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Systems Engineering Advancement Research Initiative

Quantitative Analysis of Group Decision Making for Complex Engineered Systems

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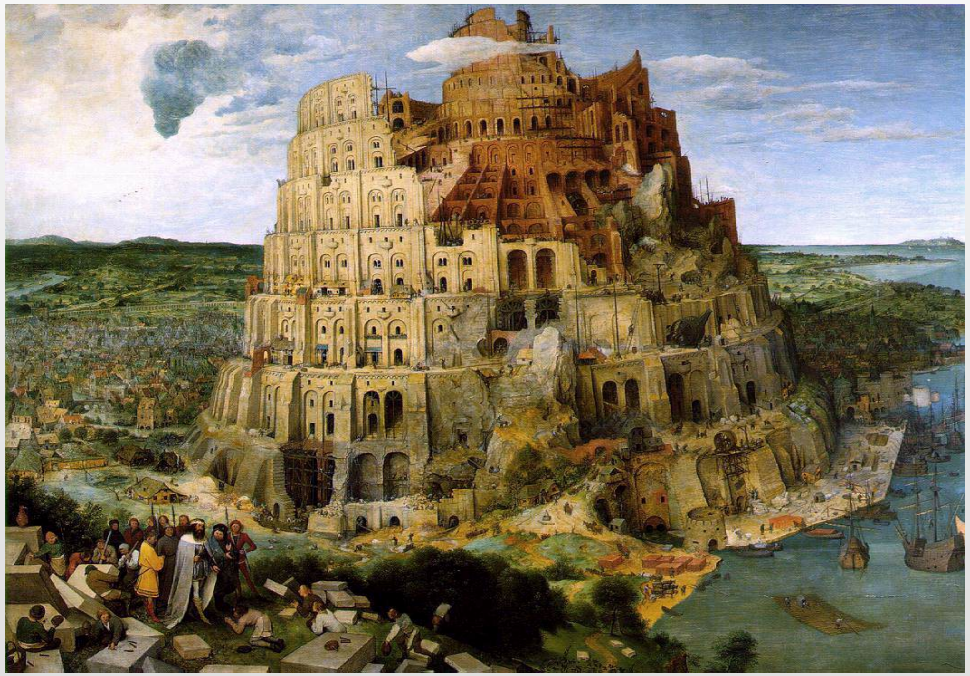
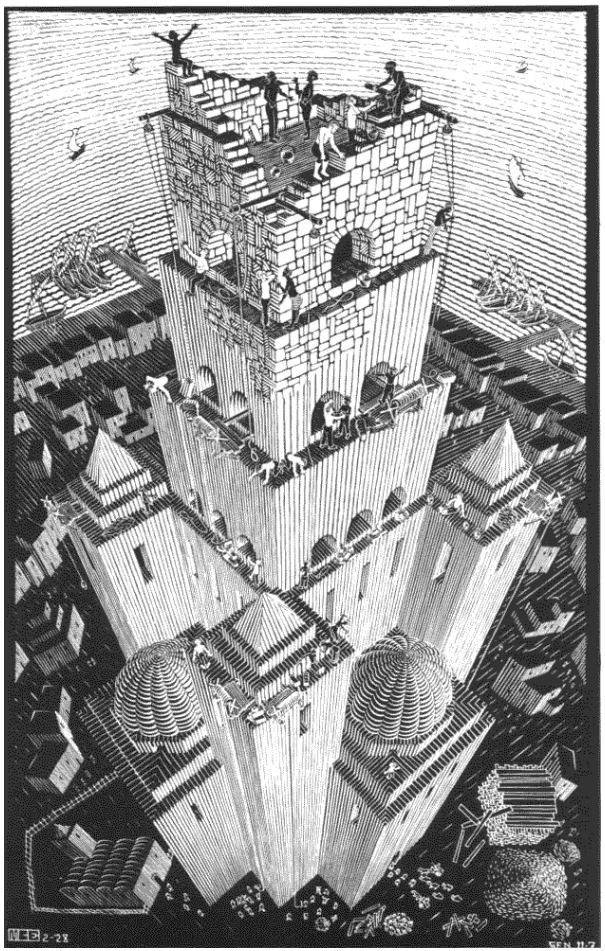


Brueghel's "Tower of Babel" – The Tower of Babel is arguably the first recorded example of a large-scale engineered system to fail due to linguistic confusion.

Multi-Stakeholder Decisions in Engineered Systems

- Large-scale engineered systems are too complex for one individual to comprehend
  - **Insufficient cognitive capacity** of one architect
- Necessitates creation of **multiple specialties**
  - Each specialist has **expertise** and **evidence** from **multiple domains**
  - Specialized **training** leads to **acculturation**
  - Each expert possess **different views** and **languages**
- Scope of problem is
  - **Large-scale**: Impacts billions of lives
  - **Social**: Multi-stakeholder decisions
  - **Technical**: Device and process design



"Tower of Babel" M. C. Escher

The Problem: Expert Group Decision-Making

- **Different perspectives & values** make it difficult to generate consensus on interpretation of data

  > *"…all bring **distinct readings** of the evidence to decisions that may have heart-rending **implications for quality, cost, and fairness**…"*
  >
  > *(Gelijns, Brown et al. 2005)*

- **Institutional Framing**: Experts' interpretations influenced by institutional frames *(Douglas 1986)*
  - **Institution**: e.g., a particular profession, specialty, or organization
- **Examples:** Medical device approval in FDA, technical standards-setting, joint-development/design, multi-disciplinary teams, innovation in regulated sectors

Key Questions

1. How do the institutional backgrounds of individual advisory panel members interact to impact a given panel decision?
2. How do advisory panel members' different institutional backgrounds affect their initial perceptions of a device, and how do those perceptions change and interact during the decision-making process?
3. How might we design approval processes so as to enable desirable behavior on the part of medical device approvals?

