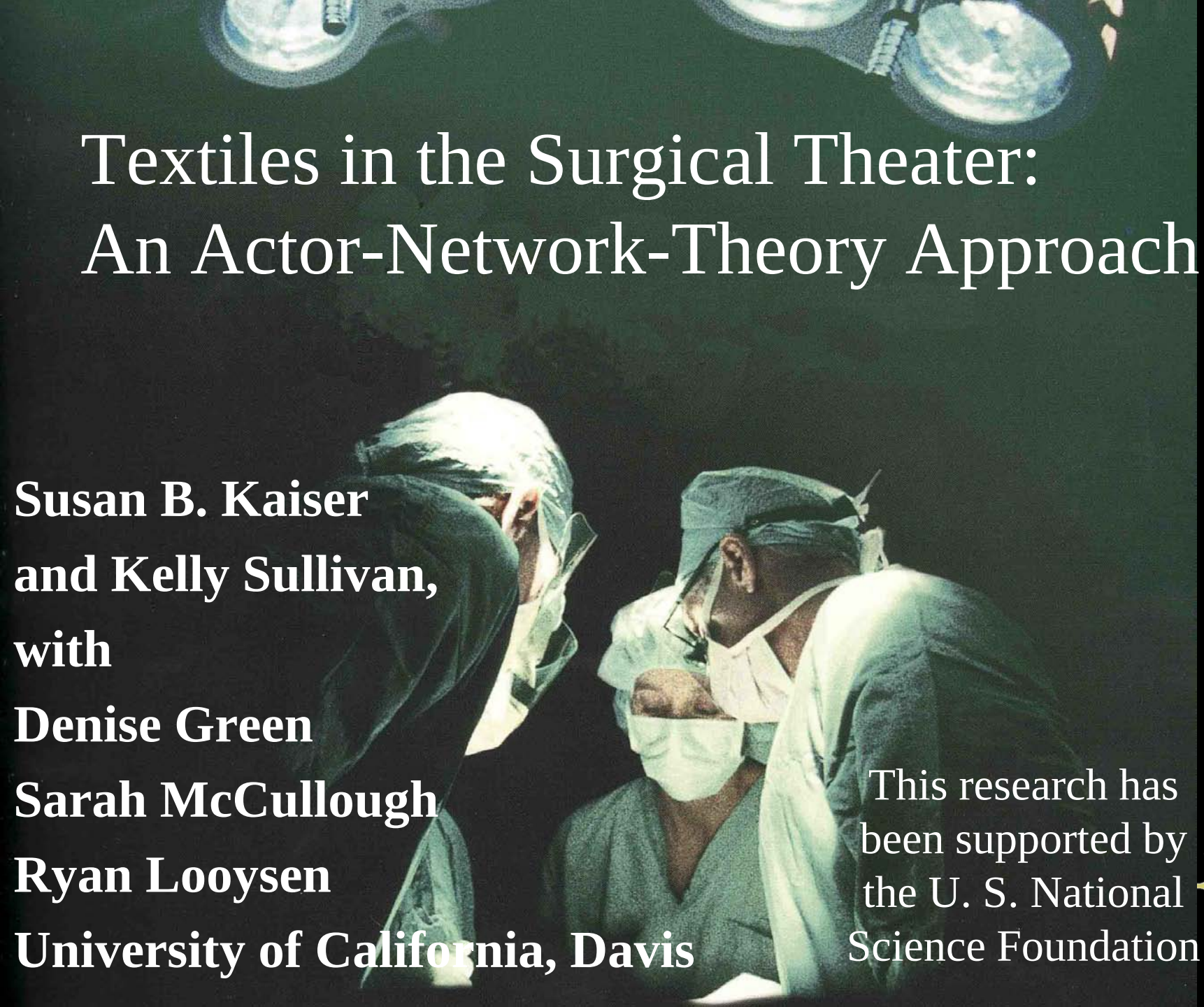
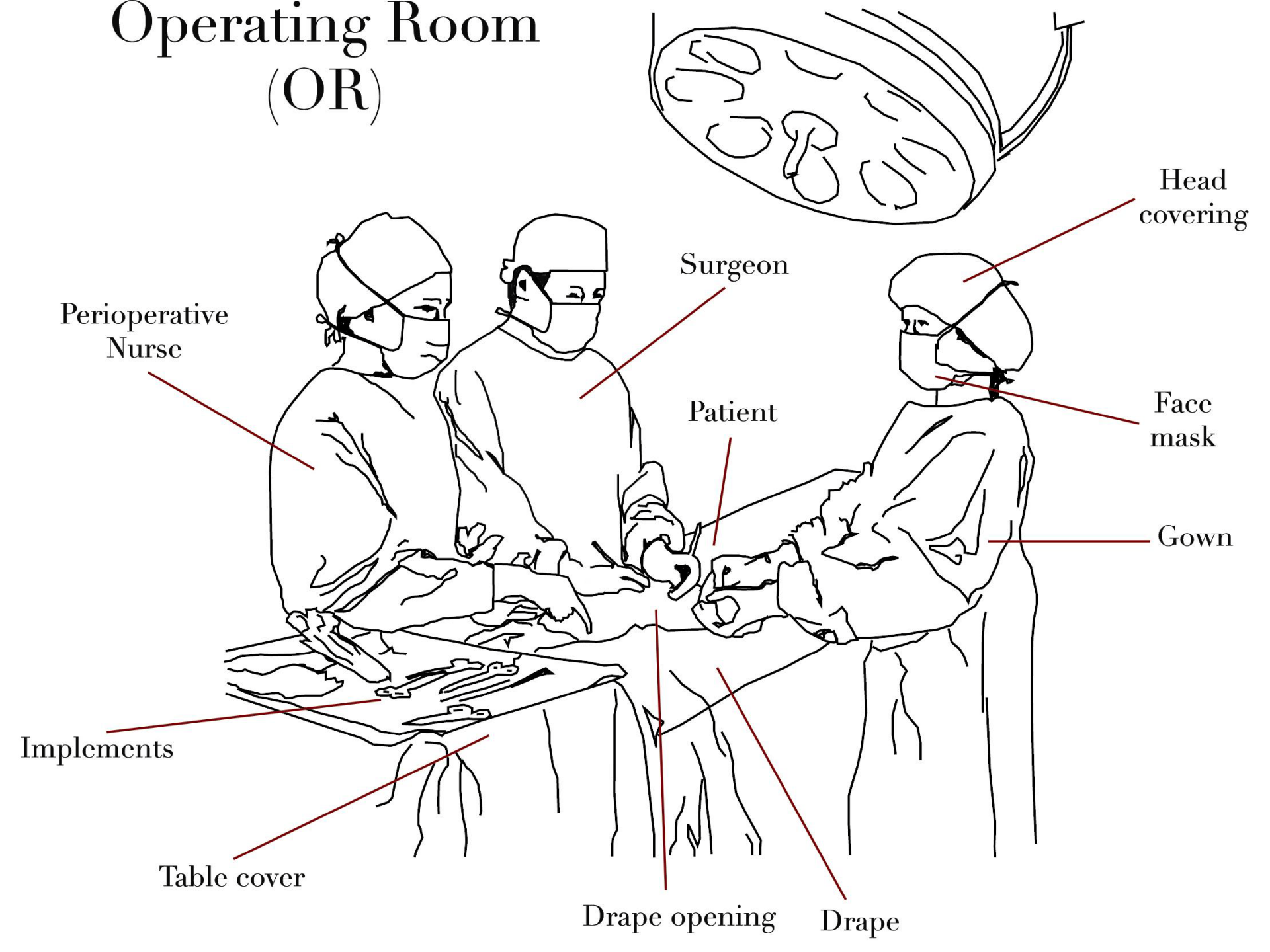


