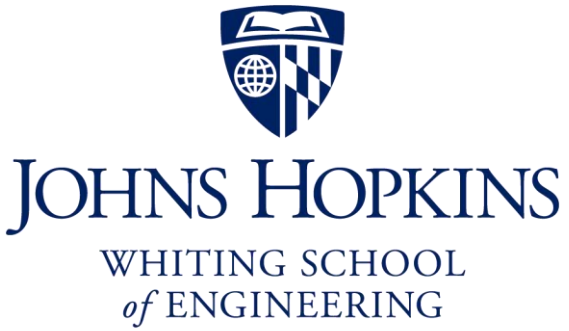
A STRUCTURED PROCESS FOR BIOMEDICAL INNOVATION

AEAI MedTech CONFERENCE

MAY 20, 2024



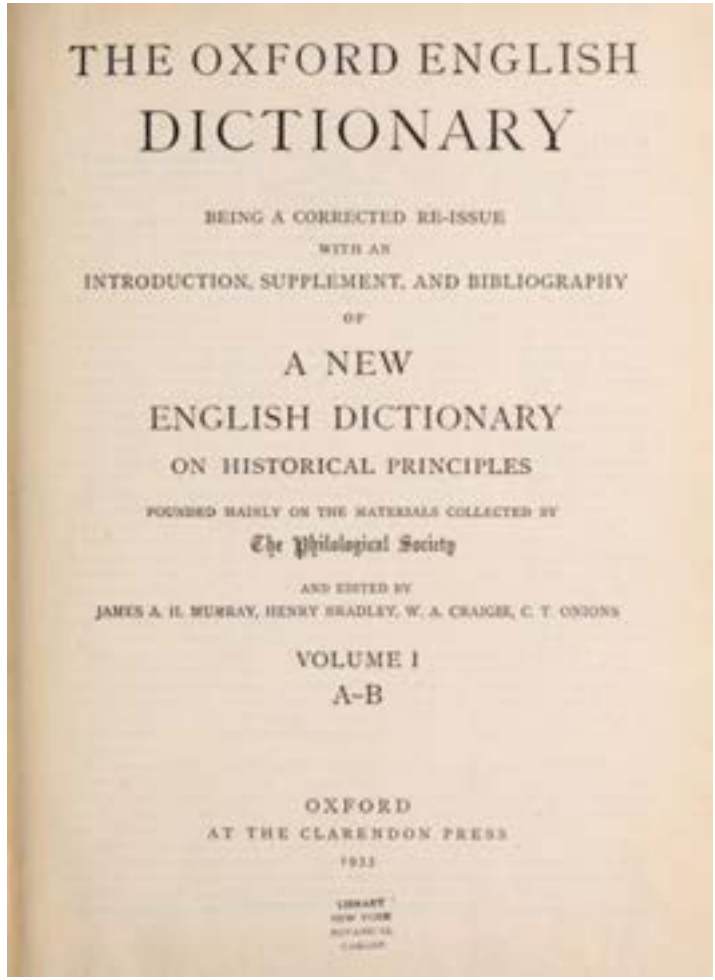
Defining Innovation (per the OED)

From the 16th century:

1. The action of innovating; the introduction of **novelties**; the alteration of what is established by the introduction of new elements or forms.
2. Revolution.
3. A change made in the nature or fashion of anything; something newly introduced; a novel practice, method, etc.

From the 20th century

4. The action of introducing a **new** product into the market; a product newly brought on to the market.


THE OXFORD ENGLISH DICTIONARY

BEING A CORRECTED RE-ISSUE WITH AN INTRODUCTION, SUPPLEMENT, AND BIBLIOGRAPHY OF

A NEW ENGLISH DICTIONARY ON HISTORICAL PRINCIPLES

FOUNDED MAINLY ON THE MATERIALS COLLECTED BY The Philological Society

AND EDITED BY JAMES A. H. MURRAY, HENRY BRADLEY, W. A. CRAIGIE, C. T. ONIONS

VOLUME I
A-B

OXFORD
AT THE CLARENDON PRESS
1933

https://biblio.com.au/book/supplement-oxford-english-dictionary-vols-i/d/512062367
https://www.oed.com/dictionary/innovation_n?tab=meaning_and_use

Why does Innovation Matter?

Per Michael Porter, innovations shift competitive advantage:

1. New technologies;
2. New or shifting buyer needs;
3. The emergence of a new industry segment;
4. Shifting input costs or availability; and

https://www.fsg.org/people/michael-e-porter/Michael Porter, *The Competitive Advantage of Nations* (The Free Press: 1990).

The Source of Innovation 1

History tells us that there are four common sources of opportunities – opportunities that are more than mere ideas – that any would-be entrepreneur can use.

1. Opportunities created by **macro trends** in society
2. Opportunities found by living and **experiencing the customer problem**
3. Opportunities created through **scientific research**

https://tedxlondonbusinessschool.co.uk/john-mullins/

John Mullins, "Entrepreneurial Gold Mines" in *Business Strategy Review* (Spring 2004).

The Source of Innovation 2

These two critical elements are indispensable to every single innovation story in the world:

1. One element is **the big idea**… a compelling and value-creating idea of some kind—**a new combination of thoughts**.
2. The other element is **the illuminating insight** (or insights). Without fail, every big idea was preceded by at least one insight—a new and penetrating

https://speakers.com/speakers/rowan-gibson/

Rowan Gibson, *The Four Lenses of Innovation* (John Wiley & Sons: 2015)

The Source of Innovation 2a

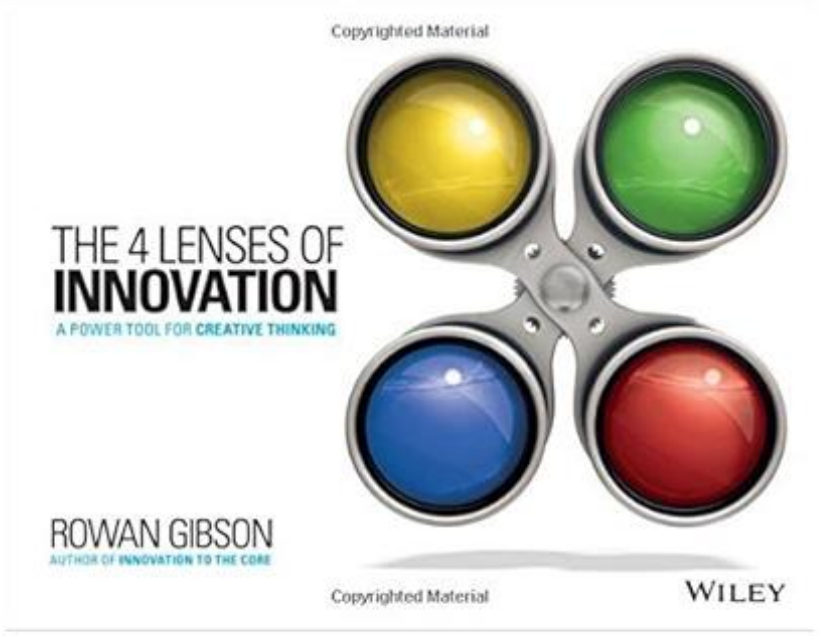
Insights come from the *Four Lenses of Innovation*:

1. **Harnessing Trends:** Recognizing the future potential of emerging developments, and using these trends to open up new opportunities

2. **Understanding Needs:** Paying attention to issues and frustrations others have ignored, and experimenting with new solutions to problems

3. **Challenging Orthodoxies:** Questioning deeply entrenched beliefs and assumptions (i.e. received wisdom), and exploring new and highly unconventional answers

