

# DSHS Grand Rounds

April 15

## Ethical Issues in New Medical Technologies and Emerging Infectious Diseases

Presenter: Nathan Allen, MD, FACEP,  
Baylor College of Medicine



# Logistics

Registration for free continuing education (CE) hours or certificate of attendance through TRAIN at:

<https://tx.train.org>

Streamlined registration  
for individuals not requesting CE hours  
or a certificate of attendance

1. webinar: <http://www.dshs.state.tx.us/grandrounds/webinar-no-CE.shtm>
2. live audience: sign in at the door

For registration questions, please contact Laura Wells, MPH at  
[CE.Service@dshs.state.tx.us](mailto:CE.Service@dshs.state.tx.us)

# Logistics (cont.)

**Slides and recorded webinar available at:**

<http://www.dshs.state.tx.us/grandrounds>

## Questions?

There will be a question and answer period at the end of the presentation. Remote sites can send in questions throughout the presentation by using the GoToWebinar chat box or email [GrandRounds@dshs.state.tx.us](mailto:GrandRounds@dshs.state.tx.us).

For those in the auditorium, please come to the microphone to ask your question.

**For technical difficulties, please contact:**

GoToWebinar 1-800-263-6317(toll free) or 1-805-617-7000

# Disclosure to the Learner

## **Requirement of Learner**

Participants requesting continuing education contact hours or a certificate of attendance must register in TRAIN, attend the entire session, and complete the online evaluation within two weeks of the presentation.

## **Commercial Support**

This educational activity received no commercial support.

## **Disclosure of Financial Conflict of Interest**

The speakers and planning committee have no relevant financial relationships to disclose.

## **Off Label Use**

There will be no discussion of off-label use during this presentation.

## **Non-Endorsement Statement**

Accredited status does not imply endorsement by Department of State Health Services - Continuing Education Services, Texas Medical Association, or American Nurses Credentialing Center of any commercial products displayed in conjunction with an activity.



Kirk Cole  
Interim DSHS Commissioner  
is pleased to introduce our  
DSHS Grand Rounds speakers

# Ethical Issues in New Medical Technologies and Emerging Infectious Diseases



Nathan Allen, MD, FACEP

Assistant Professor of Medicine and Medical  
Ethics, Program Director, GME; Ethics  
Professionalism and Policy Program Section of  
Emergency Medicine, Dept. of Medicine Center  
for Medical Ethics and Health Policy, Baylor  
College of Medicine

# Learning Objectives

Participants will be able to:

1. Describe the ethical challenges produced by emerging medical technologies such as ECMO, destination therapy with mechanical circulatory support devices, and 3D-Bioprinting.
2. Explore a clinical ethical taxonomy for choosing treatments and interventions in emerging infectious diseases.



# **Ethical Issues in New Medical Technology and Emerging Infectious Disease**

**Nathan Allen, MD, FACEP**

# **Conflicts of interest**

**I do not have any financial conflicts of interest to report**

**I will not be talking about off label uses of medications**



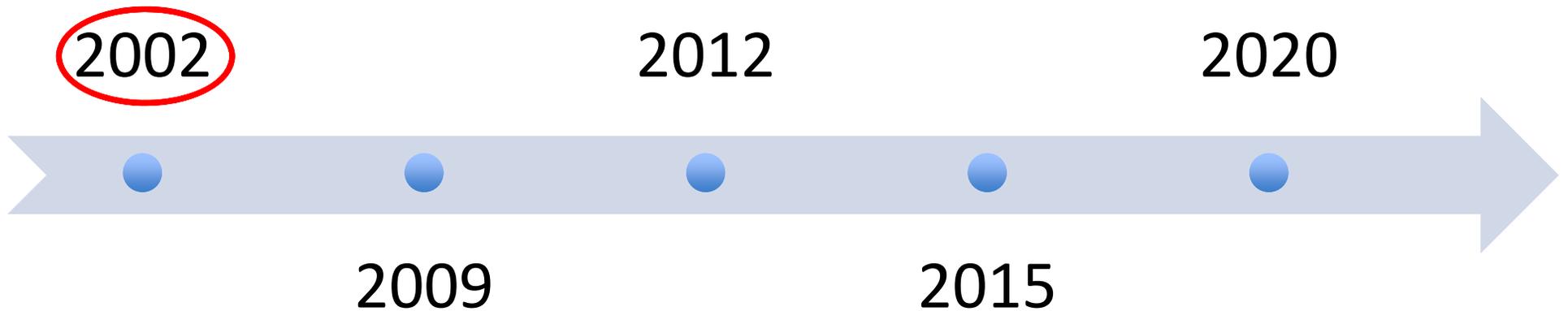
# **Talk Outline: A Case Based Approach**