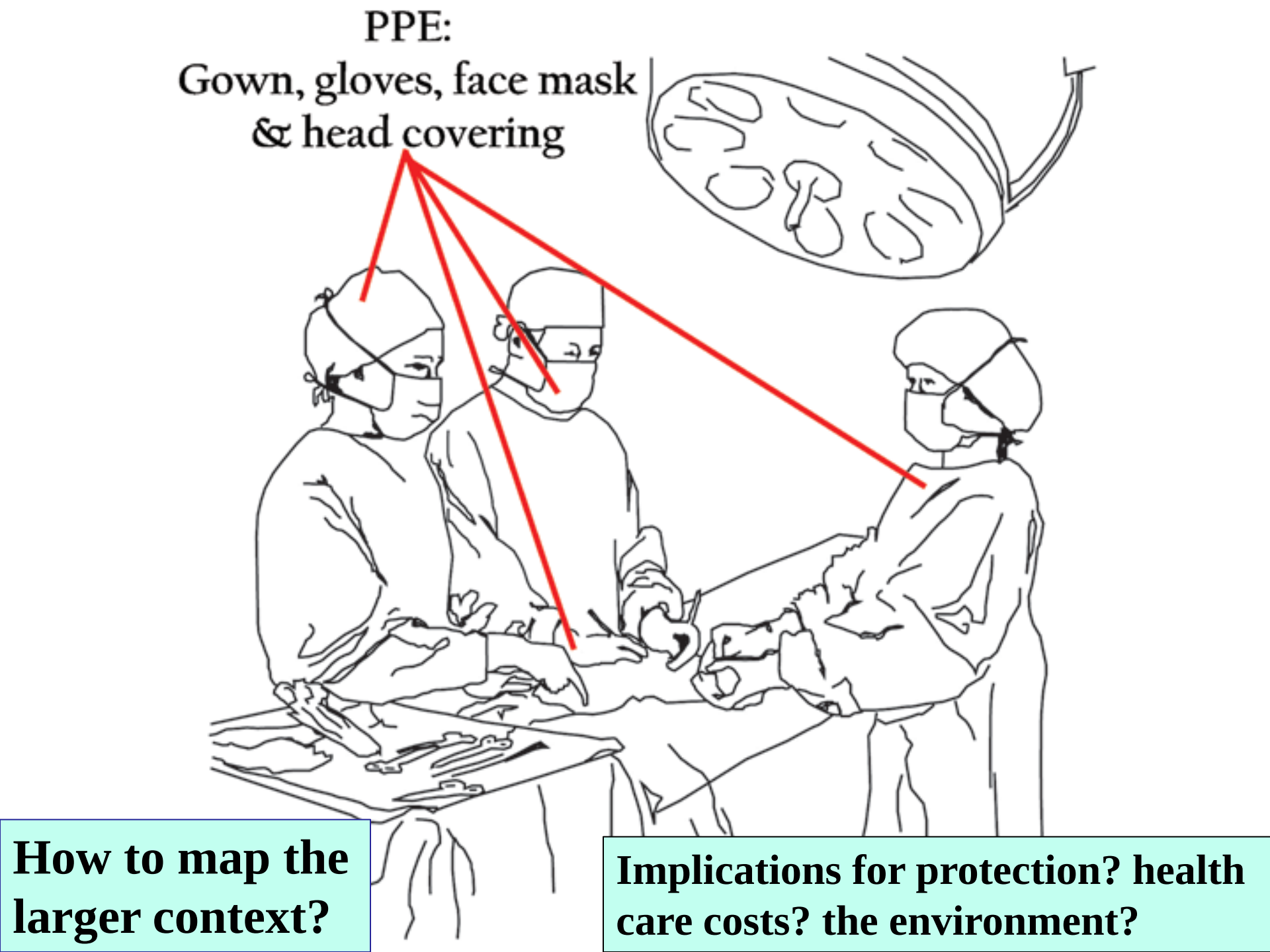
Textiles in the Surgical Theater: An Actor-Network-Theory Approach

Susan B. Kaiser
and Kelly Sullivan,
with
Denise Green
Sarah McCullough
Ryan Looysen
University of California, Davis

This research has been supported by the U. S. National Science Foundation

Operating Room (OR)





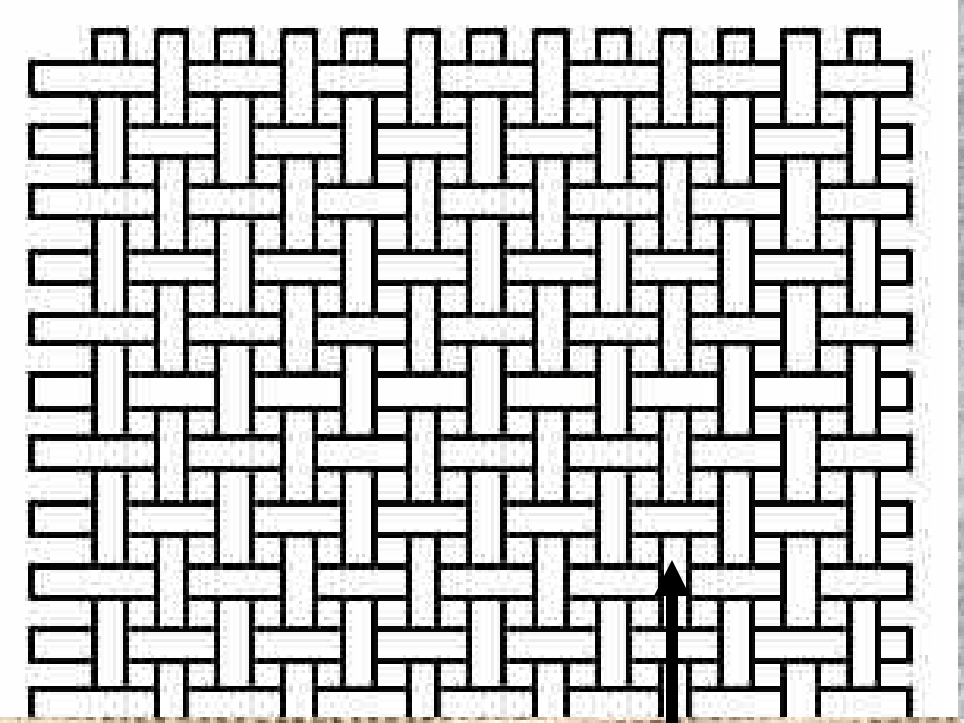
How to map the larger context?

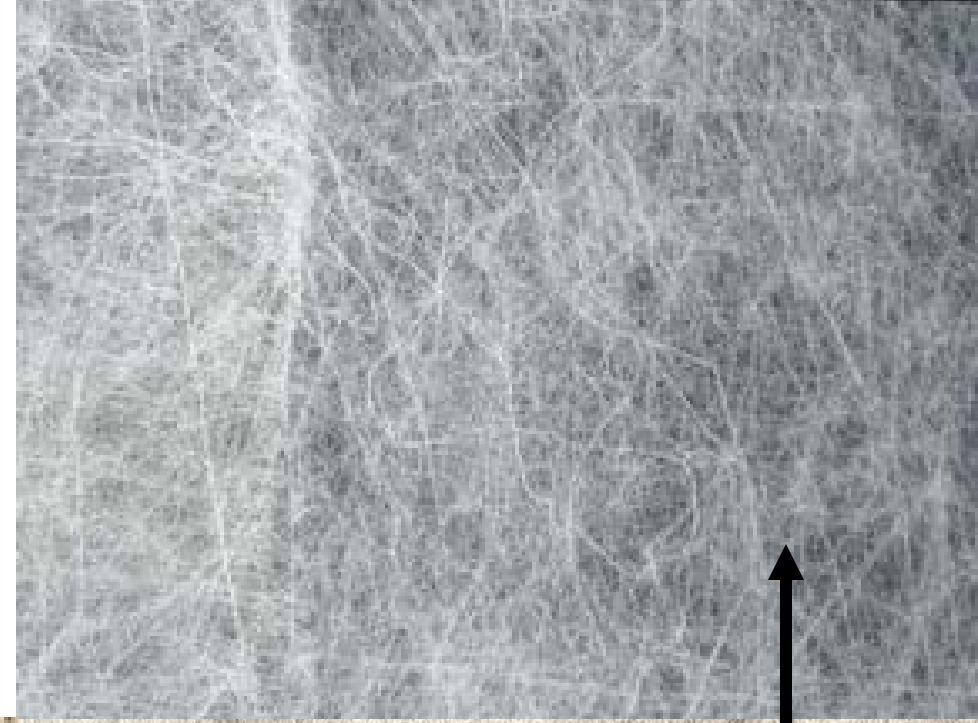
Implications for protection? health care costs? the environment?