4. **Leveraging Resources:** Understanding our limitless



Rowan Gibson, *The Four Lenses of Innovation* (John Wiley & Sons: 2015)

The Source of Innovation 3

In a study of the Tokyo Rope Corporation (*Tokyo Seiko*) in the Meiji era (1868-1911), the researchers point out **three factors essential for innovation**:

1. rebuilding a corporate governance structure for **ambidexterity**, which refers balancing the exploitation of existing products with the exploration of new developments;
2. intellectual **communication** between academic researchers and practitioners; and

https://intmech.vn/san-pham/tokyo-rope-shinko-cap-thep/
https://mpra.ub.uni-muenchen.de/119536/1/MPRA_paper_119536.pdf

Creating a Portfolio of Innovation

https://www.mckinsey.com/business-functions/marketing-and-sales/our-insights/now-new-next-how-growth-champions-create-new-value

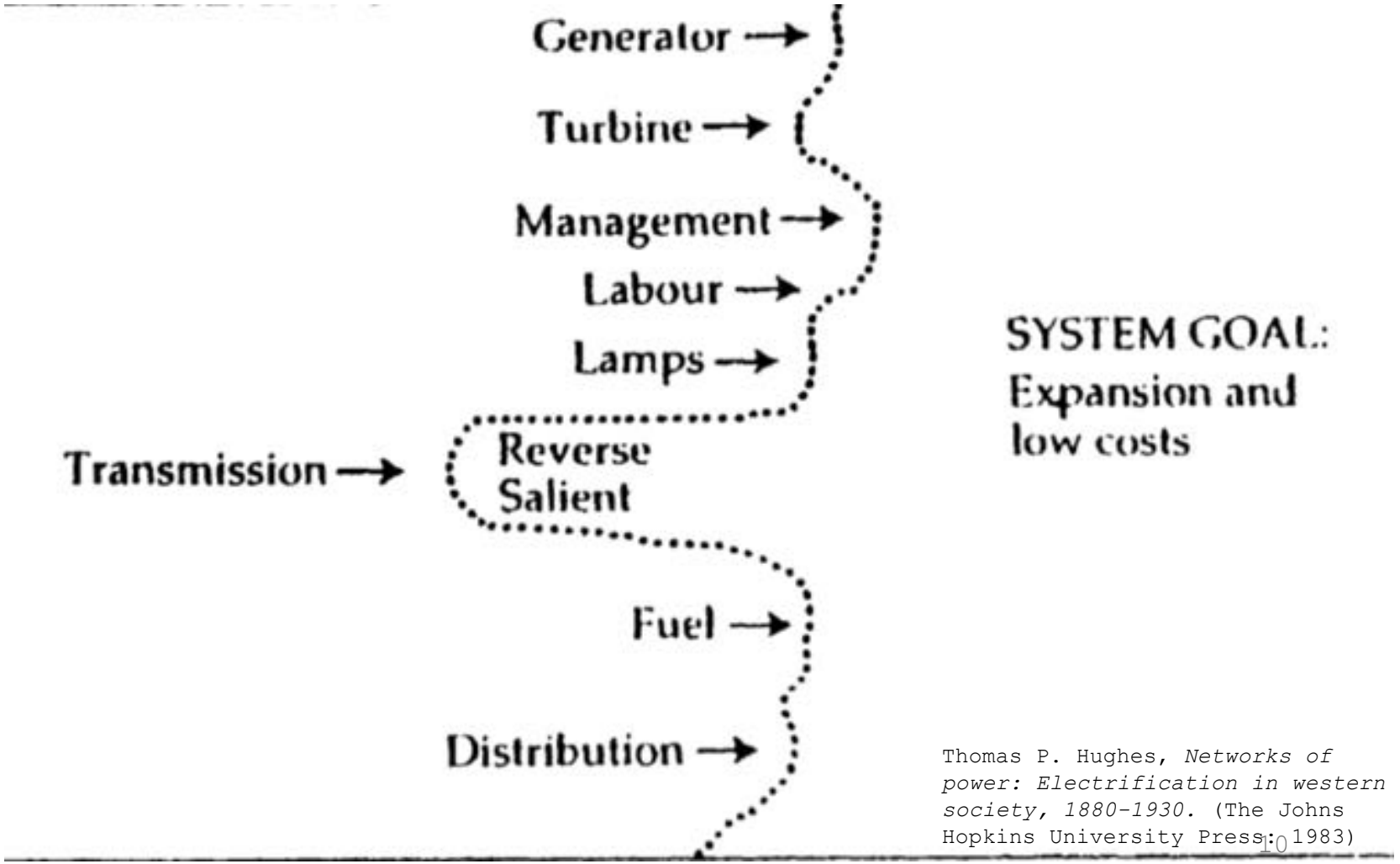
Three Components of Innovation

For any Now, New, or Next, there must be

1. A **problem** worth solving
2. A **solution** that solves the problem
3. A **business case** that allows the solution to enter the market and to scale

Reverse Salient: The High Cost of Transmission

- Thomas Hughes' theory about the progress of innovation
- A reverse salient is the facet of a system that holds back the progress of the entire system
- In this case, the reverse salient impeding the expansion of electric power transmission is the high cost of transmission



Thomas P. Hughes, *Networks of power: Electrification in western society, 1880-1930*. (The Johns Hopkins University Press: 1983)

Solving the Problem of Reverse Salients

1. **Brute Force**
    1. Grid search of every potential solution until one works
    2. Example: Thomas Edison trying thousands of materials to determine the best filament for the lightbulb
2. **Targeted Development**
    1. Theory informs potential solutions
    2. Example: Li-ion batteries developed with heavy guidance from research in electrochemical theory
3. **Eureka Moment**
    1. Solution results from a chance event (randomness)
    2. Example: MOSFETs developed after accidentally discovering that current in a semiconductor can be controlled with electric field (rather than current, as in traditional bipolar junction transistors (BJTs))

Two Kinds of Innovations:

1. **Directional innovations**: where we know where we are going (Now? New?).
2. **Intersectional innovations**: where we combine concepts between multiple fields, generating

Portrait by Agnolo Bronzino at the Uffizi in Florence Italy.

https://en.wikipedia.org/wiki/Lorenzo_de%27_Medici
Frans Johansson, *The Medici Effect* (Harvard Business Press: 2006)

Getting Out of the Building

- From grocer to philanthropist, a man named Johns Hopkins laid out a plan to use his wealth to establish a hospital that would provide care to anyone, regardless of sex, age or race.
- This hospital would be named The Johns Hopkins Hospital and opened in 1889, with The Johns Hopkins University School of Medicine four years later.

https://www.hopkinsmedicine.org/about/history/history-of-jhh/index.html
https://en.wikipedia.org/wiki/Johns_Hopkins_Hospital#/media/File:Johns_Hopkins_Hospital_in_Baltimore_1900s.jpg

Example: Getting Out of the Building

- A new product from six Johns Hopkins University grad students **updates current IV infiltration detection tech to help cancer patients avoid a condition called lymphedema.**
- The term refers to a gradual buildup of lymphatic fluid in the extremities, often following cancer treatment, that causes swelling and pain. It's treatable if caught early, but once a patient feels something wrong, it's typically too late.

https://technical.ly/startups/johns-hopkins-lymphasense/
https://www-oed-com.proxy1.library.jhu.edu/view/Entry/151726?rskey=mEkh7F&result=1&isAdvanced=false#eid

Directional or Intersectional?

https://en.wikipedia.org/wiki/Guglielmo_Marconi
https://www.burrosabio.net/guglielmo-marconi-biography/

Or Here?

