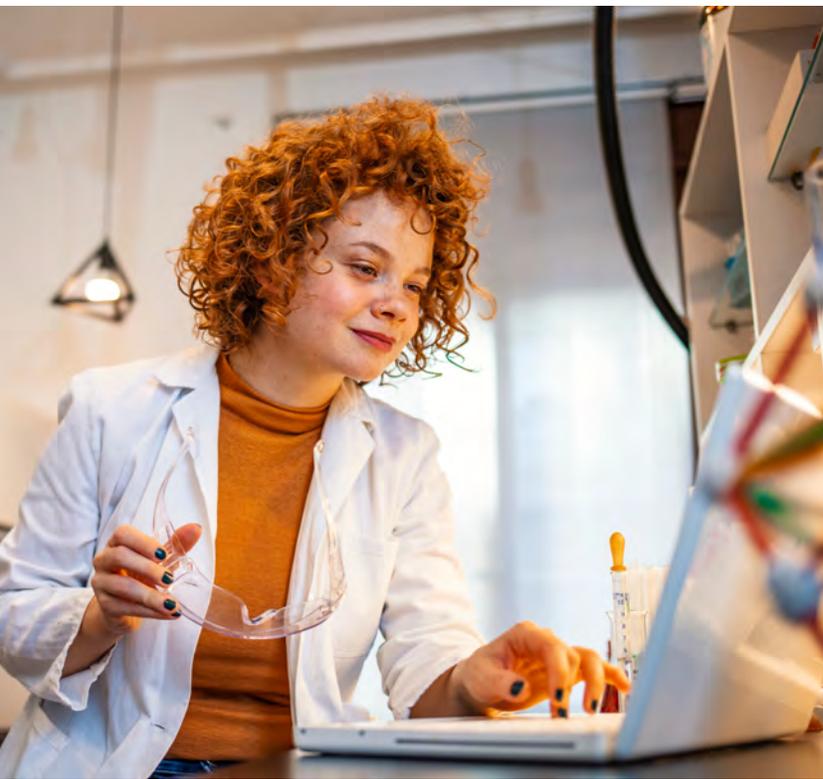
general resources

General Resources

Biodesign

- Innovation Process Tech + Device Development [website]
- Stanford Center for Biodesign [website]

Human Factors

- Human Factors and Ergonomics Society [website]
- How to Validate A Need – Jobs To Be Done Theory [website]
- US FDA Human Factors [website]
- US FDA Human Factor Considerations [website]

Nurse Engineer

- Health Care Innovation: Embracing the Nurse–Engineer Partnership [article]
- Teamwork Between Engineers and Nurses Triggers High-tech Healthcare Inventions [website]
- The nurse+ engineer as the prototype V-shaped professional [article]
- Nurse-scientists and nurse-engineers: Nurse- driven device innovations and inventions can improve patient care [article]

Health Technology

- Conceptual Model for Technology, Nursing, and Patient Safety [website]
- Digital Technology's Promise for Better Health Care Delivery [ebook]
- Exploring the Technology Trends That Will Define the Future of Healthcare [article]
- Health Tech: SnapNurse's Technology Can Make an Important Impact on Our Overall Wellness [article]
- How Women Are Reimagining The Field of Health Tech [article]
- Making Sense of Health Technology [article]

general resources

General Resources (cont.)

<u>Pediatric Resources</u>
- KidsX Accelerating Pediatric Innovation [website]

Robotics
- Robotics and The Impact on Nursing Practice Case Study and Pilot Site Analyses [article]

Websites
- AAMI Standardization [website]
- AccessGUDID [website]
- Adva Med Medical Device Industry Facts [website]
- American National Standards Institute [website]
- I-Corps [website]
- International Organization for Standardization [website]
- ISPI [website]
- Medical Device & Diagnostic Industry [website]
- Medical Device Innovation Consortium [website]
- Medical Device Network [website]
- NEST Coordinating Center [website]
- The Noun Project [website]
- United States Patent & Trademark Office [website]

Podcasts
- Tech Vitals [podcast]

government

Government

- Advanced Research Projects Agency for Health (ARPA-H) biomedical and technology health research [website]
- CFR – Code of Federal Regulations Title 21 [website]
- Classify Your Medical Device [website]
- How to Determine if Your Product is a Medical Device [website]
- ISO Standards for Medical Devices [ebook]
- MAUDE – Manufacturer and User Facility Device Experience [website] (reporting device suspected death/injury/malfunction)
- Medical Device Identification—Access GUDID [website]
- Network of Digital Health Experts [website]
- Regulatory Requirements Overview: Medical Devices [website]
- Rapid Acceleration of Diagnostics (RADx) COVID Testing [website]
- The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs [website]

legislation + policy + ip

Legislation + Policy

- Policy for Device Software Functions and Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff [report]
- Overview of Regulatory Requirements: Medical Devices [transcript]

Intellectual Property

- European Commission: IP Management and Resources [website]
- International Trademark Association [website]
- Patent Landscape Analysis [website]
- Patent Landscape Reports [reports]
- Protect your Intellectual Property [website]
- USPTO [website]
- USPTO Patent Basics [website]
- USPTO Resource Glossary [glossary]
- US Chamber of Commerce Global Innovation Policy Center: Why is Innovation Important? [website]
- World Intellectual Property Organization [website]
- World Intellectual Property Organization IP for Business [website]

