New and Emerging Biotechnologies in Military Medicine: Technical Capabilities and Ethical Considerations

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The author of over 350 peer-reviewed publications, 9 books, and 52 government reports, he is Chair Emeritus of the Institute of Electrical and Electronics Engineers (IEEE) Brain Initiative Ethics Program; was an appointed member of the Neuroethical, Legal and Social Issues Advisory Board of the Defense Advanced Research Project Agency (DARPA); and an appointed member of the U.S. Department of Health and Human Services (DHHS) Secretary's Advisory Committee on Human Research Protections.

An elected member of the European Academy of Science and Arts, and Overseas Fellow of the Royal Society of Medicine (United Kingdom), Dr. Giordano was formerly a designated aerospace physiologist who served with the U.S. Navy and Marine Corps.

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Dr. Applewhite completed her General Surgery Residency at Lahey Hospital and Medical Center and her Endocrine Surgery training at the University of Chicago, where she also completed the MacLean Fellowship for Clinical Medical Ethics. She was previously an Associate Professor of Surgery at Albany Medical College and the John A. Balint MD Chair of Bioethics Education and Research.

Her research interests include surgical ethics education, healthcare of the incarcerated patient population, and military medical ethics.

Disclosures

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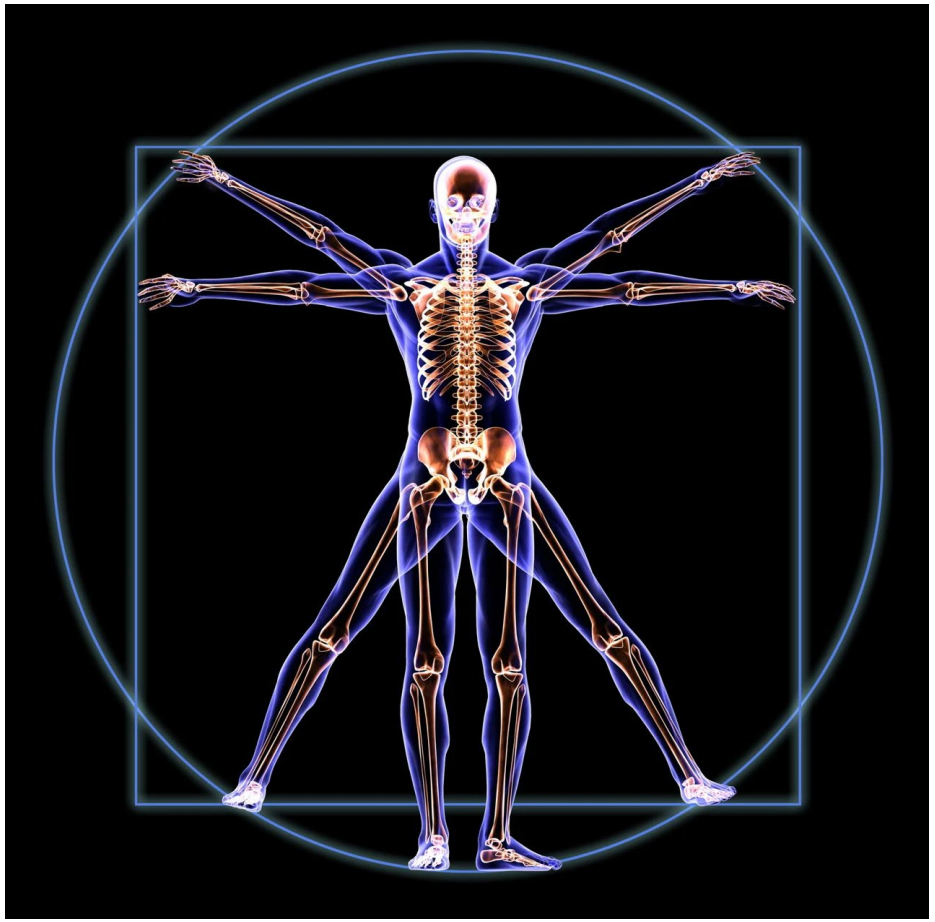
Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Identify current domains of bioscience and technology applicable in military medicine.
2. Explain key capabilities and limitations of these bioscientific and technological tools and methods.
3. Discuss major ethical issues arising in and from the use (and/or non-use/mis-use) of these techniques and technologies in military medicine.
4. Describe a general structural and functional ethical approach to addressing and potentially resolving such issues.