Delta's Parallel Reality

https://www.businessinsider.com/delta-parallel-reality-board-detroit-displays-personalized-flight-information-

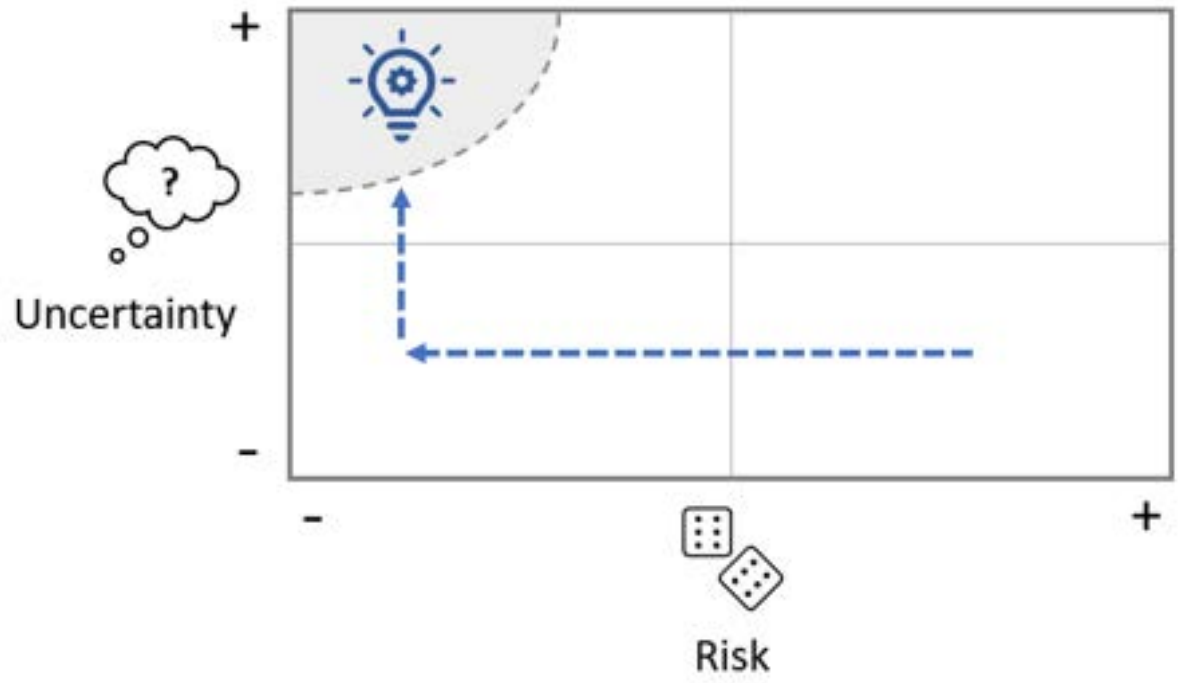
A Structured Process for "Doing Innovation"

Innovation under Uncertainty includes **two intersecting models:**

1. A structured process to **identify problems** to be solved and to generate a bank of opportunities.
2. An analytical framework to identify the best opportunities – those that take advantage of

Building a Portfolio

- Uncertainty:
  1. Demand
  2. Technological feasibility
- Risk:
  1. Financial
  2. Political
  3. Reputational
  4. Managerial



1. Who plays in each quadrant?
2. What kind of problem are you solving?
3. What tools should be used?

A Taxonomy of Problems

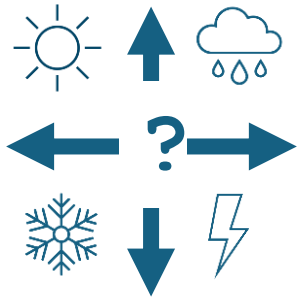
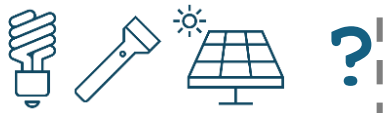
What is – possible, plausible, probable:

1. Un-defined – imagine the future in order to anticipate problems
   - Question: What might the future look like? What problems will we find there? What's over the horizon?
2. Ill-defined – find a problem worth solving
   - Question: What is the next big thing here? What's next for us?
3. Well-defined – solve the problem
   - Question: What is the best solution to this specific problem?

Examples: Different Kinds of Questions

1. **Well-Defined:**
    a. How can we make a brain controlled prosthetic hand with a sense of touch (sensory feedback) for less than $1000?
2. **Ill-Defined:** What is the next big thing here?
    a. 3D printing and prosthetics
    b. Robotics and prosthetics
    c. Personalized prosthetics
    d. How prosthetics are acquired
3. **Un-Defined:**
    a. What is the future of prosthetics?

Three Kinds of Problems

	Un-Defined	Ill-Defined	Opportunities	Well-Defined
				
Question:	What's over the horizon? What's possible?	What's the next opportunity? What's plausible?	What are the possible offering concepts?	How do we make this?
Analytic Tools:	Macro Trending Scenario Planning Analogies	Near-term trending Emerging technologies Challenging paradigms	Design Thinking Jobs-to-be-Done Prototyping	Traditional product development
Examples:	What could our markets look like in 10 years?	What market(s) should we enter?	What specific offerings could we develop?	How do we make this offering?

A Structured Process

1. Use a structured approach to create a portfolio of opportunities by
    a. Exploring un-defined spaces
        - Imagine alternate futures ("what's the future of…") and the problems that might be found there
    b. Mining un-defined spaces for ill-defined problems
    c. Exploring ill-defined problems
        - Imagine "what's next" for customers, industries, or society (using trends, changing tastes/preferences, changing terms of competition, etc.)
2. Choose the best opportunities
    - those where the solution is likely to be found in the high uncertainty/low risk quadrant
3. Turn the best opportunities into well-defined problems
4. Validate and solve them
5. Use the solution to further explore un-defined and ill-defined

Case Study: Fitting All the Parts Together

What is the future of military medicine?

And what kinds of innovations should be developed now to address the most serious problems likely encountered by combat medics a decade from now?