*Intellectual Property Articles on Page 12

universities + academia

Universities and Academia

- Duquesne University – Nurse Engineering Program [article]
- Florida Atlantic University Christine E. Lynn College of Nursing BSN to MS in Biomedical Engineering [website]
- John Hopkins [Website]
- Med Tech Innovation + Entrepreneurship [website]
- University of Connecticut Nursing and Engineering Innovation Center [website]
- UMASS Amherst – Nursing Engineering Laboratory [website]
- U Penn - Cross Training Nurses & Bioengineers [website]

jedi

JEDI (Justice, Equity, Diversity, Inclusion)

- Designing for inclusivity: How and why to get started [website]

organizations

Organizations

- Association for the Advancement of Medical Instrumentation [website]
- American National Standards Institute [website]
- Avatar Group [website]
- Avatar Vascular Device Types [website]
- Azure Health Bot [website]
- GE Healthcare [website]
- HIMSS [website]
- International Organization for Standardization [website]
- MakerNurse [website]
- Mass Device [website]
- Medical Device Academy [website]
- Medical Device and Diagnostic Industry [resource]
- Medical Device Innovation Consortium [website]
- Medical Device Network [website]
- Medical Tech Startup Resources [website]
- National Capital Consortium for Pediatric Device Innovation [website]
- National Pressure Injury Advisory Panel [website]
- NEST Coordinating Center [website]

conferences

Conferences

- AIDH Med Info 23 [website]
- CES [website]
- Heart Rhythm Society [website]
- Healthcare Design Conference [website]
- HIMSS Global Health [website]
- IMSH [Website]
- INACSL [Website]
- IVRHA [Website]
- Medical Intelligence & Innovation Institute Summer Internship Program [website]
- MTEC [Website]
- Operational Medicine Symposium [Website]
- Reuter's Digital Health [website]

articles + research

Articles + Research

- A Nurse Innovator Paves the Way for Other Nurses [Article]
- Collaborative Nurse-Engineer Product Innovation [Article]
- Digital Technology and Nursing Care: A Scoping Review on Acceptance, Effectiveness and Efficiency Studies of Informal and Formal Care Technologies [article]
- Empowerment Through Academia [Article]
- How Do Hospitals Make New Equipment Purchases? [Article]
- Innovation In Nursing: 6 Ways The Field Is Propelling Forward [article]
- Medical Device Industry Facts [article]
- Nurse-Engineer Partnerships in Academia [Article]
- Nurses' Perceptions of Technology Used in Language Interpretation for Patients with Limited English Proficiency [article]
- The History of Technology and Innovation in Nursing [article]
- Patient Care Technology and Safety [book]
- Patient Care Device Technology Transformation: Nurses Seek Partners to Achieve Patient Care Excellence [Article]
- Understanding Medical Product Supply Chains [Book]

articles + research

Intellectual Property Articles & Books

- Patient Care Technology and Safety [book]
- A Patent Landscaping Tutorial Using the PatSnap Analysis Tool and CRISPR as the Focus Technology [article]
- An Examination of nurse-authored patents: Implications for Nursing Practice [article]
- Best Business Practices for Monitoring and Protecting Intellectual Property [article]
- Copyright Law Basics for the Nursing Professional [article]
- Copyright Law for the Nursing Professional Part 2: Protecting your Work [article]
- Developing Effective Intellectual Property Partnerships article
- Discovering New Value in Intellectual Property [article]
- Drafting a Provisional Application [article]
- Harvard Sample Licensing Agreements [website]
- Intellectual Property Rights: An Overview and Implications in Pharmaceutical   Industry [article]
- Introduction: To White Space Analysis and Patent Landscape Analysis [article]
- Limited Intellectual Property License Agreement [agreement]
- The Best Approach to Launching a Development Monitoring Strategy [blog]
- What is White Space Patenting? [article]

transdisciplinary + interprofessional

Transdisciplinary

- Interdisciplinary and Innovative: A Nursing and Computer Science Collaboration to Create a Barcode Medication Administration System [article]
- Teamwork Between Engineers and Nurses Triggers High-tech Healthcare Inventions [article]

Interprofessional

- Moving Nursing Innovation To Prime Time Through Creative Partnerships [article]

Faq's

Q: Why should nurses be engaged in the tech/device space?

A: Nurses are the experts on the tools and equipment they need to provide optimal patient care. They also know what tools and equipment don't work well for them or their patients and why. Nurses' expert knowledge is essential for leading and contributing to the development of tools and equipment that promote the best patient outcomes and adhere to ethical standards. This ANA Innovation Guide was created to help you get started as you learn more about the medical technology and device workspace.

"Technology has not been as kind to nursing as it probably should be, in some cases, has been unforgiving and cumbersome, has added to the workload, and it has im-pacted nurses' well-being…" Katie Boston-Leary, PhD, RN, director of nursing pro-grams at the American Nurses Association, told Becker's. "A lot of technology has been implemented for physicians to help their workflow, help with how they do sur-gery, etc. So those investments are being made to that end. The key is to make the call a clarion call for them to be made on this other end for nurses as well." [website]

Faq's

Q: What are some examples of nursing practice challenges that tech/devices help solve?