Personal Protective Equipment (PPE)

Disposable gown

Reusable gown
(made with Gore components)





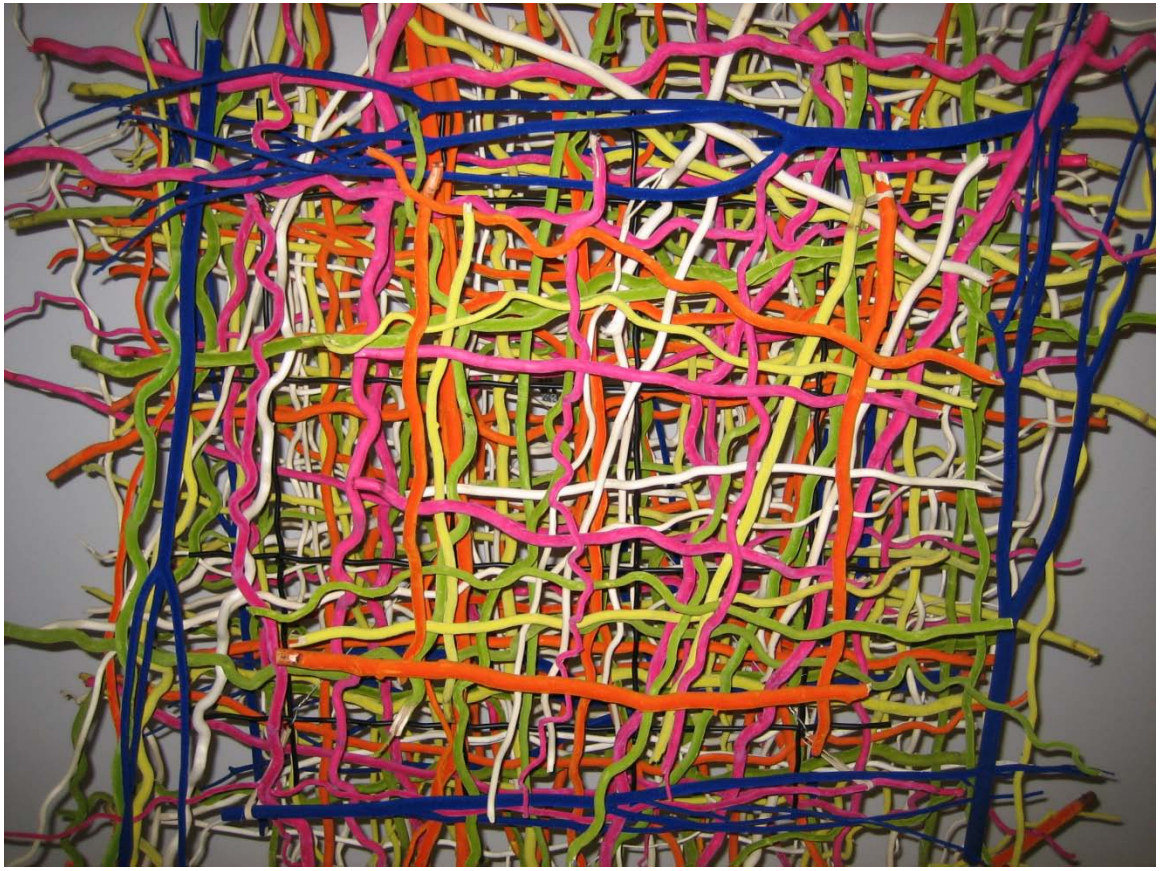
Woven textiles

(Reusable)

Nonwoven textiles

(Single use)

Strategic entanglements



To develop and explore new ways of thinking that move beyond the dichotomy of reusable versus single-use, encouraging critical and creative ways to bridge the single-use/reusable divide.

Objectives

- To examine producer/user perceptions of surgical textiles.
- To understand the factors and forces influencing perceptions of surgical textiles.
- To interpret scientific, economic and cultural discourses associated with medical textiles.
- To examine and include all perspectives, from historical reflection to current viewpoints and future possibilities.

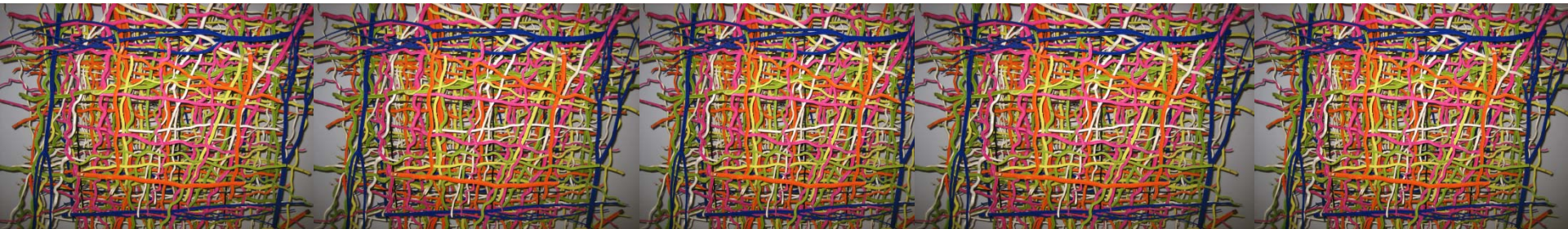
Methods

- Discourse analysis of literature, standards, reports
- Observations at laundry and waste facilities
- Interviews with healthcare professionals, members of professional/trade associations, manufacturers, launderers, hospital waste management personnel, and academic and industry researchers. Interviews were conducted in the U.S. and in the European Union.
- Outreach

1. Actor Network Theory (ANT)

2. Historical overview

3. Strategic entanglements through the "circuit of culture"



Actor-Network-Theory (ANT)

Bruno Latour

Based upon ethnographic studies in laboratory settings

(beginning in the late 1970s)

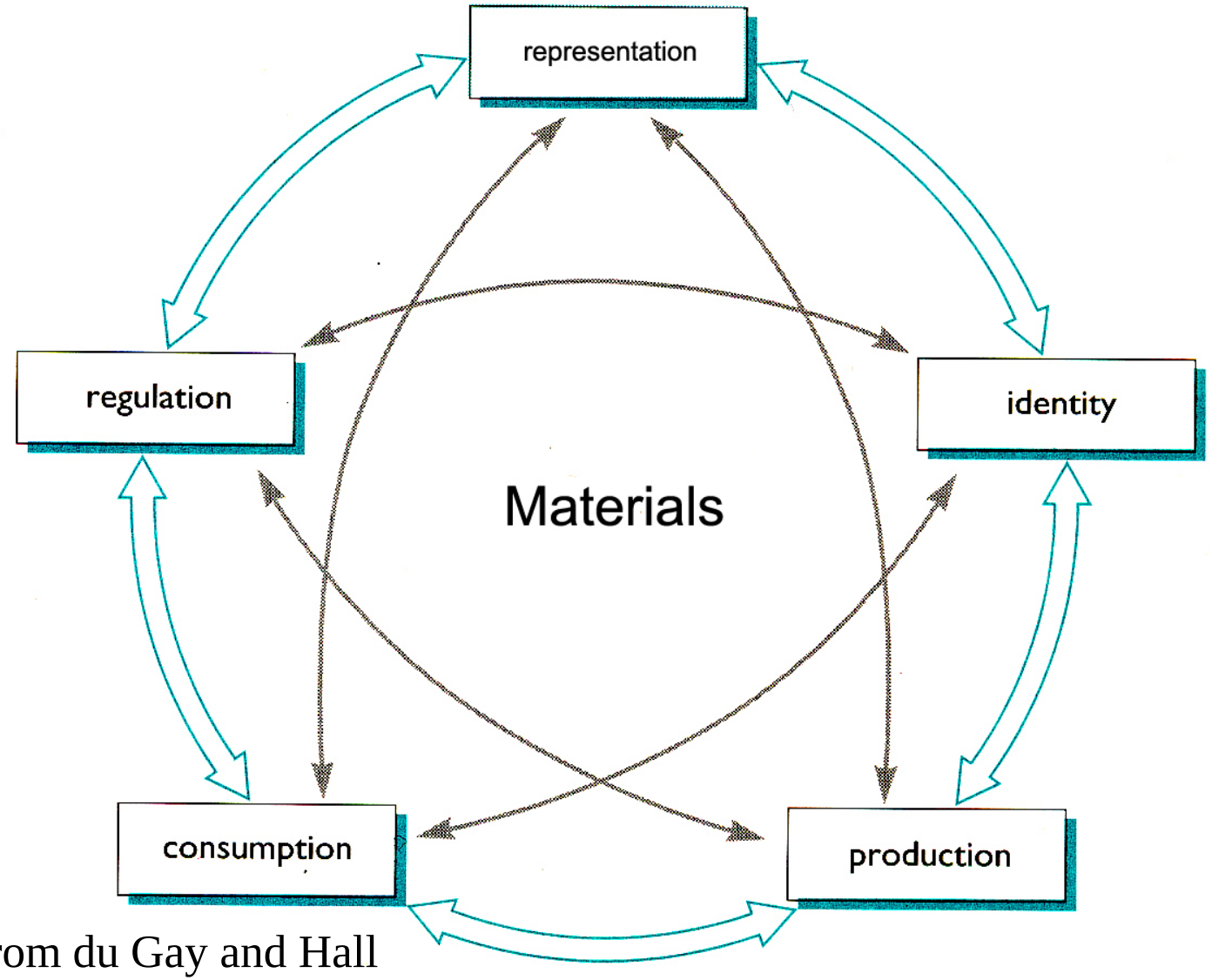
Finding:

Interplay between social and physical realities

"Social" networks are more than human; they include non-human materials, tools, instruments, etc.