Domain of Analysis: Medical Device Approval

- The **Food and Drug Administration** oversees medical device safety, efficacy and innovation *(Merrill, 1994)*
  - Medical technology can save lives or be overused/harmful
    (Cutler, 2001; Devers, Brewster et al., 2003; Dalkon Shield)
  - Device approval is expensive, complex & strategically important
- Interdisciplinary **expert advisory panels** oversee most innovative devices *(Sherman, 2004)*
- Do panels' recommendations improve decision outcomes?
  - Conflict of interest & "specialty bias" *(Friedman 1978*; *Lurie, Almeida et al.* 2006)

Data Source: FDA Advisory Panel Meeting Transcripts

- **Data availability**: Convenient unit of analysis; hundreds of potential samples
  - 21 committees over 11 years with ~2 meetings per year
- **Data consistency & validation**: Committee members' votes are recorded in "court-reported" transcript & minutes
- **Relevance to Problem**: Device approval is a group decision with uncertain consequences within complex socio-technical system
- **Domain Relevance**: FDA currently revising its advisory panel procedures, device evaluation criteria and conflict of interest rules

  (Lurie, Almeida et al. 2006)

Approach: Studying Institutional Background via Language

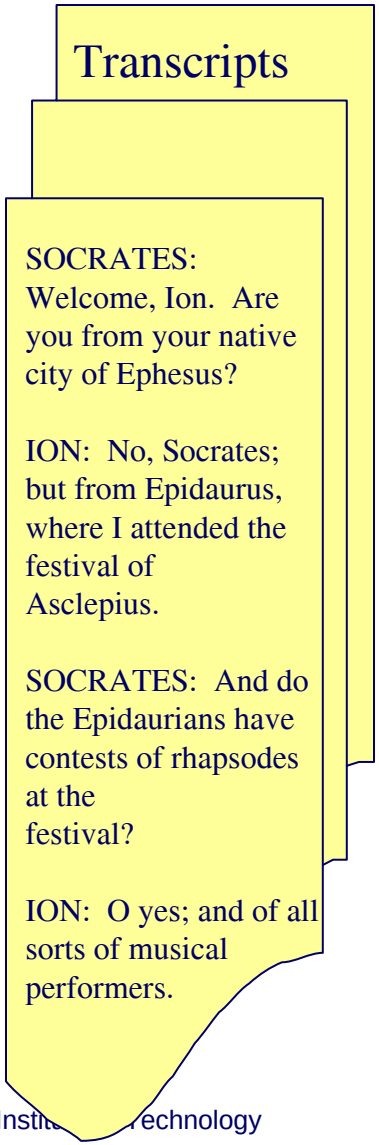
- **Group membership** influences perception of data
  (Douglas and Wildavsky 1982; Elder and Cobb, 1983)
- Group membership **is reflected in language** (problem definition; jargon; symbolic redefinition)
  (Douglas and Wildavsky 1982; Cobb and Elder, 1983; Elder and Cobb, 1983; Nelson 2005)
- Analysis of language use patterns **provides insight into institutional frames**
  (Nelson 2005; Cobb and Elder, 1983; Elder and Cobb, 1983)
- Use of Natural Language Processing algorithms – e.g., **Bayesian Topic Models**
  (Blei, Ng & Jordan 2003)

Bayesian Topic Models

- Bayesian probabilistic clustering
  - Originally developed for information retrieval and document summarization.
- Variants have been applied to
  1. Analysis of structure in scientific journals *(Griffiths and Steyvers 2004)*
  2. Finding author trends over time in scientific journals *(Rosen-Zvi et al., 2004)*
  3. Topic and role discovery in email networks *(McCallum et al. 2007)*
  4. Analysis of historical structure in newspaper archives *(Newman and Block 2006)*
  5. Identifying influential members of the US Senate *(Fader et al. 2007)*
  6. Group discovery in socio-metric data *(Wang et al., 2005)*
  7. Also applicable across fields (e.g., genomics)
- Enables consistent analysis of large numbers of texts

Data Pre-Processing

- FDA Transcripts are divided into **utterances**
  - One paragraph in length, as defined by court-recorded
  - Typically conceptually coherent
- Words are **stemmed**; **stop-words** are removed
- Utterances are parsed into a **word-document matrix**