A: Care coordination for transitional care follow-up [after an ED visit with transitions to home care, inpatient discharge to home care, etc.]. Chatbot/AI solutions can help with this practice challenge. Body worn sensors can help with early detection of deterioration [changes in biometric readings], for all settings of nursing practice.

Q: How do I begin to engage with other nurses in the tech/device space?

A: Connect with nurses in the innovation space through LinkedIn/Social Media, professional conferences, research, committees, focus groups, professional organizations; visit the ANA Innovation website [website], and SONSEIL [website]. There are conferences such as I/ITSEC (Interservice/Industry Training Simulation, Education Conference), IMSH (International Meeting on Simulation in Healthcare IMSH and THinC Conference.

Q: Have nurses invented new technologies or devices?

A: Many nurses have developed products that are important to the work we do every day. From digital products to medical devices, nurses have made transformative contributions in this space!

An examination of nurse-authored patents: Implications for nursing practice [article]
The Nurse Innovator Index [website]
SecureMove-TLC® [website]
EzInduction device [website]
Activating Nursing To Address Unmet Needs In The 21St Century. [website]

Q: What are different roles nurses have in the tech/device space or products nurses have developed?

- Representatives for device companies
- R&D for device companies
- Practice facilitators
- Quality and biomed roles in the hospital
- Work with device trials and FDA
- Principal investigator in academic research on technology and devices in the healthcare space
- Principal investigator in academic research on technology and devices in the healthcare space
- Intrapreneur developing innovations within a healthcare organization
- Entrepreneur developing innovations as a commercial enterprise
- Nurse expert on an interdisciplinary innovation team

Faq's

Q: How do I participate in the tech/device space in the academic sector or in collaboration with my hospital?

A: Participating in the tech and device space in the academic sector or with your hospital has many advantages. Most academic institutions value innovation and interdisciplinary innovation and have resources to support this work, including internal funding opportuni-ties. Ask people you trust about potential collaborators across the institution (e.g., engi-neering, computer science). Search faculty bios to find content experts. Innovating within academia is more like intrapreneurship than entrepreneurship.

Discoveries developed using your institution's resources, including your time and effort, will be partly owned by the institution. To understand these processes, contact your legal department as soon as you have an idea. Larger institutions will have an innovation office, otherwise contact your institution's office of general counsel to learn more about intellectual property protection.

The University of Pittsburgh commercialization office is a great resource for understanding the broader steps in product development/commercialization in the academic setting: [website]

Network and be willing to pitch your interests and ideal role, consider partnering with quality, innovation, and workforce efforts – understand where innovation is happening in your organization. Join professional organizations like NPUAC, AAMI, Vascular access society, AORN, etc. Seek funding opportunities to support interdisciplinary problem-solving. Make your faculty profile visible on academic research sites or on your department website. Include "innovation" as a key term so others in your institution can find you when looking for potential collaborators.

Q How do I participate in the tech/device space in industry?

A: There are lots of different opportunities to participate in product development that don't require being the product inventor. Offer to trial/ participate in validation of new products, be a part of human factors testing, providing feedback to the vendors. Ask the product vendor if they use co-production models whereby end-users participate in the development life cycle. Become a device rep, go into marketing or R&D at a device manufacturer, join a start-up team.

Faq's

Q: What is being done to elevate nurses in the tech/device space?

A: Many corporations/health systems are requiring that a nurse is present on all teams to ensure the solution meets nursing practice needs. The Future of Nursing report has a chapter on informatics and the importance of nursing representation. The role of the Chief Nursing Informatics Officer has expanded within health systems and corporations. [website]

Nurses are advocating for and listening to nurses in the innovation space. Advocating for and including nurses on boards and in leadership positions will increase visibility of nurse innovation and lead to greater opportunities for nurses to engage in and lead innovation. All nurses must raise awareness about how technology and devices impact their work and pa-tient safety.

Q: What future nursing roles are needed in the tech/device space to improve healthcare?

A: Nurse innovators are needed in every healthcare sector, from hospitals, to academia, to the biotechnology industry. Nurses who are risk takers with divergent thinking, tolerance for failure, agility and flexibility are needed to fill current and emerging roles to lead digital health transformation across healthcare settings. These roles include maker-nurses, nurse-engineers, nurse entrepreneurs, nurse intrapreneurs, chief innovation officers, chief information officers, chief imagination officers, chief digital officers, and innovation educators and researchers. Nurses as FDA reviewers for patient care devices

Q: What education is needed for different tech/device roles?