{In surgical theater: materials that are "bundled," disposed, or sterilized}

A Cultural Studies Approach: The Circuit of Culture



Adapted from du Gay and Hall

The “actors” in networks are not only human, but also non-human.

The task of ANT is to trace:

"a trail of association between heterogeneous elements," or the connections among "things that are not themselves social" (Latour, p. 5).

This "trail of association" in terms of sustainability can include:

- the natural resources required for materials (in relation to human choices)

- the making or manufacture of materials (including the labor, know-how, etc.)

- physical properties and their implications for human use

- management of laundry or material waste

ANT metaphor

ant: "a blind, myopic, workaholic, trail-sniffing, and collective traveler" (Latour, 2005, p. 9)

ANT accounts: like travel guides that *suggests* trails to pursue further…

The ANT task is to:

- "deploy the many controversies about associations w/out restricting in advance to the social to a specific domain"

- figure out (trace) what enables "actors to stabilize controversies"

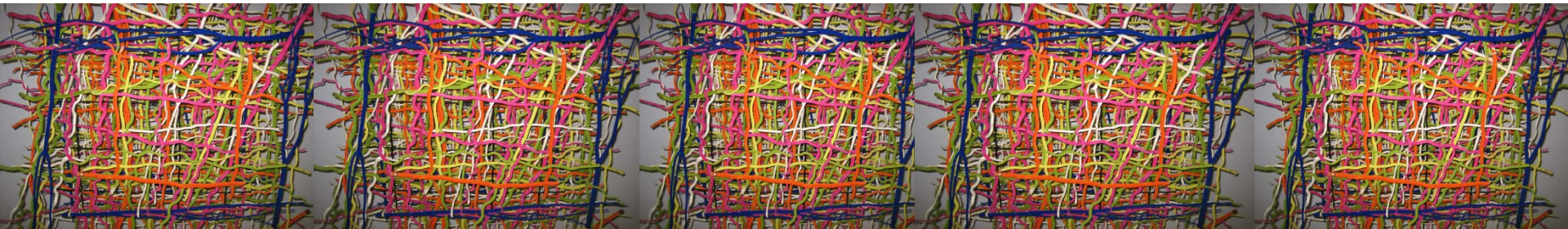
- allow to "unfold their own differing cosmos"

(Latour, 2005, p. 23).

1. Actor Network Theory (ANT)

2. Historical overview (1930s to present)

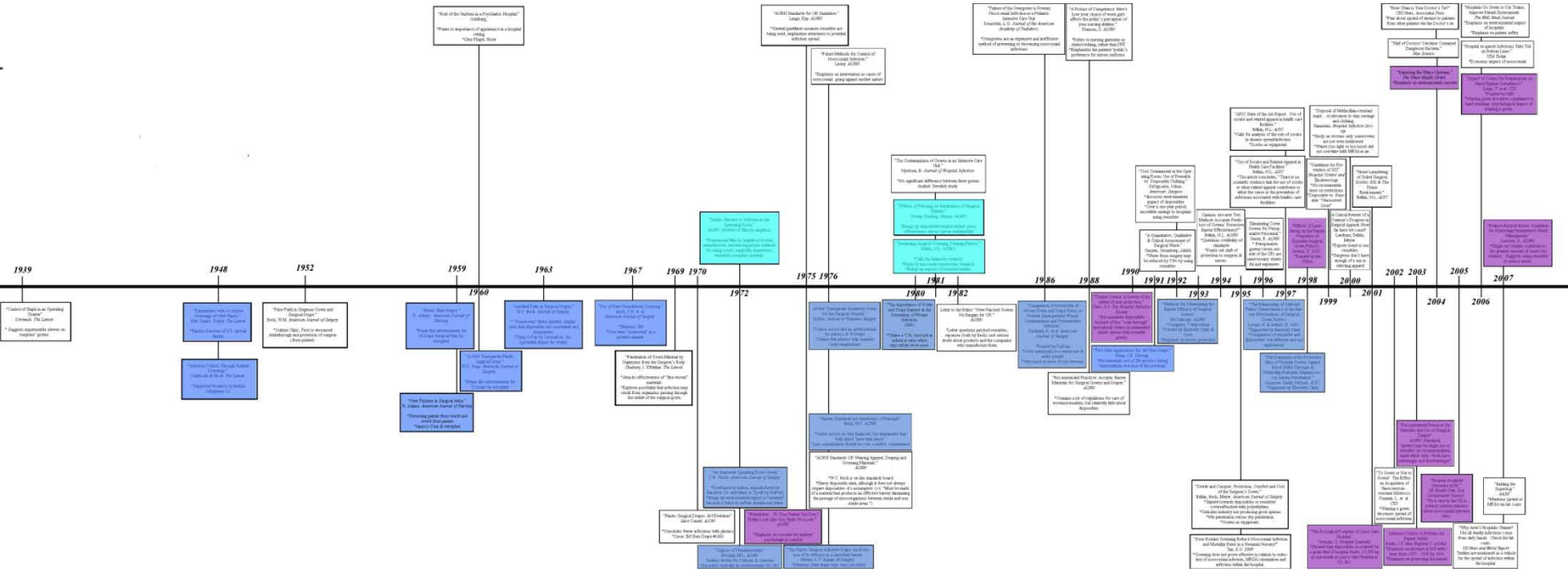
3. Strategic entanglements through the "circuit of culture"



Key

Funding Source

- Disposables Industry
- Reusables Industry
- Government/Not-For-Profit
- Unknown/Investigator Initiated



1948

1950

1952

1958

1960

1967

1970

1972

1980

1982

1990

1992

1998

2000

2003

False Faith: "*A wet drape is a contaminated drape.*"

Two studies in Britain confirm that once a textile is soaked, it no longer serves as a protective barrier.

Association for the Advancement of Medical Instrumentation (AAMI) is founded.

The Disposables Association becomes the International Non-wovens and Disposables Association (INDA)

"Dispose of Nondisposables" First article published by an industry representative appears in an academic journal.

1958-1972
A collection of new materials research emerges to address the problem of permeable surgical textiles. Much of this research was funded by corporations, such as 3M, Kaycel (now Kimberly-Clark), Tyvek (Dupont), Johnson & John-

1982-1992
Rising concerns over HIV/AIDS and Hepatitus B & C results in increased protection in the OR. Focus shifts from protecting the patient to protecting surgical staff from the patient. Greater focus on "strikethrough" during procedures.

American Reusable Textile Association (ARTA) is founded by Dr. Belkin. Belkin and others refute Moylan's study, and begin to actively defend reusables.

Moylan et. al publish an article that claimed a 50% decrease in hospital infection rates when disposables were used.

1992-1998
A series of comparative studies, funded by both reusables and disposables, identify the cotton, muslin gown as the "common enemy."

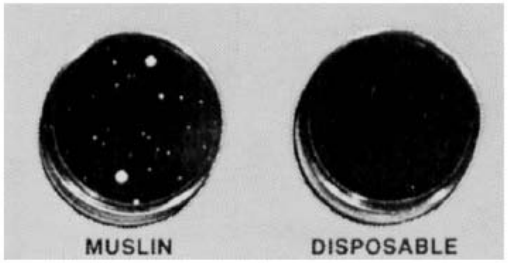
Two article address environmental concerns related to OR waste. Both determine that disposable gowns and drapes are more costly to the environment and hospital budgets.