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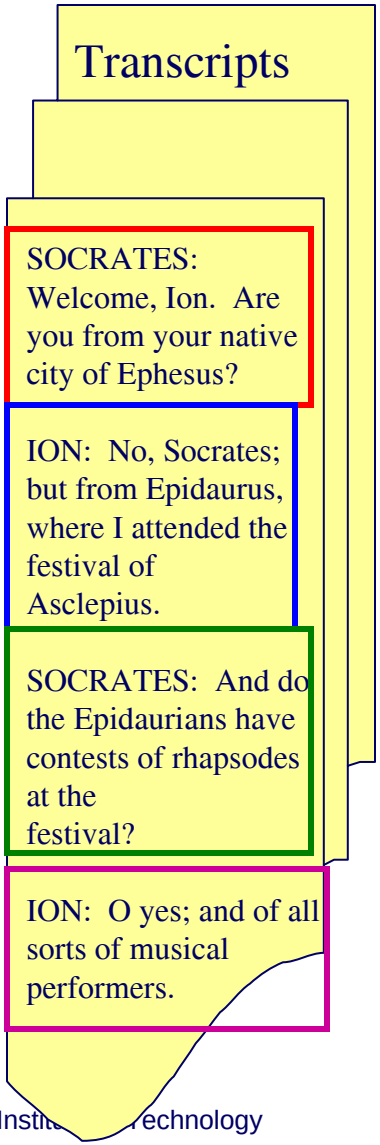