A: To promote nurses as leaders in the tech and devices innovation space, nursing curricula at all levels must include education on nurse-led innovation. Consistent with the American Association of Colleges and Nursing Essentials for nursing education, undergraduate students should be exposed to digital health, telehealth, and the importance of nurse-led inno-vation. Graduate programs with emphasis on these content areas are needed to develop leadership and administrative roles to support and promote nurse-led innovation across healthcare settings. [website]

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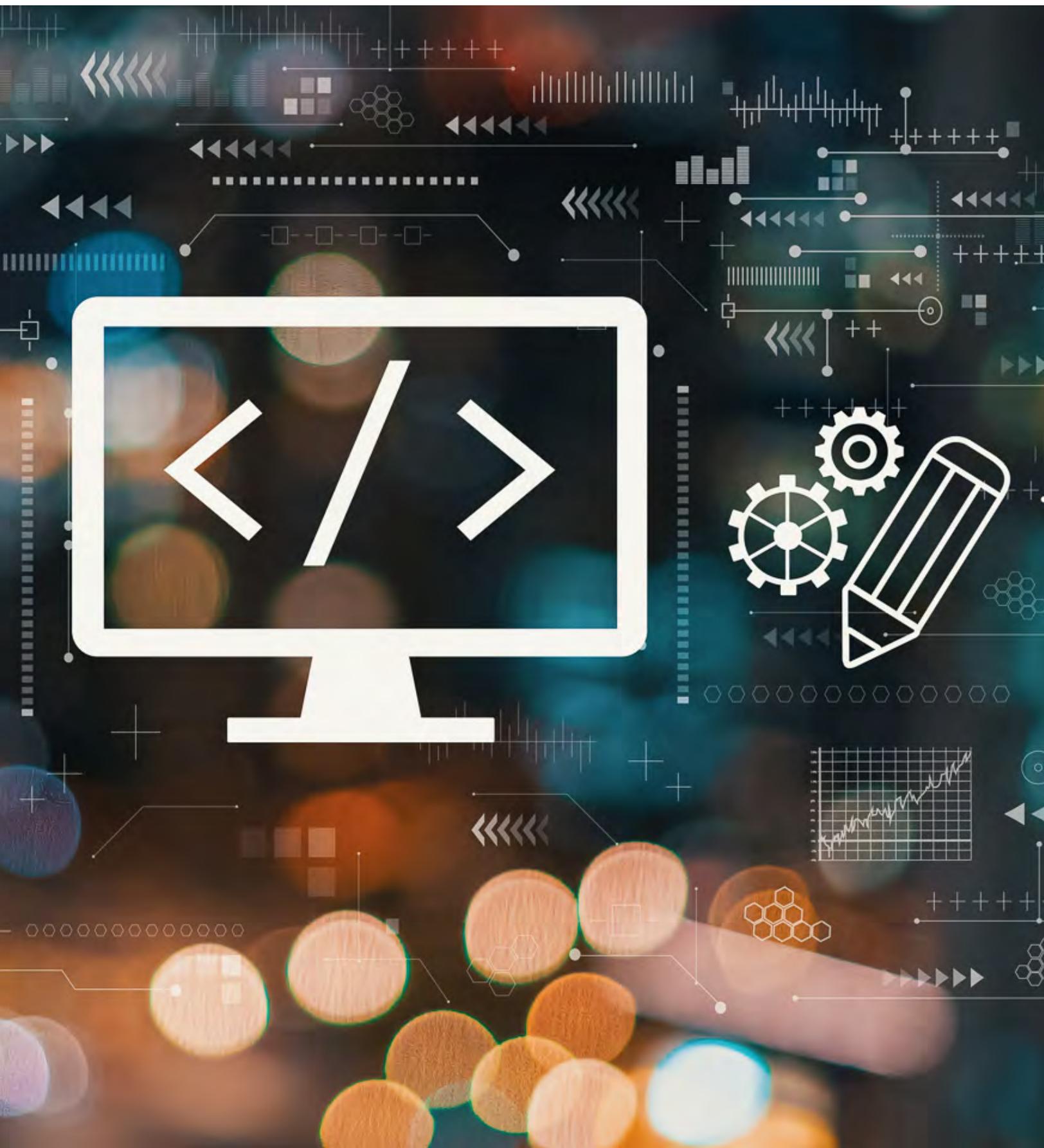
Faq's

Q: Where do I start with a new tech device idea?

A: Go to the ANA Innovation site and follow the pathway - if you own the idea (not assigned to your hospital/company) –DO NOT share it publicly. Start creating a competitive table and benchmark of all products that you can find out there that do the same thing or have a similar function and look into the patent landscape (google patents is a good place to start). [Website]

To identify if your idea would be owned by your hospital look at your contract. If your idea is owned by your hospital - go to your technology transfer department, speak with leadership, quality, and begin communicating the need for your idea. Collect information on size of the problem and cost of the problem for the institution.

Q: What is a prototype and why should I make one?

A: When you have an idea, a great way to further develop this idea and "test" it out is to create a prototype. A prototype is an early model of your product. It does not have to be fully functional or high-tech – you can create it from materials you have at work or at home.

A prototype is a physical model of your solution. There are lots of reasons to make it - but first and foremost is to bring it to life! Use it to communicate with others, to explore barriers, limitations, etc. Then you can make more and better ones to test functionality, perfor-mance or explore materials. There is never a bad time for a prototype. Just be sure your in-tellectual property is protected and that the prototype purpose is clearly identified.

Q: Why is product design important?