Bio-Science and Technology (BioS/T)…

puts human biology at our fingertips



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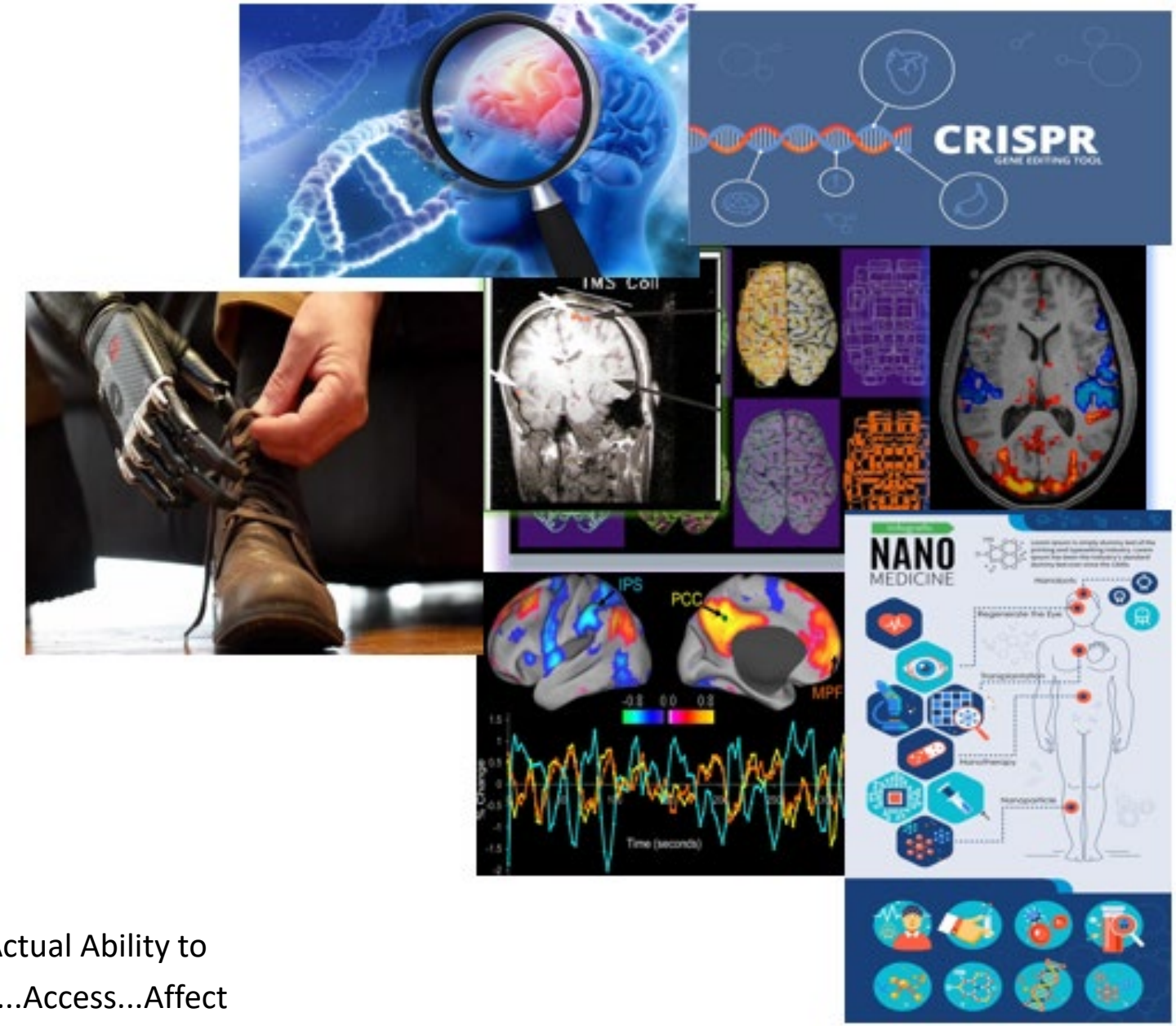
(BioS/T)