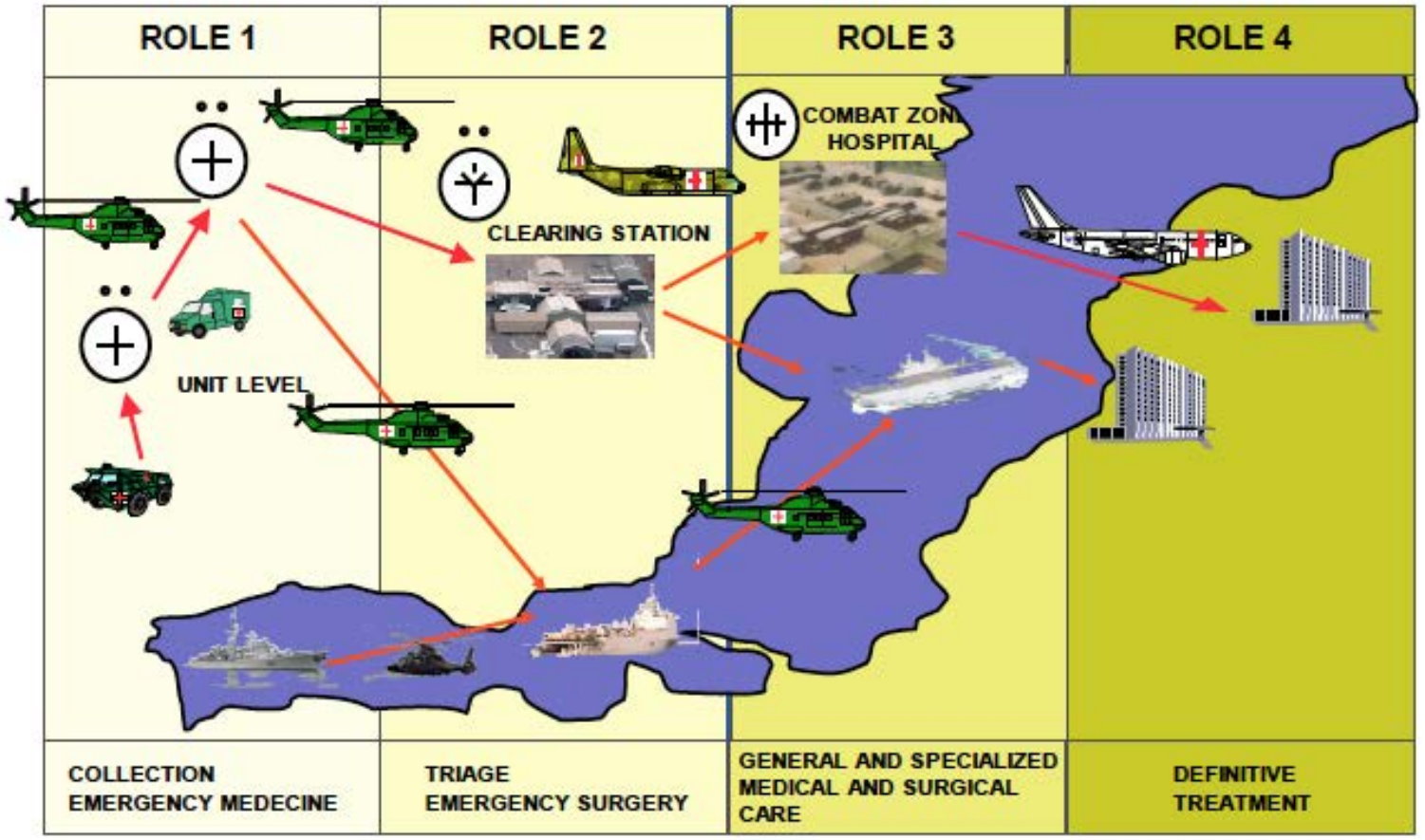
An Un-Defined Problem

For NATO, what will combat medicine look like post-Afghanistan?

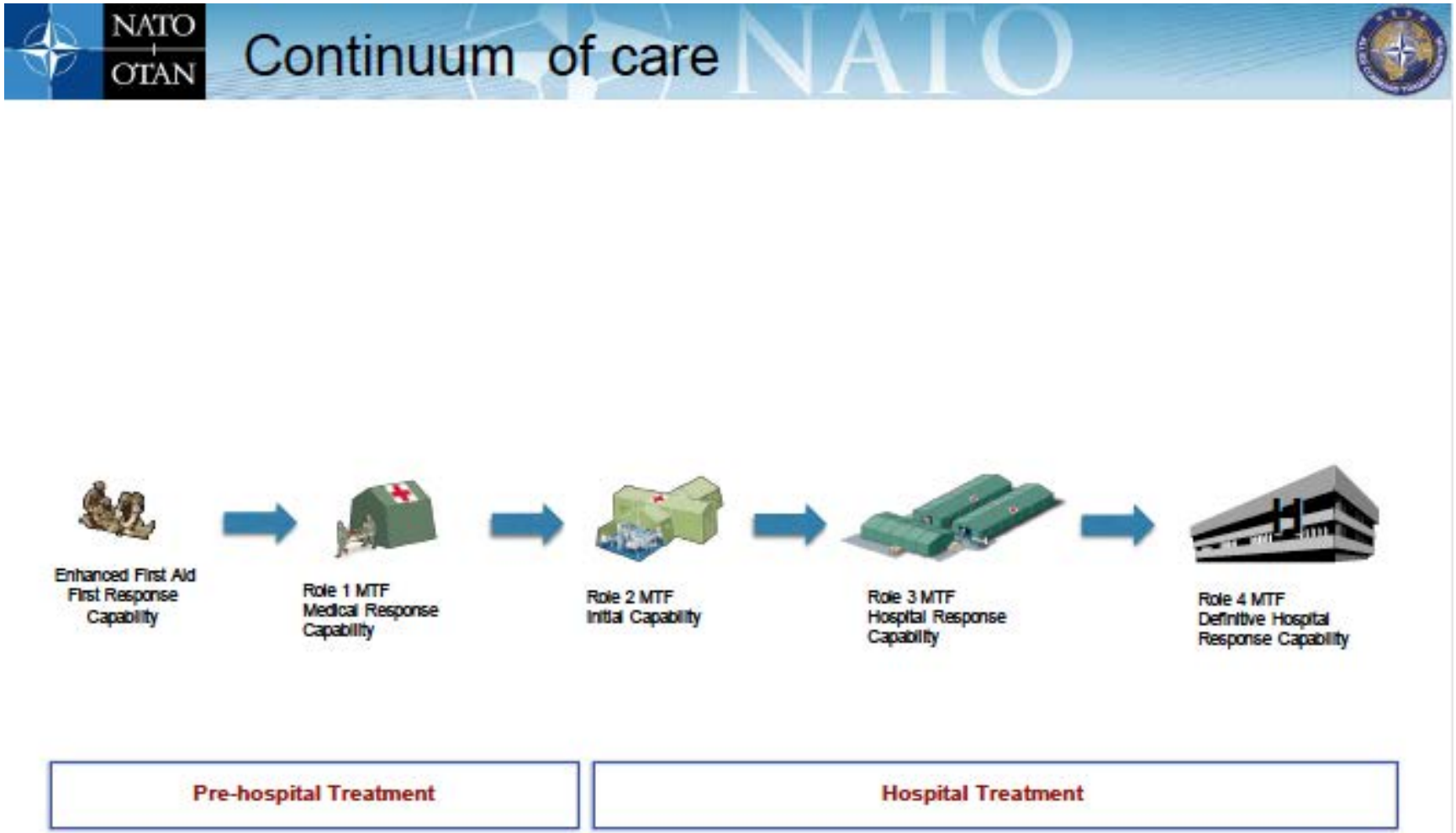
A UH-60 Black Hawk medical evacuation helicopter lands as U.S. Army paratroopers secure the area in Afghanistan's Ghazni province, July 23, 2012. The soldiers are assigned to the 82nd Airborne Division's 1st Brigade Combat Team and the helicopter crew is assigned to the 82nd Combat Aviation Brigade. The soldiers evacuated a wounded