A: Design is everything! Do your research and find design methods that speak to you. This is your way of embodying requirements into the physical object/tech you will make. [Article]

Product design should be evaluated by its 1) 'fit' to the problem or issue it aims to address 2) the correct 'form' or physical medium/shape/material and 3) functionality or pragmatic use for those persons who will interact with the product.
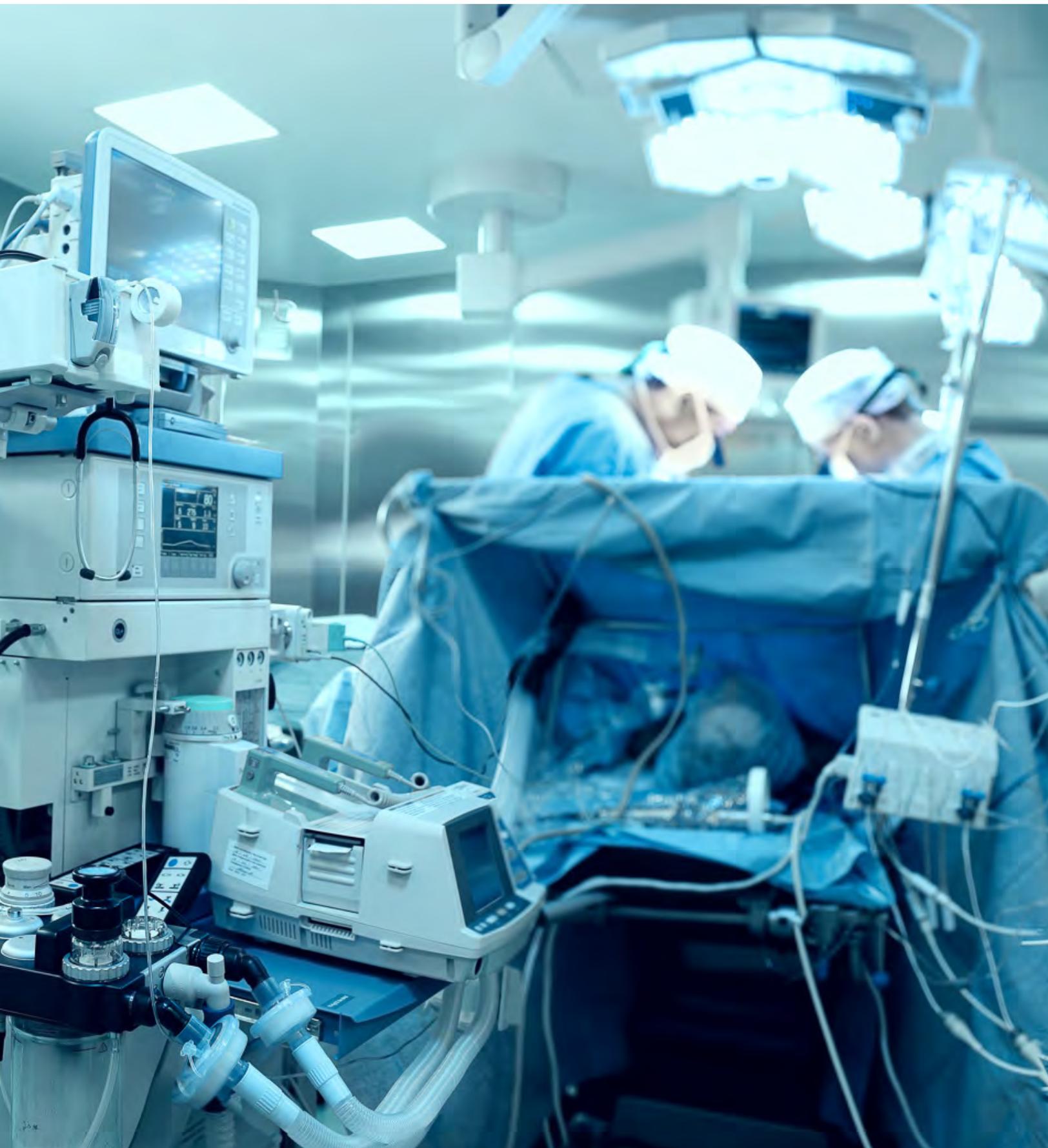
Faq's

Q: Can I talk about my idea with others?

A: First decide if you want intellectual property protection, and if so - who owns your intellectual property. Write down your idea in a confidential place in as much detail as you can, sign and date it. Then make a copy of this and mail the original to yourself via the US postal service (but do not open it when you get it). This will be a government time and date that would be recognized in a court of law if another person claims that they had your idea first.

Seek professional help for next steps. Be careful how you discuss your ideas with others and what you discuss. It is always a good idea to have someone sign a non-disclosure agree-ment (or NDA). There are some generic NDA agreements that can be found online, though having a legal expert is always recommended.

Once you discuss your idea with someone (even a hospital break room or over coffee) it can be considered a "public disclosure" unless the right protective steps are in place. This will start a 6 month or 1 year timeframe for when you need to file intellectual property (a patent). If a non-disclosure form is signed by the person you are talking with or you are talking to an attorney this does not count. Once you have filed a patent (and there are different types of patents) you can talk more about your idea, but it is still good to be cautious and know what's covered in your intellectual property.

With Trademarks and copyrighted material...