- Assessment
  - Biomarkers
  - Genetics/genomics
  - Imaging
  - Brain modeling/mapping

- Interventional
  - Technopharmaceutics
  - Gene editing
  - Nanomaterial implants
  - Transcranial Modulation
  - Deep Brain Stimulation
  - Brain-computer interface (BCI)
  - Advanced Bioprosthetics

- Derivative
  - -Artificial neural networks
  - -Artificial Intelligence (AI) technologies



A-3: Actual Ability to

Assess...Access...Affect

To What Effect(s) and Ends?

Integrative Scientific Convergence (ISC) in BioS/T

Conjoins:

- **Natural sciences**
- **Biotechnology**
- **Anthro/social science(s)**

Focus upon assessment, access and manipulation of biological structure and function(s):

-Individuals

-Groups

RELIANT UPON DATA INTEGRATION, SHARING AND USE...

BIG DATA

Domains of Use

- Clinical
  - Medical
- Para-clinical
  - Occupational
    - Training
    - Performance
- National Security
  - Intelligence
  - Weapons
- Public (DTC; DiY)
  - Educational
  - Wellness/Lifestyle

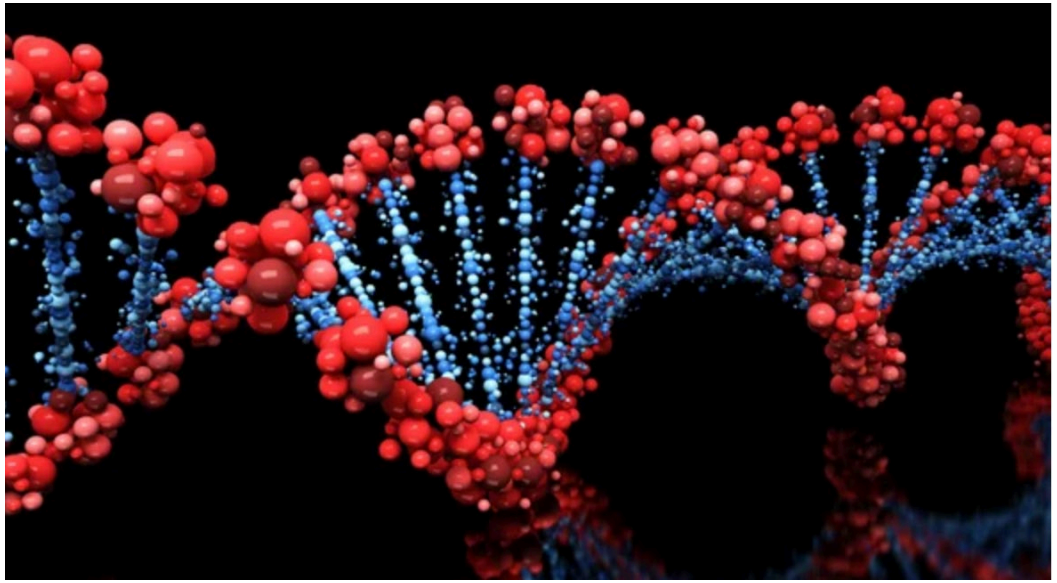
(istockpro.com; stock.adobe.com)

Clinical Domain: CRISPR

What is it?