**A framing case from  
emerging infectious  
disease**

**Apply these lessons  
to several cases of  
“new technology”**

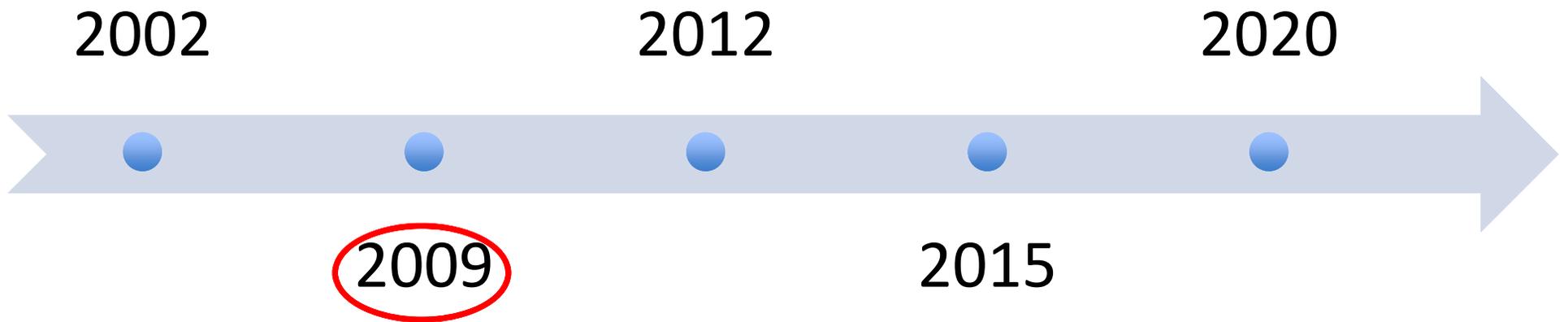


# Recent Infectious Disease Challenges



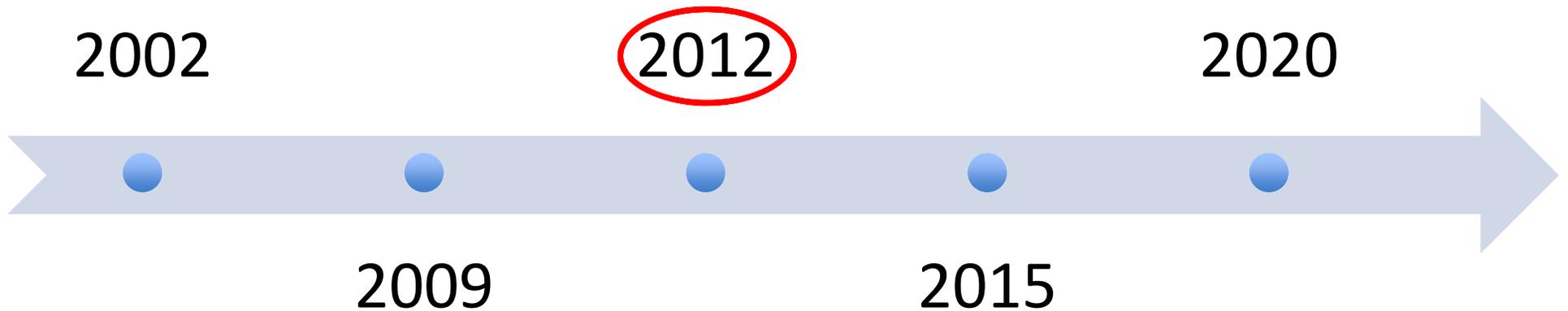
**SARS**

# Recent Infectious Disease Challenges



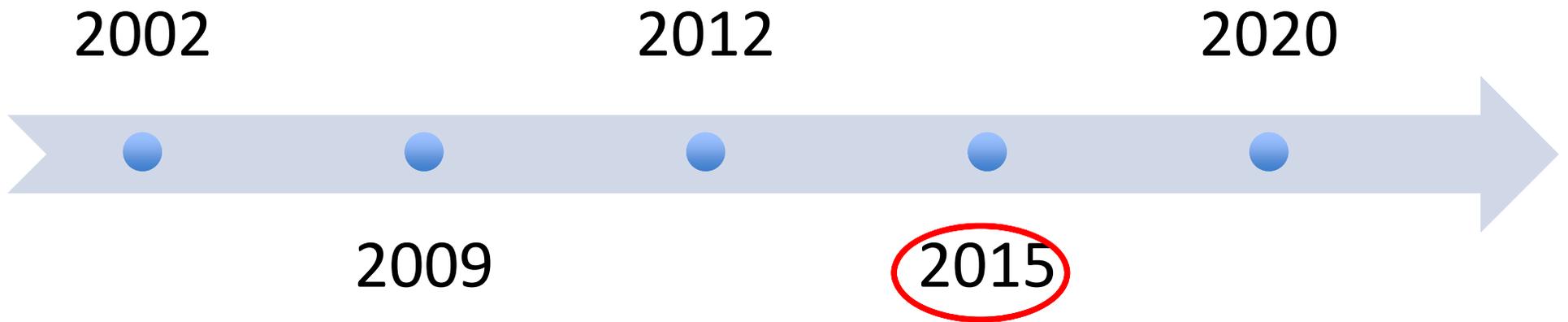
**H1N1**

# Recent Infectious Disease Challenges



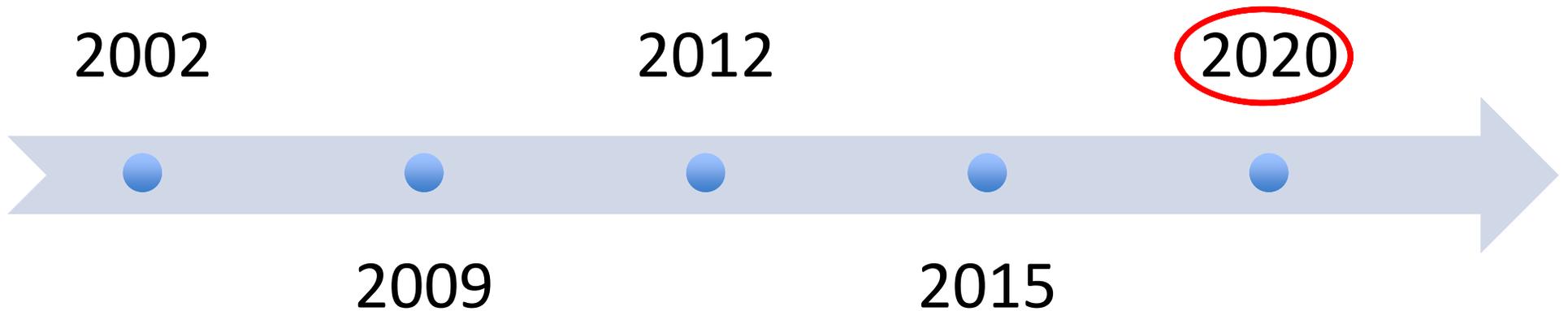
**MERS**

# Recent Infectious Disease Challenges



**EBOLA**

# Recent Infectious Disease Challenges



???

**EBOLA**



# A million questions

**Do I have to do CPR?**

**Should we give the experimental drug?**

**What if I'm pregnant?**

**What about the students?**



# A million questions

**Do I have to do CPR?**

**Should we give the experimental drug?**

**What if I'm pregnant?**

**What about the students?**



# How do you address ethical challenges?

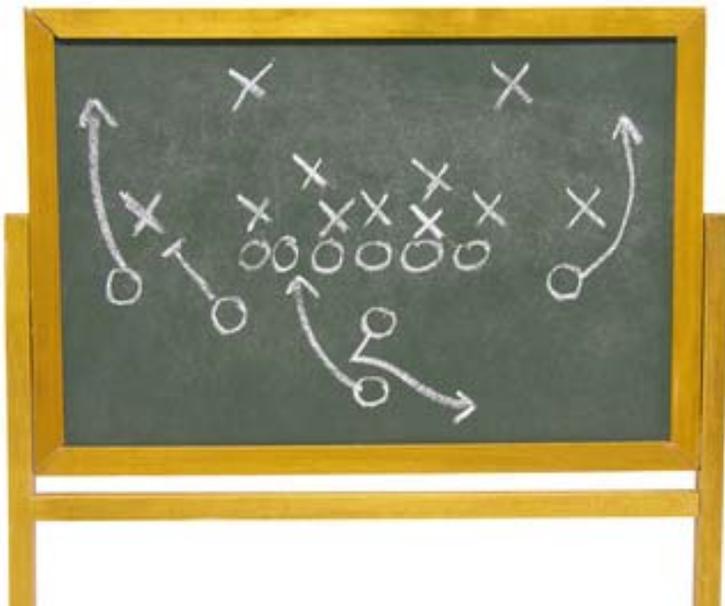
1. Broad frame →
2. Relevant ethical issues →
3. Organizational ethics →
4. Clinical ethics decisions