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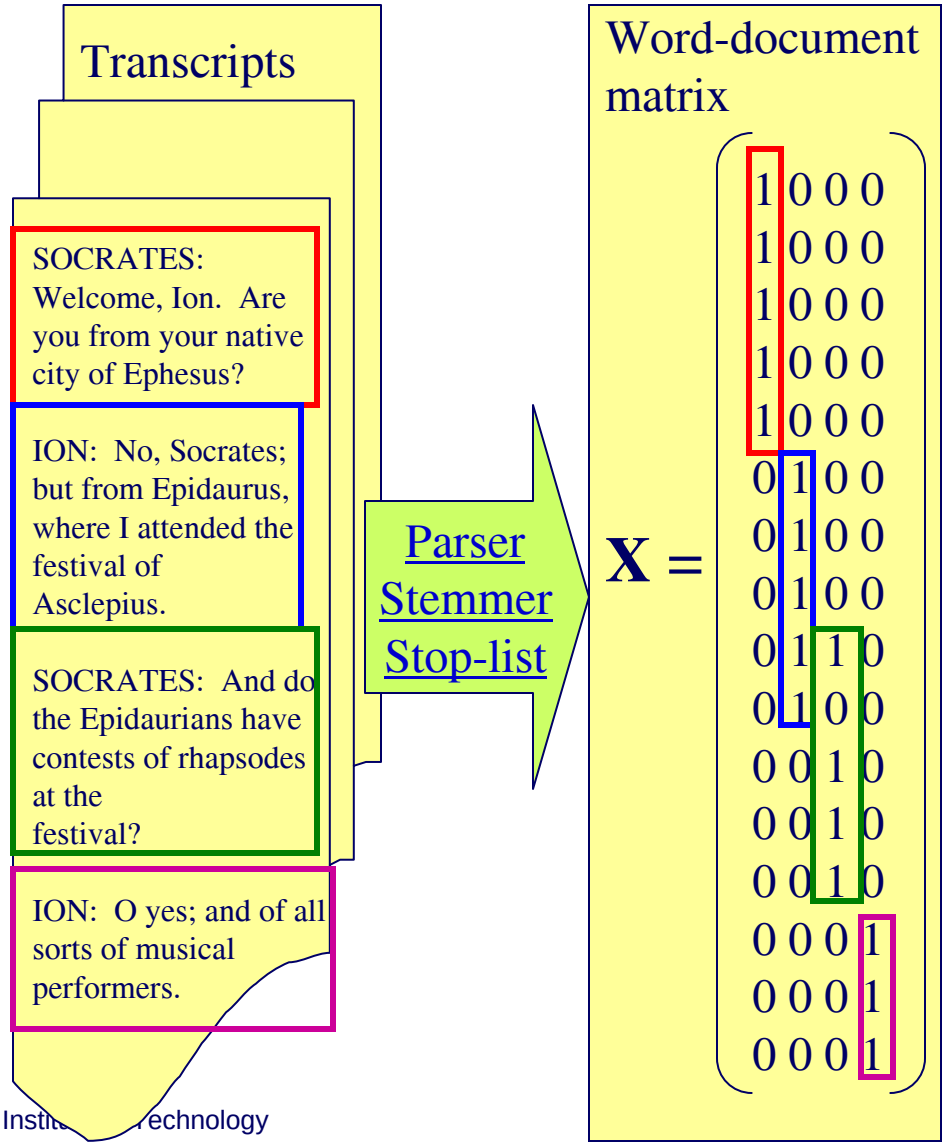
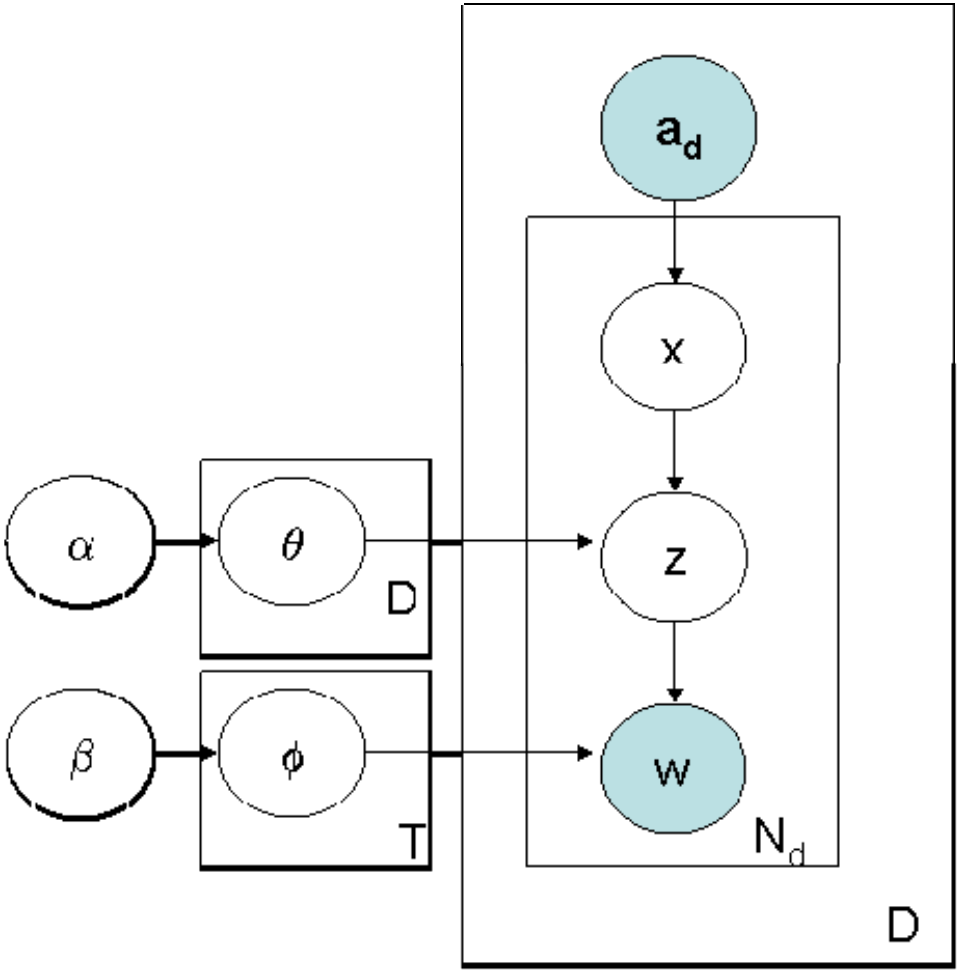
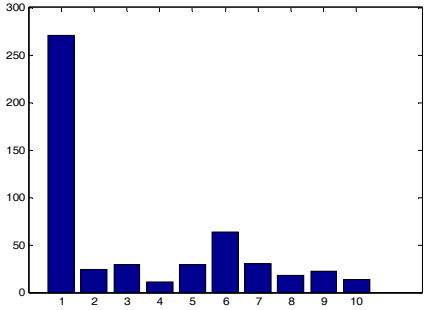
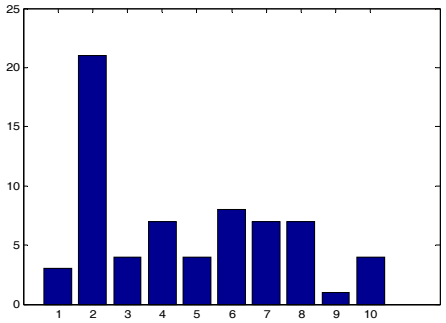
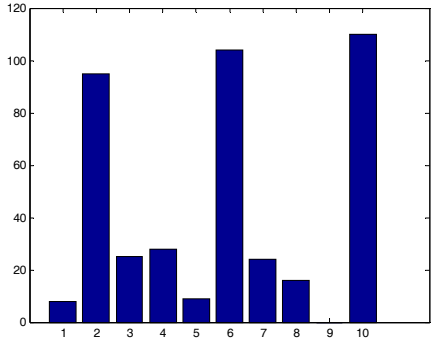
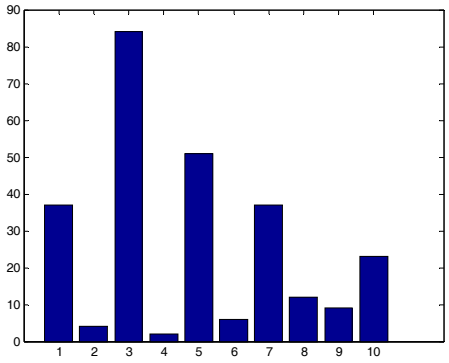
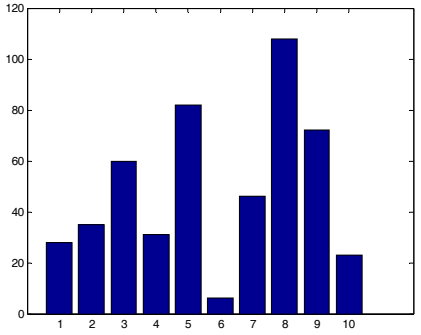
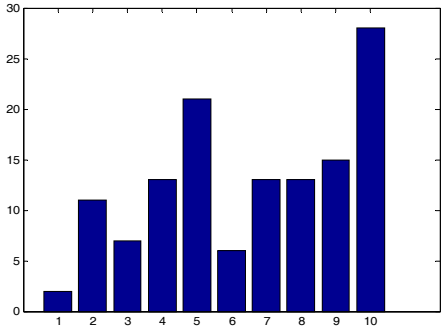


The Author-Topic Model (Rosen-Zvi et al., 2004)