- Protein Cas9 acts as “molecular scissors” and cuts DNA. This allows DNA to be cut and pasted, and the functions of the DNA are modified as a result. Modifying DNA has the power to do many things: correct genetic defects, treat disease, prevent the spread of diseases, improving crop production and quality, the possibilities are vast…

(gettyimages.com)



SCIENTIFIC AMERICAN®

STAT BIOTECH

Potential DNA Damage from CRISPR “Seriously Underestimated,” Study Finds

A flurry of recent findings highlight a contentious question in this area

(scientificamerican.com)

Molecular Technologies & Bioterrorism

- Manipulation of microorganism to increase virulence and transmissibility to maximize casualties
- Ability to tailor these microorganisms to specific areas of efficacy, and protect others
- Resistance to environmental factors
- Control for timeliness
- Diligence, preparedness, and frameworks for intervention are necessary to attempt to control the effects of bioterrorist attacks

(Moorchung et al., 2009)

POLITICO

Biowarfare

CORONAVIRUS

‘It is not science fiction anymore': Coronavirus exposes U.S. vulnerability to biowarfare

For years, experts have warned that terrorists and hostile states could launch a biological attack against a United States that remains woefully underprepared.

(politico.com)

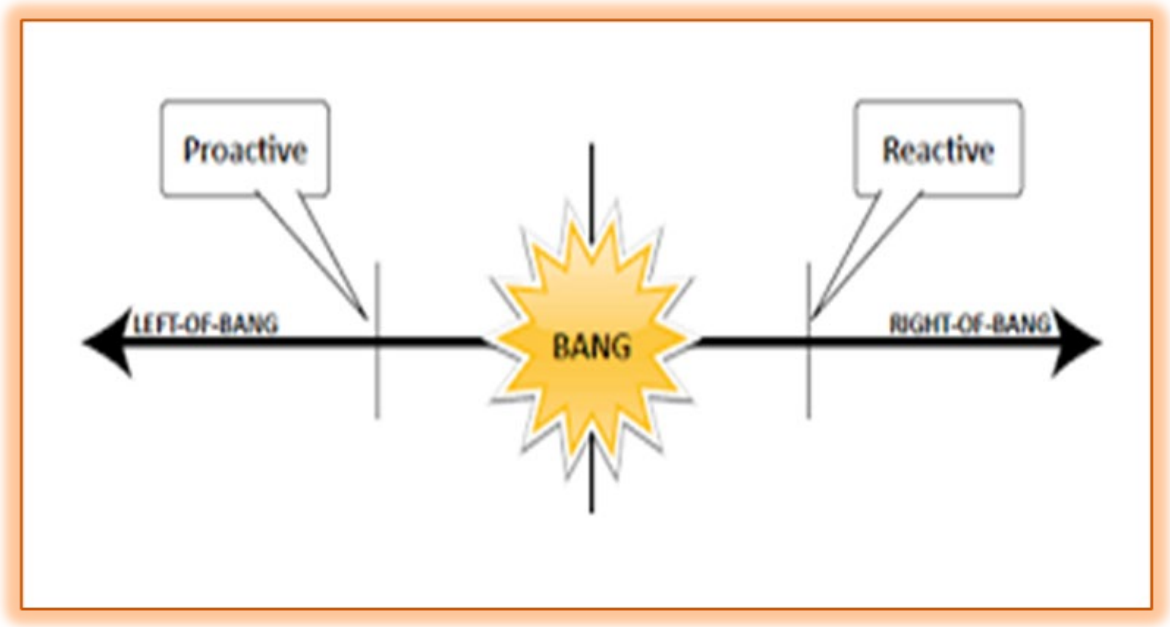
Clinical Domain: Direct-to Consumer Genetic Testing

- DNA testing kits (e.g., 23andMe, ancestryDNA, FamilyTreeDNA), isolate DNA from a saliva sample
- Scan genomes for risks associated with certain diseases: Alzheimer's, Parkinson's, Diabetes, certain cancers – but they are not diagnostic
  - Population-level data - cannot take into account individual risk
  - Consumers left with numbers, no counseling unless sought separately
- Data may be sold, court order – should results limit career choices?
- Pediatric tests: athletic or academic aptitude
  - Consent issues, who "owns" that genetic information, predictability unreliable at best
- Ancestry tests
  - Accuracy and precision varies by company, also can of worms…
- Life, disability, and long-term care insurance
  - Not under the same constraints as employers or health insurance

(Nitkin, 2018)

Bio-HOPE

Health, Operational Performance, Enhancement



(Van Horne et al.)