https://www.defense.gov/Multimedia/Photos/igphoto/2001186140/

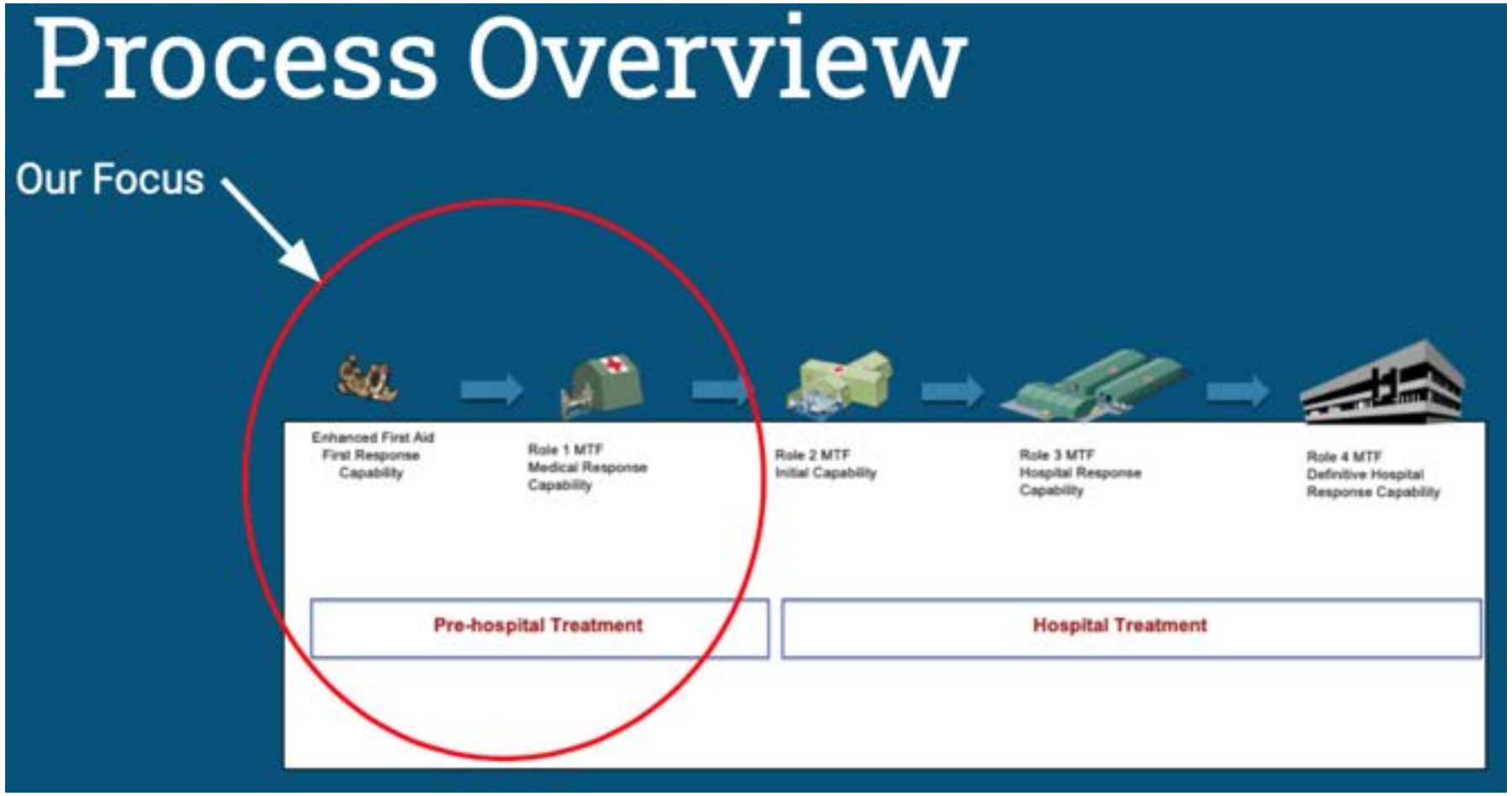
Understanding the Continuum of Care



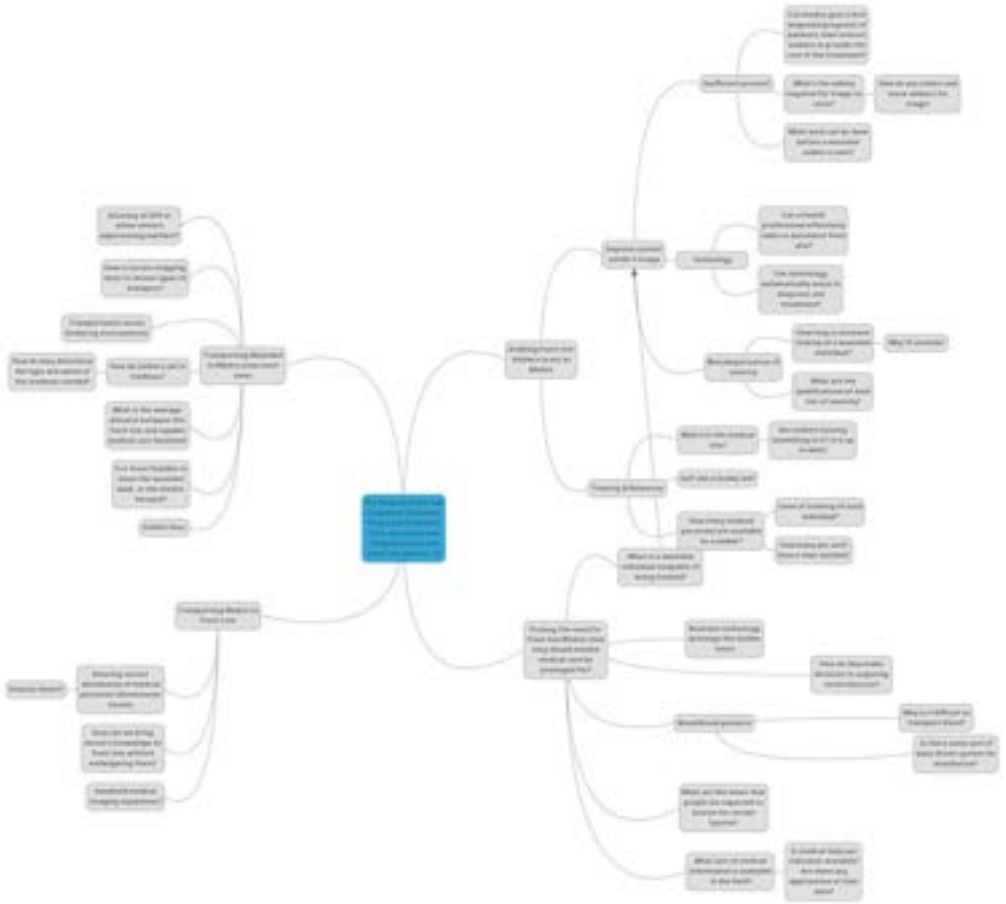
Breaking the Continuum of Care Down



Step 1: Limit the Search Space



Research the Space and Build a Mind Map



Step 2: Scenario Analysis

Assumptions:

1. European location
2. Contested environment
3. Rapid evacuation not possible
4. Kinetic only

Parameters (2x2 box):

1. Urban / Non-urban
2. Single casualty / Mass casualty

Scenario Analysis

	Single Casualty	Mass Casualty
Non-Urban		
Urban		

Source: Google Images

Scenario Analysis

	Single Casualty	Mass Casualty
Non-Urban	**Non-urban/Single casualty** *Situation* • Rural or ex-urban environment • Sparse resources (no hospitals, electricity, etc.) • Easier to distinguish victim/perpetrator • Under-resourced medical and non-medical personnel *Needs* • Locating victim • Assisting *in situ* (extraction not feasible)	***Non-urban/Mass casualty*** *Situation* • Rural or ex-urban environment • Sparse resources (no hospitals, electricity, etc.) • Easier to distinguish victim/perpetrator • **Under-resourced** medical and **non-medical** personnel *Needs* • **Locating multiple distributed** victims • **Prioritization** for treatment • Assisting ***in situ*** (extraction not feasible)
Urban	***Urban/Single casualty*** *Situation* • Cluttered and dense environment • More resources (e.g., hospitals, electricity, potable water, shelter) • Hard to locate perpetrator • Hard to distinguish victim/perpetrator • Well- or moderately-resourced medical personnel *Needs* • Securing the site • Extract and treat	***Urban/Mass casualty*** *Situation* • Cluttered and dense environment • More resources (e.g., hospitals, electricity, potable water, shelter) • Hard to distinguish victim/perpetrator • Well- or moderately-resourced medical personnel *Needs* • Securing the site • Prioritization for extraction and treatment

Source: Interviews with NATO staff; UK and Israeli military; and Johns Hopkins experts

Step 3: Create an Ill-Defined Problem

Create an ill-defined problem by intensively exploring a scenario:

- What are the possibilities for field medicine in the future

1. when there are mass casualties
2. in a non-urban environment
3. and where rapid evacuation is not possible?