> Do not discuss:
>
> - design specifics
>
> - how the device/software functions specifically
>
> - What materials your product would be made of
>
> Ok to discuss:
>
> -The problem you are trying to solve
>
> -how individuals are solving the problem now and what problems there are with those methods [website]

iac med tech + devices

Faq's

Q: How do I protect my idea?
A: Talk with an intellectual property attorney! Do your own patent searching as possible. Use google patents to start and do some generic searches for products in general as well using as many terms as possible that might cover the functionality of your device, software or service. BUT do not disclose anything until you determine your path. If you are in an academic setting, see if your institution has an innovation office; if not, contact your research program and begin broad discussions about policies and processes of innovating and pro-tecting intellectual property within your institution. [Website]

Q: Do I have to start a company to develop my idea?
A: Sometimes starting a company is the best way to get a new product to patients – but there are other ways you can get a new product to patients too! Talking with your hospital or university's commercialization office is a great place to start.
No! Look for opportunities at universities or within your organization. Most importantly determine what role you want to have in the idea development. There is nothing wrong with selling your idea to others but be sure you are fairly compensated for your intellectual property, and the work you put in to develop your product or idea.

You might also be more interested in demonstrating the value of your innovation through research and dissemination instead of taking a commercial path. If you are using hospital or academic institution resources, you do have to disclose your ideas and have them evaluated for intellectual property (IP) consideration first and your employer might also have partial rights to the IP.

Q: How do I improve a tech/device issue in my workplace?
A: Understand the technology, know who to contact for issues. Review literature for bene-fits/challenges and present ways to address the challenges.   If you want to improve some-thing, come with data, research, best practices, etc. Partner with an experienced research-er or quality improvement specialist in your organization if you need help.
Show benefits through small tests of change-quality measures. Time Saving.
File quality reports. File FDA MDE reports. Call the manufacturer. Work with quality and bio-med at your facility - show them the process, show them the pain points and how it impacts patients. [Website]
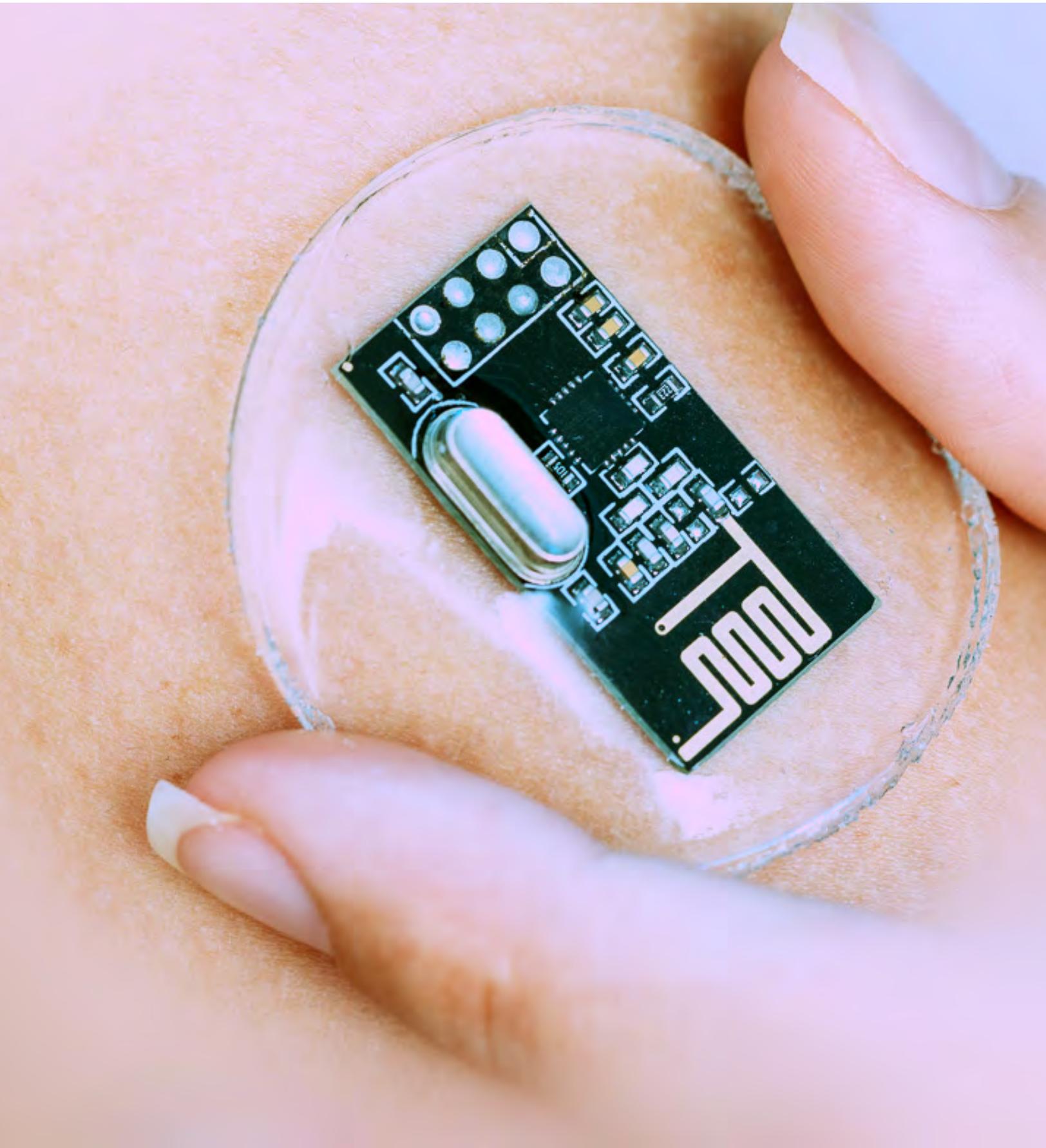
Faq's

Q: How do you advocate for solutions for tech/devices that could improve patient care?