# **Step 1: Draw up a new playbook?**

**Is this really new?**

**Is it morally disruptive?**



# Why you should stick with what works



**Sustainability**

**Consistency**

**Precedent**

# The Flu

**Resources**

**Quarantine**



# The early days of HIV

**Risk to self**

**Lack of information**



# **Step 2: Core Ethical Issues**

**What ethical principles  
are important here?**



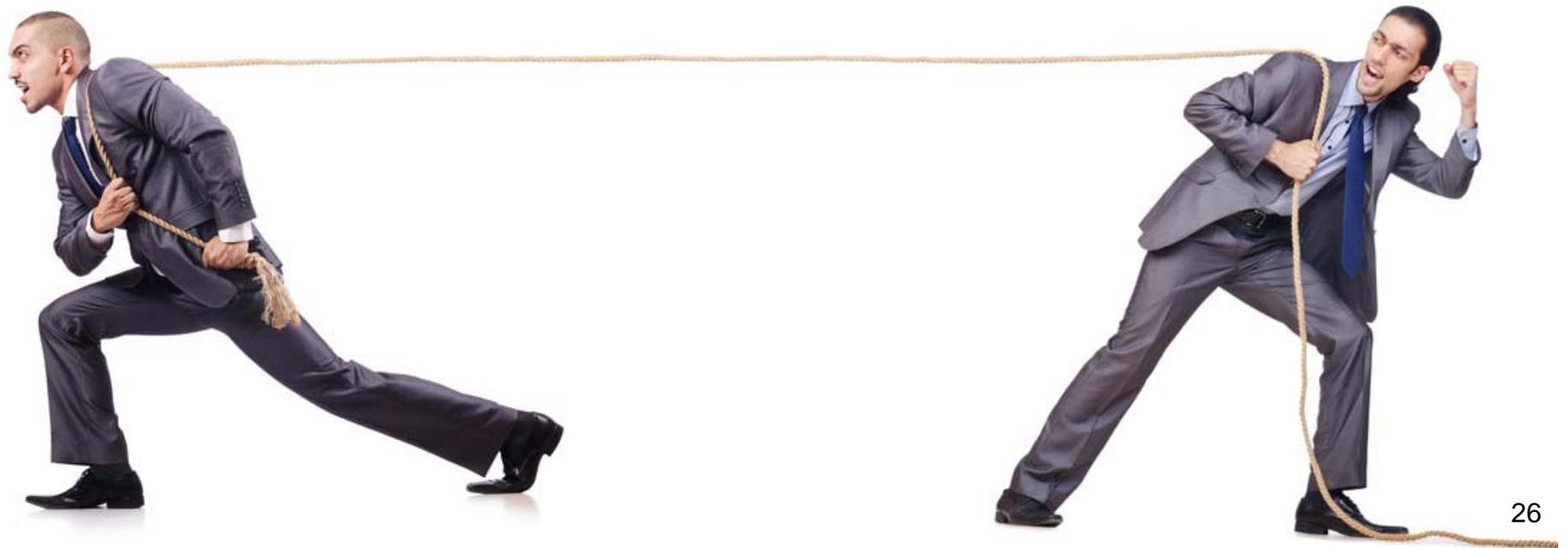
# Don't panic here!