2003-present
Environmental concerns spur changes in health care facilities. Articles in academia and the popular press bring attention to environmental impact

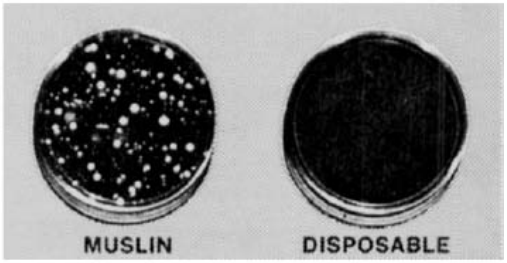
EXHIBIT II

IN VITRO TESTING

CONTACT TIME: 15 MINUTES



CONTACT TIME: 120 MINUTES



HOSPITALS for a HEALTHY ENVIRONMENT

Rising Concerns: Initial Questioning of Surgical Textiles (1939-1952)

- 1939, 1948: Scientists realized that infection could be transmitted from doctor to patient through the wet dressing, and thus was not providing the barrier necessary for protection.
  - 1939, “Control of Staph in an Operating Room Theatre,” (*The Lancet*)
  - 1948, “Experiments with Occlusive Dressings of New Plastic,” (*The Lancet*)
  - 1948, “Infection Control Through Wet Dressings,” (*The Lancet*)
- 1952, “False Faith in Surgeon’s Gown and Drape,” (*American Journal of Surgery*) A need emerged for improved materials in the OR.

Focus on Materials and Emergence of Single-Use PPE

1952-1972

- 1952, Aeroplast produced by Protective Treatments Inc. produces what the *New York Times* describes as a product that could replace gauze.
- 1959 & 1960 articles in the *American Journal of Nursing* and *American Journal of Surgery*, respectively, promote Vi-Drape by Aeroplast
- 1963, “Justified Faith in Surgical Gowns: A New Safe Material for Draping.” W.C. Beck highlights a new product by Kaycel, called Surg-O-Pack.

•1967-70, 3M produces the single-use Steri-Drape (Which is promoted by articles appearing in the *American Journal of Surgery* and *American Journal of Nursing*).

- 1972, “An Improved Operating Gown,” (*American Journal of Surgery*) MacBick Co., DuPont de Nemours & Co., Inc. promoted gown made of Tyvek

Early Debates and Development of a Dichotomous Relationship

1972 - 1982

- 1972, "**Dispose of Nondisposables**," (*AORN*) This is one of the first articles to debate the issue of single-use versus reusable medical textiles.
- 1981, "Evaluating Surgical Gowning, Draping Fabrics," (*AORN*) N. Belkin emphasized the materials research on the reusables side. This article initiated a **new discourse about reusables**.

Protecting the OR

late 1980s - present

•With the **awareness of HIV/AIDS** gave way to growing concern over the **protection of healthcare workers** from blood borne pathogens. Nathan Belkin, in a 1994 letter to the editor, wrote that, “The emergence of HIV changed the purpose of the surgical gown. Healthcare professionals began to expect gowns to protect them from patients.”

•1993, “Methods for Determining the Barrier Efficacy of Surgical Gowns,” (*AJIC*) Elizabeth McCullough wrote that, “More recently, medical personnel have become concerned about possible exposure to hepatitis B virus, HIV, and other blood-borne pathogens from the patient.”

•This represents a shift in the discourse from an emphasis on protecting the patient, to protecting the OR staff from the patient.

Protecting the Environment

1988 – Present

- 1988, United States Congress ratifies the Medical Waste Tracking Act
- 1992, "A Quantitative, Qualitative, and Critical Assessment of **Surgical Waste**" (*JAMA*) and "Cost Containment in the Operating Room: Use of Reusable Versus Disposable Clothing," (*The American Surgeon*). These two articles highlight the amount of waste (and associated cost) that comes from the OR.
- "Disposable linen accounted for 53% of the volume of surgical waste." (Myers, et. al.)

Protecting the Environment

- 2001, “The **Ecological Footprint** of Lions Gate Hospital,” (*Hospital Quarterly*). Susan German conducts the first ecological footprint analysis of a hospital in North America.
- 2006, “**Hospitals Go ‘Green**,’” (The Wall Street Journal, 10/6/2006) Articles appear in the popular press discussing environmental concerns regarding hospitals, highlighting hospitals that are making improvements.
- Associations form to promote environmental awareness in hospitals, such as Heath Care Without Harm and Hospitals for a Healthy Environment (H2E)

Gary Lausten, 2007, "Reduce-Recycle-Reuse: Guidelines for Promoting Perioperative Waste Management," (*AORN*)

TABLE 2

Red Bag Receptacle Contents Evaluation

During an unscheduled evaluation, one large red bag from an OR receptacle was obtained after an abdominal aortic aneurysm endograft procedure, and the bag's contents were analyzed.

Initial bag weight on zeroed scale: 8.64 kg
Weight of nonbiohazardous waste in red bag: 7.91 kg

Items and quantity of materials removed from red bag

Item name	Quantity	Item name	Quantity
Albumin bottles, empty	3	Oropharyngeal airway	1
Anesthesia bag	1	Packaging drape	1
Anesthesia mask for patient	1	Paper drapes	4
Anesthesia tubing	1	Paper sheets from patient monitor	7
Blood- or solution-filled syringes	3	Paper surgical gowns	3
Blood pressure cuff (nondisposable)	1	Penrose drain	1
		Plastic basins	2
Central line with wire	1	Plastic drape	1
Cloth towel, green	1	Plastic instrument packing	30
Cloth towels, blue	6	Procedure kit wrap	1
Endotracheal tube stylette	1	Small plastic saline bottles, empty	2
Endotracheal tubing	1		
Fluid tubing	2	Small cardboard boxes	4
Fluid warming set packaging	1	Soft plastic trays	4
Fluoroscopy unit cover	1	Styrofoam packaging	1
Glass bottles, empty	2	Suction tubing	2
Gloves, nonsterile	46	Syringe cases	18
Hard plastic packaging	6	Syringes, empty	16
IV bag, full, with attached tubing	1	Temperature-regulating blanket	1
		Vials, glass	5
IV bag packaging	6	Yankauer suction tip	1
IV bags, empty	8	Multiple pieces of paper packaging	
IV tubing	4		
Large saline bottles filled with urine*	2	1 wadded-up ball of bloody surgical gauze.** Unable to count, but total weight was .73 kg.	
Nasal canula	1		

** These items are considered potentially infectious material but are not classified as regulated waste; therefore they may be disposed of in the sanitary system and do not require red bag disposal.[1]*
*** This was the only material that possibly could be classified as biohazardous according to AORN standards and require disposal in the red bag receptacle. These bloody gauzes were not "dripping."*

1. Centers for Disease Control and Prevention. Guidelines for Environmental Infection Control in Health-Care Facilities. *Atlanta, Ga: US Department of Health and Human Services; 2003:143-144. Available at: http://www.cdc.gov/ncidod/dhqp/gl_environinfection.html. Accessed March 2, 2007.*

- According to Lausten, the increase in medical waste over the past 30 years has become a significant environmental concern, and his article discusses methods for reducing and managing waste.
- In this article, he has encouraged nurses and managers to "moderate negative environmental effects by promoting reduction, recycling and reuse of materials in perioperative setting."

2009

Healthcare Purchasing News

Watching your hospital's ***burgeoning waste line***

Environment

Only 73 healthcare facilities of (American Hospital Association's) or roughly 1.5 percent, have achieved Leadership in Energy and Environmental Design certification.

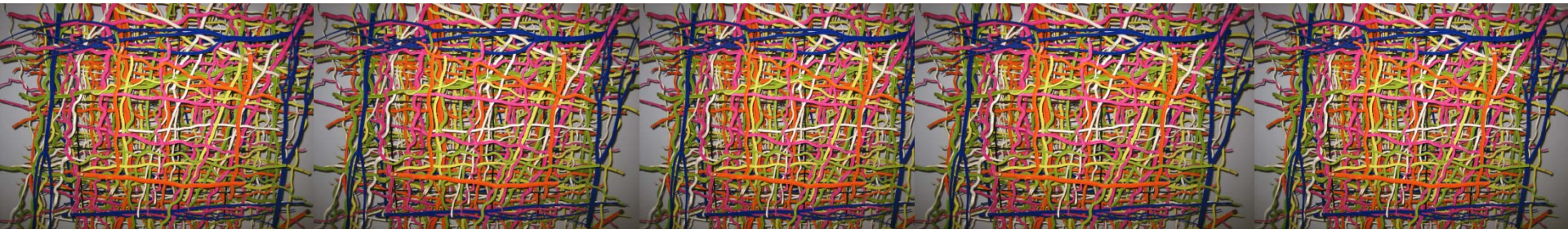
10 Years ago, according to the EPA, there were 2,400 medical waste incinerators in the US with a goal to reduce the number 50 to 80 percent by 2010. Progress had been made in the result of shutting down hundreds of on-site hospital incinerators a dozen more pending shut down.