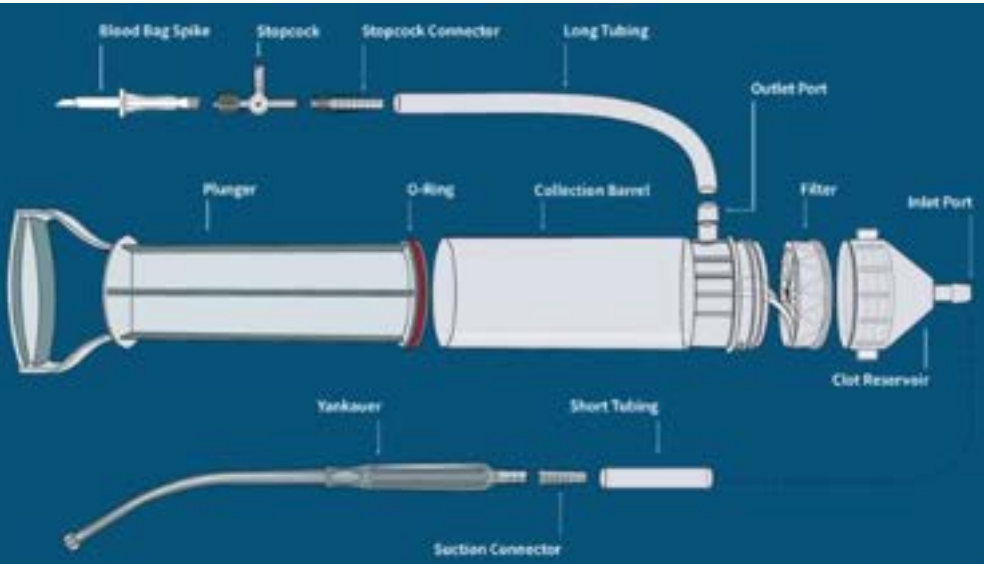
- **Address the ill-defined problem by creating a portfolio of innovative opportunities.**
- **In other words, create a list** of problems worth working on by

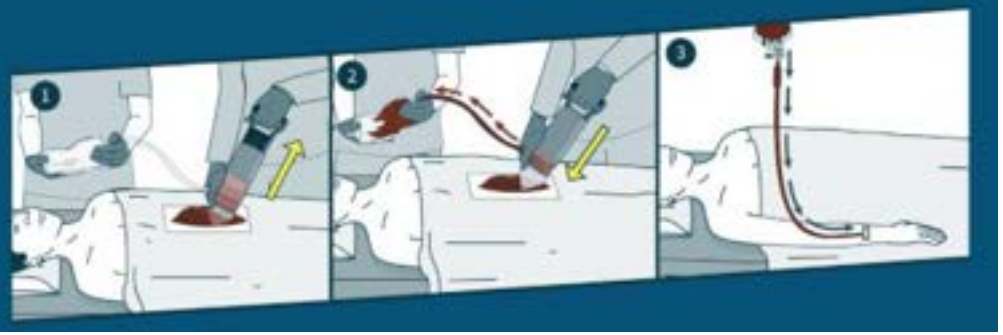
1. looking at scientific trends,
2. talking to people,
3. studying the jobs people are trying to do,
4. challenging paradigms and assumptions, and
5. changing the current terms of competition in the relevant technological and market spaces.

Opportunity 1

Hemafuse

- A handheld, mechanical device for intraoperative autotransfusion of blood
- Meant to replace or augment donor blood in emergency situations
- Reuse blood extracted from an individual's internal hemorrhages
- Developed by Sisu

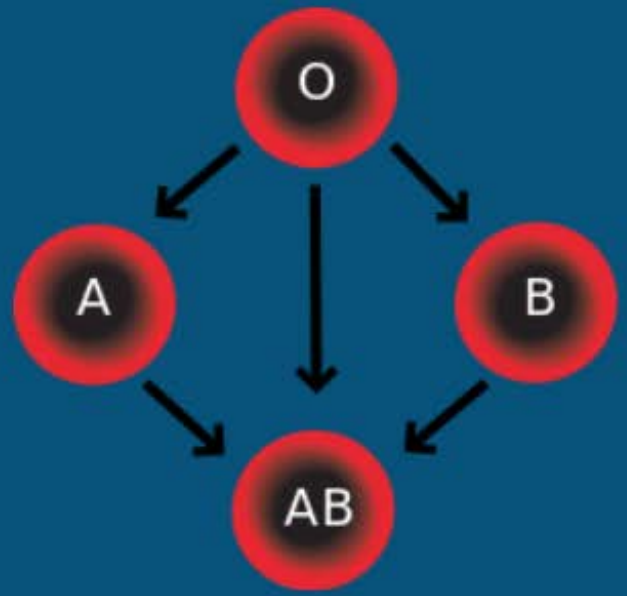




Opportunity 2

Pre-positioning Medical Resources

- Additional kits/devices in public areas like AEDs
- Data-driven, computer-generated predictions on where conflict will likely occur
- Universal donor per Platoon to donate blood on the spot
  - Solves issue of incompatible blood types



Opportunity 3

Freeze Drying Blood

- Theoretically can convert blood into a long lasting powder that can be rehydrated for use
- Can be hydrated with sterile water, no need to keep blood in refrigerated
- Still under research, as of June this year there has not been any test of transferring blood to actual humans

Opportunity 4

Automated Tourniquet

- Device that could detect the right amount of pressure to apply to the tourniquet.
  - Measuring the blood flow of the injured below the tourniquet would tell the device when enough pressure has been applied.
- Tourniquet could adjust pressure to prevent total bleed out but also allow some blood to flow if necessary.

- Similar to an ATS (link) but designed for a CCP/battlefield scenarios.

Opportunity 5

Detecting Internal Bleeding with a Wearable Device

- Use existing/developing technologies for wearable technologies
  - Shipping g-force indicators
- Potentially can detect internal bleeding by monitoring heart rate with an ECG application
- Detect irregularities in a soldiers health (monitored by an external system via telemedicine)

Opportunity 5 (contd.)

Detecting Internal Bleeding with a Wearable Device (cont.)

- Telemedicine could bring expertise forward to point of injury or role 1.
- Assist medic to help provide better care on the battlefield.
  - Wearable devices could transmit data to a doctor
- Assessments made closer to the point of injury could be used when treating patients later on.