## Lots of Scrabble™ words

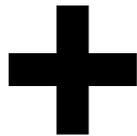


# Issues in dynamic tension

## Beneficence vs. Non-maleficence



# Help this patient vs. protect 3<sup>rd</sup> parties

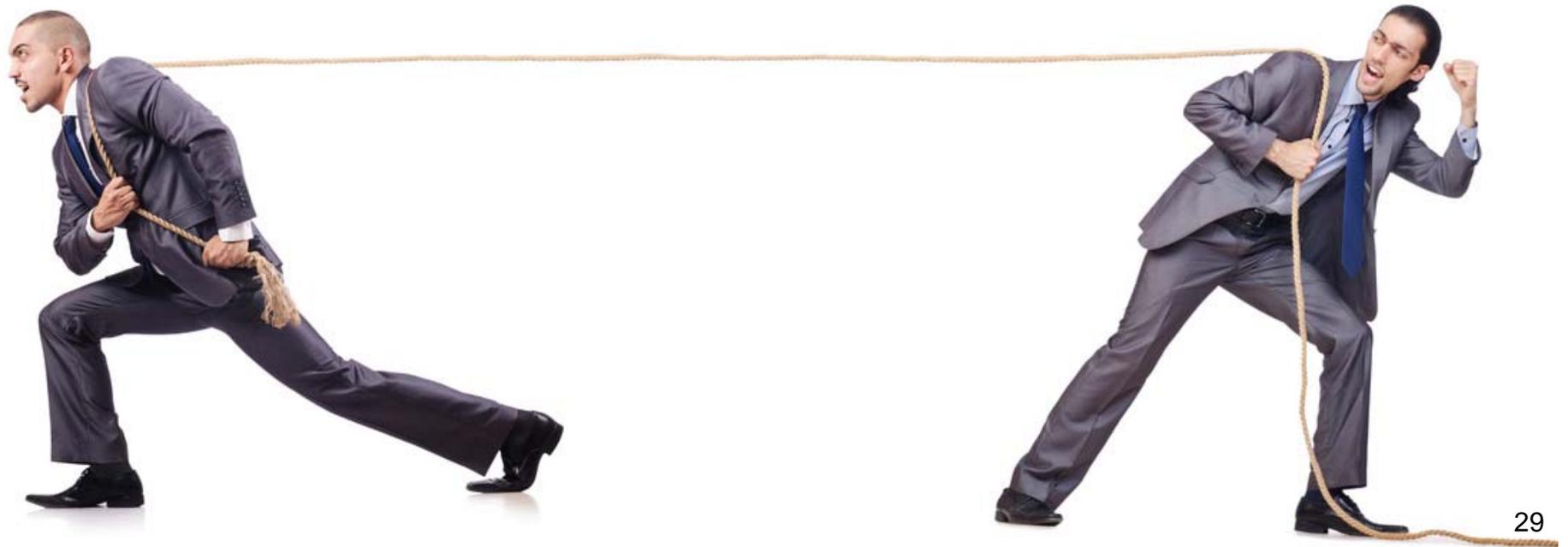


# Help this patient vs. protect 3<sup>rd</sup> parties



# Issues in dynamic tension

## Self-sacrifice vs. Legitimate self-interest



# What are YOU going to do?

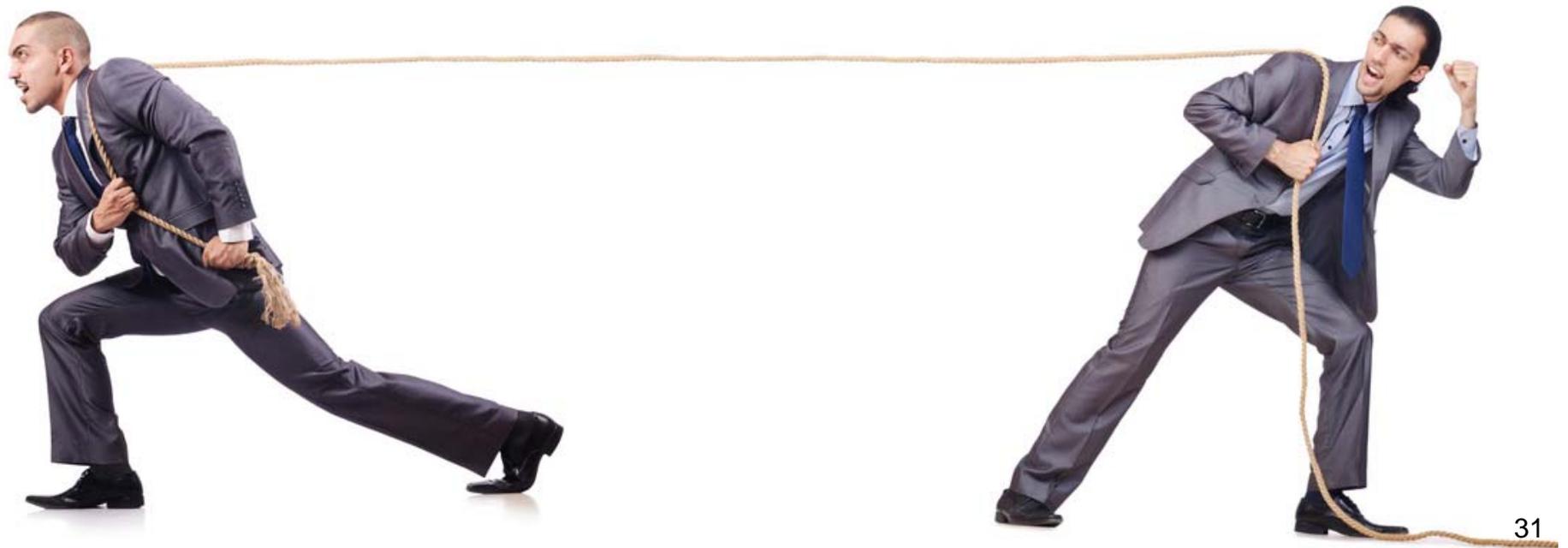


**VS.**



# Issues in dynamic tension

## Justice vs. Autonomy



# Promoting equality vs. Promoting choice

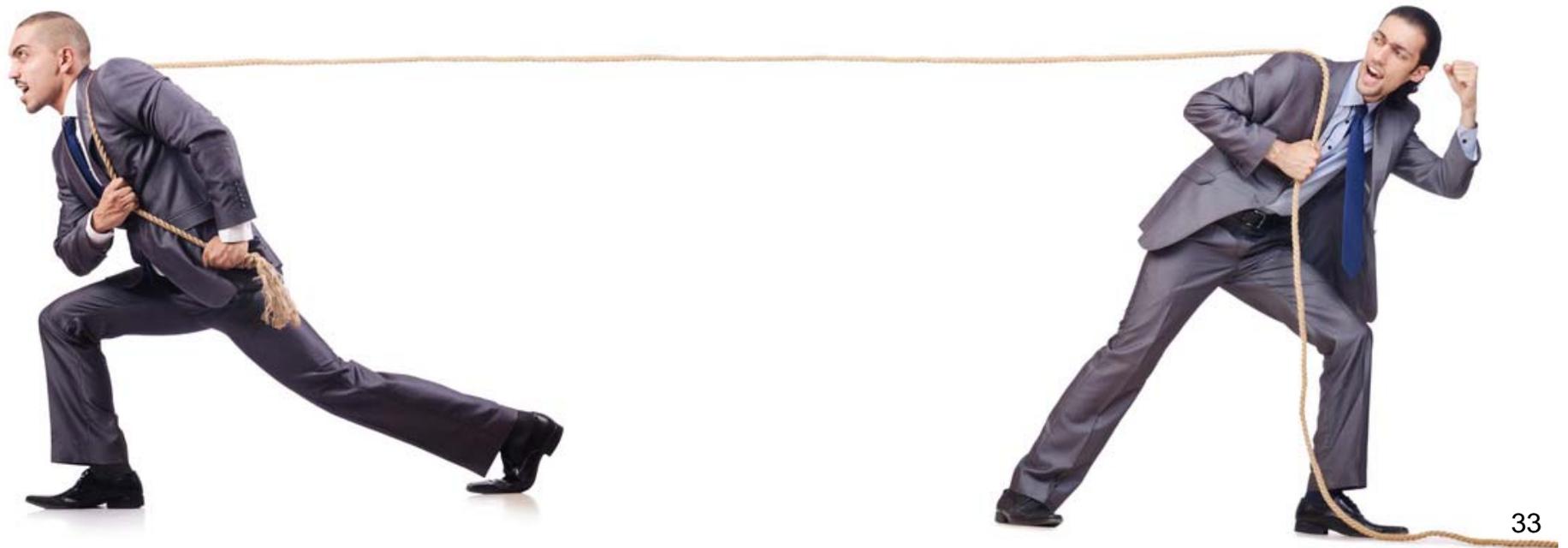


**VS.**



# Issues in dynamic tension

## Local control vs. Centralization



**I thought this was Texas!**



# Step 3: Organizational Ethics Issues



**Do we have to do this?**

**Who is going to do this?**

**How do we keep  
people safe?**

# Who is going to do this?



# PROS

Doing this well  
takes training and  
expertise

Legitimizes self-  
interests

# CONS

Everyone has  
to be ready

Risks appear to be  
reasonable

Contrary to  
public expectation

# Can organizations close their doors?



# Healthcare Professionals

**Fiduciary duty**

**Public expectation**



# Students

# NO



# Residents/Fellows/Trainees



**When is someone essential?**

**When is the right time?**

# Non-healthcare workers



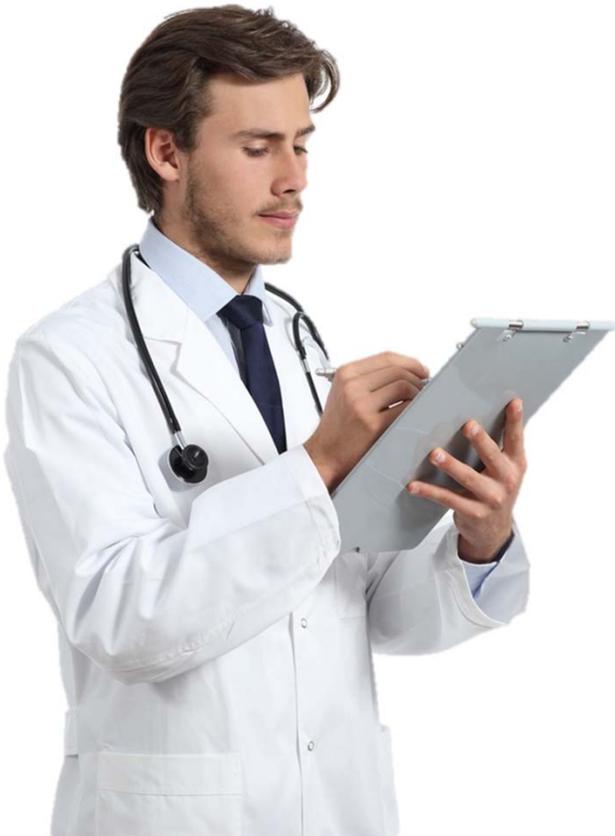
**No fiduciary duty**

**Cross training?**

# **Rx for “Who is going to do this?”**

**Recognize that  
self-sacrifice is  
not limitless**

**Construct a  
favorable  
environment**

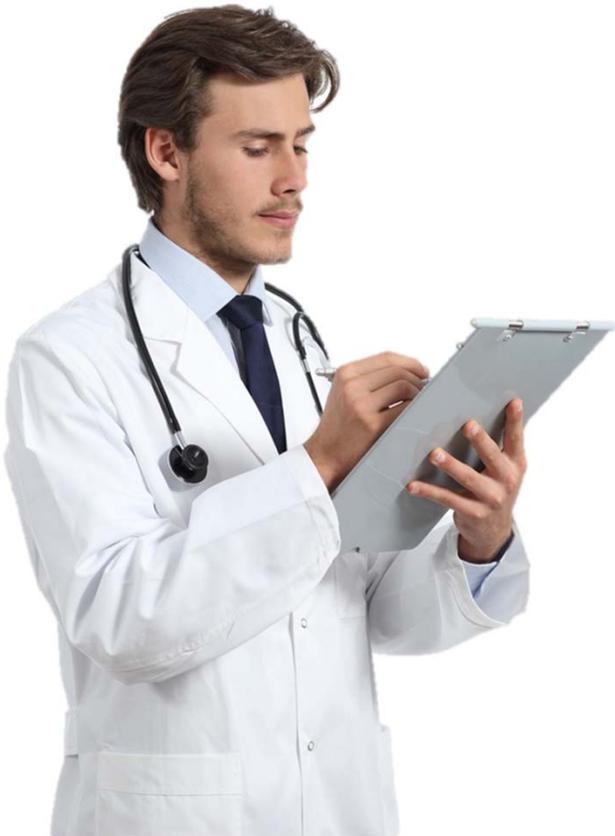


# **Rx for “Who is going to do this?”**

**Comprehensive  
indemnification**

**Allow opt-in**

**Universal  
preparedness**



A person is shown from the chest up, wearing a bright yellow biohazard protective suit. The suit has black biohazard symbols and the words "BIOHAZARD" and "STAY OUT" printed on it. The person is also wearing a black respirator mask with two yellow filters. The background is a solid blue color.

**How do we keep  
people safe?**

# Quarantine for HCWs

**Returning vs. domestic**

**Voluntary or mandatory**

**Logistically**



# PROS

Meets expectations

May reduce spread

May reduce future  
costs

# CONS

Stigmatizing

Negative incentive

Hard to enforce

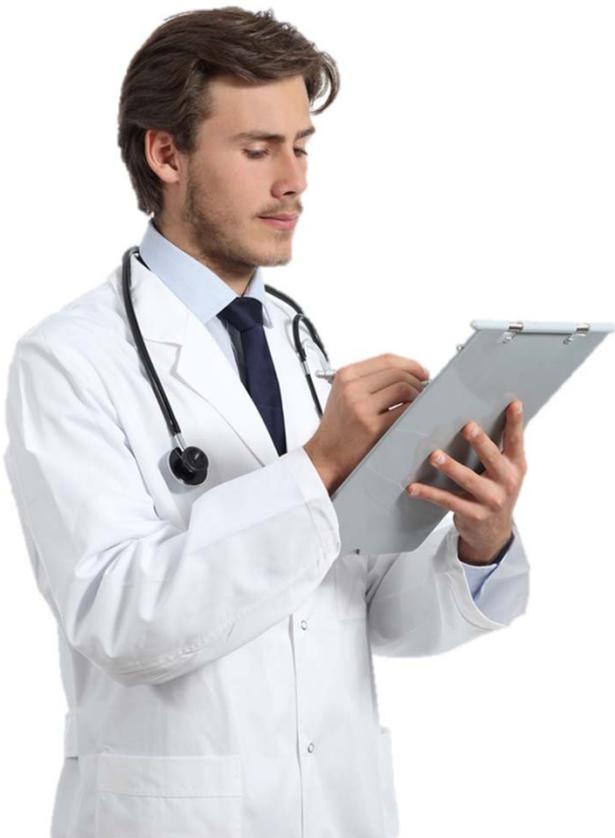
Expensive

# Rx for safety

**Quarantine should  
treat disease risk  
not fear**

**Broad educational  
duties**

**LIMIT the exposure**



# Step 4: Clinical Ethics Issues

**How do I choose therapies?**

**When can I use the new stuff?**

**What if I don't know who has it?**



# Choosing therapies

1. Does this work?
2. Can it be delivered with sustained, excellent infection control?\*