Legend:
w = words
z = topics
x = author
$w|z \sim \text{Multinomial}(\phi)$
$z|x \sim \text{Multinomial}(\theta)$
$x \sim \text{Uniform}(a_d)$
$\phi \sim \text{Dirichlet}(\beta)$
$\theta \sim \text{Dirichlet}(\alpha)$

Sample AT Model Output

	Frequent Speaker	Rare Speaker
Focused Speaker		
Multi-Focus Speaker		
Unfocused Speaker		

AT Model Applied to the Taxus ® Stent Case

- Unanimous approval
  - Conditions of approval:

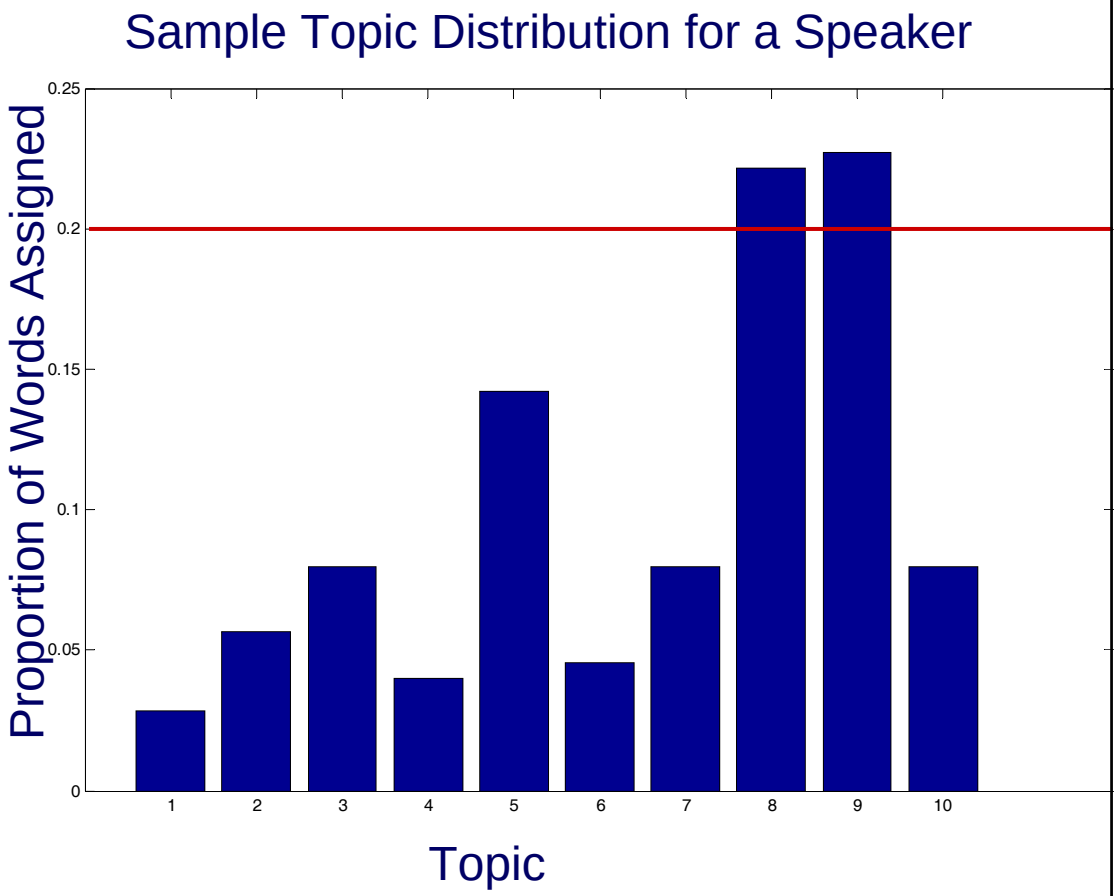
1. The labeling should specify that patients should receive an antiplatelet regimen of aspirin and clopidogrel or ticlopidine for 6 months following receipt of the stent.
2. The labeling should state that the interaction between the TAXUS stent and stents that elute other compounds has not been studied.
3. The labeling should state the maximum permissible inflation diameter for the TAXUS Express stent.
4. The numbers in the tables in the instructions for use that report on primary effectiveness endpoints should be corrected to reflect the appropriate denominators.
5. The labeling should include the comparator term “bare metal Express stent’ in the indications.

AT Model Applied to the Taxus ® Stent Case (cont.)

Committee Member	Major Topic of Interest (stemmed)	Topic Proportion	Correspon-ding Condition #
DR. HIRSHFELD	'metal bare express restenosi paclitaxel'	0.36	5
DR. WHITE	'physician stainless ifu steel plavix'	0.42	1
DR. SOMBERG	'metal bare express restenosi paclitaxel' 'materi drug interact effect potenti'	0.30 0.29	5 2
DR. NORMAND	'tabl detail denomin six number'	0.56	4
DR. MORRISON	'metal bare express restenosi paclitaxel'	0.23	5
DR. YANCY	'drug clinic present appear event'	0.23	2
DR. WEINBERGER	'angiograph reduct nine think restenosi‘	0.12	<None>
DR. MAISEL	'millimet length diamet coronari lesion'	0.34	3
DR. AZIZ	'know bit littl take present'	0.23	<None >

Generation of Social Networks

- Social relations may be inferred using the Author-Topic model
  - A speaker “discusses” a topic if > 20 % of words are assigned to that topic
  - Do two speakers discuss the same topic? If so, they are linked.