A: Seek out the Value analysis committee / product review committee/ new products committee. Every hospital has one or more. Some hospitals have these by departments and others have general committees. Speak with nursing leadership on the committee and ask about the process to evaluate a product. This can be a complex process to navigate – and it can be very helpful to talk with someone who's been through the process previously. This could be your nurse manager, a director, clinical nurse specialist, educator, clinical nurse leader. Some hospitals unfortunately do not have nurses on this committee. If you have trouble finding out who is on this committee, reach out to supply chain and purchasing at your institution after speaking with your unit leadership to find out who you would need to talk to on that committee. It is helpful to understand who are the decision makers and budget holders to bring in new products to your institution. Depending on how much the facility would spend on this product/software it may fall into different budget categories (capital budget, operational budget, unit budget) and there may be different decision makers. Get samples if you can (conferences are a great place to find samples or get in contact with someone) and show others how that tech can improve your work and/or outcomes.

Q: How do I file a complaint about a medical device?
- FDA MAUDE report [website] & [website]
- File a quality report at your facility.
- Keep the device and send it back to the manufacturer whenever possible. Patient Safety Report/Joint Commission/OIG/AHRQ–if safety issue/potential safety issue

Q: How can I engage in this space as a bedside nurse?
- Educate on best practices.
- Trial product & implement in the system.
- Bring others to the bedside (quality department)
- Work with vendors
- Raise awareness of issues and gather data about impact of the device. Learn about devices and alternatives,
- Research best practices from professional organizations

definitions

Term	Definition
Human Factors	There are multiple definitions for different fields. However the FDA defines human factors as the science of "Understanding how people interact with technology and studying how user interface design affects the interactions people have with technology" And the Human factors and ergonomics society states that the goal of Human factors is to "reduce human error, increase productivity, and enhance safety and comfort with a specific focus on the interaction between a human and the thing of interest." (technology or device in this case) Human Factors and Ergonomics Society Human Factors and Medical Devices - FDA https://www.fda.gov/medical-devices/human-factors-and-medical-devices/human-factors-considerations
Minimum Viable Product	The smallest thing that you can build that delivers customer value Minimum Viable Product (MVP) and Design - Balancing Risk to Gain Reward | Interaction Design Foundation (IxDF) (interaction-design.org)
Intellectual Property	Creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create.

definitions

Term	Definition
FDA Medical Device Regulations	The FDA defines a medical device as: "an instrument, apparatus, implement, machine, contrivance, implant, invitro reagent, or other similar or related article, including a component part or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." How to Determine if Your Product is a Medical Device | FDA
Medical Device Event Reporting	Houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers.
MAUDE Database FDA	Houses medical device reports submitted to the FDA by mandatory reporters 1(manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers. MAUDE - Manufacturer and User Facility Device Experience (fda.gov)