**$R_0$  must  $< 1$**



# Clinical ethical taxonomy

Group	Clinical Ethical Classification	Implications for Decision Making	Clinical Implications	Treatments (Not exhaustive)
A	Known to be effective	Obligatory*	Monitor for trends toward ineffectiveness or harm.  Perform continuous quality improvement.	Supportive care including:  Intravenous fluids, balancing electrolytes, maintaining oxygen status and blood pressure, and treating other infections <sup>1</sup> .
B-1	Experimental and Novel: New therapies for EVD.	Permissible* but not obligatory	Preferentially perform as IRB approved research or at a minimum adhere to WHO requirements for unregistered interventions <sup>2</sup>	Anything that is an “Ebola Specific Therapy”: ZMapp™ (Mapp Biopharmaceutical), experimental vaccines and medications.
B-2	Experimental for EVD: Proven therapies for other conditions but effectiveness for EVD unknown	Permissible* but not obligatory	Track and monitor through research or collaborative data sharing to further categorize and establish evidence based protocols	Resource intensive advanced therapies (dialysis and mechanical ventilation), other unproven interventions such as bananas
C	Ineffective, harmful, or does not meet “modicum of benefit” test <sup>3</sup>	Impermissible to offer or perform	Rule out unilaterally	CPR <sup>4</sup>
D	Cannot be provided without violating quarantine or infection control standards	Impermissible to offer or perform	Rule out unilaterally	Low yield lab testing, MRI

Source: Allen NG, et al. Placing and Evaluating Unproven Interventions Within a Clinical Ethical Taxonomy of Treatments for Ebola Virus Disease. Accepted for Publication in Amer J Bioethics

# Category A: Effective

**CDC still only lists 3**

**Ethically obligatory\***

**Monitor/continuous QI**



# Category B1: Experimental and Novel

**“Ebola specific therapies”**

**Ethically permissible\***

**IRB > WHO regs**



# **Category B2: Experimental for EVD**

**New for EVD, proven for other illnesses**

**Ethically permissible\***

**Track/monitor through  
research or collaboration**

**Establish protocols**



# Category C: Ineffective



**Ineffective, harmful, or doesn't meet "modicum of benefit" test**

**Impermissible**

**Rule out unilaterally★**

# Category D: Undeliverable

**Can't do it without  
breaking quarantine  
(e.g. MRI)**



**Impermissible**

**Rule out unilaterally★**

# Why the headache over CPR?



# CPR Resolved

**The impossible and  
the improbable are not  
worth stressing over**



The background of the slide is a vibrant green color with a pattern of vertical, slightly wavy lines, resembling heavy, draped curtains. The lighting is even, with a slight gradient from top to bottom, making the bottom appear darker.