Opportunity 6

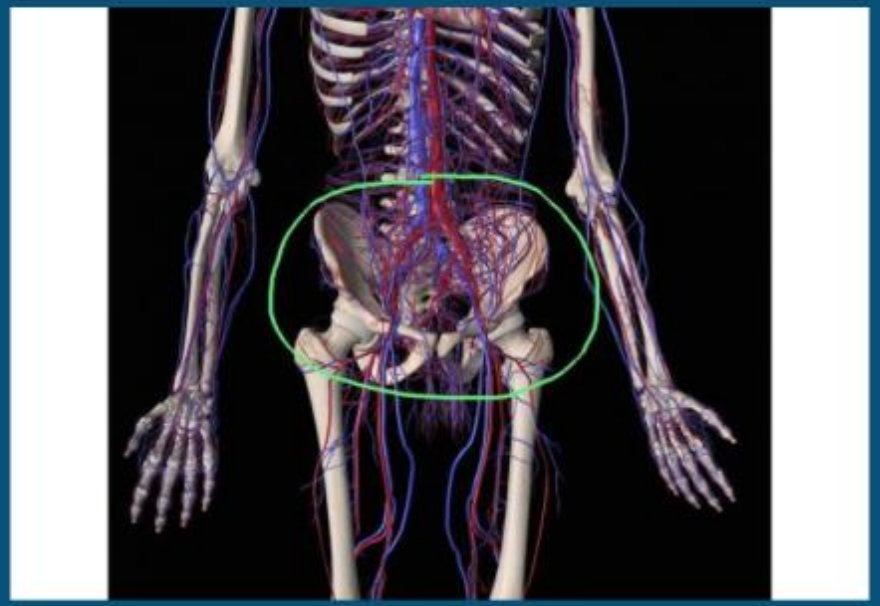
Blood Reactive Armor

- Hypothetical solution that will cause certain parts of body armor to change color when blood comes into contact with it.
- Potential distinction between arterial blood vs. venous blood
- Medics would be able to assess wounds quicker/more accurately

Opportunity 7

Universal Tourniquet

- Proper equipment that can be applied to wounds in the pelvic area (where a tourniquet would not be feasible).
- A singular (or series) of tourniquet(s) that would have distinct a shape to prevent bleed outs in areas where a tourniquet normally would not work.



Opportunity 8

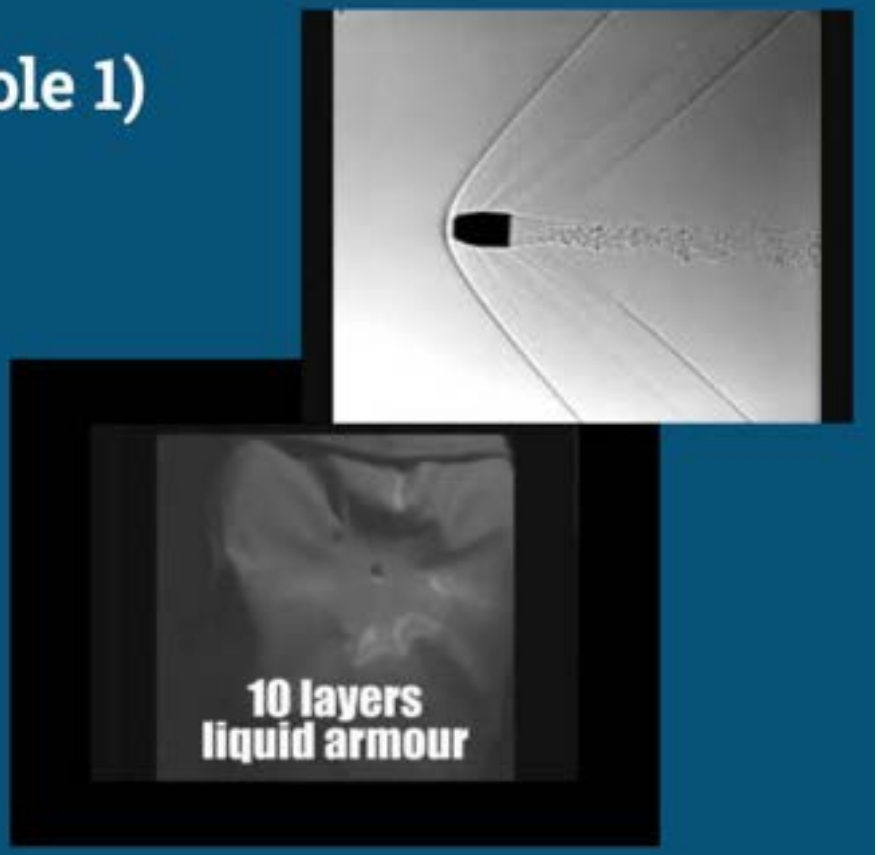
Improved Stretcher

- Stretcher that is quickly available.
- Autonomous to reduce the need for one or more individuals to help transport the injured.
- Similar to a UGV (link), wounded could placed onto vehicle for transport with a protective covering over them.

Opportunity 9

Improved Tents (for CCP/Role 1)

- Reinforced kevlar tents to protect medic and wounded inside.
- Provide a more feasible place for performing wound assessment, applying/adjusting a tourniquet, etc.
- Similar to armor being developed by BAE Systems (link) which combines a fluid with kevlar for increased protection but also is lightweight.



Other Opportunities (not researched deeply)

10. Light compact easily transportable litters, splints, and dressings
    - Reduce the workload for soldiers transporting the injured.
    - Foldable litters & splints? Combined litter and splint device?
11. Comfortable litters for longer duration (assumes no transport out)
12. Bluetooth enabled vital statistics chest strap or similar (viz., NASA)
    - Data collected would be transferred with the individual from point of injury and onward.
    - Doctors could assess the patient's condition and suggest treatment, prioritized evac, etc.
13. Man-carrying drones for evac (single person, low flying?) or robotic mules
    - Out of combat but available for aerial pick up.
14. Medical equipment drones – ability to swarm, land, and create a

Step 4: Create a Well-Defined Problem

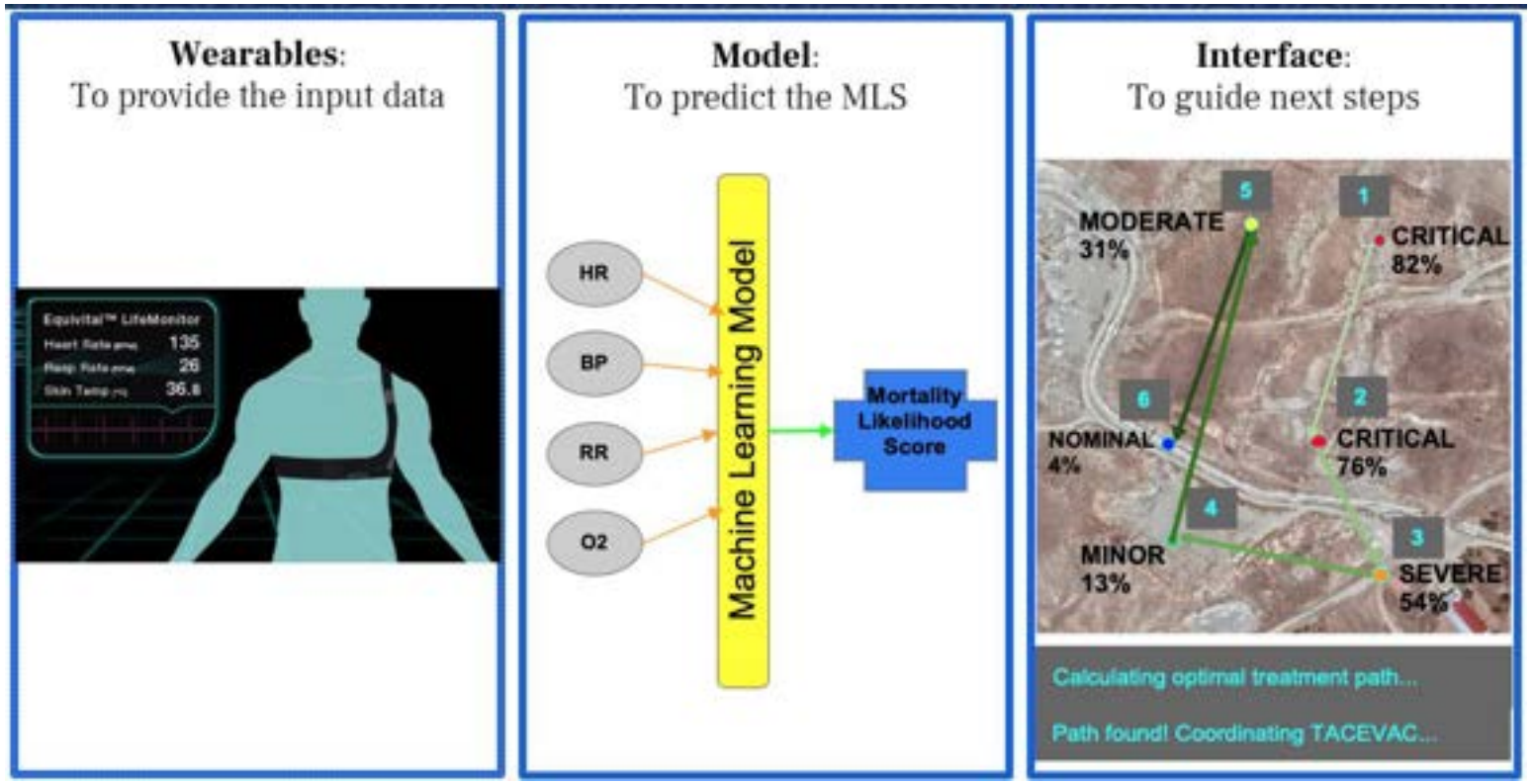
1. **Choose one opportunity**
2. Create a well-defined problem from an opportunity
3. Problem statement: Improve the triage process to reduce casualties in both military and civilian settings.