Using some reprocessed devices is a standard practice in 70 percent of U.S. hospitals. Over 3,000 hospitals currently have a reprocessing programs and 95% of the *U.S. News (& World Report)'s* 'Honor Roll' Hospitals use reprocessed devices.

1. Actor Network Theory (ANT)

2. Historical overview

3. Strategic entanglements through the "circuit of culture"



strategic entanglements

--the ways in which materials, stories, and actors assert agency as interests alternately coincide, overlap, and diverge, while reconnecting as necessary; the multiple, emergent dynamics that work through materialized and interactive networks

strategic entanglements

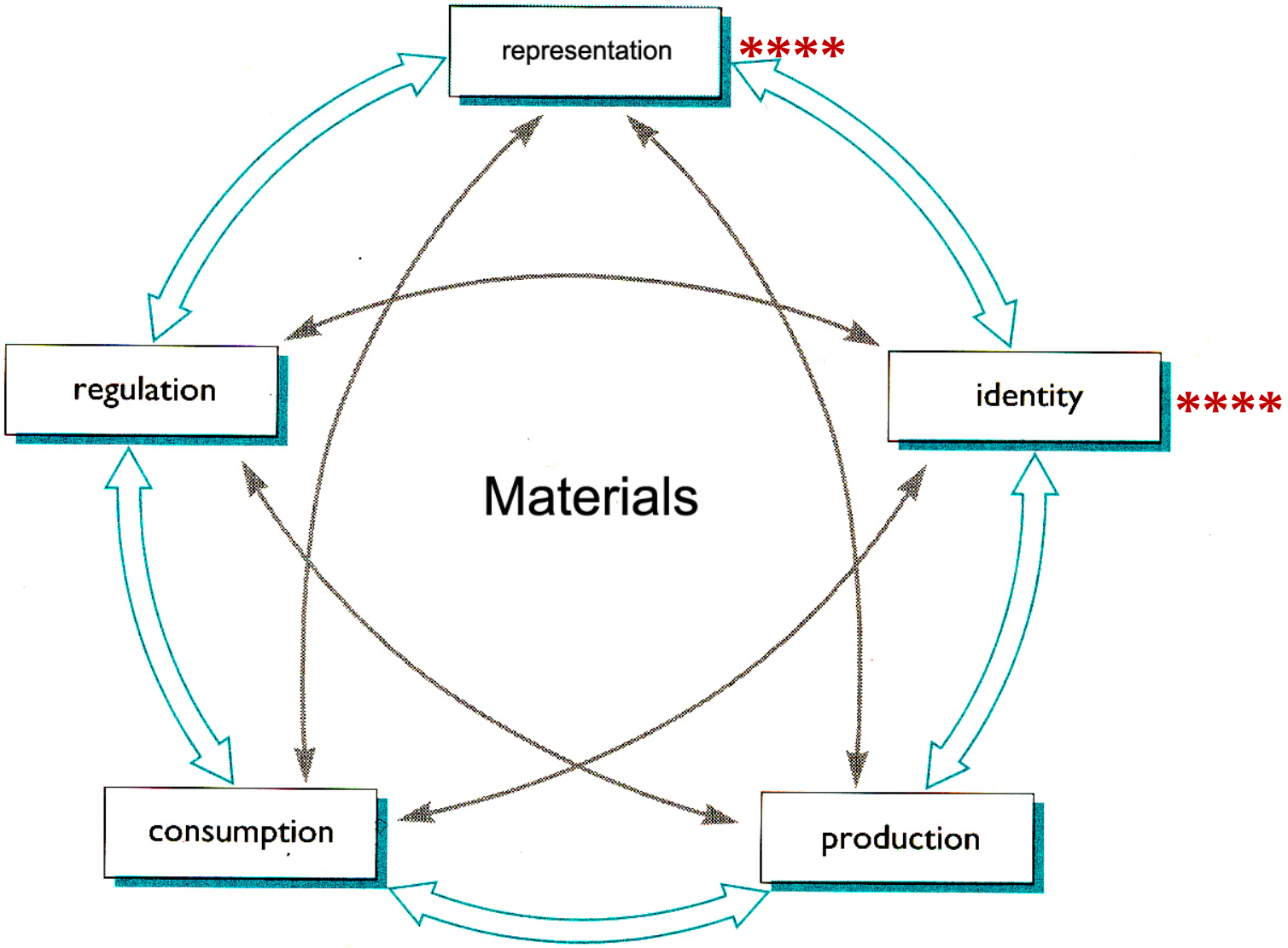
Actor-network-theory reminds us that we all care about the same things:

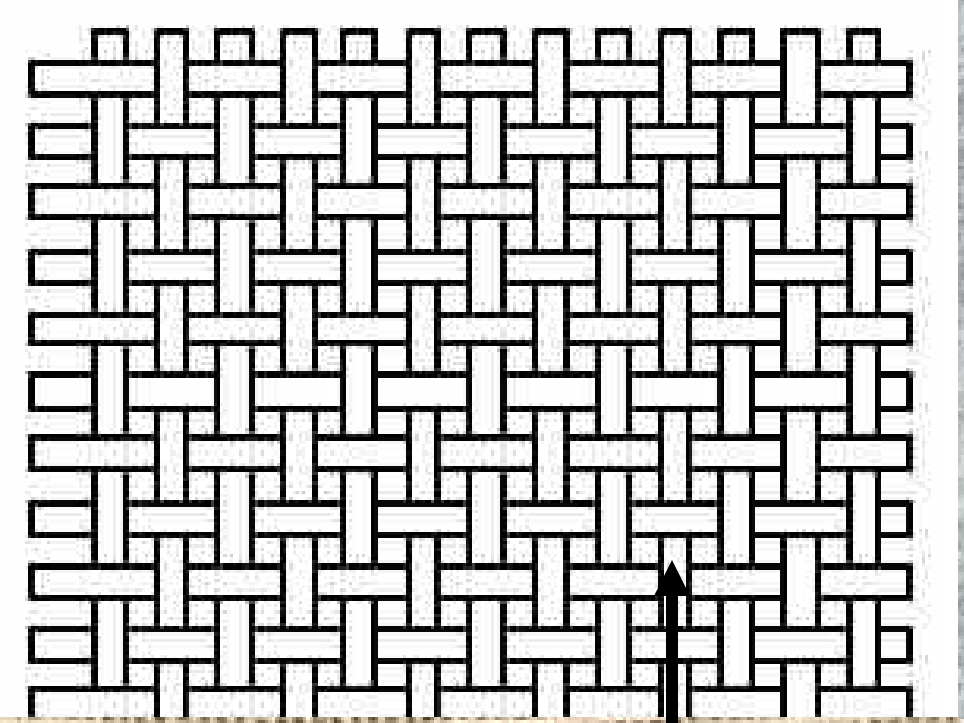
Infection control (protection)

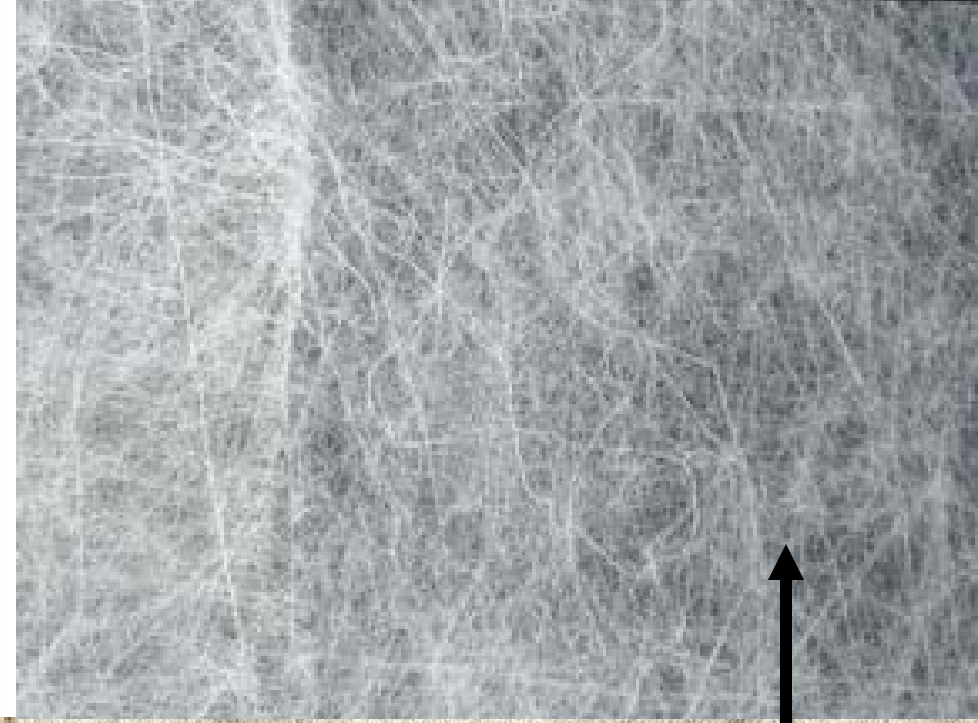
Health care costs

The environment

A Cultural Studies Approach: The Circuit of Culture







Woven textiles

(Reusable)