# Potential EVD

# What are the odds?





**People are going  
to get hurt and  
you can't prevent  
that.**

# Review of systematic approach

1. Broad frame →
2. Relevant ethical issues →
3. Organizational ethics →
4. Clinical ethics decisions



# Applying this to new technology



# New Technology Case #1: New Media? New Rules?

The image is a screenshot of a Facebook page for a community titled "Donate a lung to Sarah Murnaghan". The page features a large header image of a young girl, Sarah Murnaghan, wearing a medical mask and being held by a woman. Below the header, the page layout includes a "PEOPLE" section with 1,823 likes and an "ABOUT" section with a description of Sarah's medical condition and a link to a CNN article. A "PHOTOS" section shows two smaller images of Sarah. The main content area displays a post from June 5, 2013, titled "Good News for Sarah !!!" with a photo of Sarah and two women celebrating. Below the photo is a news article snippet titled "Judge orders girl added to adult lung transplant list" from VITALS.NBCNEWS.COM. The page also shows navigation tabs for "Timeline", "About", "Photos", "Likes", and "Videos", and a post creation area with "Post" and "Photo / Video" options.

Source: Screen capture from public Facebook page

# **New Technology Case #1**

**Frame: Part old, part new**

**Issues: Authority vs. the collective, privacy, professional integrity**

**Organizational: Policies, caution**

**Clinical: Clear criteria, clear decisions, rethink allocation?**



# **New Technology Case #2: Unintended Consequences**



# **New Technology Case #2**

**How does “Big Data” change the game in genetics?**

**Do non-participants have “rights”?**

**When is something a test?**

The word "Search" is rendered in a 3D, blocky font. Each letter is a different color: 'S' is blue, 'e' is red, 'a' is yellow, 'r' is blue, 'c' is green, and 'h' is red. The letters are slightly shadowed and reflected on the surface below them.

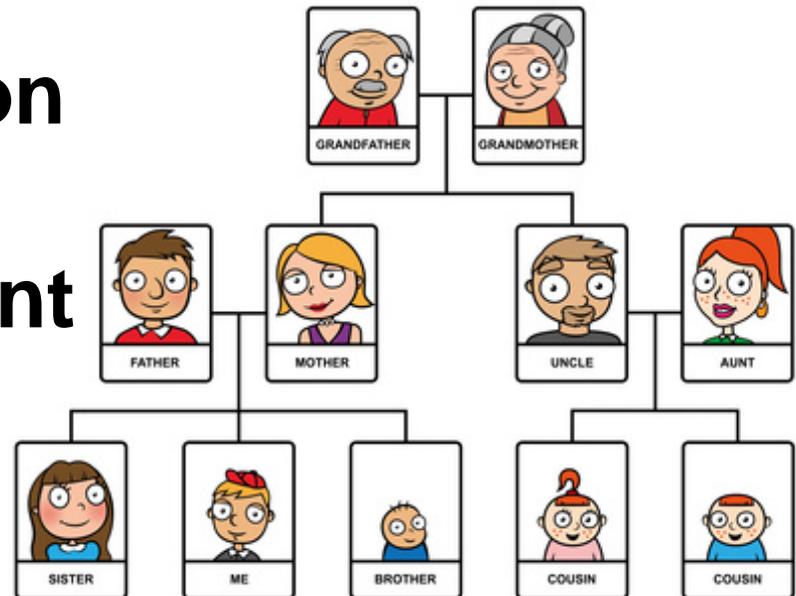
# New Technology Case #2

**Frame: Mix of old and new**

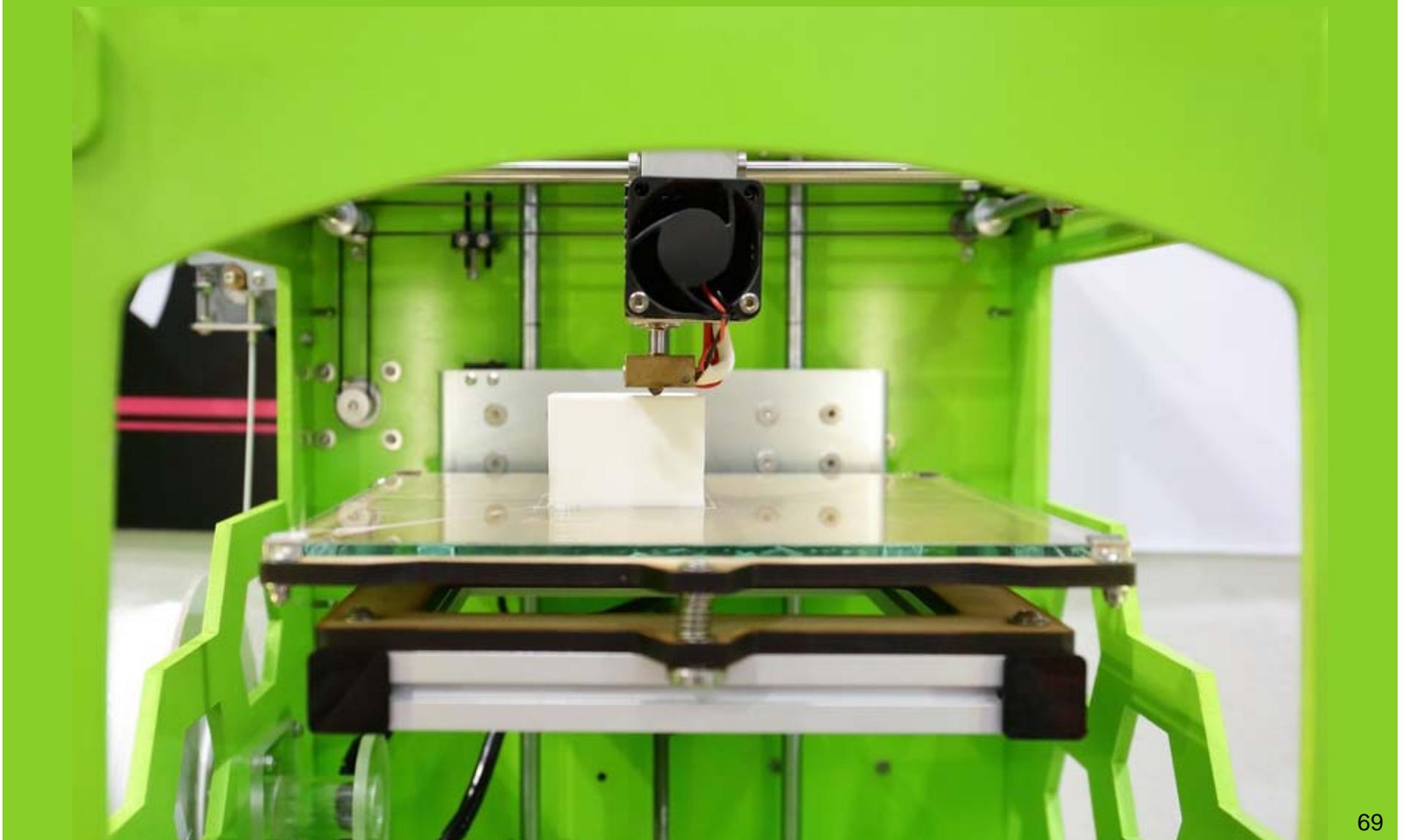
**Issues: Privacy, ownership, unintended effects**