Sample Output

Legend:

Red = Voted against Device Approval

Blue = Voted for Device Approval

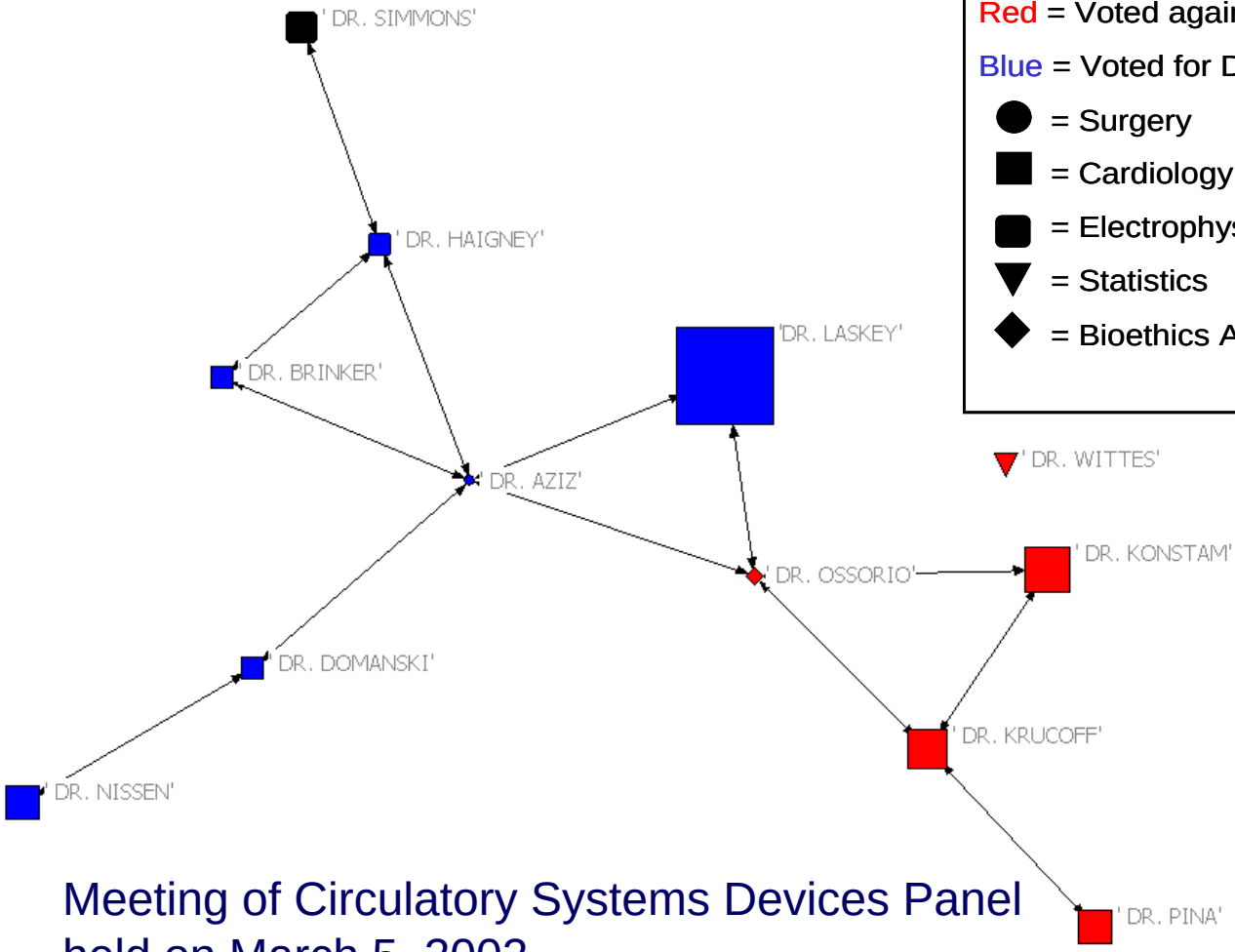
= Surgery

= Cardiology

= Electrophysiology

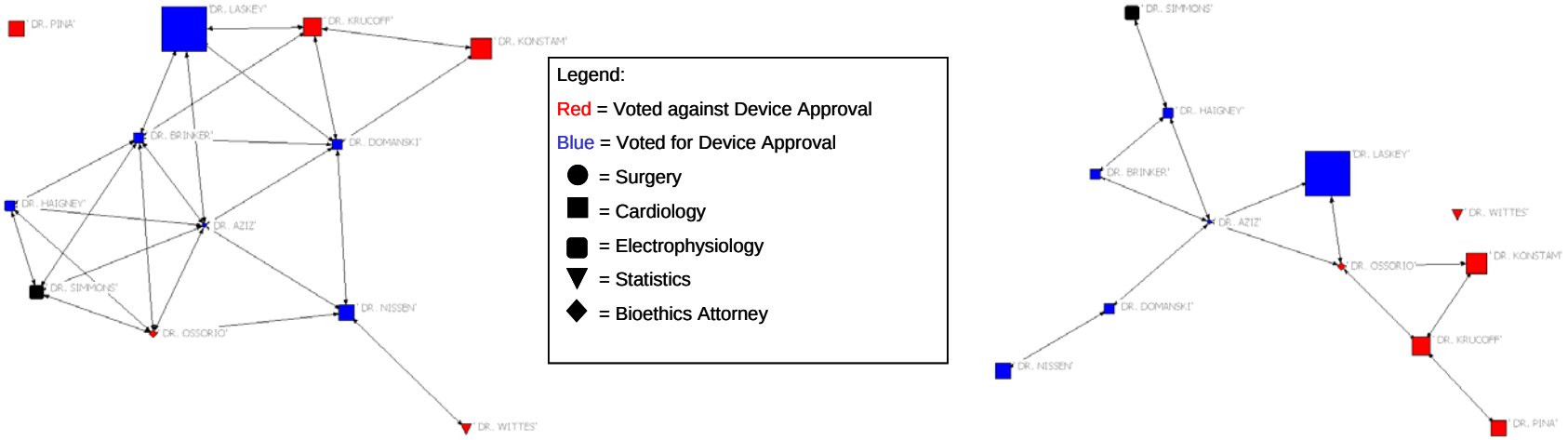
= Statistics

= Bioethics Attorney



Meeting of Circulatory Systems Devices Panel held on March 5, 2002