BioS/T…

Puts our fingertips upon many biologies…
and the individuals and groups that have them

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Potential…

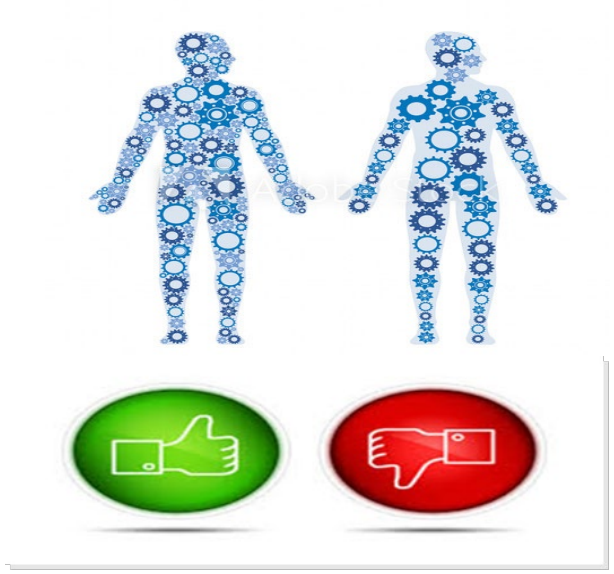
- To harness and engage BioS/T in convergent, multi-disciplinary approaches to study, define, predict and influence human ecologies
- Affect human activities on individual, group and populational levels
- To affect human relations on local, regional and global scales
- Influence postures and conduct of national security and defense agenda(s)

The Good, the Bad, and the Ugly

- Good
  - Diagnose and cure/treat disease
  - Facilitate/improve physiological and cognitive functions
  - Improve quality of life

- Bad
  - Misappropriated findings and meanings
  - Inapt use
  - Distributional asymmetries

- Ugly
  - Intentional mis-use (of information and capabilities)
  - Neglect of analysis, precaution, preparation
  - Use in warfare



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Bioethico-legal Issues & Risks

Technology-focal

- Unknowns of frontier science/technology
- Capabilities, limitations
- Validity, viability of use
- Runaway and Wexelblatt effects

Social

- Inviolability of “mind”/“cognitive liberty”
- Autonomy: Protection vs privacy
- Awareness, understanding, consent
- Treatment/protection/enhancement
- Norms, pluralization, diversity
- Justice: Provision/access
- Dual-use

BioS/T Superspeedway

- Multiple lanes
- Multiple entries
- Rapid pace
- Competitive
- Big Prizes
- Not without risks...

(drive.com.au)

ON-RAMP

***O**perationally **N**ecessary **R**isk **A**ssessment **M**itigation **P**aradigm* *(from Giordano, 2015; 2016 ©)*

6-R Approach

- *Responsibility*
- *Realistic Assessment*: of the BioS/T
- *Research*: evaluating use/effects-in-practice
- *Responsiveness:* to burdens and deleterious effects
- *Revisions:* in technology and marketing
- *Regulation*: insure rigor in development and claims

Poses key questions

Framed within defined parameters

Preparatory Paradigm

Any Consideration of Using BioS/T Should be Informed by...

6-W Questions:

- *What* BioS/T is/are available for current use?
- *Why* is BioS/T considered or advocated or use?
- *Who* will receive BioS/T?
- *When* will BioS/T be considered (algorithm/protocol)?
- *Where* will BioS/T be administered (e.g.-hospital; clinic, school; worksite; home)?
- *Which* mechanisms will be in place for ongoing provision of services/resources?

Preparatory Paradigm

As Framed by...