Nonwoven textiles

(Single use)

Identity work and representation: lead to some “strategic opposition”

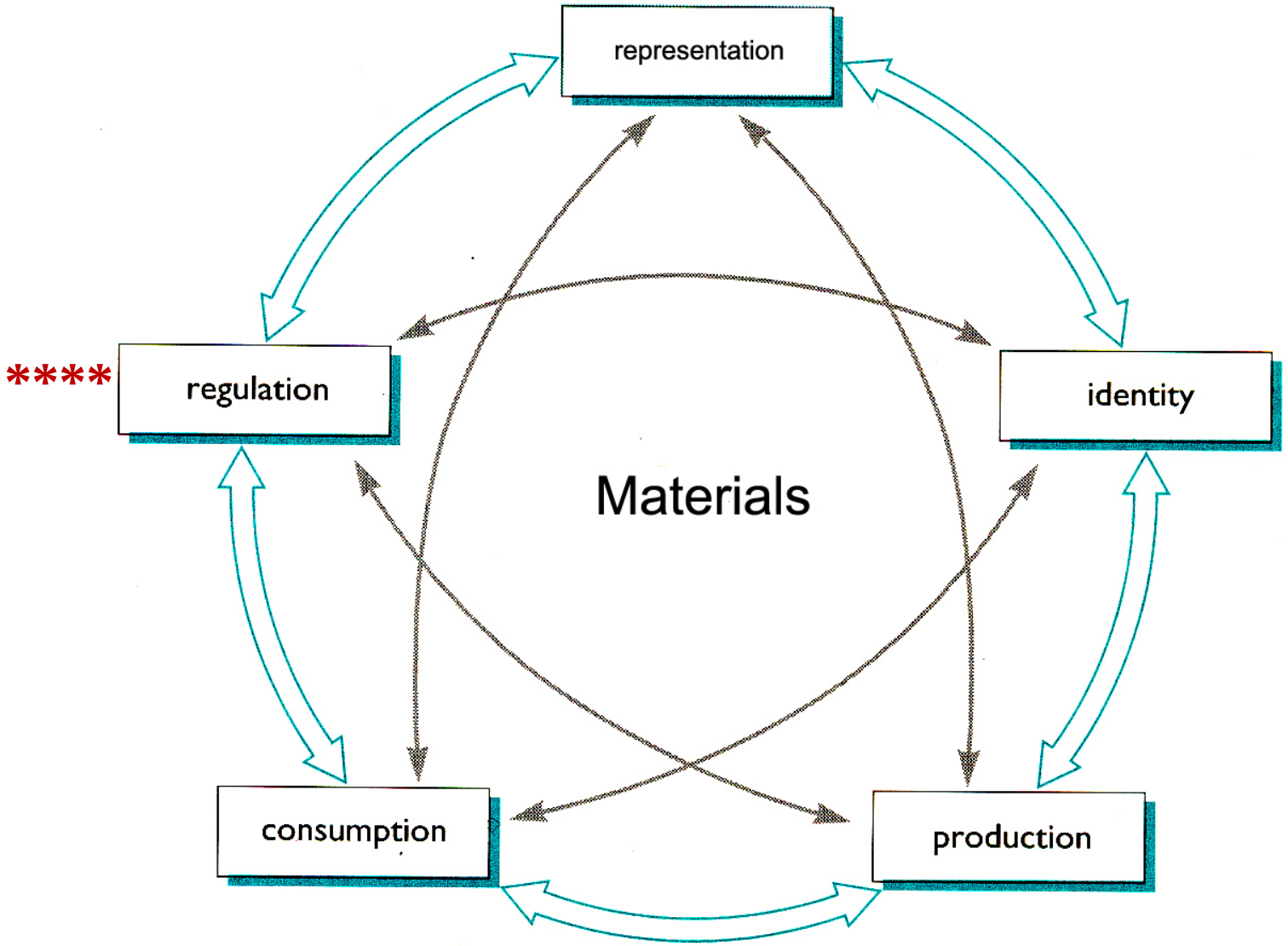
“Now remember, we’re up against a huge marketing and communication machine… [T]here is this myth of new equals good, equals quality, equals all these good aspects.”

(Trade association representative)

“We kind of have our own vested interest…We really do want to help however we can…[to] make sure whatever facts we can help provide, maybe help prevent other slants—other points of view that are not necessarily factual—from being written into the final report as a kind of the gospel” (industry representative).

“I think that single use will continue to grow. And it’s primarily based upon the concept that it’s a brand new product when you open the package…that’s reassuring to people. If I were going to ask you to go clean up a toxic waste spill and ‘Oh, by the way I have this garment here that has been used an undetermined number of times, but it will take care of you.’ Or, you can have a brand new garment that just came out of the package…which would you choose?” (Industry representative)

A Cultural Studies Approach: The Circuit of Culture



Regulatory agencies

Associations and Standards

1967 - 1982

- 1967, AAMI (Association for the Advancement of Medical Instrumentation) is founded.
- 1968, “The Disposables Association,” is founded, and becomes INDA (International Nonwovens and Disposables Association) in 1972
- 1971, OSHA founded
- 1975, AORN Standards
- 1976, FDA approves Proctor & Gamble’s boundary single-use reinforced surgical gown
- 1982, ARTA (American Reusable Textile Association) is founded by Nathan Belkin

regulation: strategic standardization

"The FDA got involved in the development of PB70 during one of the first meetings. They had two or three people at one of the first meetings. They made it clear then that they didn't think that all the products that were on the market really met the needs of the end users—that the system was somewhat flawed in that it allowed these grandfather[ed] products to be continued to be sold. And because of the concern over, you know, post-operative wound infection and protecting the healthcare worker, they really thought the industry more or less needed to do a better job of policing itself and that the [AAMI PB-70] standard would provide the industry an opportunity to do that. And you know, they more or less gave us a veiled threat that if we didn't **police ourselves** they were going to have to do it...**Producers are pushing, end users are pulling [and] PB-70 fills the gap.** I think it's going to become the best practice, and I think if any producer is really serious about staying in the game the long term, they're going to have to provide products that are compliant with PB-70, even though it is not mandatory" (industry representative)