Author-Topic model is Probabilistic

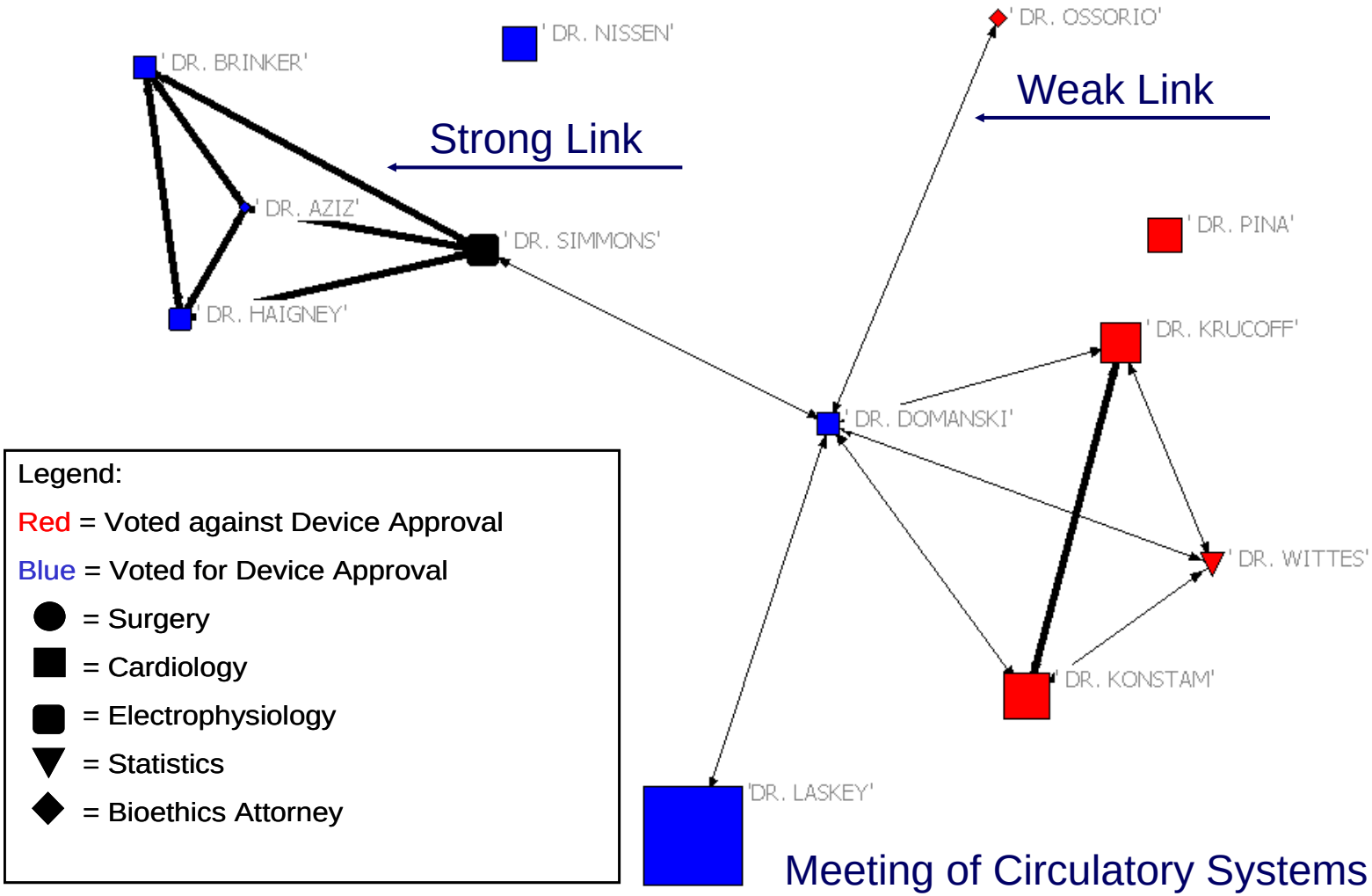


- Result: Different samples from the model will yield different networks
  - Each of these represent draws from a *distribution* over possible network topologies
  - We would like to find an aggregate representation