6-C Considerations:

- *Capacities* and limitations of the BioS/T
- *Consequences* incurred by BioS/T on recipients, families, and society in the short, intermediate, and long-term
- *Character* of the research and recipient (e. g, patterns of cognition, emotion, and behavior) affected by BioS/T
- *Contexts* of need and value that influence use of BioS/T
- *Continuity* of research and clinical care
- *Consent* through provision most information possible

Audits

1.BioS/T
2. Bioethics
3. Medico-social Views/Expectations of Both
4. Regulations and Policies

Que será...

- Use-in-practice will incur unanticipated/deleterious effects
- Does NOT necessarily proscribe use
- DOES obligate need for:
  - Rigorous monitoring
  - Continuing R/D
  - Clinical engagement
  - Revisable guidelines/regs
  - Ongoing ethical guidance
    (and iterative ethical development)

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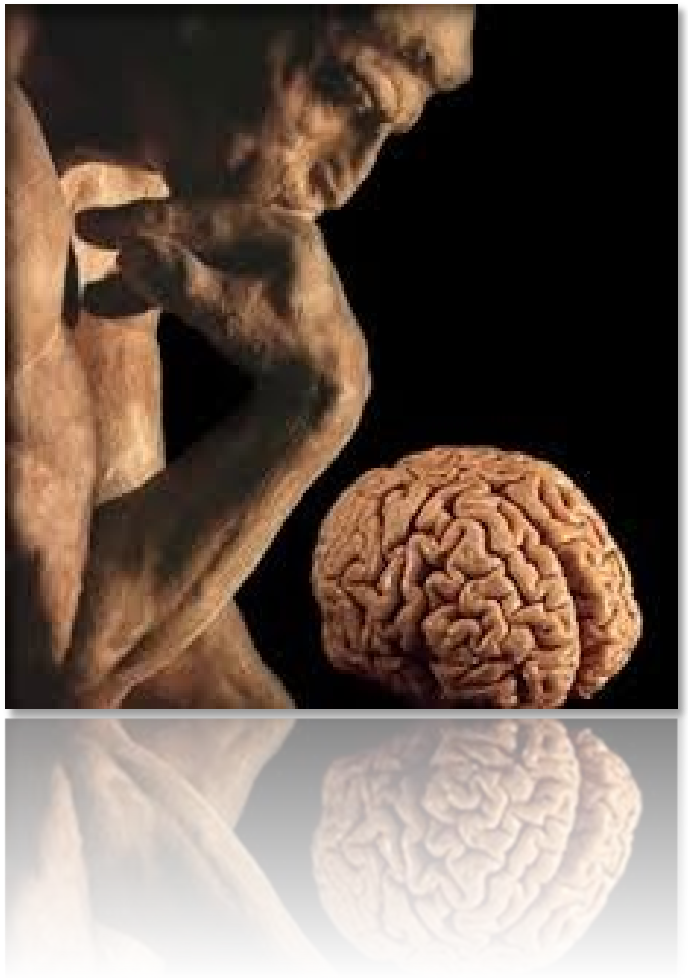

Moving forward…

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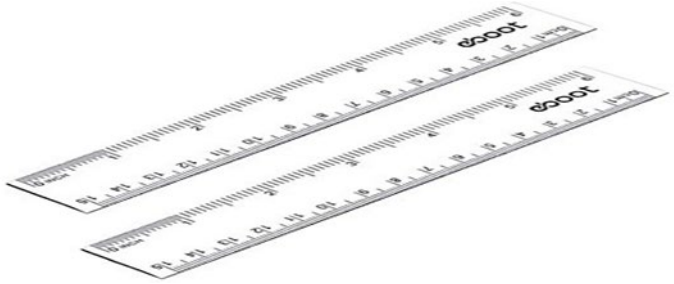
Key Takeaways



1. BioS/T is developing with considerable breadth and at rapid pace.
2. BioS/T generates great capability – and concern(s) – in military medicine
3. Reflection, insight and prudence must be the stepping stone for all future acts of inquiry, invention and intervention…
4. “Measure twice, cut once”, for all too often, there is no turning back

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