strategic standardization

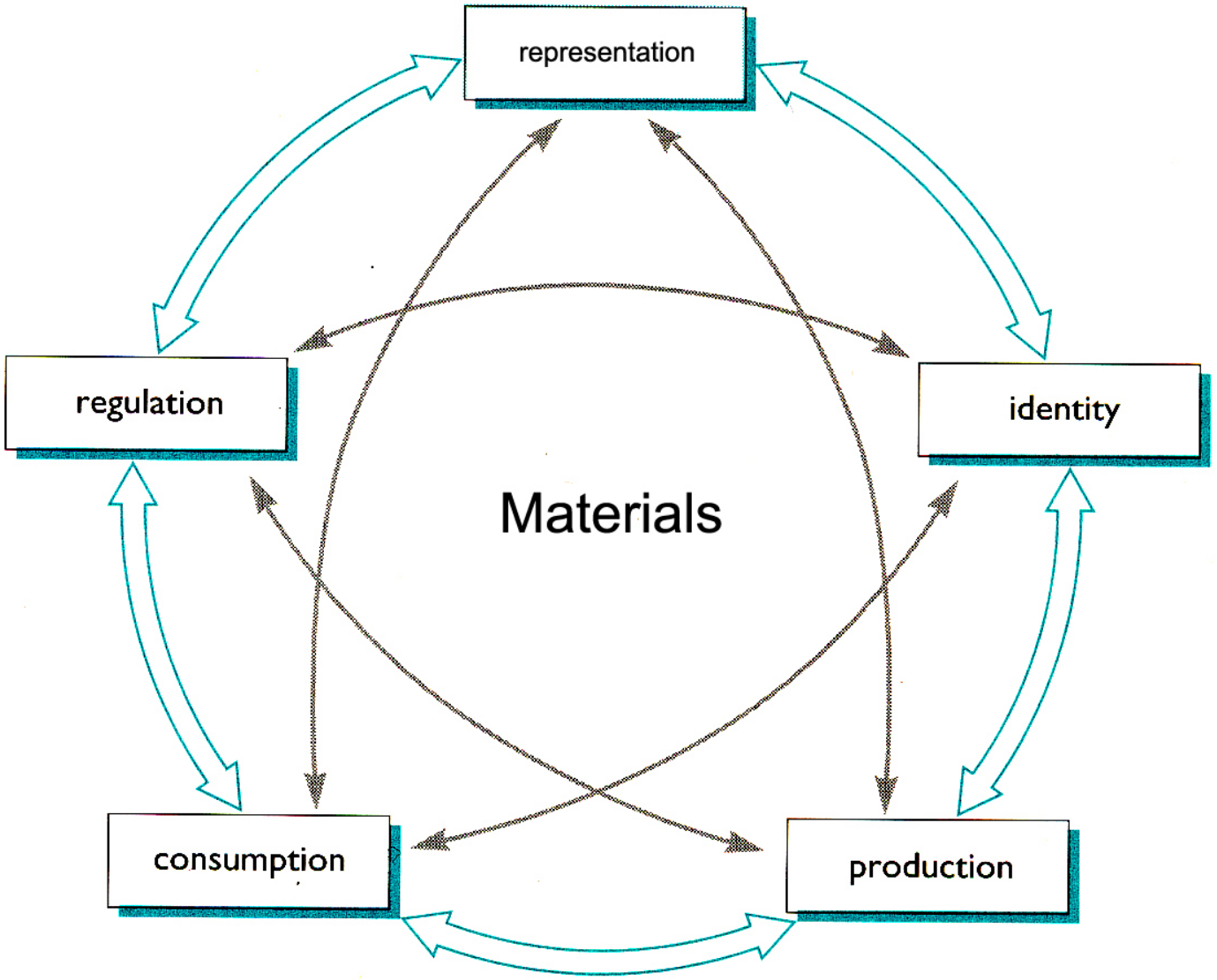
the players with the most powerful system of allies in the surgical textiles field work together to develop standards, approve test methods, and identify the appropriate barrier properties for the classification of materials for different types of surgeries

Actor-network-theory (Latour 2005):

"Whereas subjects easily behave like matters of fact, material objects never do." (p. 128)

"In following the stabilization of controversies, we are greatly helped if we bring to the foreground the crucial notion of *standards*" (p. 227)...."Standards that define for everyone's benefit what *the social itself* is made of might be tenuous, but they are powerful all the same" (p. 230).

Ongoing Challenges

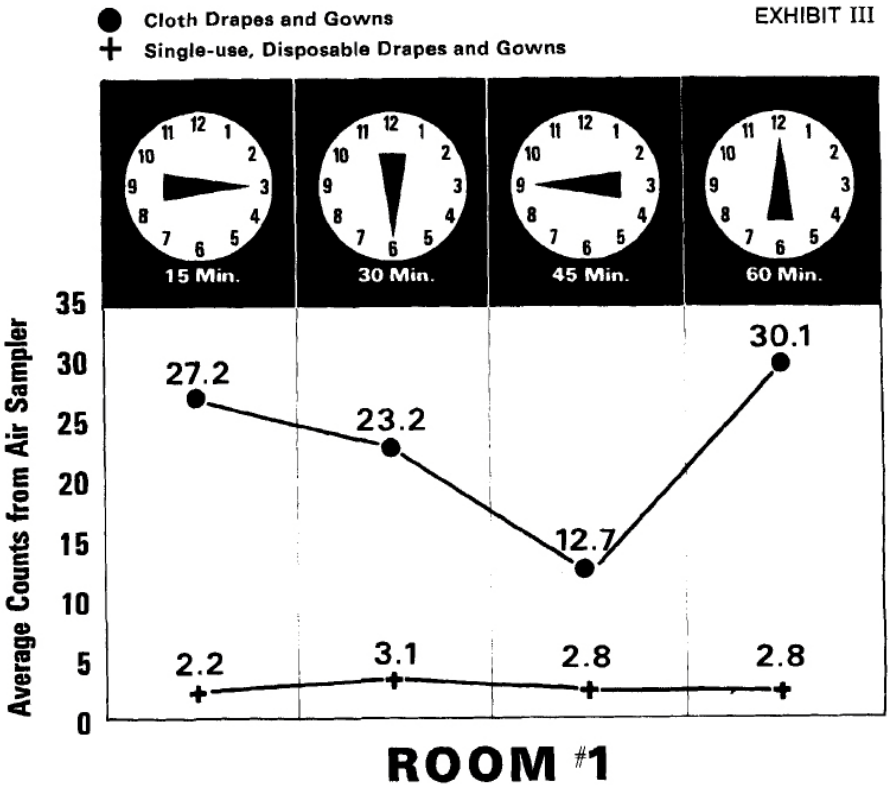


Infection Control

Table 1. Nosocomial Infections in the United States.*

Variable	Year	
	1975	1995
No. of admissions ($\times 10^{-6}$)	37.7	35.9
No. of patient-days ($\times 10^{-6}$)	299.0	190.0
Average length of stay (days)	7.9	5.3
No. of inpatient surgical procedures ($\times 10^{-6}$)	18.3	13.3
No. of nosocomial infections ($\times 10^{-6}$)	2.1	1.9
Incidence of nosocomial infections (no. per 1000 patient-days)	7.2	9.8

*Data are from Weinstein[4] and Jarvis.[5]



Representation of Interests in a Global Context

"Standards committees are a collection of competitors trying to write a standard for performance that doesn't eliminate their product from the marketplace. When you go to a standards committee, on an international level, you are actually supposed to go representing your country. Probably three out of ten people I know represent their country; they represent their company most of the time... [W]e wrote a global standard for medical packaging that was rigorous…but doesn't discount any one material from use." (industry representative)

Environmental Controversies

Recent resurgence of interest in “green,” “sustainable” hospitals. Newly developed organizations address these sentiments:

- Hospitals for a Healthy Environment (H2E)
- Health Care Without Harm
- Practice Greenhealth

Controversies around waste management in the hospital setting

- Important class issues revolving around the circulation of waste
- Who creates the (biohazardous) waste versus who handles the waste


Handling of waste: Protection of Workers and the Environment
DANGER
STAY
CAUTION
In-Hospital Waste Processing
Sacramento, California


Sterilized Biohazardous Waste

Local Landfill Davis, California

Energy and Water Use

Reusable Laundry and Surgical Instrument Reprocessing Center

Stockton, California

St. Joseph's Hospital Laundry and Sterilization Facility, Stockton, CA

Economic Controversies

Group Purchasing Organization (GPO)

- Product Bundling

Who pays the bill?

- Hospital owned, rental, or billed to patient
- Decentralized hospitals—savings in one department does not translate to another

Contractual Entanglements: Level Playing Field?

"I can provide a product at a lower price, but because I'm not on the GPO contract they [the hospital] may not want to buy from me… That's the cost of doing business for us. We're learning the hard way. We figured, ahhh, we'll save them money, we won't worry about the GPO… So if you participate in a GPO contract, the rebates the hospital gets are basically fees that we have to pay to the GPO. It's a racket." (industry representative)

Ongoing Innovation?

"Ever since I've been in the business, and that's been a couple of years now [since 1979], I've seen some major changes, like the invent of spunbonding, that didn't exist thirty years ago…That's 40 per cent of all nonwoven production in the world, so it is really important. Then we saw the invent of water [hydro] entanglement…I'd say it's 10 years old, 12 years old…since these two technologies, I haven't seen anything…I'm not sure that we will see anything like a new spunbonding or another addition of water entanglement…I'm not sure that there's much to invent in the nonwoven field." (trade association representative)

Strategic entanglements, meaningful dialogue…