Creating an Aggregate Graph

- A large number of samples is taken from the Author-Topic model's posterior distribution
  - We generate 200 samples
- How often is each author pair linked?
  - > 50% of the time is a strong link
  - > Average over all author pairs is a weak link
- All other author pairs are unlinked
  - Spurious links are eliminated

The Aggregate Graph



Legend:

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● = Surgery

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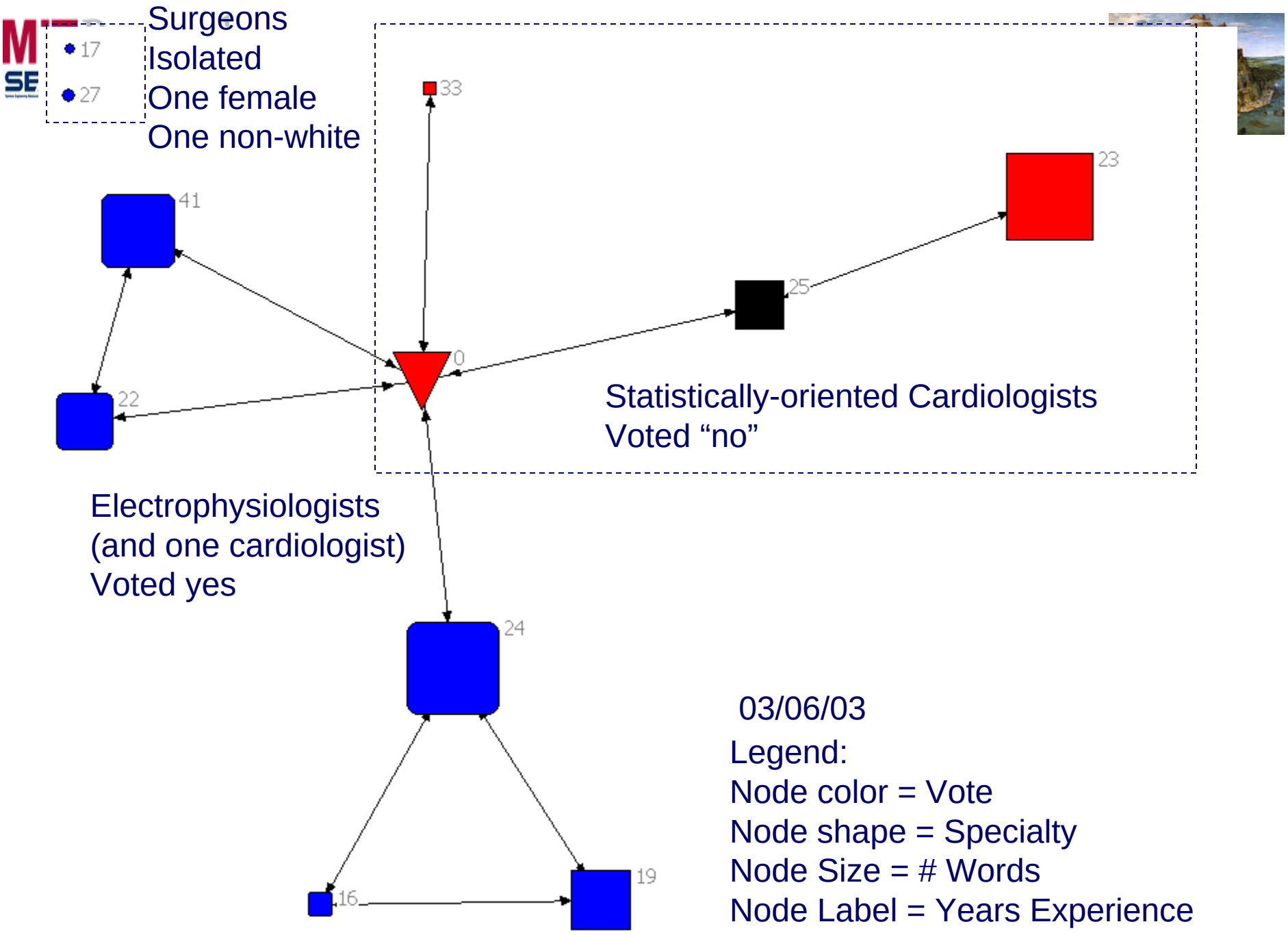
Future Work

- Analysis of social networks to identify speaker roles
  - Frequent speakers who are densely linked – engaged in coalition-formation and argument
  - Frequent speakers who are sparsely linked – focused on one topic that others do not respond to.
  - Infrequent speakers who are strongly linked – may be connectors.
  - Speakers who speak infrequently and are sparsely linked do not seem to have participated much in the formation of a group decision
- Refinements in the algorithm yield grouping by medical specialty and by vote
  - Exploration of other demographic features
    - Institutional Affiliations (e.g., location of training)
    - Race & Gender
    - Years of Experience



Summary

- Medical device approval is strongly influenced by institutional background
  - Strongly social and technical in nature; multi-stakeholder decisions, contained within a complex engineered system (health care)
- Expected Contributions:
  - **Methodological**: Algorithms and method for the analysis of expert committee decision making via language
  - **Theoretical**: New insights into group decision-making focusing on linguistic sources of influence.
  - **Practical**: Policy recommendations for how best to structure approval committees to enable medical device safety and efficacy while still promoting innovation

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