- Solution: build a digital triage assistant that
  1. Collects a range of frontline soldier's health data starting from the point of injury, throughout the continuum of care
  2. Calculates an instantaneous morality-likelihood score for each wounded soldier based off a mortality likelihood model
  3. Iteratively improves model from data collected in Goal #1
  4. Aids medics in immediately knowing the severity of a wounded soldier's injuries
  5. Collects data can be carried up the continuum of care
  6. And therefore, also provides insight into which soldiers should be triaged first by medics, especially during mass casualty incidents

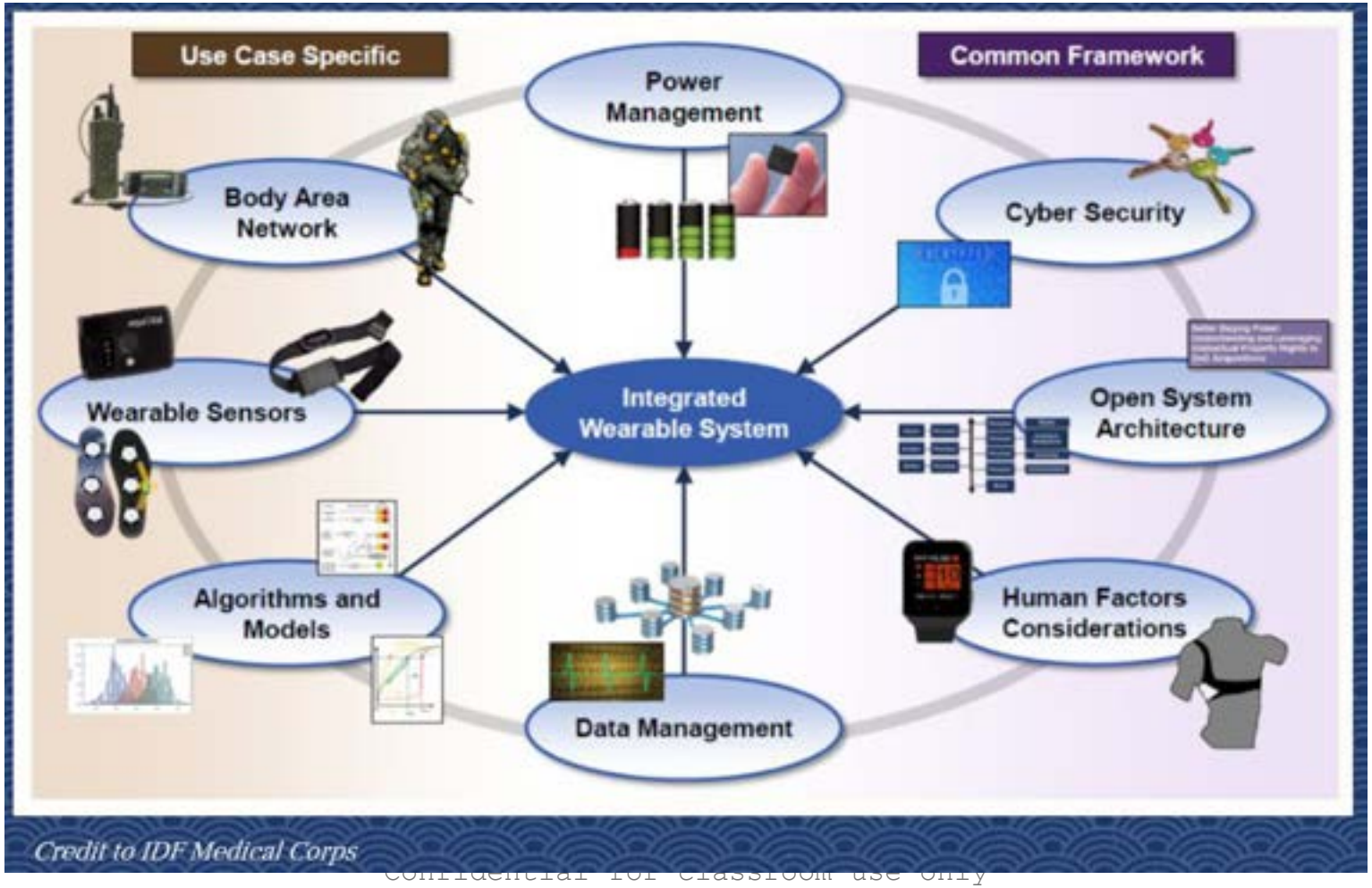
Research the Space and Build Another Mind Map

Step 5: Design a Minimum Viable Product (MVP)

- Wearables (or prototypes) that can individually report target parameters (heart rate, blood pressure, oxygen saturation, respiratory rate, and other parameters that indirectly measure Cardiac Output (CO))
- Algorithm that can take in parameters (simulated or from wearables) and output a Mortality Likelihood Score
- Health information dashboard with GPS location



Embed the Innovation into a Bigger System



The Future is Here

- United States Army now preparing for combat with highly dispersed troops, high casualty rates and limited means of communication
- Ukraine conflict has validated JHU student team scenarios of the future of combat medicine and the need for localized triage and medical care in the

DefenseNews Air Warfare Land Naval Space Cyber C4ISR Pentagon Congress Global TV/Video Thought

Army prepares for dispersed warfare with high casualties

By Todd South

Tuesday, Oct 11

U.S. soldiers provide security during training in Yavoriv, Ukraine, July 29, 2015. (Sgt. 1st Class Walter E. van Ochten/Army)

WASHINGTON – Fighting in Ukraine continues to show senior Army leaders and thinkers the value of two things that the service hasn't been doing at scale for a long, long time — reconstitution and long-range, large-unit dispersion.

https://www.defensenews.com/news/2022/10/11/army-prepares-for-dispersed-warfare-with-high-casualties/

Summary: A Structured Process

1. Use a structured approach to create a portfolio of opportunities by
   a. Exploring un-defined spaces
      - Imagine alternate futures ("what's the future of…") and the problems that might be found there
   b. Mining un-defined spaces for ill-defined problems
   c. Exploring ill-defined problems
      - Imagine "what's next" for customers, industries, or society (using trends, changing tastes/preferences, changing terms of competition, etc.)
2. Choose the best opportunities
   - those where the solution is likely to be found in the high uncertainty/low risk quadrant
3. Turn the best opportunities into well-defined problems
4. Validate and solve them
5. Use the solution to further explore un-defined and ill-defined