definitions

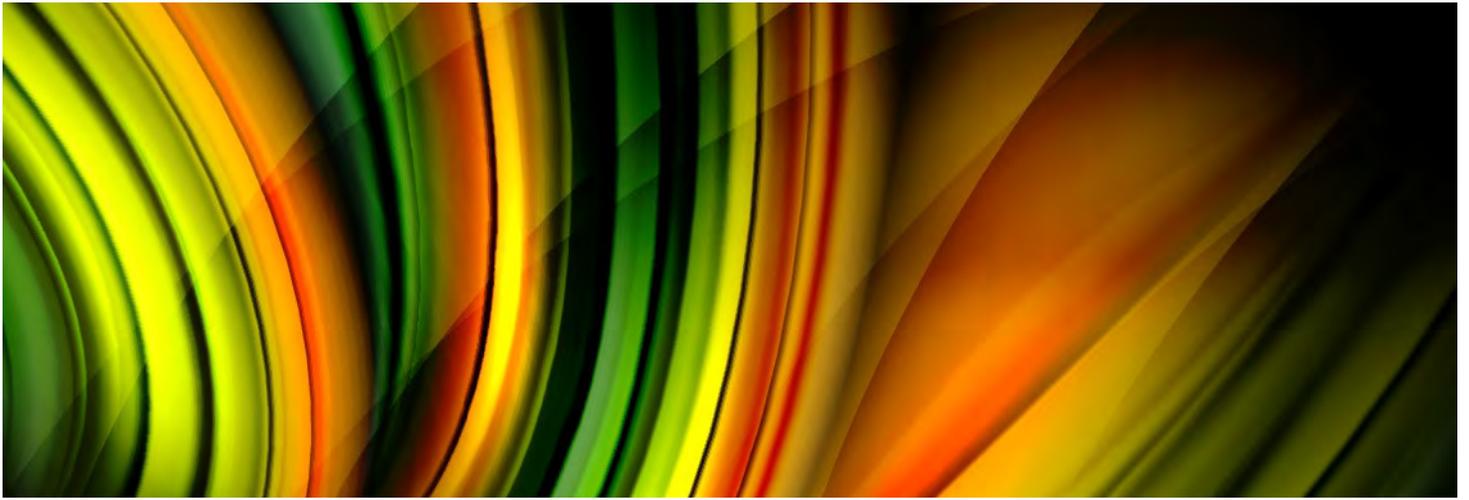| Term	Definition
FDA Predicate Device	"The FDA may look at a "predicate device" to determine the steps required for regulatory approval of a medical device. This is a device that has already gone through the FDA and can provide a template for necessary testing, data collection, and other steps before FDA regulatory registration or approval can be completed." How to fine and effectively use predicate devices - FDA
General Wellness Device	"Products that meet the following two factors: (1) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons. General wellness products may include exercise equipment, audio recordings, video games, software programs4 and other products that are commonly, though not exclusively, available from retail establishments." General Wellness: Policy for Low Risk Devices | FDA
Virtual Care and/or Telehealth	"Allows for health care provider or nurse to provide care over phone or video." What is telehealth? | Telehealth.HHS.gov
Remote Patient Monitoring	"The use of technology that allows health care to be provided to patients at a distance. In other words, RPM simply entails using technology to collect, transmit, and analyze patient health data. Data can be uploaded to patient EMR for provider review. Goal to keep patients at home vs hospitalization Weights, Blood pressure, spirometry, Heart Rates, etc." Home - Cognosante Vital Sync™ Rapid Remote Monitoring | Medtronic (e.g., smart watches, Enso Ring)
Patient Care Technology	Equipment and devices to deliver direct care to patients.
Stakeholder	Anyone involved in the design, development, research, implementation, and evaluation of healthcare tech & devices, including patients.

definitions

Definitions (cont.)

Term	Definition
Value Proposition	"A statement of the benefits someone will receive as a result of the technology. May refer to benefits to users as well as investors." Lehoux, P., Miller, F. A., Daudelin, G., & Denis, J. L. (2017). Providing value to new health technology: the early contribution of entrepreneurs, investors, and regulatory agencies. *International Journal of Health Policy and Management*, 6(9), 509. doi: 10.15171/ijhpm.2017.11
Return on Investment (ROI)	"Estimation of the potential commercial viability of a technology or device." Markiewicz, K., van Til, J. A., Steuten, L. M., & IJzerman, M. J. (2016). Commercial viability of medical devices using Headroom and return on investment calculation. *Technological forecasting and social change*, 112, 338-346. https://doi.org/10.1016/j.techfore.2016.07.041
Healthcare innovation	"a new or improved solution with the transformative ability to accelerate positive health impact." World Health Organization https://www.who.int/teams/digital-health-and-innovation/health-innovation-for-impact
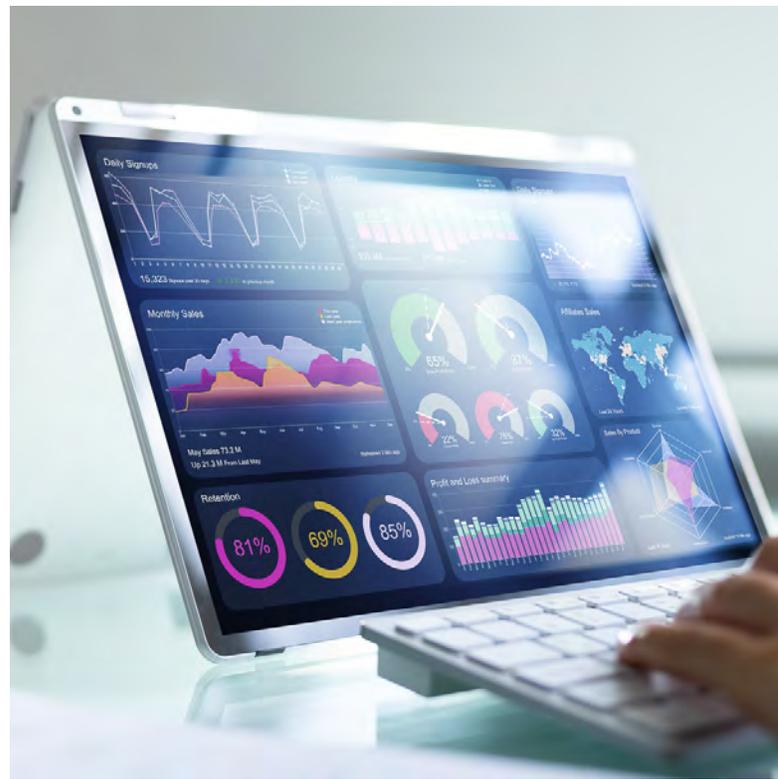
Historic Committee Members

Erik Andersen, MSN, BSN, RN [LinkedIn]

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med tech + devices

AMERICAN NURSES ASSOCIATION
ANA INNOVATION