**Organizational: Regulation**

**Clinical: Informed consent**



# New Technology Case #3: You can do what?



# New Technology Case #3



# New Technology Case #3



***World's first 3D-bioprinted  
transplant-ready organ to  
be ready in early 2015  
-RT***

# New Technology Case #3



# **New Technology Case #3**

**Frame: Transplant and genetics**

**Issues: Healing vs. augmenting,  
understanding risk**

**Organizational: An accelerant,  
regulatory possibilities**

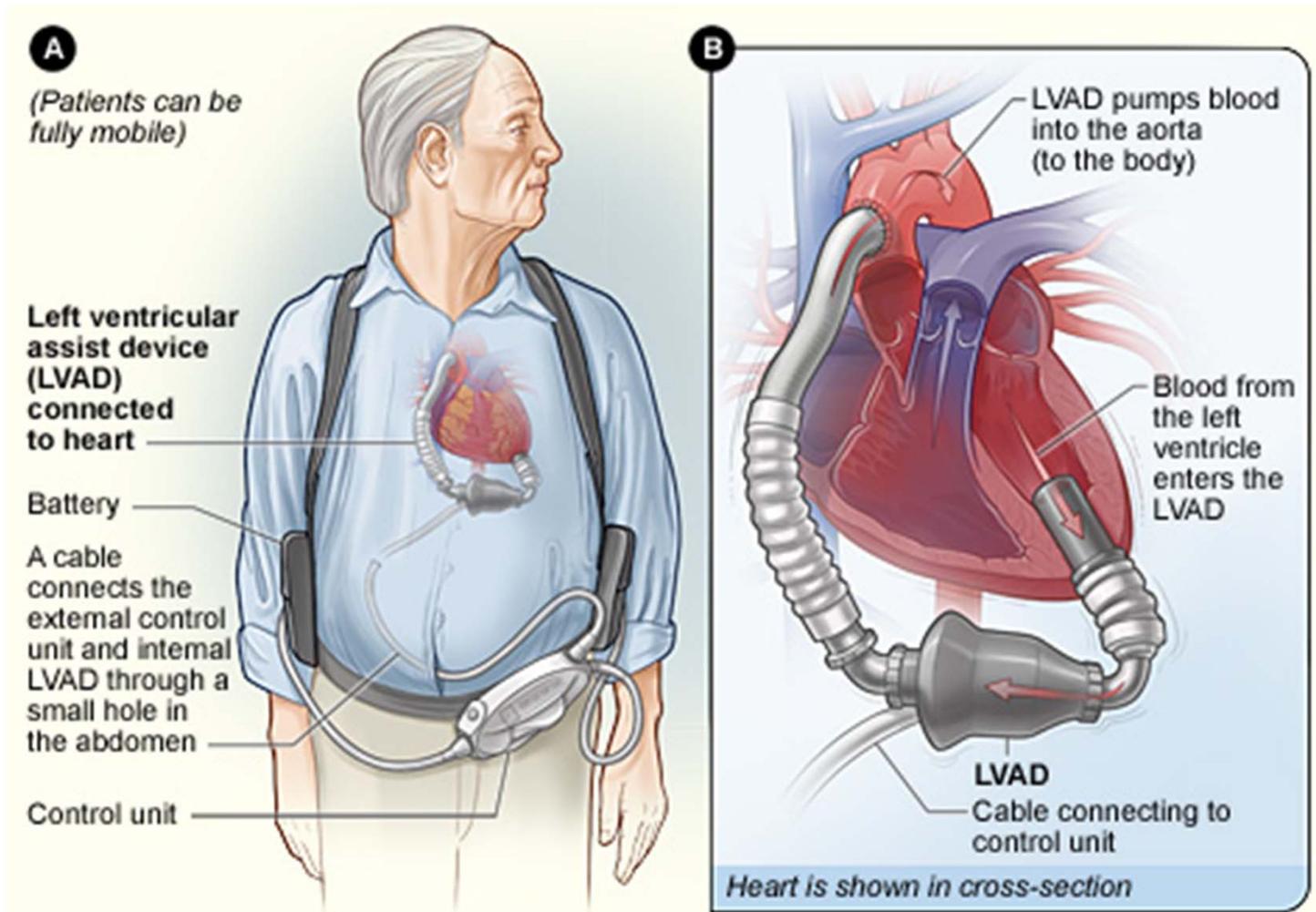
**Clinical: Informed consent**



# Mechanical Circulatory Support Devices

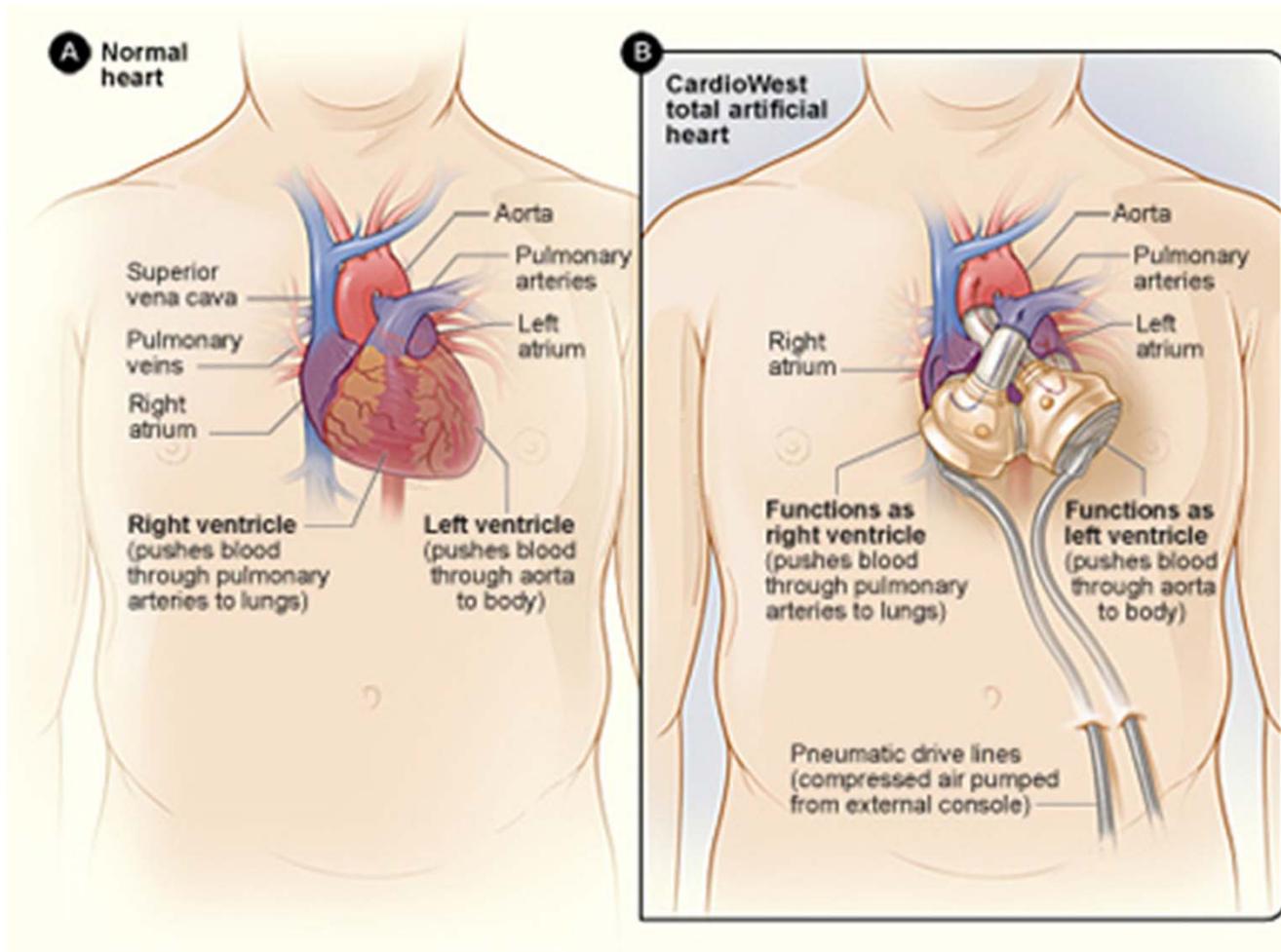


# Left Ventricular Assist Device (LVAD)



Source: National Heart, Lung, and Blood Institute, National Institutes of Health

# Total Artificial Heart (TAH)

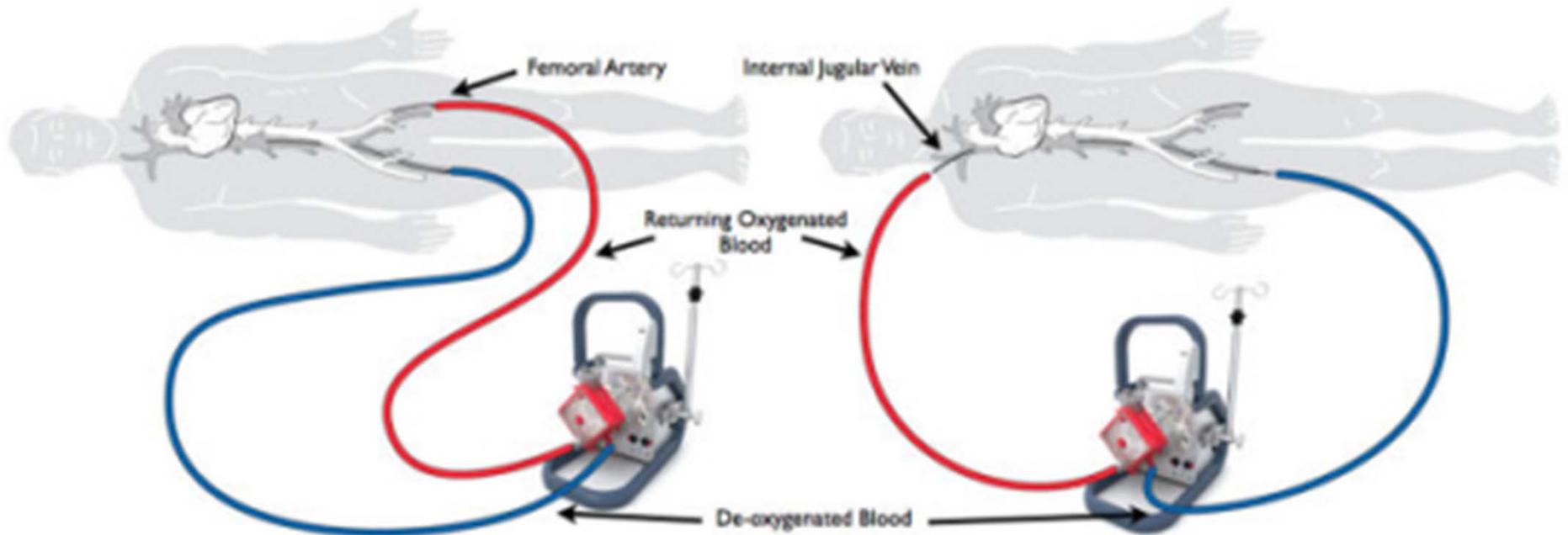


Source: National Heart, Lung, and Blood Institute, National Institutes of Health

# Extracorporeal Membranous Oxygenation (ECMO)

VA-ECMO

VV-ECMO



Source: PubMed Central Open Access

# **New Technology Case #4: A Difficult Destination**



# **New Technology Case #4:**

**Frame: Novel therapies, End-of-life**

**Issues: Autonomy, Professional integrity, Resource allocation**

**Organizational: TADA?, Stewarding resources**

**Clinical: Informed consent, Better research**



# **New Technology Case #5: A “Bridge to Nowhere”**



# **New Technology Case #4:**

**Frame: Novel therapies, End-of-life,  
Reboot/reframe of CPR/DNR controversy**

**Issues: Autonomy, Professional integrity,  
Resource allocation**

**Organizational: TADA?,  
Stewarding resources**

**Clinical: Informed consent,  
Better research**



# Recap and takeaway

**The ebola experience has generalizable lessons**

**“New tech” isn’t always new ethically**

**Be systematic not reactionary**



# Comments or Questions?



# Questions and Answers



Lisa Cornelius, MD, MPH  
Infectious Diseases Medical Officer  
Texas Department of  
State Health Services

Remote sites can send in questions by typing in the *GoToWebinar* chat box or email [GrandRounds@dshs.state.tx.us](mailto:GrandRounds@dshs.state.tx.us).

For those in the auditorium, please come to the microphone to ask your question.

**April 22**

## **Monitoring of Psychotropic Medications: Initiatives in Texas Foster Care, State Supported Living Centers, and Nursing Facilities**

**Presenters: James Rogers, MD, DFPS;  
Lisa Glenn, MD, DADS; Michael Murray,  
MD, DADS**

